POLICY BRIEF

Mandates to Use State Prescription Drug Monitoring Programs (PMPs): Implications for Health Care Providers

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Executive Summary

Forty-six (46) Americans die each day from prescription opioid overdoses. The growing problem of prescription drug abuse and diversion has stakeholders at all levels – Federal, State, and Local – working hard to try and reverse the trend. Forty-nine states (49), Guam and the District of Columbia have – or are in the process of implementing – prescription drug monitoring programs (PMPs) with the goal of collecting information on controlled substance dispensations and sharing this information with clinicians, pharmacists and other critical stakeholders to identify and curb prescription drug abuse and/or diversion.

However, many states' programs get limited use from the healthcare community. The most commonly cited reasons include: a) the data is not integrated into the clinical workflows; b) data access is cumbersome and slow; and c) when data is available, it is not presented in the most usable and actionable form. To drive utilization of this important data, several states (twenty-five at the time this paper was written) mandate that in specific circumstances prescribers, and sometimes dispensers, have to check the PMP before they prescribe or dispense controlled substances.

The growing trend of state laws mandating the use of PMP data while treating a patient, without effective integration of the data into electronic health records and pharmacy management systems makes compliance administratively burdensome and takes away valuable time from patient care.

The healthcare providers who daily confront these challenges need to earnestly and actively seek out the tools and mechanisms that hold the most promise for facilitating their efficient and effective use of PMP data. In so doing, providers not only help themselves, but also inform government efforts about what works to truly shape a PMP that in practice improves patient care and safety.

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Scope of the Prescription Drug Abuse Problem

Forty-six (46) Americans die from prescription opioid overdoses every day.[i] With the release of this disturbing statistic, U.S. Senators Joe Manchin and Tim Scott announced on May 22, 2015 the establishment of the Senate Prescription Drug Abuse Caucus (Caucus). The mission of the newly formed body is to "raise awareness about the significant harms of prescription drug abuse…", and to "work together and with stakeholders toward innovative and effective policy solutions that address prevention, treatment, and more to help every community overcome this devastating problem."[ii] The Caucus is the latest in a series of initiatives intended to address the challenges reflected in the numbers about prescription drug abuse:

- 145,000 prescription opioid deaths in 10 years;[iii]
- 4 times as many deaths in 2013 as in 1999;[iv]
- For every prescription opioid overdose death in 2011, there were:
  - 12 treatment admissions for opioids;
  - 25 emergency department visits for opioids;
  - 105 people who abused or were dependent on opioids; and
  - 659 nonmedical opioid users.[v]
- During the 2008-2010 period, roughly 83% of past year frequent nonmedical users of opioid pain relievers reported using opioids prior to heroin initiation.[vi]

Government officials use labels like "epidemic" or "crisis" to try and express the magnitude of the problem. However, it is the numbers that reveal a consistent and fundamental truth. The problem is ubiquitous. It does not rest in one geographic region or with one socioeconomic group. All of us, through our families, friends, schools, communities or workplaces are somehow touched by the abuse and diversion of, and addiction to, prescription drugs.

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PMPs: A Priority Tool in Solving the Prescription Drug Abuse Problem

Prescription drug monitoring programs (PMPs) are statewide electronic databases administered by state agencies that collect data on prescription controlled substances dispensed in, and sometimes delivered into, the state. A PMP provides in one location a more complete picture of a patient's prescription history than can often be found in any other single source. State laws require pharmacists in the state to report data on prescriptions filled for a patient to one PMP administering agency. That agency's database therefore maintains information on all the patient's prescriptions dispensed by reporting pharmacies around the state. In contrast, other databases contain more limited information about the patient's prescriptions because the sources from which they receive data are more limited. A national pharmacy chain will only store data on prescriptions the patient fills at its pharmacy outlets. A state health information exchange transmits only the patient's prescription information that is maintained by health care providers who participate in the exchange. The PMP is a state's most comprehensive repository of prescription data for a patient.

