

Office of Drug Control Prescription Drug Monitoring Program (PDMP)

February 26, 2010

What the Program Does and Does Not Accomplish

The Problem – Illegal Diversion and Abuse of Prescription Drugs

- Florida has a serious problem with illegal prescription drug diversion and abuse. Scheduled drugs that are prescribed by physicians are diverted from their intended use and then abused or illegally sold. Drugs diverted include Schedule II, III, and IV controlled substances. Many of the diverted drugs are powerful pain killing opiates that have a high potential for addiction and abuse.
- Prescription drugs now kill six Floridians per day – five times as many as caused by all illegal drugs combined.
- The rate of deaths caused by prescription drugs is also increasing nearly *five times as fast* as the rate of deaths caused by all illegal drugs
- In 2008, when alcohol is excluded, prescription drugs account for 75% of all drug occurrences in the Medical Examiners Report.
- The rate of deaths (per 100,000 residents) caused by prescription drugs is over *three times as high* as the rate of deaths caused by all illegal drugs combined
- In Florida, drug-related deaths continue to increase:

<u>2003</u>	<u>2004</u>	<u>2005</u>	<u>2006</u>	<u>2007</u>	<u>2008</u>
6,767	7,128	7,573	7,741	8,620	8,556

- A major problem is the establishment of “pill mills”
 - A “pill mill” is a doctor’s office, clinic, or health care facility that routinely conspires in the prescribing and dispensing of controlled substances outside the scope of the prevailing standards of medical practice in the community or violates the laws of the state of Florida regarding the prescribing or dispensing of controlled prescription drugs
- According to the Drug Enforcement Administration’s Automation of Reports and Consolidated Orders System (ARCOS) reports, Florida physicians dispense five times more oxycodone than the national average of dispensing physicians.
- Prescription drug diversion costs lives, increases crime and misery from drug addiction, and accelerates costs connected to treatment, medical expenses and Medicaid fraud.

Bottomline: The state of Florida has an epidemic causing death and the loss of human dignity due to controlled Prescription Drugs; it is a public health and safety problem for Florida.

The Goals of the Prescription Drug Monitoring Program (PDMP)

1. Support access to legitimate medical use of controlled substances
2. Help identify and deter or prevent drug abuse and diversion
3. Facilitate and encourage the identification, intervention with and treatment of persons addicted to prescription drugs by health care practitioners
4. Help inform public health and safety initiatives through the outlining of use and abuse trends of controlled prescription drugs
5. Help educate individuals about PDMPs and the use, abuse and diversion of and addiction to controlled prescription drugs

The Attributes of the PDMP: How the Program Operates

- FS 893.055 creates the Prescription Drug Monitoring Program (PDMP): and the accompanying Public Records law FS 893.0551 limiting access to confidential and private information in the PDMP database.
- Establishes the Patient Advisory Report (PAR) for use by practitioners to alert them of patients that are possibly “doctor shopping.”
- Requires dispensing practitioners to report dispensed II – IV controlled drugs to the database electronically no later than 15 days from the date of dispensing.
- Allows practitioners to request access to the patient’s prescription history information during office visit to ensure better patient standard of care, avoid prescribing medications that may be dangerous when taken in combination and identify possible “doctor shoppers”
- Limits access to database information to only practitioners and six entities including patients. The six entities do not have direct access to the database; they must request it from the PDMP Program Manager: Attorney General, health care regulatory boards, law enforcement (defined as Florida Department of Law Enforcement, Florida Sheriffs’ Offices and Florida Police Departments), the Department of Health, the Implementation and Oversight Task Force and patients to verify their prescription history.
- Requires the Department of Health to use the information to undertake public health care and safety initiatives that take advantage of observed trends
- Requires training for user knowledge of how to access/request information and provide knowledge of the program as determined by the Department of Health
- Requires an annual report by the Implementation and Oversight Task Force to the Governor, the President of the Senate, and the Speaker of the House of Representatives regarding implementation, compliance, and measures taken to ensure privacy and confidentiality of records.
- Establishes a Direct Support Organization (DSO) in order to fund the PDMP with non-state funds; Department of Health in order to implement the PDMP does not use state legislative appropriations
- Requires the use of requesting patient identification by dispensers if the patient or person picking-up the controlled prescription drug is unknown to the dispenser

