Prescription Drug Monitoring Programs *(May 2016)*

Prescription Drug Monitoring Programs (PDMPs) are statewide databases, usually administered by a state agency to track the filling and dispensing of prescription drugs. In most states, only prescription drugs that are delineated as Schedule II through IV on the Drug Enforcement Administration's (DEA) drug schedule are monitored. The intent of these databanks is to ensure appropriate prescribing practices 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 suppliers of opioids.

Deterring doctor shopping is becoming increasingly important as the opioid epidemic worsens across the country. The DEA announced that deaths from overdoses exceed deaths from motor vehicle accidents, making drug overdoses the leading cause of death from injury. Since 2002, deaths caused by prescription drugs outweigh even the deaths caused by cocaine and heroin combined.[i] In 2015, states proposed and enacted various policy provisions with the goal to address this rising opioid issue. Of this number 18.6 percent dealt with pain clinics, 11.9 percent targeted rescue drugs and devices, 38.1 percent were aimed at PDMPs, and 31.4 percent addressed other interventions.[ii]

Currently all states, with the exception of Missouri, utilize or are implementing some type of PDMP to monitor prescription drug activity. The structure and format of the databases enacted, however, vary depending on the state. Some differences may include funding mechanisms, who is required to report or be enrolled, data warehousing, and timeframes. For example, the funding for such programs may come from the state's legislative appropriations (Colorado), the state's Board of Pharmacy (Mississippi), or from a surcharge on controlled substance registration certificates (Alabama). Some states require all prescribers to enroll in the program and to report information to the PDMP (Idaho), but some make enrollment voluntary and exempt certain providers from reporting (Indiana). Many states do not require prescribers to report if they are in a facility setting[1] or if the supply quantity is less than a threshold amount.[2][iii]

The Model Act

The National Alliance for Model State Drug Laws has created a Model PDMP Act, which incorporates provisions representing the best practices for policymakers to implement these systems. The first element of the Model Act is to establish the PDMP in consultation with an advisory committee, which should provide input on how to most effectively utilize the database in various settings and create methods for evaluation of the program. The committee should be made up of 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 sheriffs' association, among others. The Model Act also allows the state agency to contract with other state agencies or a private vendor to develop and maintain the PDMP.

Most states require similar information to be reported to the PDMPs; however, the Model Act mandates that each dispenser submit the relevant information within 24 hours of dispensing the drug. Nevertheless, certain waivers of submission or time extensions should be granted for good cause. Prescribers or authorized users are required to query the program prior to prescribing or dispensing the

[1] 37 states have some regulation excluding reporting for dispensing in a facility setting as of 2014
[2] 15 states have some regulation excluding reporting for a nominal amount as of 2014

substance to the individual. There are certain instances that do not warrant a query, including when a controlled substance is dispensed to a hospice patient or to someone as part of treatment for a surgical procedure in a health care facility; when the quantity does not exceed an amount for a seven-day treatment period; when the substance is directly administered to the patient; in an emergency situation; or when the program is not operational due to disaster or electric failure.

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. It does suggest both the state agency and advisory committee work in conjunction to establish procedures for protecting information security, while simultaneously creating processes for providing information to appropriate parties such as law enforcement, data warehousing entities, and necessary providers. There are, however, provisions relating to the misuse of information housed in the PDMP that warrant civil and criminal penalties.

Most of the statutes enacting PDMPs and the Model Act include provisions relating to education and treatment of individuals found to be obtaining prescriptions inappropriately. The Model Act requires the state agency to work with the advisory committee in developing training and education for authorized users of the PDMP, including continuing education on prescribing practices and the treatment of patients with addiction or alcohol abuse. Additionally, the two entities should collaborate with alcohol and drug addiction treatment professionals to support those individuals identified through the PDMP as needing assistance. This provision shifts the purpose of the legislation from that of criminal sanctioning to a means of improving public health.

