



# Prescription Drug Monitoring Program Models October 2016

Prescription Drug Monitoring Programs (PDMPs) are statewide databases that track the filling and dispensing of certain prescription drugs in an effort to control opioid addiction. The database securely stores patients' prescription information to monitor abuse or misuse. Practitioners, such as physicians, pharmacists, and physician-extenders are alerted by the system if any suspicious activity is detected. The intent of these databanks is to reduce inappropriate prescribing by doctors and to deter illegal behavior, such as "doctor shopping." Doctor shopping occurs when an individual visits multiple physicians to obtain prescriptions that are not clinically necessary. It is a common practice among people who are addicted to prescription drugs and those who obtain drugs illegally for resale.

Policies to discourage doctor shopping are becoming increasingly imperative as the opioid epidemic worsens across the country. The Drug Enforcement Administration (DEA) announced that deaths from overdoses have surpassed fatalities from motor vehicle accidents, making drug overdoses the leading cause of death from injury. Since 1999, the rate of prescribing opioids has quadrupled and prescription drug overdoses have increased by 200 percent. Between 2013 and 2014, Missouri's drug overdose death rate increased by 4 percent. For more information on the severity of the prescription drug epidemic, please see our first publication in the PDMP series – Prescription Drug Monitoring Programs 2016.

Currently all states, with the exception of Missouri, operate or are implementing some type of PDMP to monitor prescription drug activity. The structure and format of the databases vary greatly depending on the state. The purpose of PDMPs is not to infringe upon the practitioner/patient relationship, but rather to enable physicians to better identify drug misuse among their patients. This issue brief will highlight the diverse models of PDMPs across the nation and provide information on emerging and best practices for PDMP implementation and operation.

#### **Characteristics of PDMPs**

Differences among PDMPs may include funding mechanisms, who is required to report or be enrolled, and timeframes. There are many common trends among models, yet some states continue to impose unique regulations or parameters on their systems.

### A. Enactment & Governing Authority

All states have enacted their PDMPs through statewide legislation. The statutes dictate how the systems will be implemented, maintained, and used for effective monitoring. The National Alliance for Model State Drug Laws created a Model PDMP Act, which incorporates provisions representing the best practices for policymakers to implement these systems. The suggested statutory clauses include the use of an advisory committee, time intervals for submitting information, safeguards to protect confidentiality, and treatment for individuals identified as at-risk. Despite having the best practices outlined in the Model Act, many states create alternative requirements or exclude certain provisions altogether.

# **B.** Operation & Maintenance

PDMPs are generally operated by either the state board of pharmacy, the state health department, or the state human services agency. In some states, however, the system may be partially or wholly operated by the state's chief law enforcement agency, a professional licensing agency, or consumer protection agency. For example, California's PDMP is housed within their state's Department of Justice, while Connecticut's system is maintained by their Department of Consumer Protection.

#### C. Substances Monitored

Certain prescription drugs are placed on drug schedules established by the DEA. The schedule ranges from I to V, with Schedule I substances having no acceptable medical use and Schedule V having the lowest potential for abuse or misuse. All scheduled drugs can be found in the Controlled Substances Act. All states collect information on prescription drugs that are categorized as Schedule II-IV, but only 34 states and the District of Columbia capture data on Schedule V drugs. Some states even require users to report and gather information on certain non-controlled substances that are known to be highly addictive. As of 2015, 17 states monitored certain non-scheduled or non-controlled substances. Mississisppi's statute explicitly states that Schedule II-V drugs shall be monitored, along with other non-controlled substances as established by the state's Board of Pharmacy. For example, prior to the DEA's revision to the Controlled Substances Act, the Board of Pharmacy required that any tramadol prescriptions be monitored through the system.