Many believe PMP data are vital to improving (1) prescribing and dispensing practices, (2) early intervention with patients who may be abusing or addicted to prescription drugs, and (3) identification and prevention of prescription drug diversion.

Persuaded that PMPs have an essential role in curbing prescription drug abuse, agencies and organizations of divergent perspectives collectively support the establishment and operation of the programs. Among the supporters are the Office of National Drug Control Policy (ONDCP), the Centers for Disease Control and Prevention (CDC), the National Governors Association (NGA), the National Conference of Insurance Legislators (NCOIL), the Association of State and Territorial Health Organizations (ASTHO), the Trust for America's Health (TFAH), the Center for PMP Excellence (COE) at Brandeis University, the National Safety Council (NSC), and the American Medical Association (AMA).

Forty-nine (49) states, Guam and the District of Columbia (District) have laws to develop a PMP.[vii] All state PMPs and the Guam program are actively collecting and disseminating prescription controlled substances data. The District's PMP will soon be fully functioning.

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PMP Access and Use Requirements: A Patchwork of Mandates

As the nation focuses more on the benefits of PMPs, some policymakers may assume health care practitioners will extensively use the databases. However, reports of underutilization by practitioners have emerged.[viii] Policymakers find themselves facing a seemingly unexpected reality: the prescription information that PMPs make available is often unseen and unused by the very professionals policymakers intend the data to help.

The lack of use has been explained by health care professionals and their representatives. Reluctance to use PMPs is caused by their concerns regarding data quality and currency, and difficulties obtaining and interpreting the data for clinical purposes.

Many state legislators are unfamiliar with the nuances of a health care practice or clinical workflow. Gaps in knowledge make it harder for them to determine how to achieve the effectiveness of information delivery needed for a time-sensitive health care environment.

At the same time, studies are finding that use of PMP data changes the amounts and types of drugs being prescribed.[ix] In most cases, medication prescribed after checking the PMP is less than originally planned. In some cases, the practitioner prescribes more medication than originally planned because the PMP gives no indication of drug abuse behavior.[x] A review of a patient's prescription history can result in more informed and appropriate prescribing decisions. Additionally, PMP information can confirm a suspicion of abuse or diversion that a health care professional has after initial evaluation of a patient.[xi] Surveys of authorized users of PMPs by PMP Administrators reinforce that the data are important in deciding which medications to prescribe and dispense.[xii] Individual physicians are publicly discussing the value the PMP reports add to their practices.[xiii]

Legislators in state after state are deciding how they will try to increase utilization of PMPs by health care professionals. While supporting the improvement of PMPs as health care tools, they nonetheless believe the urgency to change prescription drug abuse trends places a high priority on immediate use of the prescription information that is available in the PMP.

Twenty-five (25) states now specify situations in which prescribers, and sometimes dispensers, have to check the PMP when treating a patient.[xiv] The most common components of the states' mandates are (1) the fact that the states have a mandate, and (2) the intent that the prescriber and dispenser review the PMP data before making critical treatment decisions. The remaining details are as different as the states themselves.

Some states rely in whole or significant part on the professional judgment of the practitioner. Delaware triggers the requirement to access the PMP when the prescriber or dispenser has reason to believe that the patient