Status in Missouri

According to the Centers for Disease Control and Prevention, Missouri experienced a 4 percent increase in the prevalence of overdose deaths between 2013 and 2014, rising to 1,067 deaths in 2014.[iv] Opioid and heroin use are both large contributors to overdose deaths. Although the increase in deaths between 2013 and 2014 is not deemed statistically significant, the state still faces issues combating drug abuse. Between 2005 and 2014, hospital utilization and Emergency Department visits in Missouri for opioid overuse increased by 137 percent across all payer-types.[v] This percentage was even greater for individuals who are uninsured, whose utilization spiked 268 percent in the same time period. The regions with the fastest growing rates of opioid abuse are Northeast, Southeast, and St. Louis, though they are not necessarily the regions with the highest prevalence.[vi]

In the 2016 legislative session, Representative Holly Rehder from Sikeston, Missouri filed HB 1892, known as the Narcotics Control Act. This bill would have created a state PDMP to monitor the dispensing of all Schedule II through Schedule IV controlled substances. As part of the PDMP, all drug dispensers would have been required to submit specific information to the Missouri Department of Health and Senior Services within seven days. This timing is substantially delayed compared to the best practices outlined in the Model Act. The proposed legislation would have given the Department the authority to issue a waiver to a dispenser who is unable to electronically submit such information and allow that individual to submit by other means.

To ease implementation of the PDMP, the Department would have been required to reimburse each dispenser for any fees or costs related to the submission of the necessary information and would have been obligated to develop and implement educational courses on the reporting requirements. This bill also encouraged the Department to follow-up with individuals who have been identified as addicts and help them to receive addiction treatment.

The bill mandated that all submitted information be confidential and not subject to public disclosure, except in certain situations. If the Department had reason to believe that an individual or provider may have violated the law or breached relevant professional standards, it must notify the appropriate law

enforcement entities or agencies. Any dispenser who knowingly fails to submit the required information or knowingly submits incorrect information would be subject to an administrative penalty of $1000 per violation. Additionally, the bill would have made the unlawful disclosure of any prescription or dispensation information a Class D felony through 2016 and a Class E felony beginning on January 1, 2017.

The Department would have had the ability to contract with other agencies or vendors that currently run narcotics control programs to help streamline the Missouri process. The agency would be authorized to release non-personal, general information for statistical or research purposes. Despite this provision, the proposed legislation differs from other states by failing to include a provision relating to an advisory committee or evaluation of the program.

Two amendments were added to the bill during the perfection process. One amendment created a civil cause of action for individuals who are harmed by any violation of the PDMP. The second amendment changed a handful of logistical and enforcement provisions, including a clause that would prohibit state, federal, or local authorities from using the PDMP to prevent an individual from owning a firearm. The bill originally only forbid authorities from using the PDMP to restrict an individual's ability to obtain a concealed carry permit. This provision appears to be unique among other state legislation authorizing PDMPs.

This bill did not pass in the 2016 legislative session due to opposition and the threat of a filibuster. This proposed legislation is not the first of its kind. Rather, analogous legislation has been offered every year since 2011. Representative Rehder filed HB 130 in 2015, which was not passed because of concerns about consumer privacy and security. Two additional bills were introduced in 2015, HB 816 and SB 63, but did not pass for similar reasons.

Challengers of this bill contend that there is no evidence suggesting the enactment of a PDMP will stop illegal prescriptions. They also raise civil liberty concerns about a government-controlled database that contains private information. Opponents claim that this bill would be a violation of Fourth Amendment search and seizure rights that could possibly impede individual rights. Conversely, proponents of the bill dispute privacy concerns claiming that safeguards exist in the bill to uphold civil rights. Proponents also raise the fact that Missouri's lack of monitoring serves as a "loophole" for bordering states. They claim that individuals who are stopped from doctor shopping in neighboring states have the ability to come to Missouri to continue their illegal practices. In addition to addressing issues related to drug abuse, proponents assert that the intended purpose of a PDMP is to enhance doctors' and pharmacists' ability to prescribe more appropriately to better serve their patients.

Evidence of Effectiveness

PDMPs have become the preferred policy intervention to address opioid addiction, as illustrated by its widespread adoption across the United States. The prevalent use of PDMPs seems to be leading to positive outcomes both on the provider end by changing prescribing practices and on the patient side by decreasing inappropriate supply and doctor shopping. A 2012 study found an association between PDMPs and smaller increases in drug misuse and hospital admissions caused by opioid abuse.[vii] There is also data showing that when providers identify questionable activity, they tend to make referrals to the appropriate behavioral health providers rather than legal authorities.

