



Prescription Drug Monitoring Programs (PDMPs)

Report and Recommendations of the Workgroup on PDMPs

*Adopted as policy by the Federation of State Medical Boards
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INTRODUCTION

In April 2017, the Federation of State Medical Boards (FSMB) Chair, Gregory B. Snyder, MD, DABR, appointed a Workgroup on Prescription Drug Monitoring Programs (PDMP) in accordance with FSMB Resolution 17-1: Mandatory Use of Prescription Drug Monitoring Programs, which was adopted by the FSMB's House of Delegates and which directed the FSMB to establish a task force to study PDMP use in the United States and its territories. The Workgroup was charged with evaluating the impact of mandatory PDMP query on patient outcomes and the prescribing of controlled substances; evaluating challenges to increasing PDMP utilization, including, but not limited to: a) authority to access; b) currency of data; c) Electronic Medical Record (EMR) integration; and d) interoperability; and developing recommendations to state medical and osteopathic boards (hereafter referred to as "state medical boards") regarding physician utilization of PDMPs, including a recommendation regarding mandatory query.

This document provides recommendations for state medical boards and other state agencies to maximize the effective use of PDMPs.

In developing the recommendations that follow, the Workgroup conducted a review of PDMP statutes, rules, and state medical board policies currently enacted across the United States, research reports and peer-reviewed articles in the medical literature and policy statements regarding the use of PDMP.

Section 1. Background

Overdose deaths from prescription opioids in the United States quintupled between 1999-2016, totaling more than 200,000 deaths during that time. In 2016, more than 46 people died every day from overdoses involving prescription opioids.¹² This escalating public health epidemic has led to a wave of implementations and upgrades to states' prescription drug monitoring programs over the past decade in an effort to curb substance use disorder.

State regulatory, administrative, and law enforcement agencies have long seen the need to establish systems to track and monitor the prescribing and dispensing of certain controlled substances, a recognition that dates to 1918.³ California has the oldest continuous program, created in 1939. Early PDMPs were paper-based and collected data on Schedule II prescribing and dispensing only. Collected data was typically reported into such systems within 30 days of the time from dispensing.

In 1990, a new era of electronic PDMPs broke ground when Oklahoma became the first state to require electronic transmission of such data, which helped reduce operational costs and increase accuracy and timely submissions. By 1992, 10 states had operational PDMPs and many other states were considering establishing their own. In 1995, Nevada became the first state to expand the type of drugs reported to the PDMP, expanding from Schedule II only to Schedules II-IV. At the same time, Nevada also became the first state to provide unsolicited reports back to prescribers. By 2000, 15 states had established PDMPs. Between 2000-2012, 34 additional states established such a program, bringing the total number to states with PDMPs to 49. In 2014, the District of Columbia established a PDMP, bringing the total of operational PDMPs to 49 states, plus D.C. and Guam. Puerto Rico has also enacted legislation creating a PDMP but it is not yet operational.

As of September 2017, Missouri remains the only state without a statewide, operational PDMP. To work around this obstacle, St. Louis County established its own PDMP in March 2016 and, since then, this PDMP has gone live (as of April 2017) and more than 50 counties in the state and several individual cities have joined as participants, representing more than 70 percent of Missouri's population and 91 percent of its prescribers.⁴ Separately, in July 2017, the Missouri governor issued an executive order to create a statewide PDMP that allows the Missouri Department of Health and Senior Services to analyze and identify inappropriate prescribing, dispensing, and obtaining of controlled substances, and to address these actions by making

¹ Centers for Disease Control, Opioid Data Analysis. <https://www.cdc.gov/drugoverdose/data/analysis.html>

² Centers for Disease Control, Wide-ranging online data for epidemiologic research (WONDER). Atlanta, GA: CDC, National Center for Health Statistics; 2016. <http://wonder.cdc.gov>

³ Blumenschein, Karen, et. al. "Review of Prescription Drug Monitoring Programs in the United States." Institute for Pharmaceutical Outcomes and Policy, University of Kentucky, June 2010. <http://chfs.ky.gov/NR/rdonlyres/85989824-1030-4AA6-91E1-7F9E3EF68827/0/KASPEREvaluationPDMPStatusFinalReport6242010.pdf>.

⁴ St. Louis County Prescription Drug Monitoring Program, "PDMP Program Update." <http://www.stlouisco.com/Portals/8/docs/document%20library/PDMP/UPDATE-%20St.%20Louis%20County%20PDMP.pdf>

referrals to appropriate government officials, including law enforcement and professional licensing boards.⁵

While the common goal of PDMPs is to provide prescribers and other health care professionals with accurate information about the prescriptions that patients have obtained, a state's decision to apply comprehensive mandates varies widely. The differences between states relate to the types of drugs monitored and the types of prescribers who are mandated to query, as well as to the circumstances which necessitate querying the PDMP, among other differences.⁶⁷ For instance, some PDMPs monitor Schedules II-IV controlled substances, while others monitor Schedules II-V or certain non-controlled substances.⁸ Thirty-six states and the District of Columbia mandate PDMP query under certain circumstances. Of those, 27 states require querying the PDMP during the initial prescribing of a designated substance, while nine states require querying the PDMP before each prescription of a designated substance. Twelve states mandate querying the PDMP when prescribing for the treatment of pain and 14 states require it when prescribing for drug addiction. Among those states requiring a prescriber to query the PDMP prior to the initial prescription of a designated substance, some only require it if it is a Schedule II or III opioid, while others require it only if the initial opioid prescription surpasses a seven-day supply.⁹

This report aims to provide guidance to state medical boards about effective PDMP use, one of many strategies being recommended to address the growing prescription opioid epidemic.

