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THE STEEP RISE IN OVERDOSE
DEATHS HAS BEEN FUELED BY
THE DRAMATIC INCREASE IN
OPIOID PRESCRIPTIONS.

Prescription Drug Monitoring Programs: Evolution and Evidence

Overdose deaths from prescription opioids in the U.S. quadrupled from 1999 to 2015, reaching 22,000 in 2015. This increase has been fueled by a dramatic rise in the amount of opioids being prescribed, creating a vast supply of drugs at high risk for misuse. Prescribers, therefore, are a vital link in addressing the current epidemic of overdose deaths and substance use disorders. The challenge is to develop and implement systems that help prescribers identify potential cases of misuse or diversion, while still allowing appropriate prescribing of opioids for pain control.

All states except Missouri now have functioning prescription drug monitoring programs (PDMPs) that collect data from pharmacies on all dispensed controlled substances. These statewide databases have many potential uses: they can help prescribers identify patients who are "doctor-shopping" or who might need substance use disorder treatment; they can help government agencies and medical licensure boards monitor prescribing practices and identify unusual prescribing patterns; and they can inform community-based prevention strategies.

For a PDMP to be effective, however, it must be used. Despite the promise of PDMPs, actual use of PDMPs by prescribers remained low until recent years. A 2014 national survey found that 72 percent of primary care physicians were aware of their state's PDMP, but only 53 percent of primary care physicians ever used it, and many did not use it routinely. Since then, some states have implemented mandates for provider participation in PDMPs.

This Issue Brief reviews the current status and characteristics of PDMPs, their use, and evidence of their effectiveness. It summarizes best practices for PDMPs and the needs for further research and evaluation.

Current status and characteristics

Not surprisingly, PDMPs have evolved differently across states and over time. Most states provide access to their PDMP to a wide range of health professionals who prescribe or dispense controlled substances, including physicians, nurse practitioners, physician assistants, dentists, pharmacists, and podiatrists. But PDMPs vary considerably in their data collection, processes, and protocols. In a 2015 survey, more than half of states (26) reported that dispensers must submit

data daily, while 15 states require weekly input. Fourteen states report some efforts to integrate their PDMP into a health information exchange or electronic health record (EHR). Eighteen states report having an enhanced user interface of some type, such as risk assessment tools or red flags.

One of the key differences is whether a state requires authorized prescribers and dispensers to register/enroll in or use the system. This aspect of PDMPs is rapidly changing; the maps below reflect these differing mandates as of April 2017:

Mandatory PDMP Enrollment

Prescribers and Dispensers (23)
Prescribers Only (5)
Dispensers Only (3)
No Mandatory Enrollment (21)
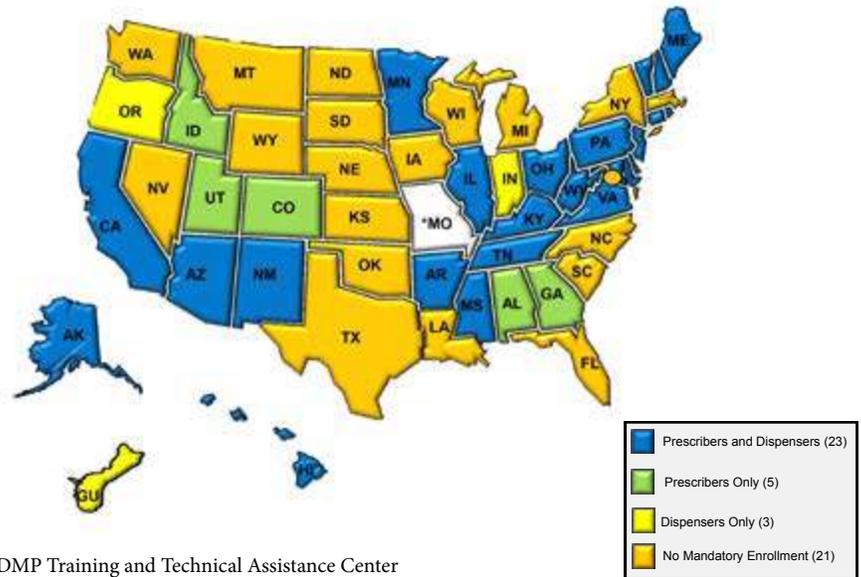
Source: PDMP Training and Technical Assistance Center

Mandatory PDMP Use

Prescribers and Dispensers (13)
Prescribers Only (21)
No Mandatory Query (18)

Source: PDMP Training and Technical Assistance Center

While enrollment mandates are generally comprehensive, mandates of use vary in strength and scope. The Centers for Disease Control and Prevention defines "universal use" as a requirement that prescribers consult the PDMP before initially prescribing controlled medication for a given patient and at least every three months after that; as of July 2015, only four states met that rigorous

standard. Other states had no requirement for initial prescribing, no requirement for subsequent checks, or included subjective standards or broad exceptions.

