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Table of Contents

Course Correction: The Opioid Crisis, Regulatory Efforts, and the Role of Physicians

Elizabeth M. Hein
Post & Schell PC
Philadelphia, PA

Emily B. Grey
Breazeale Sachse & Wilson LLP
Baton Rouge, LA

By all accounts, the opioid addiction epidemic is one of the most profound tragedies and public health challenges of our time. Each day, the news is replete with stories about the significance and wide-ranging impact of the opioid crisis in the United States. The overwhelming flow of addictive pain medications is a topic at the forefront of our national awareness. This article provides an overview of key statistics that show historical trends culminating in the current crisis, a summary of recent regulatory efforts to deal with the epidemic, and practice points on the central role physicians have to fill in addressing the crisis.

The Bad News: Startling Statistics and Scary Truths

The increase in the prescription of opioids over time is startling. Between 1999 and 2015, the amount of opioids prescribed per person *tripled*.[1] By 2015, Americans were being prescribed enough opioids for every American to be medicated 24/7 for three weeks.[2] In some states, more prescriptions have been dispensed for opioid pain pills than there are people in the state. The rates of opioid prescribing are important because, not surprisingly, the rates of opioid overdose deaths have been shown to closely track these prescribing rates.[3]

The significance and result of the extensive prescription of opioids cannot be overstated. The current statistics tell a harrowing tale of the tremendous cost of the opioid crisis in the form of economic losses, a corresponding heroin epidemic, and in deaths. First, from a purely financial perspective, it is estimated that in a single year, prescription opioid misuse and

Arizona Prescription Monitoring Program – A Rapidly Evolving Response to the Opioid Crisis

D'Arcy Downs-Vollbracht
Concierge Legal Group PLLC
Kingman, AZ

The United States is in the midst of a public health crisis that impacts all physicians and health care workers, professionally and legally. Opioid overdoses and addiction are straining families, the economy, health care infrastructure, and public budgets. Currently, six states, Massachusetts, Virginia, Alaska, Maryland, Florida, and Arizona have enacted public health states of emergency in response to opioid epidemics. On October 26, 2017, President Trump declared the opioid crisis a national public health emergency and indicated it was a crisis of epic proportions impacting every community in all 50 states.[1] The designation as a state of emergency or a national emergency includes providing authority and funding for increased government surveillance and oversight of the prescribing of opioids. These designations also initiate emergency rulemaking provisions, and various agencies and lawmakers have been tasked with implementing guidelines and rules with the goal of reducing opioid-related overdoses and deaths, but those goals can have significant impacts on medical providers.[2]

Prescription Drug Monitoring Systems Become Critical To Combating Opioid Crisis

One key component of the nationwide response to opioid abuse is the tracking and monitoring of the use of controlled substances. Ostensibly to assist law enforcement in identifying illegal activity related to prescribing, dispensing, and consumption of controlled substances, the Controlled Substance Prescription Monitoring Program (PMP) database also provides invaluable information to medical practitioners regarding patient care. The information allows for informed clinical decisions, increased patient safety, and minimizes professional liability risks. All states now have a statewide version of a PMP. This monitoring system is vitally important in combating the opioid crisis and it creates legal obligations for providers.[3]

According to information derived from the Arizona PMP, there were over 205 million opioid pills prescribed to Arizonans from January 2017 to July 2017.[4] Using Arizona as an example and focusing on its PMP highlights the significance of rapid changes that can occur once a state of emergency is declared. Arizona Governor Doug Ducey declared a state of emergency due to the opioid overdose epidemic on June 5, 2017.[5] This placed authority and responsibility for emergency opioid prescribing, surveillance, and treatment rules squarely in the hands of the Arizona Department of Health Services (ADHS). By July 28, 2017, the Emergency Opioid Rule Package regarding the prescribing and monitoring of controlled substances was promulgated and in effect.[6]

Each state designates a state agency to oversee its PMP—in Arizona it is the State Board of Pharmacy (ASBP). Over the last year, numerous revisions to regulations and laws related to opioid use, dispensing, and related overdoses and deaths have been enacted, including several major changes to the controlled substance PMP-mandated reporting requirements.[7] The ASBP began collection of dispensing pharmacy data in October 2008 and practitioner data in October 2009 following the passage of H.B. 2136 and A.R.S. 36-2602, which required a computerized central database tracking system for the prescribing, dispensing, and consumption of controlled substances in Arizona.[8] Originally, the requirement was applicable to Schedule II, III, and IV controlled substances but as of August 9, 2017 the requirement was expanded to include Schedule V controlled substances. This revision also expanded the scope of use and release of patient and provider information contained in the PMP to include ADHS "regarding persons who are receiving or prescribed controlled substances in order to implement a public health response to address opioid overuse or abuse."[9]

