PAINS PROJECT

TRANSFORMING THE WAY PAIN IS PERCEIVED, JUDGED AND TREATED

POLICY BRIEF

PRESCRIPTION MONITORING PROGRAMS

Issue 2

POLICY **BRIEF**
PRESCRIPTION MONITORING PROGRAMS

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This policy brief is a product of the Pain Action Alliance to Implement a National Strategy (PAINS), in collaboration with the Center for Practical Bioethics, the American Academy of Pain Management (AAPM), and the Pain and Policy Studies Group (PPSG) at the University of Wisconsin. It was funded by the United States Cancer Pain Relief Committee.

INTRODUCTION

Prescription monitoring programs (PMPs, also known as prescription drug monitoring programs, or PDMPs) are state-operated databases that collect, store, and distribute information about controlled substance prescriptions. The specific characteristics of these programs (e.g., which controlled substance schedules are included, who can access the data, which agency runs the program, etc.) can vary from state to state, but nearly all are designed to help address the twin public health crises of prescription drug abuse and inadequately-treated chronic pain, with this objective stated explicitly in some PMP laws.

In nearly every discussion about possible solutions to the prescription drug abuse problem, PMPs are mentioned as a key feature[1-3]. Although less recognized by policymakers, PMPs also can be extremely helpful clinical tools for healthcare professionals treating people with conditions necessitating the use of controlled substances, including pain. As the "owner/operators" of PMPs, policymakers have a vested interest in facilitating the implementation and development of PMPs as effective tools.

BACKGROUND AND HISTORY

The first PMP was established in California in 1939. Based in the Department of Justice, the program was designed to monitor prescriptions for Schedule II controlled substances through the use of triplicate prescription forms. The use of triplicate and/or serialized prescription forms characterized a number of programs established throughout the 20th century, but by the late 1990s, PMPs began to assume modern characteristics, with electronic data transfer and storage replacing standardized prescription blanks.

Coinciding with increased awareness of prescription drug abuse, PMPs began to proliferate in the late 1990s. By 2004, about 16 states had a functional PMP, with rapid growth following passage of the Harold Rogers Act in 2005. **Figure 1** illustrates the expansion of PMPs during the first decade of the millennium. As of late 2013, 49 states have passed legislation to establish PMPs; only the District of Columbia and Missouri have yet to do so. Two of the newer programs, in New Hampshire and Nebraska, are in the process of implementing programs that were recently approved.

As PMPs became established as important public health tools, the need for sharing information across state lines became more apparent. For many people living near state borders, some portion of medical care is delivered by prescribers in the neighboring state. Additionally, individuals seeking controlled substances for purposes of abuse and/or diversion can minimize their risk of detection by obtaining prescriptions on both sides of the state line. To address this concern, the U.S. Department of Justice's Bureau of Justice Assistance sponsored an effort to establish standards for interstate data sharing. Arising out of this effort has been a number of agreements between individual states to share data, as well as PMP InterConnect[4], the national program sponsored by the National Association of Boards of Pharmacy. **Figure 2** illustrates the status of state PMP participation in PMP InterConnect as of October 2013. Note that many of the non-participating states may have prohibitions against interstate data sharing in their statutes, an area that may be of interest to policymakers.

"As of late 2013, 49 states have passed legislation to establish PMPs; only the District of Columbia and Missouri have yet to do so."

FIGURE 1

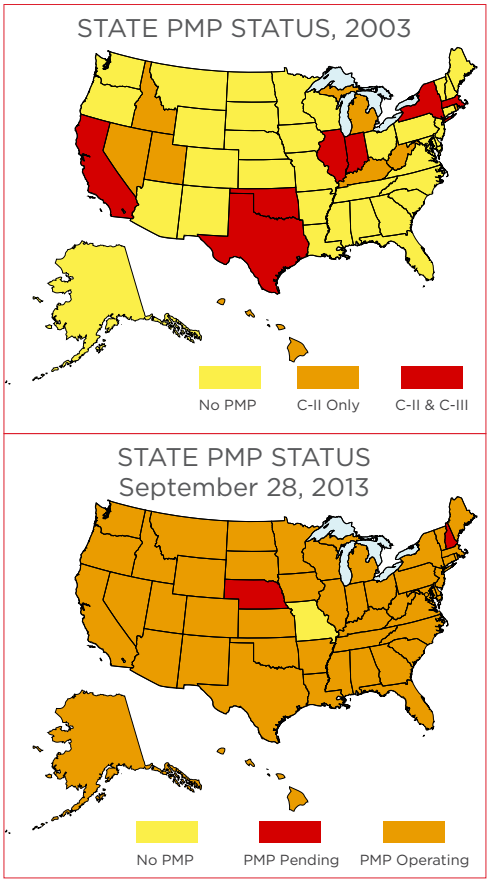
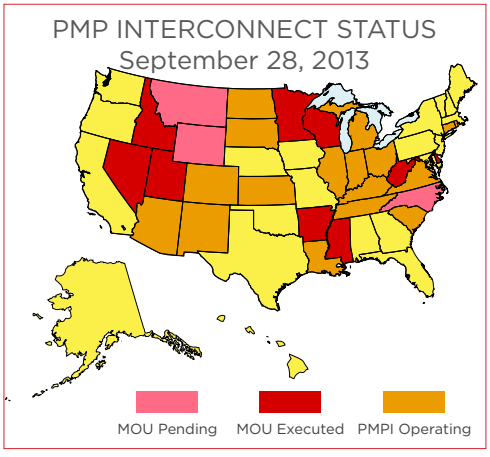