Effectiveness: the latest evidence

The overall effectiveness of PDMPs is difficult to ascertain, given the state-specific attributes of each system and the evolving nature of state policies and provider participation.

Single state studies have reported some successes, although they suffer from weak designs and lack of generalizability. One study found that oxycodone-caused mortality abruptly declined (by 25 percent) in the month after Florida implemented its PDMP; another study found that Florida's PDMP was associated with a 1.4 percent decrease in opioid prescriptions and a 2.5 percent decrease in opioid volume compared to Georgia, effects that were concentrated among the four percent of Florida providers responsible for 40 percent of opioid prescriptions at baseline. In New York, a pre-post study found that the PDMP was associated with a 78 percent reduction in quantity of opioid pills prescribed by dentists in an urgent care center three months after implementation. In a survey in Maryland, 74 percent of physicians said the PDMP was "very useful" in deciding whether or not to prescribe opioids and 70 percent reported that they had reduced their opioid prescribing because of access to a PDMP.

In the following section, we focus on the latest studies across states, and what they reveal about the effects of PDMPs on providers, patients, and health outcomes.

Provider Prescribing Behavior

Bao, Pan, Taylor et al. (2016) used data from the National Ambulatory Medical Care Survey to assess the effects of PDMPs on prescribing behavior in 24 states from 2001 to 2010. They found that implementation of a PDMP was associated with more than a 30 percent drop in the rate of Schedule II opioid prescribing (the category with the highest potential for abuse). After adjusting for patient and state attributes, the probability of prescribing a Schedule II opioid at an office visit for pain went from 5.5 percent to 3.7 percent after implementation of a PDMP. The effect was seen immediately after the launch of a program and continued in the second and third years afterward.

Moyo, Simoni-Wastila, Griffin, et al. (2017) looked at the impact of PDMPs on opioid utilization among Medicare beneficiaries in 10 states that implemented programs from 2007-2012. Compared to states without programs, PDMP implementation was associated with reduced prescribed opioid volume (using cumulative monthly morphine milligram equivalents), but no change in number of prescriptions, after one year. This suggests shifts in the type or dose of the drugs prescribed, or changes in the days of supply per prescription. These effects differed by Medicare eligibility status and plan type, with greater effects on disabled Medicare beneficiaries (versus elderly ones) and enrollees in Medicare Advantage plans (versus Medicare Part D plans).

> THE OVERALL EFFECTIVENESS OF PDMPS IS DIFFICULT TO ASCERTAIN, BUT RECENT STUDIES SUGGEST THEY CAN CHANGE PRESCRIBING PATTERNS.

In a study of Medicare Part D beneficiaries, Yarbrough (2017) found that PDMPs were associated with a 5.2 percent decrease in days supply prescribed per physician for oxycodone in addition to smaller reductions for hydrocodone and opioids overall (2.8 percent and 2 percent, respectively). The effects of PDMPs were limited to states that mandated use of the PDMP.

Wen, Schackman, Aden & Bao (2017) evaluated the effects of mandates on opioid prescriptions received by Medicaid enrollees, a population at heightened risks for prescription opioid misuse and overdose and a priority population for any state drug control policies. They found that PDMP mandates of any kind implemented between 2011 and 2014 were associated with a 9-10 percent reduction in the use of Schedule II opioids by Medicaid enrollees compared to states without mandates. When the researchers differentiated between registration mandates and use mandates, they found that the reduction in prescriptions of Schedule II opioids were largely attributable to mandates of registration. Mandates of use, either alone or in combination with a mandate of registration, were not associated with (incremental) reductions in Schedule II opioid prescriptions received by Medicaid enrollees. The authors estimate that if every state adopted a mandate of registration, Medicaid programs nationwide could save over $166 million on Schedule II opioids over a 12-month period. This likely underestimates the full effect, as Medicaid is also the most common payer of opioid-related hospitalizations.