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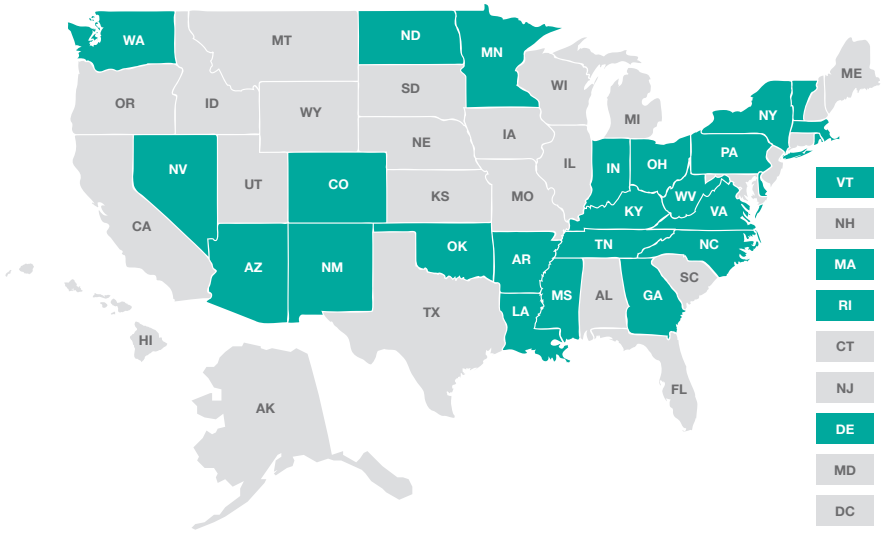
wants the medication for a non-medical purpose. Pennsylvania's new PMP law requires prescribers to query the PMP for each patient the first time the patient is prescribed a controlled substance or if the prescriber believes or has reason to believe that a patient may be abusing or diverting drugs.

Other states rely primarily on objective circumstances when the practitioner has to access the PMP, carving out triggers in which the discretion of the treating professional plays little or no role. Some jurisdictions require Opioid Treatment Programs (OTPs) to access the PMP. In workers' compensation cases in a few states, the prescriber has to access the patient's PMP prescription data. Providers at pain management clinics or registered pain management practices in some states must review PMP reports for patients. In other areas, practitioners treating pain with controlled substances, regardless of type of facility or location, must query the PMP. Broader use laws exist in many jurisdictions that mandate checking the PMP prior to prescribing or dispensing certain controlled substances, particularly when initiating a new course of treatment or when the controlled substances are part of the treatment for a designated period of time. Frequency of accessing the PMP after obtaining a patient's initial prescription report may be three months, six months, a year, or other time as specified by state statute or regulation. Health care professionals may discover that the rules in neighboring states differ significantly from their own state despite the cross-border travel of patients.

In the 2015 state legislative sessions, numerous states passed PMP access and use requirements, either for the first time or as an expansion of the situations in which checking the PMP has to occur.[xv] Mandates are here to stay for the foreseeable future.

STATES WITH MANDATED PMP USE LAWS



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Legal, Professional and Financial Consequences for Practitioners

Policymakers often enact required PMP checks without a corresponding dedication of resources to address data quality and timeliness concerns. Transformation of PMPs into highly effective health care information delivery tools has yet to be implemented. While state officials take progressive steps towards the goal, most practitioners are still unable to access PMP data through their electronic health records. Without the integration of PMP data into health care systems, practitioners continue to experience problems accessing, understanding and applying PMP data in hospitals and other health care facilities.

These difficulties can force health care professionals to make decisions that can have serious legal, professional and financial results. Anecdotal evidence indicates that a technologically savvy emergency department physician in one mandated use state will spend approximately four to five minutes accessing a patient's PMP report. How should the physician, Dr. Johnson, spend those four to five minutes? If she uses the time to access the patient's PMP report, the patient that arrived in an ambulance could die or suffer serious medical complications during that time. Patient care may suffer, and the physician faces a possible civil lawsuit and professional disciplinary action. The negative ramifications of her decision will not be hers alone to bear, but will likely be shared by her employer. If she forgoes the PMP report and tends to the patient, she may miss a critical piece of the patient's prescription history that could inform her treatment decision. Again, patient care may suffer. Again, legal and professional consequences remain a very real possibility.