## D. Oversight

As recommended in the Model Act, states are encouraged to include an oversight mechanism in their PDMP statutes. Most states (30 states and the District of Columbia) use an Advisory Committee or similar council of representatives to aid in implementation and evaluation. Responsibilities of the advisory committee may include the development of: criteria for referring PDMP data to appropriate law enforcement or professional licensing agencies; measures to ensure confidentiality of information; standards for detecting patients with potential addiction issues and the process for rehabilitation; and standards to assess the design, training, and effectiveness of the program. The Model Act recommends that members of the Committee include various representatives elected by relevant state associations dealing with substance and alcohol abuse, pharmacy associations, and prescribing provider associations. Other relevant committee members may include representatives from consumer rights organizations, the state hospital association, the state Attorney General's office, and the state sheriff's association, among others.

## E. Use & Query Requirements

Although all states, with the exception of Missouri, have statewide PDMPs, the use and query requirements differ by state. Some states require that all dispensers and prescribers fully utilize the system by mandating that they register, submit information, and query the system when consulting with patients. Oklahoma is one of 16 states with comprehensive PDMP mandates, which requires dispensers to enter information into the system and obligates practitioners to review the system prior to prescribing certain medications. Other states require only that prescribers and/or dispensers register with the system and do not dictate standards for querying the system. Currently,

A) As of 2015, CT, DE, D.C., HI, ID, IL, KS, LA, MA, MS, NJ, ND, OH, VA, WA, WI, WY

30 states require all prescribers and/or dispensers to register with the PDMP as a means to promote utilization amongst practitioners. $^{\rm vi}$ 

Despite registration, states may only require dispensers or prescribers to take action in certain circumstances. There are 37<sup>B</sup> states that have statutory or regulatory mandates requiring practitioners to access and use the system in specific situations. VII Conversely, there are 16 states with laws that explicitly do not require practitioners to access information on the PDMP. Further, states may not require both dispensers and prescribers to access the system. Arkansas mandates dispensers take certain actions upon distributing the prescription, but only encourages prescribers to access the system. VIII

In addition to requirements surrounding use and query of the system, states also outline time intervals for submitting dispensing information into the system. Best practices suggest that data collection should occur in real-time, yet only Oklahoma has real-time submission requirements. Further, only three states mandate practitioners submit information to the system within 24-hours. A number of states require daily submissions, but many states have interpreted this as requiring transmission only on business days. Data collection intervals are significant factors to ensuring that systems are accurate and reliable in deterring doctor shopping and inappropriate prescribing. Failure to submit or query information may be grounds for disciplinary action from the relevant licensing board.

### F. Confidentiality & Notice

One of the largest controversies with implementing a PDMP centers on the confidentiality of information housed in the database. The Model Act states that information must remain confidential and cannot be subject to open records laws or court order in a civil case. All states with PDMPs characterize the information in the system as confidential. Nevertheless, only 33 states and the District of Columbia have statutory or regulatory language relating to the PDMP prohibiting information from being subject to public or open record laws. The Model Act suggests both the state housing agency and Advisory Committee work in conjunction to establish procedures for protecting patient information, while simultaneously creating processes for providing information to appropriate parties such as law enforcement, data warehousing entities, and necessary providers. There are also provisions governing misuse of patient information stored in the PDMP that warrant civil and criminal penalties. Penalties can be assessed for wrongly disclosing, using, and/or obtaining data from the PDMP and vary depending on the state. Some states penalize individuals for one, two, or all three of these individual acts. Nine states issue penalties for wrongly disclosing or obtaining data, whereas two states only impose penalties for individuals who wrongly obtain data.

Another element of PDMPs that remains a priority for consumers is the notification process of having one's information collected in the system. As of May 2016, only 11 states and the District of Columbia require prescribers and/or dispensers to notify their patients that their prescription information may be accessed or reported through the PDMP.xi Of these states, five require both dispensers and prescribers to provide notice to consumers, whereas only seven require one to do so.xiiC

B) Of these 37 states, TX and AL have implicit versus implicit mandates.

C) Some states only require such notification if the patient is enrolled in a rehabilitation program or clinic, such as methadone clinics or opioid treatment centers.