Average predicted numbers of prescriptions for Schedule II prescription opioids per 100 Medicaid enrolees per quarter in states with and without prescriber mandates, 2011–14
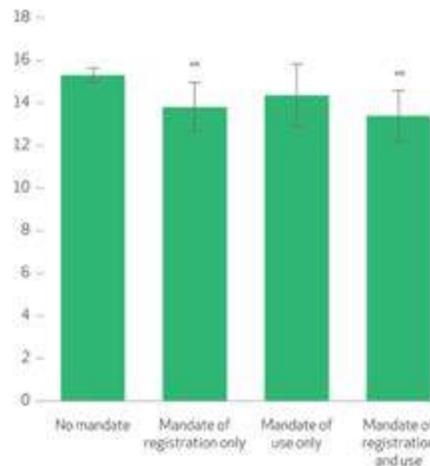
Wen et al., Health Affairs 2017; 36: 733-741

Contrary to the common belief that mandates of registration alone might have limited effects, this study supports adoption of mandates of registration in all states as an effective and relatively low-cost strategy to enhance prescriber participation in PDMPs.

Patient Behavior

Meara, Horwitz, Powell, et al. (2016) looked at the impact of a variety of state drug laws, including PDMPs, on patient behaviors in a high risk population: disabled fee-for-service Medicare beneficiaries younger than 65 years of age, half of whom

used opioids in a given year. In an analysis of laws enacted from 2006-2012, they found that PDMPs were not associated with decreases in the behaviors they are designed to identify, including measures of doctor shopping and diversion. The authors acknowledge that the analysis did not account for the robustness of each state's PDMP, and that more than 20 states strengthened or enacted mandates after their study period ended.

An NBER paper by Carey and Buchmueller (2017) sheds light on how the robustness of a PDMP affects these patient behaviors. The authors compared Medicare opioid prescription data in 10 states that enacted use mandates from 2007-2013 with 17 other states implementing PDMPs without use mandates. In states with mandates, the percentage of Medicare enrollees who obtained prescriptions from five or more doctors was eight percent lower, compared with other states. The percentage of people getting opioids from five or more pharmacies was 15 percent lower. The researchers found that most of the effects were driven by the younger Medicare population on SSI disability, particularly people who were disabled and had low incomes.

States with use mandates also saw a decline in the number of Medicare enrollees filling opioid prescriptions before the previous one had run out, or obtaining more than a seven-month supply of opioids in a half-year period. These states also saw a 15 percent reduction in the number of Medicare enrollees with four or more new patient visits in six months. The authors estimate that Medicare would save $348 million annually in unnecessary new patient visits if every state mandated use of its PDMP.

Population Health Outcomes: Drug Overdoses

Using national mortality data from 1999-2008, Li, Brady, Lang, et al. (2014) found that implementation of a PDMP did not reduce drug overdose deaths in most states, although the impact varied considerably by state. Meara, Horwitz, Powell, et al. (2016) found that implementation of a PDMP between 2006-2012 had no effect on the percentage of younger disabled Medicare beneficiaries treated for nonfatal prescription opioid overdoses.

Other studies have shown more promising results. Patrick, Fry, Jones & Buntin (2016) focused on 34 states that had implemented a PDMP from 1999-2013 and found that a state's implementation of a program was associated with an average reduction of 1.12 prescription opioid-related overdose deaths per 100,000 population in the year after implementation. (The states in the study had an average opioid-related overdose death rate of 6.2 per 100,000 population in 2013.) Additionally, states whose programs had robust characteristics—including monitoring greater numbers of drugs with abuse potential and updating their data at least weekly—had greater reductions in deaths, compared to states whose programs did not have these characteristics. The authors estimated that if Missouri adopted a PDMP and other states enhanced their programs with robust features, there would be more than 600 fewer overdose deaths nationwide in 2016, preventing approximately two deaths each day.

Similarly, Pardo (2017) studied programs between 1999 and 2014, and found that states that had more robust PDMPs have fewer prescription opioid overdose deaths than states with weaker ones. He estimated that the more robust programs were associated with an 18 percent reduction in prescription opioid overdose deaths compared to no program. Whether some of these deaths avoided may be offset by individuals overdosing after substituting heroin for prescription opioids requires further investigation.

Best Practices and Next Steps for PDMPs

PDMPs are works in progress, and their effectiveness depends on how they are implemented and the extent to which they are used. As the knowledge base and experience with PDMPs expands, a number of experts have proposed a set of best practices for states to consider. But as Ashburn (2016) notes, many, if not most, of these best practices have not yet been shown to improve patient outcomes or decrease non-medical use of controlled substances.