The November 5, 2017 Draft Arizona Opioid Prescribing Guidelines require a health care provider or institution to develop a system for opioid stewardship, i.e. monitoring opioid prescribing practices, outcomes, and provider alignment with guidelines and best available evidence.[10] The first step for any provider in Arizona is to review the patient report and information contained in the PMP in order to determine what controlled substances the patient has been prescribed or is currently using to assess potential risks, adverse outcomes, and complications should opioids be prescribed, and to explain in a meaningful way the risks associated with opioid use to the patient in order to obtain informed consent. A key component of any prescribing or course of treatment involving the use of an opioid is the reporting of any prescription to the PMP database. The accuracy of information contained in the PMP database depends on accuracy of information reported by providers and pharmacies.

Revisions to Arizona regulations have directly impacted the prescribing of opioids and the role of the PMP. For instance, A.R.S. 36-2606 now requires all medical practitioners who are licensed under Title 32 or Title 36 and who possess a United States Drug Enforcement Agency (DEA) license or an active registration under the Controlled Substances Act[11] to register with the ASBP for access to the PMP. Each DEA license must have an associated registration, and each DEA licensed provider in the practice must have an individual PMP registration.[12]

Clinical Flow and Practical Use of the PMP

Providers can, and should, also query their own controlled substance prescribing history to make certain that they are not listed as the prescriber for non-patients and that their DEA license has not been compromised. If there is a discrepancy or mistake the provider should reconcile the information to ensure both provider and patient information in the database is accurate.[13]The PMP is a valuable tool for ensuring patient care and provider safety but, in order to be effective, it must be accurate and well utilized. Pursuant to federal law, "all prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner."[14] This information is contained in the PMP and providers who monitor their own prescriber information or "report card" and identify incorrect information can correct mistakes. The first step is to contact the dispensing pharmacy and verify the details. If the information is indeed incorrect, the pharmacy needs to correct the information and resubmit their data to the ASPB. If the inaccuracy is larger in scope, the provider can contact the PMP administrative staff at ASPB directly for assistance.[15]

Each provider can designate a "delegate" (an employee or person to act on the provider's behalf) who can access the PMP, query a patient record, and put the patient PMP report in front of the treating provider for review. In a multi-provider practice, providers can have the same delegate but it is important for the delegate to ensure they are properly logging in as a delegate under the provider who will be treating that patient so that PMP information is accurate as to which provider queried and reviewed patient PMP data. This is an often misunderstood function because in some practices the medical director or a sole provider has an account, but doesn't designate a delegate or require all providers in a practice to register for their own separate account. Sometimes, the medical assistant or practice manager will query the patients on the schedule for the next day in the account of the medical director or registered provider for the treating provider to review. When this happens, the PMP will only reflect the fact the medical director or sole registered provider queried the patient PMP, though the patient was treated by a different provider. While the provision of care may be proper and the PMP is being reviewed and patients are being counseled accordingly, the information contained in the PMP is incorrect. This specific example can lead to the medical director or registered physician account in a multi provider practice being used to query excessive numbers of patients. Due to the incorrect use of a single ID login the data can falsely indicate that other providers in the practice are not properly reviewing patient reports or accessing the database at all, despite prescribing controlled substances to those patients. This type of practice error can lead to skewed and inaccurate PMP data that can in turn be referred to various licensing boards and investigative agencies for review and investigation.[16]

In order for the data contained in the PMP to be accurate and reliable, every provider must be registered separately and the delegate must use the proper login for the provider PMP access. This maintains the integrity within the database of each provider's account, accessing history, prescribing history, and patient records and it avoids the appearance of overprescribing.

Arizona PMP Requirements Change Rapidly Under State of Emergency

In Arizona, the latest mandate for all providers to use the PMP database became effective October 16, 2017.[17] Each medical practitioner's regulatory board will notify its respective licensees of the mandate. A medical practitioner may be granted a one-year waiver from the mandated PMP registration requirement due to technological limitations that are not reasonably within the control of the practitioner or other exceptional circumstances demonstrated by the practitioner pursuant to a process established by the ASBP. Despite the possible exception, the rapid rule-making and focus on the opioid crisis has led to a situation where the rule became effective before there was a process in place for providers to seek the waiver.[18] As of the date of this writing, there are no rules or process yet in place for obtaining such a waiver, which means those physicians not registered and using the PMP are not in compliance.