# G. Funding

Funding mechanisms also vary depending on the state. Generally, annual operating costs of a PDMP range from \$125,000 to nearly \$1 million.xiii One of the costs included in the annual operating costs are the fees associated with the transmission of data from dispensers. There are also average implementation costs ranging from \$250,000 to over \$1.5 million associated with PDMPs that encompass hardware, software, connectivity, and security.xiv

There are a variety of methods to finance the costs of a state PDMP. Funding can come from public or private grants, state appropriations, licensing fees, manufacturing fees, state controlled-substance registrations, and direct support organizations. Grants given at the federal level for PDMP efforts include the Harold Rogers PDMP Grant (Department of Justice); the National All Schedules Prescription Electronic Reporting Act of 2005 (NASPER) Grant (Department of Health and Human Services); and the Prevention for States Program Grants (Centers for Disease Control and Prevention).<sup>xv</sup> As of September 2015, nine states had some legislative appropriations dedicated to financing their state's PDMP. State appropriations come from general revenue funds that are created through state-administered taxes. Many of the states with legislative appropriations also use a combination of other financing mechanisms to supplement their state funds.

Licensing fees for prescribers or dispensers are used in 17 states. Both Texas and Vermont place fees on pharmaceutical manufacturers. Conversely, some states prohibit the use of fees to fund the PDMP, such as Maryland and Arkansas, whose statutes explicitly bar the program from assessing fees on prescribers or dispensers. \*\*vi\* States may also finance systems through controlled substance registration fees that are imposed on drug manufacturers and distributors. Registration fees can also include those placed on practitioners to obtain a certificate to dispense controlled substances within the state. Alabama's PDMP statute authorizes a \$10 surcharge per-year on the controlled substance registration certification to licensed practitioners in addition to their licensing fees. \*\*viii\* Other funding streams may include regulatory board funding, health insurance licensing fees, Medicaid fraud settlements, and PDMP registration fees. \*\*viiii\*

#### H. State Evaluations

One popular element of PDMP statutes are provisions covering evaluation. Incorporating evaluation allows the state to measure effectiveness and assess design and use features. There are 26 states with statutory or regulatory language requiring a PDMP evaluation report be submitted to the legislature. Reports can be published on behalf of the PDMP and the housing agency, or on behalf of an Advisory Committee. Most states require that reports be submitted on an annual basis. Common metrics used to measure effectiveness of the system include the increase of utilization among practitioners; any decrease in inappropriate use or prescribing of covered drugs; the number of referrals for rehabilitation, professional sanctioning, or legal intervention; and rates of unwarranted system access.

## **Issues for Consideration**

PDMPs have become the presumptive mechanism to battle opioid abuse across the United States, but many variances exist between states in terms of system design. The deployment of PDMPs have generated positive outcomes in many states, both by reducing incidences of drug misuse and hospitalizations for overdoses. States have also realized large reductions in the number of patients identified as doctor

shoppers. Despite these findings, studies have illustrated that lower usage rates and lack of access to patient data hampers the success of PDMPs.

States can look beyond their borders to make comparisons and develop more efficient databases. Issues relating to utilization, access, and efficacy can easily be addressed through legislative action or administrative rulemaking, depending on the state's authorizing legislation. Reducing the inconsistencies between states, as well as broader adoption and use requirements would ensure that PDMPs are more effective at limiting drug abuse. Being the only state in the nation without a PDMP, Missouri is well positioned to use models from the other 49 states and the District of Columbia to create a system that works effectively for Missourians.