In 2016, the National Governors' Association laid out a "road map" for states to use in addressing the opioid epidemic, and suggested five steps to optimize PDMPs and improve their effectiveness.

- Require providers to check the PDMP before prescribing controlled substances.
- Use PDMP data to provide proactive analyses and reporting to professional licensing boards and law enforcement.
- Require pharmacists to report to the PDMP within 24 hours.
- Make PDMPs easier to use by integrating PDMP data into electronic health records and health information systems and by allowing prescribers to establish delegate accounts.
- Ensure PDMP interoperability across states.

In recent years, more states are adopting stronger and more comprehensive mandates of use. But as indicated by Wen, Schackman, Aden & Bao (2017), mandated registration of providers may have as much or more of an effect. The added value of mandating use needs to be further assessed as mandate policies continue to evolve, along with potential unintended consequences such as excessive infringement on prescriber autonomy. While enforcement of registration mandates can be relatively low-cost (for example, if paired with prescriber license renewal), enforcing mandates of use will be costly if not impossible. More research is needed on the optimal way to improve provider participation in PDMPs, one that maximizes prescriber buy-in and minimizes other barriers, such as time burden, password resets, and privacy and security concerns for information on controlled substance use.

The proactive use of PDMP data for clinical, enforcement and education purposes has intuitive appeal, although it is largely unexplored. Proactive uses can involve unsolicited reports or alerts to prescribers and dispensers, the development of prescriber report cards with peer comparisons, and the use of de-identified data to identify geographic hot spots and communities at risk. Currently, 12 states are participating in the Prescription Behavior Surveillance System, a longitudinal

database of de-identified PDMP data. The effectiveness of this and other proactive uses of PDMPs has not yet been evaluated.

Integrating PDMPs into existing electronic information systems such as EHRs and pharmacy databases would greatly increase their clinical value, although the lack of uniform standards across systems is a significant barrier. Demonstration projects have proven that integration is feasible, albeit on a small scale. From 2012-2016, SAMHSA funded projects in nine states, and the CDC evaluated the initiative in 2017. Eight states succeeded in some level of integration, and most reported large increases in queries to the system. Kansas integrated PDMP data into a health system network, and reported sevenfold increases in solicited reports from the health system; Washington made its PDMP interoperable with a statewide Emergency Department Information Exchange, and reported 80-fold increases in solicited reports from EDs; Illinois integrated its PDMP in a hospital's EHR and reported a 145-fold increase in solicited reports, a 22 percent decrease in the number of opioid prescriptions issued by the hospital's prescribers, and a 40 percent decrease in the number of patients with at least one opioid prescription.

In the same initiative, Illinois, Kansas, and West Virginia successfully initiated two-way data exchanges with most of their border states, and reported increasing amounts of out-of-state data in reports solicited by in-state providers. Data exchange or interoperability between states could limit patients' ability to cross state lines to avoid detection in cases of doctor-shopping or diversion, but its added value has not been evaluated.

A remaining challenge is that PDMPs do not identify patients who have not been prescribed controlled substances in the past (opioid naïve) but may nevertheless be at risk for substance use disorder based on other risk factors. It will be important to assess whether a "clean" PDMP record can provide false reassurance to providers for these patients, encouraging them to prescribe more liberally than they otherwise would.

PDMPs will continue to evolve as important tools in state efforts to combat the opioid epidemic. Best practices will evolve as well, as state programs mature and evidence about effective processes and functionality expands. Although early versions of PDMPs did not produce measurable changes in outcomes, they remain a promising way to reduce morbidity and mortality from prescription opioid misuse, while encouraging appropriate prescriptions for pain relief.

PDMPs will continue to evolve as important tools in the state efforts to combat the opioid epidemic.

About Penn LDI: Since 1967, the Leonard Davis Institute of Health Economics (Penn LDI) has been the leading university institute dedicated to data-driven, policy-focused research that improves our nation's health and health care. Originally founded to bridge the gap between scholars in business (Wharton) and medicine at the University of Pennsylvania, Penn LDI now connects all of Penn's schools and the Children's Hospital of Philadelphia through its more than 250 Senior Fellows. For additional information on this Issue Brief or Penn LDI, contact Janet Weiner (email: weinerja@mail.med.upenn.edu; 215-573-9374).
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