Section 2. Definitions

Mandatory Registration – A state's requirement that prescribers of controlled substances must register with the state's PDMP.

Prescription Drug Monitoring Program – A patient safety tool designed to facilitate the collection, analysis, and reporting of information about the prescribing and dispensing of controlled substances.¹⁰

⁵ Missouri Executive Order. No. 17-18, 2018. <https://www.sos.mo.gov/library/reference/orders/2017/eo18>

⁶ Blumenschein, Karen, et. al. "Review of Prescription Drug Monitoring Programs in the United States." Institute for Pharmaceutical Outcomes and Policy, University of Kentucky, June 2010. <http://chfs.ky.gov/NR/rdonlyres/85989824-1030-4AA6-91E1-7F9E3EF68827/0/KASPEREvaluationPDMPStatusFinalReport6242010.pdf>.

⁷ Wen, Hefei, et al. "States with Prescription Drug Monitoring Mandates Saw A Reduction in Opioids Prescribed to Medicaid Enrollees." Health Affairs, vol. 36, no. 4, Apr. 2017, pp. 733–741., www.ncbi.nlm.nih.gov/pubmed/28373340.

⁸ "Substances Monitored by PMP." National Alliance for Model State Drug Laws, May 2016, www.namsdl.org/library/8D7261F8-E47D-B6A5-DD0CAFA98FEA4846.

⁹ "Mandated Use of State Prescription Drug Monitoring Programs: Highlights of Key State Requirements." National Alliance for Model State Drug Laws, June 2017. <http://www.namsdl.org/library/6735895A-CA6C-1D6B-B8064211764D65D0/>

¹⁰ Federation of State Medical Boards (FSMB). Model Policy for the Use of Opioid Analgesics in the Treatment of Chronic Pain. Washington, DC: The Federation, 2013.

Universal Use – A state’s requirement that prescribers must query the patient’s PDMP history before initially prescribing opioid pain relievers and benzodiazepines, and at certain intervals thereafter.¹¹

Unsolicited Reports – Proactive communications from the PDMP to prescribers, dispensers, law enforcement, and/or regulators to provide information about patient prescriptions and/or the prescribing activity of a health care professional based upon PDMP data.¹²

3. Mandatory Registration

Studies show that between 2010-2012, states with operational PDMPs saw an average registration rate of 35 percent among licensed prescribers who prescribed at least one controlled substance during that period.¹³ In 2014, a national survey found that 53 percent of primary care physicians used their state’s PDMP at least once, but many were not using the PDMP on a routine basis.¹⁴ Although there have been extensive educational campaigns to recruit prescribers to participate in their state’s PDMP, results have not always been successful.¹⁵ At the same time, however, PDMP registration has increased significantly, increasing from approximately 471,000 to more than 1.3 million from 2014 to 2016. During the same time period, queries by physicians and other health care professionals increased from approximately 61 million to more than 136 million.¹⁶

States are seeing success in increasing prescriber PDMP registration rates through other methods, such as mandatory registration. Massachusetts took a staggered, low resource-intensive approach by linking PDMP enrollment to the renewal of state controlled substance registration, where renewals are required every three years for practitioners. The process established by Massachusetts allowed for a continuous workflow for PDMP staff, rather than a surge in applications immediately after the enactment of mandatory PDMP registration legislation. As a result, the state first saw a gradual increase in registration, followed by a more dramatic increase, between 2011-2016. In 2011 and 2012, only 1 percent and 2 percent of prescribers were registered with the PDMP, respectively. By the end of 2014, however, nearly 66 percent of prescribers were enrolled. By September 2015, that percentage increased to 83 percent, and by January 2016, more than 90 percent had enrolled.¹⁷

¹¹ CDC Prevention Status Report, <https://www.cdc.gov/psr/NationalSummary/NSPDO.aspx>

¹² The PEW Charitable Trusts, *Prescription Drug Monitoring Programs: Evidence-Based Practices to Optimize Prescriber Use*, December 2016. www.pewtrusts.org/en/research-and-analysis/reports/2016/12/prescription-drug-monitoring-programs.

¹³ Wen, Hefei, et al. “States with Prescription Drug Monitoring Mandates Saw A Reduction in Opioids Prescribed to Medicaid Enrollees.” *Health Affairs*, vol. 36, no. 4, Apr. 2017, pp. 733–741., www.ncbi.nlm.nih.gov/pubmed/28373340.

¹⁴ Ibid.

¹⁵ Ibid.

¹⁶ Survey of state PDMP administrators. American Medical Association.

¹⁷ The PEW Charitable Trusts, *Prescription Drug Monitoring Programs: Evidence-Based Practices to Optimize Prescriber Use*, December 2016. www.pewtrusts.org/en/research-and-analysis/reports/2016/12/prescription-drug-monitoring-programs.