What the PDMP Does Not Accomplish

- Does not allow interstate sharing of prescription history information
- Is not National All Schedules Prescription Electronic Reporting Act (NASPER) qualified; federal grant for establishment of PDMPs with interstate sharing
 - Florida, if not NASPER qualified, may not have a preference for drug abuse competitive grants awarded by the Secretary, Substance Abuse and Mental Health Services Administration (SAMHSA) starting in FY 2012
- Does not have the ability to provide “alerts” to regulatory boards, Medicaid fraud or law enforcement regarding potential “doctor shopping” or illegal and/or unprofessional conduct by health care professionals
- The PDMP is not the one “silver bullet” that by itself will reduce all diversion and abuse of prescription drugs in Florida.

What the PDMP Does Accomplish

- In short, the establishment of this system in Florida will prevent a great number of deaths from the illegal diversion and subsequent abuse and overdose of prescription drugs in our state.
- The use of the PDMP by physicians contributes significantly to patient safety and improved patient standard of care
- The PDMP allows practitioners to see all of the Rx data of their patients
 - Rx history is available when patient is present
 - Assists with making complex prescribing decisions for the elderly
 - Provides practitioner state-wide visibility of “doctor shopping”
- The PDMP reduces the chances for patients to repeatedly and illegally divert prescription drugs.
- The program allows for health care regulatory boards and law enforcement officials to rapidly investigate cases where abuse of controlled substances is suspected; requires an active investigation to request information. See attached diagram.
- The PDMP protects both privacy and confidentiality of patients by following all state and federal laws to include HIPAA plus additional control measures beyond those requirements. See Chart 3 for Project Manger required validation of request
- It facilitates and encourages the identification, intervention with and treatment of persons addicted to prescription drugs

Conclusion: The state of Florida has established a program that will improve patient quality of care and reduce controlled prescription drug abuse and diversion. The PDMP will reduce the chances for patients to repeatedly and illegally divert prescription drugs. Overall the program will dramatically reduce doctor and pharmacy shopping.

MOST FREQUENTLY ASKED QUESTIONS

1. What states have prescription monitoring programs?

According to the Drug Enforcement Administration, as of January 2010, 34 states have operational PDMPs that have the capacity to receive and distribute controlled substance prescription information to authorized users. States with operational programs include:

Alabama, Arizona, California, Colorado, Connecticut, Hawaii, Idaho, Illinois, Indiana, Iowa, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Nevada, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Virginia, Vermont, West Virginia, and Wyoming.

Five states (Alaska, Florida, Kansas, Oregon, and New Jersey) and one U.S. territory (Guam) have enacted legislation to establish a PDMP, but are not fully operational.

See chart 1.

2. Is the program proposed for Florida in compliance with the federal Health Insurance Portability and Accountability Act (HIPAA)?

Yes. In fact, Florida's PDMP will meet all the security requirements required of the Florida Department of Health which are more stringent than HIPAA requirements. See chart 3 for required Project Manager validation of request

3. Isn't the accessibility to controlled substance prescription data a violation of patient confidentiality?

The entire program will be federal Health Insurance Portability and Accountability Act (HIPAA) compliant. The access of the patient's prescription history, when a state has authorized a PDMP, is authorized under HIPAA.

The Florida PDMP provides safeguards to protect patient confidentiality and access to controlled substance prescription information through statute. The law prohibits unauthorized access to and use of confidential patient information. Any person who willfully and knowingly violates this law commits a felony of the third degree

The entire prescription history of all patients in Florida, even beyond the Schedule II – IV drugs specified by the program, is currently available in many different locations in the private sector. Currently complete prescription information quite often resides in the local pharmacy computer database, the pharmacy's regional headquarters database, and the pharmacy's national headquarters database. Moreover, the health insurance companies and their agents who pay for medications quite often maintain the same information in a database. The PDMP mandates more stringent controls on prescription history and, in fact, imposes much greater penalties for unauthorized disclosures than anywhere in any of the many private sector databases.