FIGURE 2



USES OF PMPs

When PMPs are discussed by policymakers, the primary focus is on their use to detect and intervene with so-called "doctor shoppers," i.e., individuals who visit multiple prescribers and use multiple pharmacies, usually paying cash for medications, in an effort to remain undetected while obtaining large amounts of medication for purposes of abuse and/or diversion. PMPs are really the only effective tool available to prescribers and dispensers who may be targeted by these individuals, and routine use of the PMP before writing an initial prescription for a controlled substance should be sufficient to essentially eliminate this behavior. It should be recognized that, although "doctor shoppers" represent only about 0.7% of all opioid purchasers, they account for 1.9% of opioid prescriptions and 4% of opioids dispensed by weight[5]. This small population of individuals certainly accounts for a greatly outsized consumption of prescription opioids, and deserves the attention of both healthcare professionals and, in some cases, law enforcement.

Frequently overlooked in the discussion of PMPs is their usefulness as healthcare delivery tools. By far, the most common use of PMPs is by healthcare providers. Kansas PMP data from the fourth quarter of 2012 indicated that 99.97% of all queries for data originated with prescribers and dispensers[6]. As healthcare delivery tools, PMPs can provide three benefits:

- Reassurance that patients are using controlled substances as prescribed, allowing providers to prescribe and dispense as needed with less anxiety;
- Identification of behaviors suggestive of a substance abuse problem, leading providers to more thoroughly assess patients and obtain appropriate treatment where indicated; and
- Provision of a complete record of a patient's controlled substance prescribing history, enhancing patient safety by enabling a provider to avoid potentially deadly combinations of medications.

As is true of most pain-related policy, the uses of PMPs reflect the need for balance[7], a key concept in opioid regulation. The principle of balance states that policies need to be crafted in such a manner as to minimize access to opioids for those who intend to misuse them, while simultaneously maintaining access for those who use them for legitimate medical purposes. In the case of PMPs, balance dictates that policies allow PMPs to remain useful tools for clinical healthcare delivery while simultaneously helping to mitigate the harms associated with drug abuse and diversion.

KEY FEATURES OF PMPs

As PMPs have developed, a number of key features have emerged as considerations for policymakers intent on optimizing their PMPs. Some of these include:

Characteristic	1st Generation of PMPs	Current PMPs
Housing entities	Early PMPs were housed in law enforcement agencies.	Most of the newer programs are run by state boards of pharmacy, state health departments, or other entities within the healthcare delivery sphere.
Controlled substances schedules monitored	Early PMPs monitored schedule II almost exclusively, with rare exceptions adding schedule III medications.	Most PMPs now monitor medications in schedules II, III, and IV; a few are more limited, and a few also include schedule V medications. Some also have added "drugs of concern" that can be designated by regulation to capture non-scheduled medications that may be subject to abuse.
Frequency of reporting	Many early programs required dispensers to report prescription data on a monthly or twice-monthly basis.	Most now require data to be reported at least weekly by dispensers. The trend is toward requiring daily reporting, and one state, Oklahoma, has instituted point-of-sale reporting.
Access to the data	All PMPs initially allowed access to data by law enforcement personnel, with various restrictions. Many also allowed access by healthcare providers and, of those that did not, all except one (Pennsylvania) have since added provider access in recognition of PMPs' utility as healthcare delivery tools.	Recently, states have begun expanding access to include drug abuse counselors, coroners, probation and parole officers, and others, including patients, judged to have legitimate need for the information.
Unsolicited reporting	Early PMPs did not proactively notify prescribers and dispensers of patients who appeared to be engaged in improper behavior. In fact, many early PMPs did not allow healthcare providers to access the data at all.	Many PMPs now regularly analyze their data to identify individuals who use multiple prescribers and pharmacies, and who may be engaging in inappropriate "doctor shopping" activities. When such individuals are identified, the program automatically notifies all prescribers and dispensers involved, intending that those individuals take steps to intervene if and when they encounter the individual again.
Advisory councils	Early PMPs were operated entirely by the responsible state agencies, with no input from stakeholders.	A minority of PMPs use multidisciplinary advisory councils composed of key stakeholders as a source of additional oversight and ideas to improve the effectiveness of the programs.
Integration with electronic health records (EHRs) and health information exchanges (HIEs)	Since PMPs became primarily electronic databases, they have remained separate from other electronic databases, with strong firewalls built to prevent inappropriate access to the data they contain.	The most recent development in PMP characteristics has been integration of PMP data with EHRs and HIEs. Such integration is thought to improve provider utilization as it streamlines the workflow and increases the visibility of PMP data.