4. Universal Use

Research shows that between 2011-2014, 85 percent of states that implemented some form of a PDMP universal use mandate were based upon legislation that was of limited scope and strength. Due to the weakness of the mandates in these cases, it is unlikely that they will prove effective in improving opioid prescribing practices.¹⁸ Efforts to strengthen universal use mandates are supported by President Donald Trump’s Commission on Combating Drug Addiction and the Opioid Crisis, which recommends that federal agencies mandate PDMP querying.¹⁹

States that have established an effective PDMP, in part or in whole, employ certain evidence-based practices. These practices include delegated authority, unsolicited reports, data timeliness, streamlined enrollment, educational initiatives, integration and data sharing, enhanced user interfaces, and proper funding, with delegated authority, data timeliness, and integration and data sharing being critical elements.²⁰

Delegated Authority

Prescription Drug Monitoring Programs can serve as valuable tools to help inform prescribers’ decision making and identify potential substance use disorder, but a significant barrier to increasing prescriber use of them is the time typically needed to query the system.²¹ To decrease the time spent by prescribers reviewing patient records, many states authorize registered users to delegate non-prescriber employees the ability to access the system using sub-accounts. States vary, however, in whether a delegate has to be a licensed individual or not, as well as in the number of prescriber delegates permissible. Currently, 47 states and the District of Columbia authorize prescribers to delegate such authority, with 36 states actively doing so.²² Some states only permit two delegates per prescriber, while others impose no limits.²³

In Kentucky, the state’s PDMP, known as the Kentucky All Schedule Prescription Electronic Reporting Program (KASPER), does not restrict the number of subaccounts to licensed staff. Prescribers also have no limit on the number of designated delegates, who are also permitted to serve as a delegate for multiple prescribers. For prescribers sharing multiple delegates, delegates are able to select the prescriber from a dropdown list to accurately record for which prescriber a

¹⁸ Wen, Hefei, et al. “States with Prescription Drug Monitoring Mandates Saw A Reduction in Opioids Prescribed to Medicaid Enrollees.” *Health Affairs*, vol. 36, no. 4, Apr. 2017, pp. 733–741., www.ncbi.nlm.nih.gov/pubmed/28373340.

¹⁹ The President’s Commission on Combating Drug Addiction and the Opioid Crisis, “Final Report,” 15 November 2017. https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-15-2017.pdf

²⁰ The PEW Charitable Trusts, *Prescription Drug Monitoring Programs: Evidence-Based Practices to Optimize Prescriber Use*, December 2016. www.pewtrusts.org/en/research-and-analysis/reports/2016/12/prescription-drug-monitoring-programs.

²¹ Rutkow, L. et al. “Many primary care physicians are aware of prescription drug monitoring programs, but many find the data difficult to access.” *Health Affairs*, vol. 34, no. 3, March 2015, pp. 484-492., <http://www.healthaffairs.org/doi/full/10.1377/hlthaff.2014.1085>

²² Brandeis University PDMP Training and Technical Assistance Center. “PDMPs Authorized and Engaged in Sending Solicited and Unsolicited Reports to Health Care Providers and Patients.” http://www.pdmpassist.org/pdf/Health_Care_Entity_Table_20170824.pdf

²³ The PEW Charitable Trusts, *Prescription Drug Monitoring Programs: Evidence-Based Practices to Optimize Prescriber Use*, December 2016. www.pewtrusts.org/en/research-and-analysis/reports/2016/12/prescription-drug-monitoring-programs.

report is being queried. The prescriber is responsible for deactivating accounts of delegates who leave the practice or otherwise warrant discontinuance of PDMP access. Delegates are permitted to conduct queries and provide reports for prescriber review, but are prohibited from conducting the clinical review of data that the state's mandate requires. As a result of allowing such delegated authority, during the fourth quarter of 2015 delegates requested nearly 64 percent of in-state prescriber reports, despite accounting for 42 percent of combined delegate and prescriber master accounts by the end of that year.²⁴

Unsolicited Reports

PDMPs provide prescription history reports to authorized users upon request (these are also known as "solicited" reports), but when these reports are not requested useful information can go unseen or unused by prescribers. In an effort to increase utilization, many PDMPs proactively send "unsolicited" (and, therefore, unrequested) reports to specific prescribers, dispensers, state licensing boards, and law enforcement agencies that contain data suggestive, or indicative, of multiple provider episodes or inappropriate prescribing and dispensing.²⁵

In 2005, Maine began sending prescribers quarterly threshold notification reports via U.S. mail, but in 2013 moved to monthly emailed alerts. Originally, these alerts were sent to registered PDMP users only when one of three criteria was met by a patient: 1) exceeds a certain number of prescribers and pharmacies in a three-month period; 2) exceeds a specified average daily dose of acetaminophen coming from prescriptions of opioid-acetaminophen combination drugs; or 3) is prescribed buprenorphine and another opioid in a 30-day period. In 2015, however, the state's legislature added two new criteria to initiate alerts: 1) multiple overlapping prescriptions for medications containing opioids; and 2) prescriptions for more than 300 morphine milligram equivalents daily for more than 45 consecutive days within a 90 day period. Alert recipients must log into their PDMP account to review the patient's prescription history, which includes the other providers who prescribed to the patient, the pharmacies that dispensed to the patient, drugs and quantities and other details of prescriptions dispensed for the past three months. Additionally, the state recently enabled prescribers to request reports based on their own set thresholds. It is believed that unsolicited reports may have affected prescriber behavior from 2010 to 2014 when the state saw a steady decline in the rate of multiple provider episodes.²⁶

Additionally, in Indiana, a prescriber who believes a patient's PDMP data suggests questionable activity has the option to send email alerts to other prescribers and dispensers of the patient. These "user-led unsolicited report" email alerts do not contain a patient's name or any conclusions, but rather contains a hyperlink to a patient's prescription history report that registered users can review after logging into the PDMP, thus ensuring Health Insurance Portability and Accountability Act (HIPAA) compliance. These alerts serve to notify prescribers and dispensers that a patient may be using unnecessary prescription drugs, may be receiving controlled substances from multiple providers, or may be involved in controlled substance

²⁴ Ibid.

