By Nancy R. Steer and Mollie A. Gass

Prescription Drug Monitoring Programs as a Tool for Monitoring the Prescription Drug Epidemic

Prescription drug monitoring programs, also called prescription monitoring programs ("PMPs"), collect information regarding prescriptions for controlled substances. PMPs are most commonly designed to ensure that prescribing practitioners can confirm the type(s) and quantities of controlled substances prescribed to a specific patient by other practitioners. These useful tools help practitioners avoid prescribing additional controlled substances to patients that exhibit signs of abuse, misuse, and/or doctor shopping.

While PMPs are rapidly growing across the country and 49 states have implemented them in some form, their uses are varied. Some states use them for public health and healthcare while other states use them for law enforcement purposes. While some states have enacted laws allowing data sharing among states, other state laws make this nearly impossible. To add further difficulty, states use different vendors for their PMPs, which means that states have different interfaces for their PMPs. This likewise makes data sharing difficult.

While the use of controlled substances is considered by many as necessary, especially in the treatment of pain, the inherent risks of controlled substances necessitate the need for monitoring their use. This article outlines the reasons that opioids, specifically, are prescribed in the U.S., provides a brief history of PMPs across the country, and examines possible approaches to utilizing PMPs in the future, including potential barriers to their uses.

This article provides an objective discussion of PMPs for the purpose of informing readers regarding their use, their future, and problems that must be addressed in the future. In-house and corporate healthcare counsel should find this article useful to inform their clients of both the existence and use of these valuable tools.

Opiates Are Considered Necessary for the Treatment of Pain, but Their Use Can Have Destructive Consequences and Necessitates a Need for Monitoring

The fact that health is a human right is virtually undisputed. The International Covenant on Economic, Social and Cultural Rights emphasizes "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health." *See* International Covenant on Economic, Social and Cultural Rights, Part III, Article 12, Sec. 1.

Further, in listing both morphine and codeine—both opiates—as "essential medicines" in its Model List of Essential Medicines, the World Health Organization ("WHO") has deemed freedom from pain as a human right. *See 19th WHO Model List of Essential Medicines*, World Health Organization (April 2015); *see also* Sam Quinones, *Dreamland*, 82 (2015). The WHO stated that "[m]any controlled medicines are *essential medicines* and are *absolutely necessary* for the relief of pain, treatment of illness and the prevention of premature death." *See Ensuring balance in national policies on controlled substances: Guidance for Availability and Accessibility of Controlled Medicines*, World Health Organization (2011) (emphasis added).

It is undisputed that pain has a remarkable impact on a person's quality of living and "can have physical, psychological[,] and social consequences. It can lead to reduced mobility and a consequent loss of strength, compromise the immune system[,] and interfere with a person's ability to eat, concentrate, sleep, or interact with others." *See* Diederik Lohman, *et al.*, *Access to pain treatment as a human right*, BMC Medicine, 1 (2010).

Codeine, morphine, oripavine, and thebaine, considered natural opiates, serve as the basis for derived and/or synthesized prescription opioid medications, including Lortab, Demerol, Atarax, Dilaudid, fentanyl, oxycodone, oxymorphone, hydromorphone, and hydrocodone. *See* National Institute on Drug Abuse: *Opioids* (2015); *see also Controlled Substances - Alphabetical Order*, Office of Diversion Control, Drug Enforcement Administration (2016). The natural opioid poppy has derived almost

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two hundred other opiates, including the illicit drug heroin. *See* Quinones at 38.

It is almost needless to say that this class of drugs is highly addictive. The American Society for Addition Medicine recently published a fact sheet which stated that, "of the 21.5 million Americans 12 or older that had a substance use disorder in 2014, *1.9 million* had a substance use disorder involving *prescription pain relievers* and *586,000* had a substance use disorder involving *heroin*." *See Opioid Addiction 2016 Facts & Figures*, American Society for Addiction Medicine (2016) (emphasis added). Although a discussion of heroin addiction is beyond the scope of this article, its addiction figures are worthwhile to note because it is likewise an opiate.