Comprehensive summaries of each state's status with respect to these and other characteristics can be found on the website of the National Alliance for Model State Drug Laws (NAMSDL), at http://www.namsdl.org/prescription-monitoring-programs.cfm.

HOW EFFECTIVE ARE PMPs?

While many policymakers and healthcare practitioners assume that PMPs are effective in achieving their stated goals, very little research actually exists to confirm those assumptions. The meta-analysis of PMP outcome studies[8] by Julie Worley found only 11 published from 1994 through 2011, one of which studied a program in France. The available research is heavily criticized by the author because studies rely on data that are several years old, before the implementation of "modern" electronic PMPs that allow full access to healthcare providers and monitor all controlled substance schedules. Nonetheless, the results of the meta-analysis suggest that PMPs do limit "doctor shopping" and reduce prescription drug abuse. They also were found to decrease prescribing of controlled substances, for better or worse.

Among the studies included in Worley's meta-analysis is only one that investigates the impact of a PMP on patients in a given clinical setting. Writing in 2010, researchers from Ohio[9] reported that adding a routine check of the Ohio PMP to patient examination in the emergency department changed the treatment plan for 41% of patients; most (61% of these patients) resulted in fewer or no opioid prescriptions, while 39% of patients were prescribed more medication after the PMP results were reviewed.

Another study included by Worley is a report by Paulozzi et al.[10], asserting that PMPs demonstrated no effect on prescription drug abuse and related overdose deaths, but did appear to suppress prescribing of opioid analgesics. This study was criticized in an editorial authored by Gil Kerlikowske, Director of the Office of National Drug Control Policy, et al.[11], and in a letter to the editor by Traci Green et al.[12]. Both point out that, in essence, Paulozzi's study makes comparisons that are invalid because of the wide variation in the structure of PMPs from one state to the next, as well as the examination of obsolete programs.

Finally, in a 2012 article published too late for inclusion in the Worley meta-analysis, Reifler et al.[13] analyzed poison control center and opioid treatment surveillance databases covering 2003 through mid-2009 to determine the effectiveness of PMPs in reducing opioid abuse and misuse. The authors concluded that presence of a PMP resulted in a slower rate of increase in intentional exposures to opioids, as well as a slower rate of increase in admission to opioid abuse treatment programs. They go on to add that further work needs to be done to determine the effectiveness of various PMP components, as well as which opioids are most affected.

The paucity of outcomes research on programs that have now been established in 49 states is disappointing and leaves PMPs vulnerable to criticism regarding their effectiveness, especially with regard to their clinical utility. The identified need for a great deal of additional research supports the notion that any policy efforts designed to improve PMPs should include a required outcomes evaluation component, in service of helping policymakers develop the best and most efficient programs possible.

PMPs are not sufficient in and of themselves to mitigate the problem of prescription drug abuse and diversion. The problem is large and complex and requires a commensurately large and complex strategy, including PMPs, to address it. In developing such a strategy, policymakers have the opportunity also to provide a valuable tool to healthcare professionals treating people with conditions necessitating the use of controlled substances.

"The paucity of outcomes research on programs that have now been established in 49 states is disappointing and leaves PMPs vulnerable to criticism regarding their effectiveness, especiallywith regard to their clinical utility."

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PAINS' mission is to transform the way pain is perceived, judged and treated.

"Prescription Monitoring Programs" is the 2ND in a series of briefs profiling policy issues important to improving chronic pain care.

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