²⁵ Brandeis University PDMP Training and Technical Assistance Center, "Guidance on PDMP Best Practices: Options for Unsolicited Reporting," May 2016.
http://www.pdmpassist.org/pdf/COE_documents/Add_to_TTAC/Update%20to%20Brandeis%20COE%20Guidance%20on%20Unsolicited%20Reporting%20final.pdf

²⁶ Ibid.

diversion. Indiana first launched its user-led unsolicited reports in March 2012. After the first three months of the program, 140 practitioners had sent 2,284 alerts on 214 unique patients, at virtually no cost to the program.²⁷

Data timeliness

A prescriber's ability to effectively use PDMP data to assess a patient's prescription history can only be as complete as the data that is transmitted into the system by a dispenser. If a PDMP report does not contain information about the most recently dispensed controlled substances, a prescriber may lack valuable data to determine the best course of treatment. Because of this, it is imperative to minimize the pharmacy reporting interval. States are increasingly moving away from weekly reporting towards daily PDMP data reporting. In 2015, 24 states required daily data submissions. As of July 2017, 40 states and the District of Columbia required data to be reported within 24 hours or one business day. Oklahoma is the only state currently requiring real-time reporting,²⁸ but the transition from daily reporting to real-time required two years and involved intensive effort and overtime for the PDMP, as well as redesign for pharmacy data systems and workflow procedures.²⁹

Streamlined Enrollment

In order to access PDMP data, prescribers must typically establish online accounts with a state's PDMP system. This process requires the prescriber to submit, and the PDMP to verify, identifying information, such as name, date of birth, state controlled substance prescribing or medical practice license number, DEA registration number, driver's license number, place of employment, medical specialty, and contact information. Once the prescriber's state controlled substance prescribing or medical practice license number and a DEA registration number is verified, the prescriber may create an account and begin to query patients' controlled substance prescription history. Unfortunately for many prescribers, the process can be time consuming to complete registration applications as some states require paper applications and notarization.³⁰ To expedite PDMP registration, and to transition away from paper applications, some states began migrating to an online registration system, in addition to automatic prescriber enrollment, during initial medical licensure and licensure renewal.

In 2012, the Tennessee Legislature enacted legislation mandating that prescribers use the state's PDMP and dispensers register. The comprehensive mandate required DEA-registered prescribers and dispensers to register with the PDMP within the first eight months after the law's enactment. New licensees are required to register with the PDMP within 30 days. The universal use mandate went into effect four months after prescribers and dispensers were required to register. In an

²⁷ Indiana Scheduled Prescription Electronic Collection & Tracking (INSPECT). "Presentation on User-Led Unsolicited Reporting (ULUR)." 2012.

http://www.pdmpassist.org/pdf/PPTs/National2012/2_Allain_StatePanelInnovationsIndiana.pdf

²⁸ National Alliance for Model State Drug Laws, "Frequency of Prescription Drug Monitoring Program Data," 30 June 2017. <http://www.namsdl.org/library/03B95893-0EE2-3766-EABAD212B5C8E8D3/>

²⁹ The PEW Charitable Trusts, *Prescription Drug Monitoring Programs: Evidence-Based Practices to Optimize Prescriber Use*, December 2016. www.pewtrusts.org/en/research-and-analysis/reports/2016/12/prescription-drug-monitoring-programs.

³⁰ The Network for Excellence in Health Innovation, "Issue Brief – Physicians and PDMPs: Improving the Use of Prescription Drug Monitoring Programs," November 2015.

https://www.nehi.net/writable/publication_files/file/pdmp_issue_brief_11.18.pdf

effort to handle the influx of registrations, Tennessee adopted an online registration system. This system automatically attempts to validate a prescriber's information using electronic databases for the state's professional health care licenses, driver's licenses, and DEA prescriber registration. For prescribers who do not have health care licenses or DEA numbers, such as medical residents in hospitals in some states, PDMP registration is still processed manually. As a result of the streamlined online registration system for licensed prescribers and dispensers, the number of registered prescribers has increased 127 percent between 2011 (a year before the mandate went into effect) and 2014. Additionally, average queries per month have increased 203 percent during that same time period.³¹

Educational Initiatives

Many state medical boards require physicians to complete continuing medical education (CME) in specific content areas, such as pain management and controlled substance prescribing practices. Thirty-two of the 50 states, and the District of Columbia, mandate at least one content-specific CME course. Of those 32 states, 29 states require CME focused on either pain management or controlled substance prescribing practices, or in some circumstances both. In 26 out of those 29 states, the CME requirements are for both allopathic and osteopathic physicians. In two states, Oklahoma and Nevada, only osteopathic physicians are required to complete CME on pain management/controlled substance prescribing practices, while in Vermont only allopathic physicians are required to complete such CME. Additionally, 12 of the 29 states require CME on pain management/controlled substance prescribing practices for all physicians, while the other 17 states only require a subset of physicians to complete such requirements, such as controlled substance providers or certain providers who work in pain clinics.³²