4. Who will have access to the information stored in the statewide database?

1. Health care practitioners (pharmacists and physicians) who have registered with the Department of Health and have been validated as licensed practitioners in the state of Florida
2. The following entities may request access through the database's program manager (PM). The PM must ensure the validity of the request prior to providing the information to:
 - a. Appropriate medical regulatory board
 - b. Attorney General's Medicaid Fraud Unit
 - c. Law enforcement (defined as Florida Department of Law Enforcement, Florida Sheriffs' Offices and Florida Police Departments)
 - d. Patients to verify their prescription history
 - e. Department of Health: non-identifying information for annual report on performance measures
 - f. Implementation and Oversight Task Force: non-identifying information for annual report

In addition, see chart 3 for further explanation.

5. What are the annual costs to operate a prescription-monitoring program?

The cost of implementing and operating a prescription-monitoring program vary depending upon the type of system that is authorized by that particular state to include but not all of the functions; number of health care practitioners, volume of dispensed prescriptions, use of in-house and out-sourced functions, etc. Florida estimates that its system may cost \$480,000 dollars to purchase and initially operate the system for one year. Annual operating costs after that are estimated to be \$450,000 per year.

6. What are some of the beneficial uses of the PDMP?

Prescription drug monitoring programs can be used to improve patient standard of care by:

A. Allowing physicians to access the database for their patients and determine if their patient has been prescribed controlled substances from other physicians that might negatively interact when used together. It also allows the physician to prescribe controlled substances that will not negatively interact with medicines prescribed by other physicians.

B. Allowing pharmacists to access the database for their patients and determine if their patient has been prescribed controlled substances from physicians that might negatively interact when used together.

C. Allows health care practitioners (doctors/pharmacists) to access the database for their patients and determine if their patient has had multiple prescriptions for the same drugs from different doctors. This helps identify those patients potentially engaged in the crime of "doctor shopping" (which is a felony in Florida). This assists health care professionals in their practice and allows them to intervene on their patient's behalf and assist them in obtaining treatment, if they are addicted. .

D. When a potential illegal diversion pattern for drugs is identified by the database and doctors/pharmacists have requested the information, the information through a Patient Activity Report (PAR) is then disseminated to the doctors and pharmacists alerting them to the potential problem of "doctor shopping."

In addition, the system allows law enforcement/medical regulatory board/Medicaid fraud unit to request information. See chart 3. This will be for potential criminal activity regarding controlled prescription drugs if there is already an active investigation. This extremely limited type of access system has been very successful in thwarting controlled substances diversion and abuse in other states.

A study conducted in 2006 by Ronald Simeone and Lynn Holland Simeone Associates, Inc., regarding the ability for a PDMP to impact controlled prescription drugs concluded states that....
"monitor proactively have inhibited growth in prescription sales (for pain relievers and stimulants)..."

A May 2002 General Accounting Office (GAO) concluded that "State Monitoring Programs Provide Useful Tool to Reduce Diversion." Its Concluding Observations were: Illegal diversion and abuse of prescription drugs and the associated criminal activity are

growing problems in many states. Prescription drug monitoring programs offer states a more efficient means of detecting and deterring illegal diversion. These programs provide state health care licensing and regulatory agencies and law enforcement with quick access to comprehensive information on the prescribing, dispensing, and purchasing of controlled substances that are most likely to be targets for diversion. In addition, the report stated...."PDMPs have aided investigators and helped to reduce doctor shopping."

7. What about children who are prescribed Schedule II drugs such as Ritalin? Will they be registered in the database?

Only patients 16 years and older will be included in the electronic database. This program will not highlight or stigmatize anyone who legitimately receives and uses medications prescribed by a doctor, but it will highlight potential illegal controlled substances diversion and abuse of controlled substances. Ritalin is the brand name of the Schedule II controlled substance methylphenidate. Methylphenidate is a central nervous system stimulant similar to amphetamine in the nature and duration of its effects. In medicine, Ritalin is used to treat Attention Deficit Disorder (ADD) and narcolepsy. In recent years, Ritalin has been increasingly diverted and abused by both youth and adults. Under Federal law, dealing in Ritalin is a felony.

8. Will the PDMP eliminate all the problems caused by the "pill mills" in Florida?

A PDMP is not a "silver bullet" that will eliminate entirely the problem with those involved in the illegal abuse and diversion of controlled substances. It is one "tool in the tool kit" that will be a major capability for Florida's use in overcoming the problem with "pill mills."