A time delay in just trying to get PMP data is not limited to this one mandated use state. A 2014 national survey of practicing primary care physicians cited the time-consuming nature of information retrieval as a barrier to greater PMP use.[xvi]

Assume Dr. Johnson is in one of the 38 states that allow a prescriber or dispenser to delegate the task of accessing the PMP.[xvii] The negative consequences of the delayed access for her may be less in number and severity, but still a risk. The longer it takes for her to be able to view what prescriptions the patient has received, the greater the risk that she will have to take action regarding the patient without considering the PMP data because of the limited treatment window she has available. It is the delegate who now has to divert time from other patient care and safety responsibilities to accommodate the inefficiencies of querying the PMP.

Once Dr. Johnson finally receives the prescription history, she has to spend time figuring out what the information means for clinical decision-making. PMP reports can list pages and pages of controlled substances prescriptions. It is left to the health care professional to try and synthesize the information to glean key factors relevant to the exercise of professional judgment.

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Time spent gathering and reviewing PMP information is generally uncompensated time. Lack of reimbursement by third party payers for such activity is common. Add the approximately four to five minutes Dr. Johnson or her delegate spends pulling the report to the estimated minutes for Dr. Johnson to determine the clinical meaning of the data. Multiply that sum times multiple patients for whom the physician is required to check the PMP. Multiply that amount of time by multiple physicians, nurse practitioners and other prescribers and dispensers throughout a clinic or health care provider system who are subject to PMP use mandates. The combined total of uncompensated time can be significant.

Moreover, adding four or more minutes to the time allotted for each patient case in which a PMP report must be obtained may add to reported trends among some health care professionals to reduce or cap the number of patients that they see. According to the 2014 Survey of America's Physicians by The Physicians Foundation, 81% of physicians are either overextended or at full capacity.[xviii] Forty-four (44%) of physicians plan to take one or more steps to reduce patient access to their services, such as working part-time or seeking a non-clinical job.[xix] Other health care disciplines may be experiencing similar strained work capacities. The health care environment is already struggling to meet rapidly increasing demands for services brought about by the Affordable Care Act and an aging population of baby-boomers enrolled in Medicare. Inserting time inefficiencies into this environment may inadvertently contribute to reduced access to health care services for patients.

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The Solution

What will make the unintended negative consequences of the mandates go away? Efficient access to and effective use of PMP data within health care systems. Making PMP data actionable – easy to access and apply - is the solution. Health care professionals will then readily use the information because they can without risking patient care or safety, subjecting themselves and their employers to potential liability or professional sanctions, or suffering possible financial impacts.

However, the health care field cannot afford to wait for federal and state governments to design and execute an optimal PMP for health care information delivery purposes. The governmental path to success is necessarily slowed by competing priorities and the disbursal of scarce resources across numerous prescription drug initiatives. Those who daily confront the challenges caused by the mandates, health care providers, need to earnestly and actively seek out the tools and mechanisms that hold the most promise for facilitating their efficient and effective use of PMP data. In so doing, providers not only help themselves but also inform government efforts about what works to truly shape a PMP that in practice improves patient care and safety.