In order to assist prescribers in completing CME requirements, as well as educate prescribers who are not required to complete content-specific CME, the federal government promotes certain educational initiatives. The U.S. Department of Health and Human Services (HHS) Substance Abuse and Mental Health Services Administration (SAMHSA) and the Health Resources and Services Administration (HRSA) jointly developed the "Substance Use Trainings" webpage as an online educational resource that provides one-time and ongoing training activities dedicated to pain management and controlled substance prescribing practices. HHS's Office of Disease Prevention and Health Promotion also developed an online education resource, *Pathways to Safer Opioid Use*, while the U.S. Food and Drug Administration's (FDA) Risk Evaluation and Mitigation Strategy (REMS) for extended release/long-acting opioids requires CME to be offered by opioid manufacturers.³³ As part of REMS, the FDA released the *FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics*, which contains core educational messages for the development of continuing

³¹ The PEW Charitable Trusts, *Prescription Drug Monitoring Programs: Evidence-Based Practices to Optimize Prescriber Use*, December 2016. www.pewtrusts.org/en/research-and-analysis/reports/2016/12/prescription-drug-monitoring-programs.

³² Xu, Jing, PhD, MA; Gribble, Anna, MSW, MPH, et al. "State Continuing Education Requirements for Physicians and Dentists, Including Requirements Related to Pain Management and Controlled Substance Prescribing," *Journal of Medical Regulation*, Vol. 103, Number 3, 2017.

³³ *Ibid.*

education activities focused on safe prescribing.³⁴ The Centers for Disease Control (CDC) also provides educational materials, such as *Applying CDC's Guideline for Prescribing Opioids: An Online Training Series for Providers* and *What Healthcare Providers Need to Know About PDMPs*.^{35,36}

While a majority of states require physicians to complete certain content-specific CME, FSMB policy states that, “the FSMB believes mandatory continuing medical education is a matter reserved for the individual state jurisdictions.”³⁷

Integration and Data Sharing

The value of PDMP data is based in part on whether such data is readily available and accessible. Although PDMPs collect controlled substance prescription information in a central repository, the adoption and utilization of a PDMP by prescribers is slowed when such data is not integrated into health information technology (HIT) systems, specifically electronic health records (EHR).

There have been several efforts and initiatives to spur the pace at which PDMP data is integrated, such as SAMHSA's PDMP Electronic Health Records Integration and Interoperability Expansion (PEHRIIE) program, which funded projects in nine states from 2012-2016. The goal of this program was to increase prescriber utilization by integrating PDMP data into HITs. The program also sought to increase the comprehensiveness of PDMP data by increasing interstate PDMP data sharing.³⁸

Programs such as PEHRIIE demonstrate the effectiveness of integrating PDMP data into HITs. During the fourth quarter of 2014, the state of Washington became interoperable with OneHealthPort, a statewide HIE, enabling integration with the Emergency Department Information Exchange (EDIE), a hub connecting hospital emergency departments. In 2015, the first full calendar year after integration, the PDMP provided 2,222,446 solicited reports to prescribers, compared to 2014, when 26,546 solicited reports were provided to prescribers.³⁹ Significant increases in solicited reports were also experienced in Kansas after PDMP data was integrated with the Via Christi Health Network, the largest healthcare provider in Kansas, in late 2013. After integration, solicited reports provided to Via Christi prescribers increased from 31,156 reports in 2013 to 223,000 reports in 2015. Compared to other prescribers in Kansas, the number of solicited reports increased significantly less, from 23,171 in 2013 to 65,242 in 2015.

³⁴ United States Food and Drug Administration, *Introduction for the FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics*, May 2017.

³⁵ Centers for Disease Control, *Applying CDC's Guideline for Prescribing Opioids: An Online Training Series for Provider*. <https://www.cdc.gov/drugoverdose/training/overview/index.html>

³⁶ Centers for Disease Control, *What Healthcare Providers Need to Know About PDMPs*. <https://www.cdc.gov/drugoverdose/pdmp/providers.html>

³⁷ Federation of State Medical Boards (FSMB), *FSMB Policy 100.2, Mandating Continuing Medical Education*, Washington, DC: The Federation, 1980.

³⁸ Centers for Disease Control (CDC). “Integrating & Expanding Prescription Drug Monitoring Program Data: Lessons from Nine States,” February 2017. https://www.cdc.gov/drugoverdose/pdf/pehriie_report-a.pdf

³⁹ Ibid.

Several states also announced efforts to integrate prescription drug information into EHRs and other HITs. In August 2017, Indiana announced that it would integrate PDMP data into EHRs at hospitals and physician practices across the state at no cost to the facility or individual practitioner. The phased-in integration is scheduled to be completed by 2020.⁴⁰ Michigan also announced in June 2017 that state and federal funds will be invested over a two year period to integrate the state's PDMP, Michigan Automated Prescription System, into EHRs and pharmacy dispensation systems.⁴¹ Additionally, Arizona, Kansas, Massachusetts, Ohio, Pennsylvania, and Virginia are supporting integration into EHRs, HITs, and pharmacy dispensing systems at no cost.

