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Mandatory Use of Prescription Drug Monitoring Programs

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The United States is in the midst of a prescription opioid overdose and abuse epidemic. The rate of fatal prescription drug overdoses involving opioids almost quadrupled from 1.4 deaths/100 000 people in 1999 to 5.4 deaths/100 000 people in 2011.¹ The rate of emergency department visits involving prescription drug misuse—primarily of opioid, anti-anxiety, and insomnia medications—more than doubled from 214 visits/100 000 people in 2004 to 458 visits/100 000 people in 2011.² Forty-nine states have responded by developing prescription drug monitoring programs (PDMPs), which digitally store controlled substance dispensing information and make those data accessible to prescribers, pharmacies, and law enforcement officials. Although PDMPs are designed to curb opioid overprescribing, prescriber utilization is low. The median PDMP registration rate among licensed prescribers who issue at least 1 controlled substance prescription is 35%.³ Furthermore, not all enrolled prescribers regularly use PDMPs.

Consequently, 22 of the 49 states with PDMPs now legally mandate prescribers to query the system before writing for controlled substances with recognized potential for abuse or dependence.⁴ These requirements face pushback from prescribers, many of whom consider them to be burdensome incursions into clinical practice.⁵ For example, physician and dentist group challenges to the breadth of circumstances proposed for PDMP checks have contributed to a 2-year delay in the final implementation of a legally required mandate in

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Massachusetts.⁶ On the other hand, proponents argue that required PDMP consultation is necessary to change prescribing behavior, citing early evidence from states that have deployed mandates to demonstrate their potential to reduce opioid abuse.⁵

Some studies associate state PDMPs with lower rates of prescription drug abuse and altered prescribing practices, although evidence is mixed and inconclusive.⁷ Small (if any) demonstrated effect sizes, a dearth of detailed prescribing data prior to PDMP implementation, and a lack of precision in characterizing interventions in existing studies make attributing significant changes in total opioid prescribing or health outcomes to PDMPs a challenge.⁷ Another reason for inconsistent findings may be low and variable prescriber utilization of PDMPs. Prescribers must actually access PDMP data for the systems to have an appreciable effect. In addition, voluntary approaches have self-selection bias: already conscientious opioid prescribers are those likely to use PDMPs.

Clear benefits can derive from increased prescriber participation in PDMPs. When prescribers query the database for a patient's prescription history, they have access to information about the dose, supply, and prescriber of scheduled drugs the patient has filled. With knowledge of this information, practitioners can communicate with patients about their histories, avoid polypharmacy, and refrain from supplying opioids to those who "doctor shop" while comfortably prescribing to those who do not. When a critical mass of prescribers use PDMP information, the collective care each patient receives across providers theoretically can be improved and efficiencies are less likely to be compromised by any one uninformed practitioner. Moreover, prescribers may become accustomed to new practice norms, in which improved information and patient outcomes outweigh perceived burdens associated with checking PDMPs.

But are mandates an effective way to increase PDMP use and improve prescribing outcomes? Twenty states require licensed prescribers to register with the state PDMP.⁸ Use mandates go a step further and dictate the circumstances for PDMP queries. Some states require prescribers to access a patient's prescription history in the database if they suspect drug abuse; others rely on objective criteria (eTable in the Supplement). In Kentucky, Tennessee, New York, and Ohio—early adopters of comprehensive use mandates—there were substantial increases in queries and reductions in opioid prescribing following implementation. In New York, Tennessee, and Ohio, there were declines in doctor shopping.^{3,5} Although these results must be rigorously validated, for example, by comparing them to outcomes in states without mandates and controlling for co-interventions, they suggest the potential influence of mandates to reduce unsafe opioid prescribing.

Mandates face significant prescriber opposition across the country.^{5,6} Some objections relate to generic problems with PDMPs that would be exacerbated under a mandate. Prescribers have difficulty obtaining logins, systems can be "down," information is not integrated into clinical workflow, and data are often incomplete.⁹ Moreover, minimal guidance exists to assist users in interpreting query results. These drawbacks burden and create ambiguity for physicians and other prescribers.

Other objections are specific to mandating PDMP use. Robust evidence is lacking about how to best target mandates to prescriber types and contexts, which makes defining exemptions a policy challenge. Bluntly framed mandates could require physicians and other prescribers to search PDMPs when not clinically indicated or waste time that could be spent otherwise treating patients. Although mandates are not meant to deter opioid prescribing per se, resistant clinicians may simply decline to prescribe opioids, raise prescribing thresholds, refer patients elsewhere, or substitute to nonmonitored drugs—all of which could compromise appropriate symptom management.

Mandates also can entail substantial punitive consequences for prescribers. Penalties for failure to appropriately use PDMPs range from increased liability risk to loss of licensure or imprisonment—an extraordinary punishment for failing to access a website that may contain information of uncertain value (eTable in the Supplement). Mandates may influence courts to hold physicians negligent—for example, when a patient overdoses and harms herself or a third party—if PDMP data could have raised concerns about abuse and modified prescribing. To allay penalty concerns, about half of states explicitly provide that prescribers are immune from liability for checking or failing to check the PDMP. Whether these immunity grants provide meaningful protection remains to be seen.

Calls for more judicious opioid-prescribing practices and discretionary PDMP use have thus far failed to significantly curtail opioid abuse.¹⁰ Although increasing PDMP use seems crucial, mandates may be only one of several paths forward. Policymakers should seriously explore and evaluate more positive approaches, including pay-for-performance, malpractice discounts, or immunity from liability for prescribers who diligently use the systems.

Prescription drug monitoring program mandates are a proliferating policy tool. It will be critical to strike a balance between addressing legitimate practitioner concerns and retaining features fundamental to mandate efficacy. System imperfections, such as the lack of real-time, interstate data and lack of full integration into clinical workflow, are important drawbacks that should be addressed. However, these limitations do not render PDMPs useless, nor should they block mandates altogether. But PDMPs should enroll prescribers automatically and without difficulty. Furthermore, mandates should be implemented only when they cover clinically appropriate circumstances and include exceptions similar to those adopted in New York (eTable in the Supplement). Requirements must be evaluated regularly and rigorously. Developing guidance based on available evidence and expert consensus about how to use PDMP data to improve the quality of pain prescribing must also be prioritized. Mandates have potential, but their viability and success will depend on how carefully they are crafted, reviewed, and refined going forward.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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