9. Will it be mandatory for physicians to access the database and check every patient's prescription history?

No, health care practitioners are not required to access the database. It is only voluntary. However, it is a very helpful tool for a practitioner in providing better patient standard of care based upon the information in FAQ # 6.

10. Is there an established threshold for prescribing that can trigger a report to law enforcement authorities concerning a physician's possible over prescribing?

Not at this time. The statute does not authorize this capability.

11. Who is responsible for the operation of Florida's PDMP?

The Florida Department of Health

12. How is the PDMP being funded?

The statute authorizing the PDMP specifically does not allow the use of state appropriations for establishing the PDMP. It did authorize the establishment of a non-profit organization, which was incorporated as The Florida PDMP Foundation, Inc., to conduct fund-raising for the program. In addition, federal grants and non-state grants have and will be applied for to fund the program.

The Florida PDMP Foundation, Inc is a non-profit 501 (c) 3 organization that independently raises funding for the establishment and operation of the Prescription Drug Monitoring Program (PDMP). It is authorized by Florida Statute 893.055.

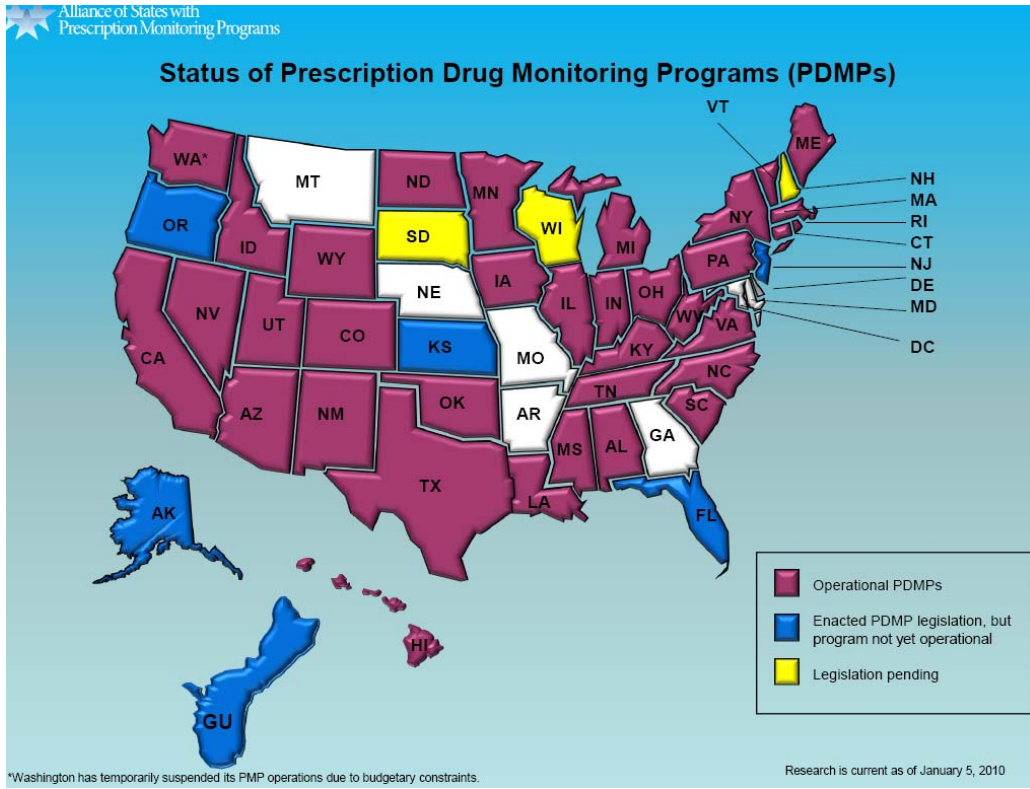
Inquiries regarding providing support to the Foundation should be directed to the Chairman, James Slattery at email: jslattery@becausepainmatters.com

13. What is a Patient Advisory Report and how is it used?

A Patient Advisory Report (PAR) is provided to a health care practitioner that has requested that if any patient is potentially “doctor shopping” that they wish to be notified. The database will have an alert capability that will then provide the practitioner the information. This helps practitioners identify those patients potentially engaged in the crime of "doctor shopping" (which is a felony in Florida). This allows the practitioner to intervene on their patient’s behalf and assist them in obtaining treatment, if they are addicted. See attachment 2 regarding the PAR.