These recent state trends to integrate PDMP data are in line with recommendations being conveyed at the federal level, including the President's Commission on Combating Drug Addiction and the Opioid Crisis, which recommended in November 2017 that "PDMP data integration with electronic health records, overdose episodes, and substance use disorder-related decision support tools for providers is necessary to increase effectiveness."⁴²

The ability for prescribers to view prescription drug history information across state lines can assist in identifying a potential substance use disorder. To facilitate interstate PDMP data sharing and integration, states have opted to connect to a data sharing hub. Forty-five states and the District of Columbia are currently engaged in some form of interstate data sharing, while three other states are in the process of implementing data sharing.⁴³ Not all states, however, allow universal data sharing among states. Some states allow prescribers in any state to access PDMP data, while other states allow prescribers from specific states within a region. These are usually in-state policy decisions that often change to expand toward a goal of universal access.

The President's Commission on Combating Drug Addiction and the Opioid Crisis also recommended supporting federal legislation mandating states that receive grant funds to comply with PDMP requirements, including data sharing, and establishing and maintaining a data-sharing hub.⁴⁴

In an effort to reduce barriers to data sharing across state lines, there have been various data sharing hubs launched to facilitate data sharing in compliance with each state's data access regulations. At the request of several PDMPs, the National Association of Boards of Pharmacy (NABP) created Prescription Monitoring Program (PMP) InterConnect in 2011. PMP InterConnect provides for encrypted data to be transmitted across state lines. To date, 45 states have executed a memorandum of understanding (MOU) with NABP to participate and 42 of

⁴⁰ Sweeney, Evan, "Indiana announces plans to integrate PDMP data into EHRs across the state," FierceHealthcare, 25 August 2017. <https://www.fiercehealthcare.com/ehr/indiana-announces-plans-to-integrate-pdmp-data-into-ehrs-across-state>

⁴¹ Office of Governor Rick Snyder, "Patient Protections Strengthened as State Fully Integrates MAPS into Health Systems," 19 June 2017. http://www.michigan.gov/snyder/0,4668,7-277-73341_73343-424218--,00.html

⁴² The President's Commission on Combating Drug Addiction and the Opioid Crisis, *Final Report*, 15 November 2017. https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-15-2017.pdf

⁴³ Brandeis University PDMP Training and Technical Assistance Center, "Interstate Data Sharing," 20 September 2017. http://www.pdmpassist.org/pdf/Interstate_Data_Sharing_20170920.pdf

⁴⁴ The President's Commission on Combating Drug Addiction and the Opioid Crisis, "Final Report," 15 November 2017. https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-15-2017.pdf

those states are now live. Each month, PMP InterConnect processes more than 15 million requests.⁴⁵

Separately, RxCheck is another data sharing hub that was created with support from the U.S. Bureau of Justice Assistance (BJA) and using the Prescription Monitoring Information Exchange (PMIX) National Architecture specifications. As of July 2017, there are four states that are engaged in interstate data sharing with RxCheck, while two states are currently implementing interstate data sharing and eight states have plans to connect to RxCheck.

Enhanced User Interfaces

While having access to PDMP data is integral for prescribers, it is equally important that prescribers are able to quickly analyze and use that data. As the amount of controlled substance prescription information available to prescribers has increased in recent years, prescribers have sought ways to quickly analyze the most important information for clinical decision making. To address this, states began exploring ways to better interpret the data. Some of these methods included adding an enhanced user interface to the PDMP system that includes, but is not limited to, a total morphine milligram equivalent (MME) calculation for each opioid prescription, a daily MME dose level, and flags or alerts if a patient's MME surpasses a certain threshold.⁴⁶

In 2016, the California PDMP, Controlled Substance Utilization Review and Evaluation System (CURES) underwent a redesign to help prescribers improve their clinical decision-making when evaluating whether to prescribe a controlled substance. The new updated program contains a dashboard that provides users patient alerts, including a list of patients who are prescribed more than 100 MME per day; have obtained prescriptions from six or more prescribers or pharmacies during the past 12 months; are prescribed more than 40 milligrams of methadone daily; have been prescribed opioids for more than 90 consecutive days; or are concurrently prescribed benzodiazepines and opioids.⁴⁷

Enhanced user interfaces are a recent development and, as such, there is a paucity of evidence on its effectiveness in identifying a potential substance use disorder or coordinating care in the case of a multiple provider event.

Data Security/Patient Protections

As the use of PDMP increases nationwide and controlled substances prescription history is increasingly used by prescribers, patients are increasingly concerned about the security of their data and the possibility of law-enforcement scrutiny. Prescribers are also increasingly concerned

⁴⁵ National Association of Boards of Pharmacy, "Connecting State Prescription Monitoring Programs Nationwide," November 2017. <https://nabp.pharmacy/wp-content/uploads/2017/11/NABP-InterConnect-Flyer-November-2017.pdf>

⁴⁶ The PEW Charitable Trusts, *Prescription Drug Monitoring Programs: Evidence-Based Practices to Optimize Prescriber Use*, December 2016. www.pewtrusts.org/en/research-and-analysis/reports/2016/12/prescription-drug-monitoring-programs.