States like New York, Tennessee, and Florida have enacted different measures to control opioid abuse. In 2012, New York began requiring prescribers to check the state's PDMP before prescribing certain painkillers, resulting in a 75 percent drop in the number of patients who were doctor shopping. Tennessee enacted the same requirements and saw a 36 percent drop in patients who were doctor shopping. Finally, in Florida between 2012 and 2013, there was an 85.2 percent increase in the number of prescribers who were formally trained to use the PDMP and a 6.4 percent reduction in the number of

adults who received painkiller prescriptions.[viii] There was also a 17.7 percent reduction in prescription drug overdose deaths in that same period.

Studies show that the effectiveness of a state's PDMP is dependent on appropriate utilization and access. For example, a study in 2011 found that there were no observed effects from PDMPs; however, this was attributed to low utilization by prescribers and limited access to data. Delays in obtaining information from the database and lack of patient verification may also contribute to the shortcomings of a PDMP.[ix] Moreover, death rates were found to be affected by drugs obtained in adjacent states.[x] The latter issue would likely lessen if all states, including Missouri, had active and effective PDMPs.

Issues for Consideration

PDMPs have become the presumptive mechanism to battle opioid abuse across the United States, but further review and analysis is needed to test the success of these programs. An improved understanding of the challenges to implementation will help states develop more efficient databases. Issues relating to utilization, access and verification can easily be addressed through legislative action or administrative rulemaking, depending on the state's authorizing legislation. Furthermore, many states have enacted and implemented databases since several of the aforementioned studies on PDMPs were published, suggesting that findings of effectiveness are outdated. Expanded use of PDMPs are likely to close gaps between states, effectively limiting abuse between borders. That being said, Missouri remains as the only state in the nation without an enacted PDMP or a similar mechanism to control opioid abuse and doctor shopping, leaving a substantial hole in the ability for neighboring states to monitor such activity. Future proposed legislation in Missouri should take into account not only the arguments of the opposition, but also the obstacles leading to diminished success.

Endnotes

i Drug Enforcement Administration. U.S. Department of Justice. DEA Releases 2015 Drug Threat Assessment: Heroin and Painkiller Abuse Continue to Concern. Headquarter News, 04 Nov. 2015. http://www.dea.gov/divisions/hq/2015/hq110415.shtml.

ii National Conference of State Legislators, Prevention of Prescription Drug Overdose and Abuse, 23 May 2015. http://www.ncsl.org/research/health/prevention-of-prescription-drug-overdose-and-abuse.aspx.

iii National Alliance for Model State Drug Laws, Prescription Drug Monitoring Programs: State Law and Policy Profiles, 2015. http://www.namsdl.org/library/2155A1A5-BAEF-E751-709EAA09D57E8FDD/.

iv Centers for Disease Control and Prevention, Injury Prevention & Control: Opioid Overdoses, "State Data", May 2016. http%3A%2F%2Fwww.cdc.gov%2Fdrugoverdose%2Fdata%2Fstatedeaths.html.

v Porth, Leslie. et al. "Opioids: A Strategy to Reduce Misuse and Abuse." *Missouri Hospital Association*, 01 Dec. 2015. http://www.mhanet.com/mhaimages/sqi/OpioidMisuse_Clinical_120115.pdf.

vi Ibid.

vii Reifler, L. M., Droz, et al., "Do Prescription Monitoring Programs Impact State Trends in Opioid Abuse/Misuse?", Pain *Medicine*, 2012, 13, 434–442.

viii 2012-2013 Prescription Drug Monitoring Program Annual Report. Florida Health, 01 Dec. 2013. http://www.floridahealth.gov/statistics-and-data/e-forcse/news-reports/_documents/2012-2013pdmp-annual-report.pdf.

ix Griggs, Christopher A., et al., "Prescription Drug Monitoring Programs: Examining Limitations and Future Approaches." *Western Journal of Emergency Medicine*, 2015, 16(1) 67–70.

x Lavonas, Eric. "Prescription Drug Monitoring Programs: Evaluation of Effectiveness". Food and Drug Administration, 2013. http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/DrugSafetyandRiskManagementAdvisoryCommittee/UCM337160.pdf.

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