#### **Endnotes**

- <sup>i</sup> Rose A Rudd, et al., "Increases in Drug and Opioid Overdose Deaths United States, 2000-2014", *Morbidity and Mortality Weekly Report*, Centers for Disease Control and Prevention, January 1, 2017.
  - http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm.
- ii Injury Prevention & Control: Opioid Overdose, State Data, Centers for Disease Control and Prevention, http://www.cdc.gov/drugoverdose/data/statedeaths.html.
- iii Mississippi Board of Pharmacy, October 2010 Newsletter.
  - $http://www.mbp.state.ms.us/mbop/Pharmacy.nsf/webpageedit/Newsletter\_2010\_sept2010/\$FILE/September\%202010.pdf?OpenElement.$
- iv National Alliance for Model State Drug Laws, Model Prescription Monitoring Program Act, 7, May 2015. http://www.nascsa.org/nascsaPMP/NAMSDL/NAMSDLmodelPMPact5.28.15.pdf.
- Y Enrolled House Bill No. 1948, Oklahoma Legislature, 2014. https://www.ok.gov/obndd/documents/HB1948%20ENR.pdf; See also, National Alliance for Model State Drug Laws, Reporting Requirements and Exemptions to Reporting, May 2016. http://www.namsdl.org/library/8D68BB10-960C-61A5-38C1365280C87090/; See also Christine Vestal, "States Require Opioid Prescribers to Check for 'Doctor Shopping'", The Pew Charitable Trusts, May 9, 2016. http://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2016/05/09/states-require-opioid-prescribers-to-
- check-for-doctor-shopping.

  vi National Alliance for Model State Drug Laws, Compilation of State Statutes States that Require All Licensed Prescribers and/or Dispensers to Register with the State Prescription, May 2016. http://www.namsdl.org/library/BEA4800D-A6A2-
- vii vii National Alliance for Model State Drug Laws, Compilation of Prescription Monitoring Programs, May 2016. http://www.namsdl.org/library/CADB8FE8-D3F1-8AB4-74F0AB49EAE9FA66/
- viii West's Arkansas Code Annotated, Section 20-7-604(b)(1)-(c)(16). http://www.namsdl.org/library/8D68BB10-960C-61A5-38C1365280C87090/.
- ix National Alliance for Model State Drug Laws, Data Confidentiality Not Subject to Public or Open Records Laws, May 2016. http://www.namsdl.org/library/C4580071-AB1F-B1B6-92D8FF26E15FE7C3/.
- <sup>x</sup> National Alliance for Model State Drug Laws, Data Confidentiality Penalties for Wrongly Disclosing, Using, or Obtaining Data, Map, May 2016. http://www.namsdl.org/library/C60ADBBD-CA1E-B07F-71500E57608A351F/.
- xi National Alliance for Model State Drug Laws, States that Require Prescribers and/or Dispensers to Notify Consumers that their PMP Information May be Accessed or Reported, Map, May 2016. http://www.namsdl.org/library/581366B1-DE11-491C-A21BC56FE26DDCC8/.
- xii National Alliance for Model State Drug Laws, Compilation of State Statutes Notice Requirements for Prescription Monitoring Programs, May 2016. http://www.namsdl.org/library/581366B1-DE11-491C-A21BC56FE26DDCC8/.
- xiii Kristin Finklea et al., "Prescription Drug Monitoring Programs", Congressional Research Services, March 24, 2014. http://www.fas.org/sgp/crs/misc/R42593.pdf.
- hI vix
- <sup>xv</sup> National Alliance for Model State Drug Laws, 2015 Annual Review of Prescription Monitoring Programs, September 2015. http://www.namsdl.org/library/1810E284-A0D7-D440-C3A9A0560A1115D7/; *See also* Brandeis University, Funding

9F1B-53EF45B0BB7FADA7/.

Options for Prescription Drug Programs, Technical Assistance Guide No. 04-13, , July 3, 2013. http://www.pdmpassist.org/pdf/PDMP\_Funding\_Options\_TAG.pdf.

- xvi Arkansas State Board of Health, Rules and Regulations Pertaining to Arkansas Prescription Drug Monitoring Program, March 2016. http://www.healthy.arkansas.gov/aboutADH/RulesRegs/PrescriptionMonitoringProgram.pdf; *See also* House Bill 437, Maryland General Assembly, 2016 Laws of Maryland.
  - http://mgaleg.maryland.gov/2016RS/Chapters\_noln/CH\_147\_hb0437e.pdf.
- xvii Alabama Code of State Regulations Section 20-2-217,
  - http://alisondb.legislature.state.al.us/alison/codeofalabama/1975/20-2-217.htm.
- xviii See supra, note xv, Brandeis University.