⁴⁷ California Department of Justice, "CURES 2.0: Prescription Drug Monitoring Program" (presentation September 2015). https://www.sfhpa.org/files/providers/Best_Practices/CURES_2.0_PPT.pdf

that medical consultations are no longer a private affair and that staff access pose the potential for unscrupulous use and data leaking.⁴⁸

Substance use disorder is a multifaceted problem and often requires collaboration among various agencies and stakeholders. PDMPs are primarily used as a public health tool, but law enforcement agencies see PDMPs as a potential law enforcement tool. An increase in law enforcement scrutiny of PDMP data may significantly affect a prescriber's clinical decision making and cause a prescriber to under prescribe.⁴⁹

A balanced approach between patient safety and data protection has been encouraged by various stakeholders. Both the American Medical Association (AMA) and the American Society of Addiction Medicine (ASAM) believe that PDMP data should be considered protected health information, and should not be released outside of the health care system unless there is authorization for release from the individual patient. The AMA also supports access to PDMP data via a warrant, as well as when the public safety demands in certain situations.⁵⁰⁵¹

The United States District Court for the District of Oregon, Portland Division affirmed the limits of law enforcement access in February 2014 in *Oregon Prescription Drug Monitoring Program v. United States Drug Enforcement Administration*. The Court found that federal drug investigators cannot access patients' prescription information without proving probable cause and obtaining a warrant. The Court also found that administrative subpoenas are insufficient to demand information relevant to investigations into potential drug violations, such as a doctor who improperly prescribes drugs.⁵² In June 2017, the United States Court of Appeals for the Ninth Circuit reversed the ruling as it found that requiring a court order to enforce the subpoena on the DEA interfered with Congress' intent to strengthen law enforcement tools against the traffic of illicit drugs. It recognized, however, that medical records require strong legal safeguards.⁵³

In Georgia, in addition to authorizing prescribers and dispensers, and their designated delegates, the Georgia Drugs and Narcotics Agency is authorized to provide requested prescription information collected to a patient, or the patient's attorney; local or state law enforcement or prosecutorial officials pursuant to the issuance of a search warrant from an appropriate court or

⁴⁸ Islam, M Mofizul and McRae, Ian S, "An inevitable wave of prescription drug monitoring programs in the context of prescription opioids: pros, cons and tensions," BMC Pharmacology & Toxicology, 6 August 2014. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4138942/>

⁴⁹ Ibid.

⁵⁰ American Society of Addiction Medicine, "Public Policy Statement on Measures to Counteract Prescription Drug Diversion, Misuse and Addiction," 25 January 2012. <https://www.asam.org/advocacy/find-a-policy-statement/view-policy-statement/public-policy-statements/2012/01/26/measures-to-counteract-prescription-drug-diversion-misuse-and-addiction>

⁵¹ American Medical Association, "Prescription Drug Monitoring Program Confidentiality H-95.946, 2015. <https://policysearch.ama-assn.org/policyfinder/detail/prescription%20drug%20monitoring%20program?uri=%2FAMADoc%2FHOD.xml-0-5325.xml>

⁵² *Oregon Prescription Drug Monitoring Program v. US Drug Enforcement Administration*, 998 F.Supp.2d 957 (2014) <https://www.leagle.com/decision/infdco20140212990>.

⁵³ *Oregon Prescription Drug Monitoring Program v. US Drug Enforcement Administration*, 860 F.3d 1228 (2017) <https://www.leagle.com/decision/infco20170626117>

official in the county in which the office of such law enforcement or prosecutorial officials are located or to federal law enforcement or prosecutorial officials pursuant to the issuance of a search warrant or a grand jury subpoena; to the Georgia Drugs and Narcotics Agency, the Georgia Composite Medical Board or any other state regulatory board governing prescribers or dispensers in this state, or the Department of Community Health for purposes of the state Medicaid program upon the issuance of a subpoena by such agency, board, or department pursuant to their existing subpoena power or to the federal Centers for Medicare and Medicaid Services upon the issuance of a subpoena by the federal government pursuant to its existing subpoena powers.⁵⁴

Proper Funding

To continually maintain and update a state's PDMP system often comes with a certain level of financial need. It is often difficult, however, for states to properly fund such operations and projects. In order to meet these demands, states use a wide variety of funding mechanisms, whether in whole or in part, including state appropriations, registration and licensing fees, and federal grants.

One source of funding for states has been legislative appropriations and state government funding. In October 2015, Ohio Governor John Kasich announced that the state would invest up to \$1.5 million a year to integrate the Ohio Automated Rx Reporting System (OARRS) directly into electronic medical records and pharmacy dispensing systems across the state, allowing instant access for prescribers and pharmacists.⁵⁵

In addition to licenses to practice medicine, several states require a controlled substance prescribing license that is separate from DEA registration. The registration fees from these state prescribing licenses frequently go to support the PDMP, whether in full or in part. This funding mechanism assesses a fee on a subset of providers while the more current thinking is that all licensed providers should have access to their patients' PDMP data.⁵⁶

Instead of allocating funds from a specific controlled substance prescribing license, some states allocate a certain percentage from all professional licensing fees to go towards the state's PDMP. Although this avenue provides consistent funding, it is limited in dollar amount and increasing the allocated percentage may affect other operations of the Board.^{57,58}

States often leverage federal grants to fund and maintain PDMP projects, as well. Since 2003, the U.S. Department of Justice's Bureau of Justice Assistance has administered the Harold Rogers PDMP Grant Program to reduce opioid misuse and the number of overdose fatalities by supporting the implementation, enhancement, and proactive use of state PDMPs. For Fiscal Year

⁵⁴ Ga. Code § 16-13-30

⁵⁵ Ohio Automated Rx Reporting System, <https://wholesale.ohiopmp.gov/Portal/Integration.aspx>

⁵⁶ PDMP TTAC, "Funding Options for Prescription Drug Monitoring Programs," 3 July 2013. http://www.pdmpassist.org/pdf/PDMP_Funding_Options_TAG.pdf