Opioids are prescribed regularly in the United States. For instance, in 2011, practitioners prescribed approximately 219 million prescriptions of oxycodone and hydrocodone alone. *See* IMS Health National Prescription Audit (NPA) (2011). Although this number is the highest in recent years, it demonstrates that the U.S. is experiencing an epidemic of opioid use.

This epidemic is costly in terms of both human lives and finances. At this time, approximately 44 people die daily as a result of prescription opioid overdose. *Deaths from Prescription Opioid Overdose*, Center for Disease Control and Prevention (2015). In the U.S. alone "prescription opioid abuse costs were about $55.7 billion in 2007. Of this amount, 46 [percent] was attributable to workplace costs (*e.g.*, lost productivity), 45 [percent] to healthcare costs (*e.g.*, abuse treatment), and [nine percent] to criminal justice costs." *Id*.

Prescription Drug Monitoring Programs Have Been in Place for Years, but Are Rapidly Expanding and Gaining Increased Support

PMPs are considered "highly effective tools utilized by government officials for reducing prescription drug abuse and diversion." *Prescription Drug Monitoring Frequently Asked Questions (FAQ)*, PDMP Training and Technical Assistance Center (2015). With today's technology, PMPs can "collect, monitor, and analyze electronically transmitted prescribing and dispensing data submitted by pharmacies and dispensing practitioners." *Id*. With such a prescription drug abuse epidemic in today's society, PMPs can serve as a tool in preventing the diversion and inappropriate prescribing of controlled substances within a state, among states, and even potentially on a national scale. Kristin Finklea, *et al.*, *Prescription Drug Monitoring Programs*: *Summary*, Congressional Research Service, "Summary" (2014).

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Currently, PMPs maintain electronic databases of prescriptions dispensed for scheduled controlled substances such as OxyContin, hydrocodone, and Xanax. *Id*. Although the information collected by these databases is used differently in states across the country, PMPs can be used to support access to the legitimate medical use of controlled substances, identify doctor-shopping patients, facilitate the identification of drug addicted individuals to enable intervention for treatment, outline drug use trends for public health initiatives, or to educate healthcare practitioners about their patient's drug use, abuse, or diversion. *Id*.

PMPs allow state governments to record protected health information for the purposes of regulation, and as early as the inception of PMPs, physicians and patients alike were concerned with the potential breach of the expectation of privacy provided in the United States Constitution. The Supreme Court of the United States weighed in on this topic in *Whalen v. Roe*, 429 U.S. 589, 97 S. Ct. 869, 51 L. Ed. 2d 64, 1977 U.S. LEXIS 42 (U.S. 1977), by holding that New York laws requiring accumulation of vast amounts of personal information regarding patients' receipt of controlled substances did not create an invasion of any right or liberty protected by the Fourteenth Amendment. The *Whalen v. Roe* holding paved the way for PMPs as they exist today.

Early PMPs: Paper Formats

Since the 1930s, PMPs have been utilized in many different forms and have been predominantly controlled by state law. Before technology allowed electronic data sharing, early types of PMPs utilized duplications of paper prescriptions regulated by each state's government, wherein the regulating agency would record the data and save the hard copies behind locked doors.

Early PMP programs were different from those utilized today, and were characterized as multiple-copy prescription programs ("MCPPs"). Aaron M. Gilson, *et al.*, *Time Series Analysis of California's Prescription Monitoring Program: Impact on Prescribing and Multiple Provider Episodes*, The Journal of Pain, 104 (2012). These MCPPs "required healthcare practitioners to use government-issued, serialized duplicate or triplicate forms to prescribe Schedule II controlled substances," as well as other medications with risks of abuse, including benzodiazepines. *Id*. In 1914, New York laws required physicians to use state-issued prescription forms for certain prescribed drugs. Finklea at 3. One problem with these early MCPP programs was that practitioners often failed to order the state-issued prescription forms, causing the physician to be unable to prescribe medically-necessary controlled substances. *Id*.

Modern PMPs: Electronic Formats

The electronic form of PMPs utilized today originated in the early 1990s. "Since the early 1990s, PMPs have increasingly utilized electronic data transmission (EDT) systems." Gilson at 104. Similar to MCPPs, "EDT systems are intended to reduce the incidence of abuse-related behaviors, including the use of multiple practitioners to

obtain different prescriptions for the same medication." *Id*. EDT PMP systems are believed to be better equipped to prevent prescription drug abuse.

PMP Growth, Funding, and Organization

Over the past 20 years, PMP growth has been widespread. In fact, 70 percent of state programs were enacted in the first decade of the 21st century. *History of Prescription Drug Monitoring Programs,* PDMP Training and Technical Assistance Center, http://www.pdmpassist.org/pdf/PPTs/LE2012/1_Giglio_HistoryofPDMPs.pdf. Even further, 35 PMPs were enacted between 2000 and 2012. *Id.*

Since 2002, Congress has provided financial support to PMP databases with the enactment of the Harold Rogers PDMP grant. This grant was intended to support "law enforcement, regulatory entities, and public health officials [who] analyze data on prescriptions for controlled substances." Finklea at 2. Further, Congress passed the National All Schedules Prescription Electronic Reporting Act of 2005 ("NASPER"), which requires the Secretary of the Department of Health and Human Services to fund both establishing and/or improving PMPs. *Id*.

Organization of today's PMPs varies among states. Through its legislature and enactment of statutes, each state determines what agency will house the PMP, which controlled substance prescriptions will be reported, who must submit data, how often data will be collected, who has access to the database (*i.e.*, prescribers, dispensers, public health officials, law enforcement), what circumstances allow access to the database, and effects of non-compliance. Thomas Clark, *et al.*, *Prescription Drug Monitoring Programs: An Assessment of the Evidence for Best Practices*, 1 (2012).

With the exception of Missouri, every state has enacted legislation allowing for a prescription monitoring program. Even though PMPs differ vastly among the states, the overall goal of effectively regulating controlled substances is generally accepted among all states.

From consumer protection agencies to law enforcement to boards of pharmacy, a variety of different state agencies control prescription drug monitoring programs. For instance, the Boards of Pharmacy house 20 state PMPs, Departments of Health house 13, law enforcement agencies house 7, professional licensing agencies house 6, substance abuse agencies house 3, and a consumer protection agency houses 1. *See Prescription Drug Monitoring Frequently Asked Questions (FAQ)*, PDMP Training and Technical Assistance Center (2015).

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There Are Varied Opinions Regarding the Use of PMPs

Many have raised concerns regarding the use of PMP data—for instance, uses for healthcare versus law enforcement. Critics have raised particular concerns with regard to maintaining privacy of protected health information and allowing continued access to controlled substances in patients with legitimate medical needs. Finklea, *"Summary."*

Prescription data—including the date distributed, name of patient, prescriber, pharmacy, prescription, dose, and form of payment—can be made available online after a request is received from an authorized recipient. Clark at 1. In fact, much of this PMP data is accessible securely on a computer. While authorized recipients are typically prescribers or pharmacists, they may also be "practitioner licensure boards, law enforcement and drug control agencies, medical examiners, drug courts and criminal diversion programs, addiction treatment programs, public and private third-party payers, and other public health and safety agencies." *Id*. However, each state varies widely with regard to which categories of users are permitted to request and receive prescription history reports. *Id*. Additionally, states vary widely with regard to what conditions are necessary for receipt of such information. *Id*.

In general, there are two schools of thought regarding the effectiveness of PMPs. The first is that these tools effectively help battle drug abuse, and the second is that they have a "chilling effect" on legitimate prescribing by healthcare providers. *Id*. at 4.

Although Many Believe PMPs Are Useful Tools That Should Be Utilized, Data Sharing Has Both Benefits and Barriers to Use

From the prescribers to the patients, a variety of individuals believe that PMPs are useful. An emergency-room physician in Tennessee stated that, "[b]ased on the patterns of drug-seeking behavior I have found in my medical practice, I believe a nationwide prescription drug monitoring program would be extremely beneficial to allow me to view whether a patient has obtained controlled substances in any of the many states surrounding Tennessee."

In *Harris v. Purdue Pharma, L.P.,* 218 F.R.D. 590, 2003 U.S. Dist. LEXIS 20097 (S.D. Ohio 2003), the plaintiffs, who were individuals who had become addicted to opioids, specifically OxyContin, sought relief in the form of "a medical and prescription monitoring program for patients prescribed OxyContin, in order to prevent or to miti-

gate addiction." *Id*. at 593, *3. While the majority of the *Harris* decision discusses the plaintiffs' request for class action certification under Fed. R. Civ. P. 23, this case demonstrates two important points. First, even patients—admittedly addicted to narcotic pain mediation—recognized the importance and utility of prescription monitoring programs, arguing that "such programs are effective" in curbing and monitoring addiction. *Id*. at 595, *12. Second, both the bench and bar recognize the importance of PMPs. Although the *Harris* court declined to certify the class because it could not achieve the commonality prerequisite, it stated that it "does not question the value of such a tool." *Id*. at 598, *24.

Consequently, it appears that physicians who prescribe this medicine, patients who recognize the risks of addiction, and members of the legal community all recognize the utility of PMPs. While the above-quoted physician referenced the need for a nationwide database, the authors recognize that some may not agree.

However, due to the opioid epidemic in this country, the need for at least some form of data sharing with regard to the prescribing of controlled substances is evident. While data sharing may not be approved on a national scale, these authors suggest that data sharing between two states, among contiguous states, or on a nationwide scale can benefit patients, prescribers, and the healthcare industry itself.

Regardless of the level of data sharing implemented, its benefits likely outweigh the barriers that will be encountered. For instance, in general, PMP data sharing can help prevent doctor shopping and crack down on pill mills. Data sharing will inform physicians regarding a patient's current controlled substance prescriptions, which can avoid the prescribing of contraindicated medications, aid in assuring continuity of care, and, perhaps most importantly, help to avoid abuse, misuse, and diversion. Further, sharing such data can assist in identifying and monitoring public health crises, such as opioid epidemics.

Data sharing presents barriers, and the most difficult to overcome are political. For instance, each state enacts its own legislation for PMPs, including but not limited to, (1) who has access to the data, (2) the entity responsible for administrating the program (*i.e.*, law enforcement, department of health, board of pharmacy, etc.), and (3) funding for the PMPs. Because each state varies significantly even with regard to these limited issues, this varied legislation presents a barrier to a states' access to another states' PMP data. This will require streamlined legislation among states, which may be difficult to achieve.

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The most significant barrier to PMP data sharing is that it will be considered by some as a form of surveillance. Despite the *Whalen* holding, data sharing will continue to implicate patient privacy concerns because this data will contain patients' protected health information. Since surveillance and privacy concerns are a hot topic of debate, data sharing will certainly be implicated, and states must work together to ensure that only the appropriate persons have access to such data.

Another barrier to sharing data from PMPs is technology. While technological issues can certainly be overcome more easily than political issues, it is worthwhile to note that different states use different vendors to host their PMPs. Each vendor uses a different interface for its programs, and the National Association of Boards of Pharmacy PMP Interconnect facilitates the transfer of PMP data across state lines to authorized users. This allows participating states to securely exchange prescription data, but problems arise with regard to incorporating this data into their electronic medical records systems. Because the interface language, so to speak, varies among states and authorized recipients of the data, problems inherently arise regarding incorporating or translating data between interfaces.

Additionally, different states use different patient identifiers. For instance, some states use a combination of the name, date of birth, and address as a way to identify a patient in its monitoring database. Other states use different identifiers, such as social security numbers. Because this is not uniform among the states or authorized users, data cannot easily be shared until it becomes uniform.

Again, the political issues regarding surveillance, privacy, and the need for uniform legislation among states will present as much more pressing, hotly-debated, and difficult issues in the future for PMPs across the country. However, technological issues must also be considered for interstate data-sharing.

Conclusion

As both the federal government and states race to find a solution for the ongoing prescription drug epidemic, the need for prescription drug monitoring programs and data sharing continues to increase. While there are many opinions regarding the appropriate level of data sharing, the fact remains that the need for it, particularly with regard to patient benefits, prescriber interests, and public health concerns, is increasingly evident.

Prescription drug monitoring programs are gaining support across the country, and legal practitioners advising clients—from solo practitioners and small clinics to expanded, multi-state medical facilities—should be made aware of this useful and ever-changing tool.