Attachments

1. Status of States with PDMPs
2. Chart on PAR operation
3. Chart on Project Manager review



SOURCE: National Alliance for Model State Drug Laws (NAMSDL). Research is current as of 1/5/2010.

Patient Advisory Report (PAR)

A Solicited Report by Doctor/Pharmacy

Conditions:

DOH rule-making committee representing appropriate medical disciplines establishes “doctor shopping” rule for scheduled drugs II - IV

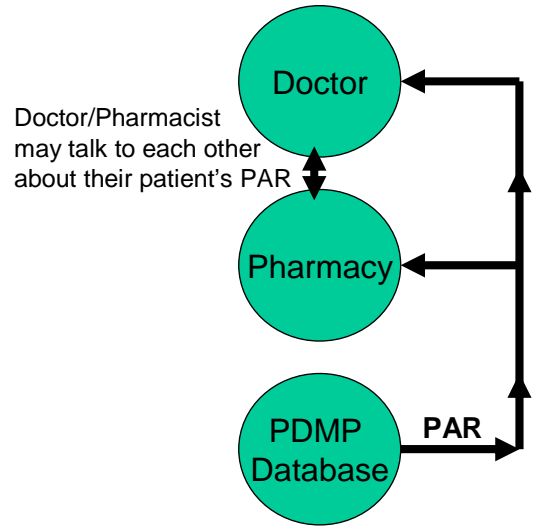
Patient Advisory Report (PAR)

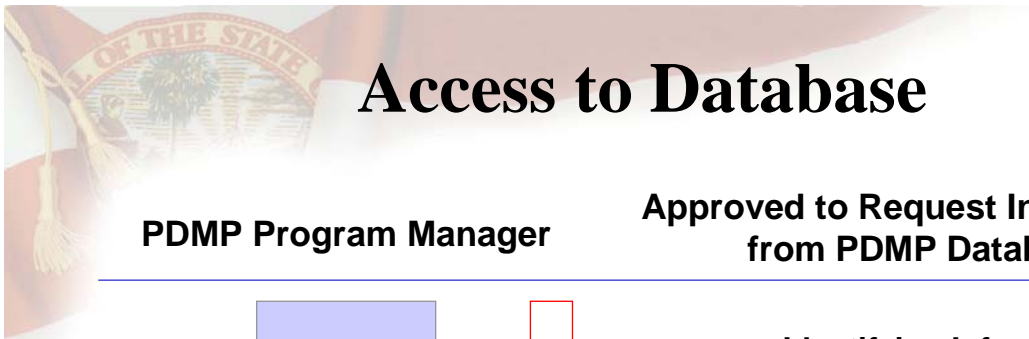
Doctor/Pharmacy requests PAR sent whenever rule condition is met by their patient

Sent after patient exceeds “doctor shopping” suspicion rule established by DOH

Sent only to patient’s doctor and pharmacist

Expectation: if the patient has a drug problem the practitioner helps them seek treatment

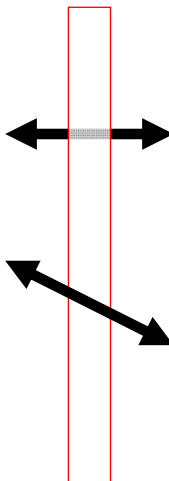
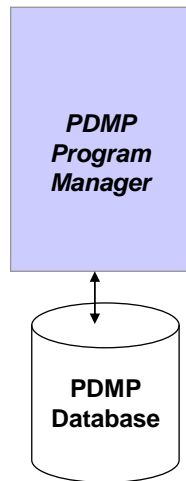




Access to Database

PDMP Program Manager

Approved to Request Information from PDMP Database



- Identifying Information**
- Medical Regulatory Boards
 - Attorney General Medicaid fraud
 - Law Enforcement (FDLE, Sheriffs and Police only)

- Non-identifying Information**
- PDMP Implementation and Oversight Task Force annual report
 - Department of Health annual report

Request submitted to PDMP Program Manager