⁵⁷ Brandeis University PDMP Training and Technical Assistance Center, "Funding Options for Prescription Drug Monitoring Programs," 3 July 2013. http://www.pdmpassist.org/pdf/PDMP_Funding_Options_TAG.pdf

⁵⁸ National Alliance for Model State Drug Laws, "Funding Provisions of PDMPs," May 2016. <http://www.namsdl.org/library/57555C8D-B77F-0F68-987334839CA29924/>

2017, two-year grants were awarded to 10 states and Puerto Rico totaling \$3,966,932.⁵⁹ The CDC also provides funding opportunities to support states' efforts to enhance and maximize PDMPs, including the Data Driven Prevention Initiative (DDPI) and Prevention for States (Pfs) Funding Opportunity Announcements.⁶⁰⁶¹ Additionally, SAMHSA also provides a variety of funding opportunities for states to enhance their PDMPs.⁶²

5. Recommendations

1. Mandatory Registration –

States should require PDMP registration for prescribers of controlled substances. This registration should take place at the time of the prescriber's initial medical licensure application or next renewal. In an effort to expedite the process, state PDMPs should facilitate online registration to meet the expected increase in applications.

2. Universal Use of PDMPs–

States should require universal use of PDMPs if the state's PDMP contains certain characteristics. Ideally, all the characteristics listed below would be present within a state's PDMP system but some are more critical than others to the functionality of the PDMP.

a. Group 1: Critical Characteristics Needed for an Effective PDMP

i. Delegation –

Each prescriber should be permitted to delegate authority to access the PDMP to any member of their health care team by creating subaccounts without limitations. Delegates should be able to be shared by multiple providers, such as a physician group or emergency department or similar setting. The prescriber must have the authority to deactivate a delegate's subaccount for any reason, including, but not limited to, leaving the practice or no longer serving in that capacity.

In order to ensure delegate accountability, prescribers must be allowed to audit their delegates' activity and use of the PDMP.

ii. Data timeliness/accuracy –

State PDMPs should require daily reporting of controlled substance prescription. Although it may be ideal to have real-time reporting, there is a paucity of data at this time to support it.⁶³

⁵⁹ U.S. Department of Justice, Bureau of Justice Assistance, Harold Rogers PDMP Grant Program, <https://www.bja.gov/funding/Category-5-awards.pdf>

⁶⁰ Centers for Disease Control, *Data Driven Prevention Initiative*. <https://www.cdc.gov/drugoverdose/foa/ddpi.html>

⁶¹ Centers for Disease Control, *Prevention for States*.

https://www.cdc.gov/drugoverdose/states/state_prevention.html

⁶² Substance Abuse and Mental Health Services Administration. Grants Related to Prescription Drug Misuse and Abuse. <https://www.samhsa.gov/prescription-drug-misuse-abuse/grants>

⁶³ The PEW Charitable Trusts, *Prescription Drug Monitoring Programs: Evidence-Based Practices to Optimize Prescriber Use*, December 2016. www.pewtrusts.org/en/research-and-analysis/reports/2016/12/prescription-drug-monitoring-programs.

In order to ensure data accuracy, prescribers should be able to review their prescribing history and provide corrections to it, if necessary.

iii. Integration and Data Sharing –

In order to minimize any workflow disruption, states should integrate their PDMP system with electronic health records and pharmacy systems. Ideally, this integration will provide near-instant and seamless access to critical prescription history information to both prescribers and pharmacists.

States should engage in interstate PDMP data sharing.

b. Group 2: Other Characteristics Needed for an Effective PDMP

i. Unsolicited reports –

In an effort to notify prescribers of a patient’s prescribing information, as well as the prescriber’s own prescribing history, PDMP systems should provide unsolicited reports. Examples of information in such reports may include multiple provider episodes, combinations of commonly misused drugs, or exceeding a designated threshold for an average daily dose of an opioid in morphine milligram equivalents.

To protect patients, prescribers should generate user-led unsolicited reports to send to other prescribers treating the same patient. These user-led unsolicited reports are sent at the discretion of the prescriber and serve as a judgment that the patient may be receiving a potentially harmful controlled substance or has experienced a situation, such as an overdose, that may increase the patient’s future risk of overdose or abuse.

When possible, these reports should be sent electronically and should not contain identifying patient information, but rather alert and direct the prescriber to query the PDMP to view the information.

ii. Educational initiatives –

A state medical board may choose to encourage or require prescribers to complete content-specific continuing medical education related to prescribing practices including, but not limited to, PDMP utilization.

iii. Enhanced user interface –

PDMP system tools to increase usability for prescribers should be considered. These components, as part of a PDMP’s interface, may include, but are not limited to, a summary of morphine milligram equivalent (MME) for each opioid prescription and a daily MME dose level, as well as any other “red” flags or alerts for a specific patient.

iv. Data Security/Patient Privacy –

States should grant PDMP data access to local, state, and federal law enforcement only when there is an issuance of warrant/judicial finding of probable cause.

States should grant PDMP data access to state medical boards when a licensee is under investigation by the board for inappropriate prescribing.

In order to protect the privacy of patient information and to ensure proper patient treatment, Medicare, Medicaid, state health insurance programs and/or health care payment benefit providers and insurers should not have access to a patient's PDMP record unless a subpoena has been issued in accordance with existing subpoena powers.

v. Proper funding –

To meet the demands of updating and maintaining a PDMP, states should implement a sustainable funding mechanism, whether through state funding or federal grant programs.

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