The impact of these recent changes will be to require that before beginning a new course of treatment that includes prescribing an opioid analgesic or benzodiazepine controlled substance listed in schedule II, III, IV and now V for a patient, a medical practitioner must obtain a PMP patient utilization report regarding that patient for the preceding 12 months and that the patient PMP report must be updated at least quarterly while that prescription remains part of the patient's treatment plan. With patients on long term controlled medications, it is advisable that the prescribing provider, often a pain management specialist, review the current PMP at each visit. This practice enables a provider to ascertain whether the patient is properly utilizing the prescription(s); has other contradictory substances such as alcohol or illegal drugs or even no trace of the prescribed medications in their system through use of recommended urine screening. The morphine equivalency dosing (M.E.D.) information contained in the PMP can provide prescribers and pharmacists the ability to ensure the patient is receiving the proper dosage(s) or treatment. These key factors can serve as red flags to providers and can significantly impact treatment and the identification of possible opioid abuse.

The PMP database in Arizona is now also used to track dispensing of Naloxone, a non-addictive drug that reverses the excessive central nervous system depression and respiratory distress that can be caused by opioid use. Under the state of emergency orders, Naloxone has been made more readily available. On June 19, 2017, a standing order, signed by the Director of the ADHS, authorized any Arizona licensed pharmacist to dispense naloxone hydrochloride or any other opioid antagonist that is approved by the United States Food and Drug Administration (FDA) to any individual without requiring a physician's prescription.[19] It also allowed prescribers to dispense Naloxone to law enforcement, jails, social workers, and laypeople. This also supports pain management providers who have implemented practice protocols for prescribing Naloxone to chronic pain sufferers who substantially benefit from long term opioid therapy. The dispensing of Naloxone now requires mandatory reporting to the PMP database.

Accuracy of Information Is Key for Providers and Patients

Information contained in the database can have significant impacts on providers and patients alike. The ASPB generates a report card for providers based on their prescribing data in the PMP. Each provider can register under one of 31 specialties and their data will be analyzed in relation to the data obtained on similarly situated providers within the same specialty. Thus a pediatrician will not be compared to a pain management specialist. However, the top 25-50 prescribers above the mean per specialty are identified and those with above average controlled substance prescribing numbers are notified by a quarterly report card issued by the ASBP that they are "outliers" in terms of PMP data. The reporting of PMP statistical information to various licensing boards presents

legal issues beyond the scope of this discussion, however it is yet another reason for providers to be especially accurate in terms of PMP reporting.[20]

Utilizing shared multistate information or accessing the PMP databases of states connected to the continuum of care for patients, is another way for providers to have more information to properly assess and treat patients. Providers in Arizona, for example, often treat winter residents. These patients are often treated by physicians in other parts of the country and it can be difficult to effectively evaluate a patient without prescription data. The American Hospital Association (AHA) in a September 21, 2017 comment letter, responding to an interim report issued in July by the new White House Commission on Combating Drug Addiction and the Opioid Crisis, supported the Commission's efforts to ensure interstate data sharing among prescription drug monitoring programs.[21] Arizona PMP registered users can select from a list of participating states to obtain multi-state approval for sharing of information between states enrolled in the PMP Clearinghouse, which is a consortium of participating states. The ASBP is a member of the National Association of State Controlled Substances Authorities (NASCSA) and is working diligently to facilitate a national reporting system as well as integrate the Arizona PMP with various electronic health record and pharmacy dispensing systems to make information more comprehensive, accurate, and readily available. Missing or inaccurate information in the database remains an issue and has been identified by providers and investigative agencies as a sound reason for improving both state and national information sharing, provider education on use of the databank, and methods to correct identified mistakes or inaccuracies.[22] Recently, the President's Commission on Combating Drug Addiction and the Opioid Crisis recommended funding to bolster PMP requirements, including development of a national data sharing hub, mandated PMP queries, PMP data integration into electronic health records, and an increase in electronic prescribing to prevent diversion and forgery.[23]

As regulations and laws continue to develop and be implemented, it will be imperative for providers to ensure accurate information is reported to the PMP. The next year will be filled with changes to the controlled substance related monitoring system, but the PMP is emerging as a key resource for addressing the opioid state of emergency in Arizona.

