TRANSFORMING THE WAY PAIN IS PERCEIVED, JUDGED AND TREATED
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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. 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.”
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. 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. 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, 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.
As PMPs have developed, a number of key features have emerged as considerations for policymakers intent on optimizing their PMPs. Some of these include:

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<thead>
<tr>
<th>Characteristic</th>
<th>1st Generation of PMPs</th>
<th>Current PMPs</th>
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<tbody>
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<td>Housing entities</td>
<td>Early PMPs were housed in law enforcement agencies.</td>
<td>Most of the newer programs are run by state boards of pharmacy, state health departments, or other entities within the healthcare delivery sphere.</td>
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<td>Controlled substances schedules monitored</td>
<td>Early PMPs monitored schedule II almost exclusively, with rare exceptions adding schedule III medications.</td>
<td>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.</td>
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<td>Frequency of reporting</td>
<td>Many early programs required dispensers to report prescription data on a monthly or twice-monthly basis.</td>
<td>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.</td>
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<td>Access to the data</td>
<td>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.</td>
<td>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.</td>
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<td>Unsolicited reporting</td>
<td>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.</td>
<td>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.</td>
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<td>Advisory councils</td>
<td>Early PMPs were operated entirely by the responsible state agencies, with no input from stakeholders.</td>
<td>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.</td>
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<td>Integration with electronic health records (EHRs) and health information exchanges (HIEs)</td>
<td>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.</td>
<td>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.</td>
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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 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 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., 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., and in a letter to the editor by Traci Green et al. 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. 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.
REFERENCES


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PAINS’ mission is to transform the way pain is perceived, judged and treated.
Despite wide agreement that prescription monitoring programs (PMPs) can be valuable healthcare delivery tools and extremely effective at preventing “doctor shopping,” PMPs remain under-utilized, with most states reporting approximately one-third or fewer of authorized prescribers and dispensers using them. Undoubtedly, one of the most important policy needs around PMPs involves ways to promote widespread, even universal, use of PMPs in patients who are prescribed controlled substances. Some policy efforts that can further this goal include:

• Supporting greater integration of PMPs with electronic health records (EHRs) and health information exchanges (HIEs). Currently, providers using EHRs and HIEs have to leave those systems, open another computer window to obtain a PMP report, and then return to the EHR or HIE and summarize the PMP report. This is a time-consuming practice that, if repeated several times per day, can quickly become tedious and could add an hour of more to a provider’s work day. Successful pilot studies integrating PMP reports directly into EHRs and HIEs have been conducted, and policymakers should carefully consider what more can be done to support rapid integration of these systems.

• Considering a requirement that all eligible PMP users be registered to access the PMP. One method to do this involves tying PMP system registration to professional license renewal. Having all eligible users registered removes one barrier to accessing the PMP.

• Considering incentivizing use of the PMP. Providers might be more likely to use the PMP if they were incentivized by, for instance, a slight reduction in malpractice insurance premiums or slightly greater reimbursement from third-party payers. Such incentives are likely to be much better received by providers than unfunded mandates to use the PMP.

• Encouraging the use of unsolicited reporting of patients who meet certain criteria to the healthcare providers prescribing and dispensing for them. Alerting providers to the behavior of these patients may help reduce “doctor shopping,” although it should be noted that it will be ineffective for the most prolific “doctor shoppers,” who rarely return for a second visit with a given prescriber or dispenser.

• Finally, considering a requirement for mandatory PMP checks with each initial prescription for a controlled substance. While such mandates are likely to meet with resistance from providers, a simple PMP check prior to writing the first controlled substance prescription for a patient should virtually eliminate “doctor shopping.”

OTHER IMPORTANT POLICY INITIATIVES

Several other key PMP policy issues that warrant consideration include the following:

• Secure funding for PMPs. Most PMPs were established and supported for their first several years through federal grant funding. However, after a few years, states lose their eligibility to receive further grant funding, and PMPs find themselves struggling to secure adequate ongoing financial support. States have found a number of innovative ways to fund PMPs, including use of settlement money from lawsuits against drug makers, small annual fees assessed to prescribers and dispensers, money obtained from the Medicaid fraud penalty account, and even contracting with HIEs to supply PMP data to populate a patient’s HIE record.

• Participation in interstate data sharing. States with large metropolitan areas located near the state line (e.g., Louisville, KY; Cincinnati, OH; Kansas City and...
St. Louis, MO; New York City, and many others) or in geographically small states (e.g., most of New England) may see large numbers of patients receiving prescriptions from prescribers and dispensers in adjoining states, either legitimately or as a means to hide illicit activity. Interstate data sharing is key to enabling prescribers and dispensers to act appropriately in response to requests from patients. It is important that policymakers realize that current interstate data sharing programs, like the PMP InterConnect, allow states to control access to their own data, so that a requester is permitted access only if he or she meets requirements in the state being queried.

**Timely reporting of data into the PMP.** “Doctor shoppers” can be quite prolific, often seeing multiple providers each week. PMPs that require only monthly or bi-monthly reporting may be much less effective at preventing this behavior than PMPs that require weekly, daily, or instantaneous reporting. The current trend among PMPs is to move to daily reporting requirements, with many states viewing the ideal being the kind of real-time reporting now in place in Oklahoma.

**Use of advisory councils.** Multidisciplinary committees of key stakeholders can be very valuable to PMP administrators, as they provide ideas for ways to use and improve PMPs based on their clinical experience with the programs. Additionally, some states use these committees to preliminarily evaluate patients and providers who appear to be acting inappropriately, as a means of ensuring that any reports to authorities are warranted.

**Efforts to identify “rogue” patients and providers.** Increasingly, data mining techniques are being used to identify patients and providers who may be outliers in terms of their behavior. It is important to realize that such identification represents only the first step in evaluating each case, and that individualized follow-up investigations are warranted before taking punitive action in each case.

**Educational efforts to enhance awareness/understanding for data users.** Providers who do not understand the information PMPs provide are likely to be less interested in using them. Education that includes case examples is likely to be an effective remedy for this. Some states have made such education a requirement in their statutes and regulations.

**Allowing practitioners’ delegates access to the database.** While asking a physician, pharmacist, or other highly-trained provider to personally query the PMP may represent an unreasonably onerous burden, it is possible to mitigate this concern by allowing other office staff to obtain the reports on behalf of the provider. Most states that have done this have required delegates to be licensed or certified healthcare personnel, and have left ultimate responsibility for delegates’ use of the system with the supervising provider.

**Protecting patient confidentiality.** Almost universally, when PMPs are criticized, it is by people concerned about accidental or intentional violations of confidentiality. It is important that all authorized users, including healthcare providers and law enforcement personnel, understand the importance of maintaining adequate confidentiality. Some legislatures have felt strongly enough about this issue that they have made violations of confidentiality a felony offense.

The prescription drug abuse problem is complex, and like most complex problems, is unlikely to be resolved by a single simple solution like a PMP. Nonetheless, a well-designed PMP that is widely used by healthcare professionals should provide a significant benefit in the fight to reduce such abuse. Additionally, PMPs provide an extraordinarily valuable tool for clinicians treating people with pain and other conditions requiring controlled substances, and increased use can only enhance treatment of those conditions, identification and treatment of people with substance use disorders, and patient safety. It is incumbent upon policymakers to take such steps to optimize their PMPs, for the good of the public.