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[i] Press Release, U.S. Senators Joe Manchin and Tim Scott, Manchin and Scott Launch Prescription Drug Abuse Caucus (May 22, 2015) (on file with author).
[ii] *Ibid.*
[iii] Debbie Dowell, M.D., MPH; Noah Aleshire, J.D., National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, Presentation at 2015 National Rx Summit, *A CDC Primer on the Prescription Opioid Overdose Epidemic* (April 6, 2015).
[iv] *Ibid.*
[v] Dr. Tom Frieden, Director, Centers for Disease Control and Prevention (CDC), Presentation at 2015 National Rx Summit, *What's Working in Rx Overdose Prevention?* (April 8, 2015).
[vi] CM Jones. *Heroin use and heroin use risk behaviors among nonmedical users of prescription opioid pain relievers – United States, 2002-2004 and 2008-2010.* Drug and Alcohol Dependence. 132(2013)95-100; http://dx.doi.org/10.1016/j.drugalcdep.2013.01.007.
[vii] State statutory and regulatory research current as of June 3, 2015.
[viii] *Prescription Drug Monitoring Program Interoperability Standards, A Report to Congress,* Hearing before the Committee on Health, Education, Labor, and Pensions, The Subcommittee on Energy and Commerce, September 2013 (statement by the Office of the Assistant Secretary for Health, The Office of the National Coordinator for Health Information Technology, The Substance Abuse and Mental Health Services Administration, the Centers for Disease Control and Prevention).
[ix] Baehren DF et al. *A Statewide Prescription Monitoring Program Affects Emergency Department Prescribing Behaviors.* Annuals of Emergency Medicine. 2010 Jul; 56(1):19-23; Weiner SG et al. *Clinician Impression Versus Prescription Drug Monitoring Program Criteria in the Assessment of Drug-Seeking Behavior in the Emergency Department.* Annuals of Emergency Medicine. 2013; 62(4):281-9.
[x] *Ibid.*
[xi] Irvine JM et al. *Who Uses a Prescription Drug Monitoring Program and How? Insights from a Statewide Survey of Oregon Clinicians.* The Journal of Pain 2014; 15(7):747-55; Sowa EM et al. *Prevalence of Substance Misuse in New Patients in an Outpatient Psychiatry Clinic Using a Prescription Monitoring Program.* The Primary Care Companion for CNS Disorders. 2014; 16(1): PCC.13m01566.
[xii] *Key Findings and Recommendations from the 2013 IPLA INSPECT Knowledge and Use Survey,* Center for Health Policy, Richard M. Fairbanks School of Public Health, Indiana University-Purdue University Indianapolis, 2014; Blumenschein, K et al. *Independent Evaluation of the Kentucky All Schedule Prescription Electronic Reporting (KASPER) Program, Executive Summary,* Institute for Pharmaceutical Outcomes and Policy, Department of Pharmacy Practice and Science, College of Pharmacy, University of Kentucky, October 2010. A new Kentucky study involving KASPER, the state's PMP, is anticipated to find numerous benefits from use of KASPER's PMP data. A public release date for the study has not yet been announced.
[xiii] Ryan A. Stanton, MD, FACEP, Emergency Room Physician, Baptist Health Lexington, KY; John "Rett" Blake, III, MD, Medical Director, Specialists in Pain Management, TN; Kelly S. Ramsey, MD, MPH, MA, FACP, Clinical Director of Special Programs, Hudson River Health Care, Inc., NY, Presentations at 2015 National Rx Summit (April 8, 2015).
[xiv] State statutory and regulatory research current as of June 3, 2015. Upon the Governors' signing of CT HB 6856 (2015) and NJ SB1998/SB2119 (2015), a total of 27 states will have mandated use provisions. States' effective dates for implementation of mandated use provisions may vary.
[xv] Arkansas SB 717 (2015); Minnesota SF 1458 (2015); Nevada SB 459 (2015); North Dakota HB 1149 (2015); Oklahoma HB 1948 (2015); Virginia HB 1841 (2015). Upon the Governors' signing of CT HB 6856 (2015) and NJ SB1998/SB2119 (2015), Connecticut and New Jersey will implement for the first time requirements to query the states' PMPs.
[xvi] Rutkow L et al. *Most Primary Care Physicians Are Aware of Prescription Drug Monitoring Programs, But Many Find The Data Difficult To Access.* Health Affairs 2015; 34(3):484-492: http://content.healthaffairs.org/content/34/3/484.full.html.
[xvii] State statutory and regulatory research current as of June 3, 2015. Upon the Governors' signing of CT HB 6856 (2015), IL HB 1 (2015) and NJ SB1998/SB2119 (2015), Connecticut, Illinois and New Jersey will allow practitioners' designees to query the PMP in certain circumstances. With enactment in all three states, a total of 41 states will authorize use of delegates.
[xviii] The Physicians Foundation, *2014 Survey of America's Physicians, Practice Patterns & Perspectives 8* (2014).
[xix] *Ibid.*