1 Brian Zimmerman, "6 States Fighting Opioid Epidemic with Emergency or Disaster Declarations," Becker's Hospital Review, Aug. 10, 2017, *available at* https://www.beckershospitalreview.com/opioids/6-states-fighting-the-opioid-epidemic-with-emergency-or-disaster-declarations.html.

2 Notice of Emergency Rulemaking, Title 9 Health Services Chapter 4 Arizona Department of Health Services.

3 *E.g.,* A.R.S. 36-2606 mandates each medial practitioner who is issued a license and possesses an Arizona registration under the Controlled Substances Act must have a current PMP registration and access to the database tracking system. S.B. 1283 further requires practitioners to obtain a patient utilization report regarding the patient for the preceding twelve months at the beginning of each new course of treatment; before prescribing an opioid analgesic or benzodiazepine listed in Schedule II, III, IV, and V; and on a quarterly basis if the substance remains part of treatment.

4 ADHS Draft Arizona Opioid Prescribing Guidelines, Oct. 5, 2017, *available at* http://azdhs.gov/documents/audiences/clinicians/clinical-guidelines-recommendations/prescribing-guidelines/az-opioid-prescribing-guidelines.pdf; 2016 ADHS Arizona Opioid Report, *available at* http://www.azdhs.gov/documents/audiences/clinicians/clinical-guidelines-recommendations/prescribing-guidelines/arizona-opioid-report.pdf; and President's Commission on Combating Drug Addiction and the Opioid Crisis Chairman's Letter, November 1, 2017.

5 https://azgovernor.gov/sites/default/files/related-docs/opioid_declaration.pdf.

6 A.A.C. R9-10-Article 1 focuses on health and safety while implementing regulatory consistency for all health care institutions.

7 https://pharmacypmp.az.gov/new-pmp-reporting-mandates-naloxone-and-c-v-0.

8 4 A.A.C. Title 4. Professions and Occupations, Chapter 23, R4-23-501, Board of Pharmacy, Article 5.

9 Chapter 283, Senate Bill 1023, amending A.R.S. Sections 36-2602; 36-2604 and 36-2608 became effective on August 9, 2017 and included the required reporting of Schedule V controlled substances prescribed, dispensed, or consumed to the PMP database, *available at* https://www.azleg.gov/legtext/53Leg/1R/laws/0283.pdf.

10 Arizona Opioid Prescribing Guidelines, November 5, 2017 *available at* http://azdhs.gov/documents/audiences/clinicians/clinical-guidelines-recommendations/prescribing-guidelines/draft-opioid-prescribing-guidelines.pdf.

11 21 U.S.C. § 801-904.

12 Arizona Prescription Monitoring Program User Support Manual Section 2.2, *available at* https://pharmacypmp.az.gov/sites/default/files/documents/files/Arizona%20-%20PMP%20AWARxE%20Requestor%20User%20Support%20Manual.pdf.

13 Perrone J, Nelson LS, *Medication reconciliation for controlled substances an "ideal" prescription drug monitoring program*, N Engl J Med. 2012;336(25):2341-2343.

14 Title 21 C.F.R. § 1306.05(a).

15 https://pharmacypmp.az.gov/sites/default/files/documents/files/Report%20Card%20FAQs_4.pdf.

16 State of Arizona, Exectutive Order 2017-04, Enhanced Surveillance Advisory requires law enforcement, licensing boards, state agencies, and providers to participate in mandatory reporting and sharing of information. *See also Oregon Prescription Drug Monitoring Prog. v. DEA*, No. 14-35402 (9th Cir. June 26, 2017).

17 https://www.azleg.gov/viewDocument/?docName=http://www.azleg.gov/ars/36/02606.htm.

18 A.R.S. 36-2606(F) enumerates the mandate and the exception to the rule, but defers the process for obtaining a waiver to the ASBP.

19 https://pharmacypmp.az.gov/sites/default/files/documents/files/naloxone-standing-order.pdf.

20 Arizona PMP Task Force Meeting 2017 Minutes.

21 http://www.aha.org/advocacy-issues/letter/2017/170921-let-thompson-eop-opiodcrisis.pdf.

22 *How Clinicians Use Prescription Drug Monitoring Programs: A Qualitative Inquiry*, Pain Med. 2014 Jul; 1179-1186. *See* Table 2.

23 https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf.