

Report to Congress: State Challenges and Best Practices Implementing PDMP Requirements Under Section 5042 of the SUPPORT Act

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Contents

	Page
Executive Summary	1
Introduction	3
Methods	5
Prescription Drug Monitoring Program Variation Across the United States Prior to the SUPPORT Act	6
Access and Use	6
Cross-State Access to PDMP Data	8
Volume of Providers Accessing the PDMP	8
Placement of PDMP Data within Medical Records	9
PDMP Privacy Protections	11
Standards for PDMP Data Exchange	11
Use of 100 Percent Federal Medicaid Match to Advance State PDMPs	15
Approved Funding	
Operating State Agency	
State Mandates PDMP Access	
State Status with Respect to Qualified PDMP Requirements	
Plans for Use of the 100 Percent Enhanced Federal Match	
Planning and Development	
Integration	
Infrastructure	
Data and Analytics	
Other	
Outcome Measures	
State Challenges Implementing Qualified PDMP Requirements Under the SUPPORT Act Patient Matching	
Vendor Costs	
Time	
Alternative Funding Sources	
Comprehensiveness of Data	
State Coordination	
PDMP Data Integration with Medicaid Data	
Qualified PDMP Requirements	30

Promising Practices in PDMP Implementation	31
Internal State Coordination	31
Collaboration Across States	31
CDC Funding	31
PDMP Access for EMS Personnel	32
State Models of Promising Practices to Maximize Effectiveness of PDMPs	33
Colorado	33
Nebraska	33
Rhode Island	34
Consultations with Key Stakeholders	35
Lessons Learned	42
Extended Timeline for Expending Funds Approved for Federal Match	42
National Data Standards	42
Clarification of Requirements for a Qualified PDMP	42
Flexibility in Use of Federal Funds	43
Identification of State Legislation That Impedes PDMP Development and Use	43
Coordination with Federal PDMP Programs	44
Comprehensive State Mandates	44
Funding for State Collaboration	
Increased Integration Between PDMP and EHRs	45
Best Practices on Increasing Enrollment and Use of PDMP	
Enhanced Education and Training for Providers, Payers, and Patients	
Evaluation of Impact of PDMPs	
References/Bibliography	47

Exhibits

	Page
Exhibit 1. State and Territories with Requirements for Providers to Check PDMP	7
Exhibit 2. State Variation in PDMP Access Roles	
Exhibit 3. States With Statutory or Regulatory Language Authorizing Placement of	
PDMP Data Within the Medical Record	9
Exhibit 4. Nationwide Status of PDMP Integration into Hospitals	10
Exhibit 5a. States Using PMP Interconnect to Share Data with Other States	13
Exhibit 5b. States Using RxCheck to Share Data with Other States	14
Exhibit 6. States Approved for 100 percent enhanced Federal Match for Investments in	
PDMP, Approved Funds and Date of CMS Approval $(n = 15)$	16
Exhibit 7. State/Territorial Agency in Charge of SUPPORT Act-Funded PDMPs $(n = 15)$	17
Exhibit 8. State Mandates and Requirements for Accessing the PDMP* $(n = 15)$	18
Exhibit 9. Qualified PDMP Requirements Under Section 5042 of the SUPPORT Act	18
Exhibit 10. Percentage of Providers with an Established PDMP Account across States	
Approved for 100 percent Enhanced Federal Match, by State $(n = 15)$	19
Exhibit 11. States Approved for 100 percent Enhanced Federal Match with Integration	
Between Their PDMP and HIE ($n = 15$)	20
Exhibit 12. Number of Other States with Which States Approved for the 100 percent	
enhanced Federal Match Can Exchange PDMP Data (n = 15)	21
Exhibit 13. Approved Activities for States Approved for 100 Percent Enhanced Federal	
Match	
Exhibit 14. Measures Reported by States Approved for Federal Match	25

Executive Summary

Background

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act was signed into law (Pub. L. No. 115-271) on October 24, 2018, as a bipartisan effort to address the nation's opioid epidemic.

Section 5042(a) of the SUPPORT Act requires all States to establish a qualified prescription drug monitoring program (PDMP). A PDMP ensures that providers have access to information about current and previous opioid prescriptions and other controlled substances at the time of an encounter. However, PDMP access is only the first step in addressing the opioid overdose epidemic. PDMP use must be part of a comprehensive approach that considers potential, unintended consequences.

Beginning in October 2021, all State PDMPs must meet the requirements outlined in the legislation. The SUPPORT Act also authorizes the Centers for Medicare and & Medicaid Services (CMS) to match State investments in their PDMP at 100 percent for approved design, development, and implementation activities, for quarters during fiscal years 2019 and 2020.

Further, section 5042(b) of the SUPPORT Act directs the Administrator of CMS, in collaboration with the Director of the Centers for Disease Control and Prevention (CDC), to generate a report describing best practices on the use of PDMPs and on protecting the privacy of model practices to protect Medicaid beneficiary information maintained in and accessed through prescription drug monitoring programs. Section 5042(c) of the SUPPORT Act also requires the Secretary to develop and publish model practices to assist State Medicaid program operations in identifying and implementing strategies to utilize PDMPs- agreements. State efforts to coordinate care between Medicaid and PDMPs is very nascent, limiting our ability to confidently highlight best practices. However, we do describe promising initiatives that states have enacted which have been informed by published recommendations.

This report satisfies the requirements of section 5042(b) and (c) of the SUPPORT Act to the extent that such data is available to support the best practices and information provided therein. This report is divided into seven complementary sections: (1) PDMP variation across the States; (2) State activities funded through the Federal match authorized by the SUPPORT Act, (3) PDMP-related challenges cited by several States, (4) effective uses of the PDMP to improve patient safety, (5) examples of innovative uses of the PDMP, (6) feedback on the benefits and limitations of the PDMP shared by key stakeholders; and (7) lessons learned for State and Federal legislators to support and advance State PDMP investments.

How States Have Used The 100% Federal Match

The SUPPORT Act offered States a 100 percent Federal match of Medicaid dollars for approved investments to accelerate the establishment or augmentation of a qualified PDMP. A total of 14 States and one territory applied and were approved for the Federal match to fund the integration or enhancement of their State's Medicaid information system and the State PDMP. Approvals occurred on a rolling basis between summer 2019 and summer 2020. Across the 15 States approved for the enhanced Federal match, the median funding request was \$6 million reflecting a

large volume of smaller (less than \$10 million) requests. The value of approved Advance Planning Documents (APDs) for the States totaled \$170,669,792 and ranged from just under \$1.5 million (New Jersey) to \$51 million (Nebraska).

An analysis of the approved State APDs revealed commonalities in State plans. Proposed uses for funding were categorized into four key domains: (1) Planning; (2) System Integration; (3) Infrastructure Development; and (4) Enhancements, Data, and Analytics.

Lessons Learned

Discussions with States and key stakeholders highlighted the following lessons learned and areas in which legislative changes at the Federal or State level could facilitate State PDMP efforts:

- Extended Timeline for Expending Funds Approved for Federal Match States suggested that the U.S. Congress consider extending the timeline in order to leverage the funding in a way that best support the PDMP enhancement initiatives,
- National Data Standards Although States are collaborating to improve patient matching to support data exchange, it was noted that these collaborative efforts would benefit from Federal guidance on data content and exchange standards.
- Clarification of Requirements for a Qualified PDMP Several States expressed confusion regarding how to interpret some of the language in the SUPPORT Act legislation, resulting in unanticipated issues related to tracking and enforcing compliance.
- Flexibility in Use of Federal Funds Several Federal agencies have offered States PDMP funding, but each opportunity comes with restrictions, which have impeded the State from focusing on its State-specific priorities.
- Identification of State Legislation That Impedes PDMP Development and Use Some State legislative mandates, including data privacy laws, have created barriers to effectively developing and implementing PDMPs.
- Improved Coordination with Federal PDMP Programs Several Federal health programs operate their own PDMP, including the Department of Defense (DOD) and the Department of Veterans Affairs (VA). Data from State residents receiving services from these Federal programs may not be currently captured in the State PDMP.
- Comprehensive State Mandates A number of States have enacted laws to encourage and promote greater use of the State PDMP. There should be more consistency across States that have enacted these policies and supporting policies in place to monitor compliance.
- Funding for State Collaboration Collaboration with peer States has proven very effective in communicating best practices, leveraging limited resources, and increasing efficiencies.
- Increased Integration Between PDMP and EHRs Improving the technical workflow to enable providers to check the PDMP through their electronic health record (EHR) system during the time of the patient encounter or before prescribing controlled substances has proven effective in increasing provider compliance with checking the PDMP.
- **Best Practices on Increasing Enrollment and Use of PDMP** While some States have successfully enrolled many providers to use the PDMP, other States are experiencing

challenges. The Federal government can help overcome these obstacles by conducting a case study that examines and highlights best practices for provider enrollment, collaborate with State medical boards, NPPES, State PDMPs, and credentialing offices to facilitate PDMP registration at the time of medical license renewal, and provide technical assistance for healthcare provider directory solutions.

- Enhanced Education and Training for Providers, Payers, and Patients Improving education and training on how to effectively use the PDMP and its limitations can improve patient safety, clinical care, and coordination.
- Evaluation of Impact of PDMPs Conduct formal analyses to identify best practices that can be adopted by other States while also confirming that the PDMP achieves its intended goals.

Introduction

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act was signed into law (Pub. L. No. 115-271) on October 24, 2018, as a bipartisan effort to address the nation's opioid overdose epidemic.

The SUPPORT Act requires all States to establish a qualified prescription drug monitoring program (PDMP). A PDMP ensures that providers have access to information about current and previous dispensed opioid prescriptions and other controlled substances at the time of an encounter or other prescribing event. However, PDMP access is only one step in addressing the opioid overdose epidemic (Murthy 2016; SAMHSA 2017). PDMPs use must be part of a comprehensive statewide approach that considers potential, unintended consequences (Haffajee 2019).

Beginning in October 2021, all State PDMPs must meet the requirements outlined in the legislation. The SUPPORT Act also authorizes the Centers for Medicare & Medicaid Services (CMS) to match State investments in their PDMP at 100 percent for approved design, development, and implementation activities, for quarters during fiscal years 2019 and 2020.

Further, section 5042(b) of SUPPORT Act directs the administrator of CMS, in collaboration with the director of the Centers for Disease Control and Prevention (CDC), to generate a report describing best practices on the use of PDMPs and on protecting the privacy of Medicaid beneficiary information maintained in and accessed through prescription drug monitoring programs. Section 5042(c) of the SUPPORT Act also requires the

Features of a Qualified Prescription Drug Monitoring Program

- Administered by a State
- Record of prescription drug history with respect to controlled substances
- Medicaid providers must check PDMP before prescribing a controlled substance
- Information from PDMP must be integrated into provider workflow
- Annual reports of key metrics
 - Percentage of providers who checked PDMP
 - Total quantity of prescribed daily morphine milligram equivalents (MME)
 - Number and quantity of MME per patient
 - Types of controlled substances prescribed
 - Dates of prescriptions for controlled substances
 - Prescriptions of controlled substances within specific populations (e.g., elderly)

Secretary to develop and publish model practices assist State Medicaid program operations in identifying and implementing strategies to utilize data-sharing agreements.

This report satisfies the requirements of section 5042(b) and (c) of the SUPPORT Act to the extent that such data is available to support the best practices and information provided therein. This report is divided into seven complementary sections: (1) PDMP variation across the States; (2) State activities funded through the Federal match authorized by the SUPPORT Act, (3) PDMP-related challenges cited by several States, (4) effective uses of the PDMP to improve patient safety, (5) examples of innovative uses of the PDMP, (6) feedback on the benefits and limitations of the PDMP shared by key stakeholders; and (7) lessons learned for State and Federal legislators to support and advance State PDMP investments.

Methods

The content of this report was generated from three primary data sources:

- 1. **State Advance Planning Documents (APDs).** Staff conducted a detailed review of the APDs submitted by State Medicaid agencies that applied and qualified for the Federal match.
- 2. Peer-reviewed literature and other publicly available data, reports, and resources. Staff from CMS, CDC, and the Office of the National Coordinator for Health Information Technology (ONC) identified relevant resources, including Federally funded reports¹ and articles published in peer-reviewed journals. These materials assisted in identifying additional resources. Information was supplemented with publicly available data from the PDMP Training and Technical Assistance Center, funded by the Bureau of Justice Assistance (BJA) within the Department of Justice (DOJ). This data is updated regularly.
- 3. Meetings with State representatives and other appropriate stakeholders or Federal partners. Staff also engaged with States, Federal partners, and other stakeholders to solicit detailed information. In July, CMS facilitated calls with seven States to review their draft APDs.² In September, 2019, CMS hosted an in-person meeting attended by representatives from 12 States.³ Following this meeting, staff reached out to five States to gather detailed information about their PDMP implementation efforts.⁴ In October, and as required by section 5042(c) of the SUPPORT Act, staff interviewed key stakeholders representing the National Association of Medicaid Directors, managed care entities, pharmaceutical benefits managers, healthcare providers, patient advocates, and individuals with expertise in health information technology.

¹ All references are included in the bibliography at the end of this report.

² The states that participated in one-on-one calls with CMS were Louisiana, Maryland, Michigan, Nebraska, New York, North Dakota, and Ohio.

³ The 12 states in attendance at the September 19, 2019, in-person meeting were Colorado, Idaho, Louisiana, Minnesota, Nevada, New Mexico, Ohio, Oregon, Rhode Island, Texas, Washington, and Wyoming.

⁴ The following states met with staff to share their insights regarding their state PDMP: Kentucky, Minnesota, Nebraska, and Rhode Island.

Prescription Drug Monitoring Program Variation Across the United States Prior to the SUPPORT Act

When conducting a landscape analysis of technology adoption, researchers traditionally consider a total of 56 entities: 50 States; Washington, DC; and five U.S. territories. In this section, we provide a landscape analysis of State and territory PDMPs prior to passage of the SUPPORT Act. For the purposes of this report, we use the term 'States' to refer to both states, territories, and the District of Columbia. This cross-State analysis identifies common practices, differences in the ways in which PDMPs are used, and challenges encountered by the States.

Before passage of the SUPPORT Act, 46 States had an operational PDMP (PDMP Training and Technical Assistance Center 2020); however, there was significant variability in requirements, data integration and access, State policies, data timeliness, and provider use and access (ONC 2019).

Access and Use

Use of the PDMP by providers and pharmacists is driven largely by State policies. Most States have passed a mandate that requires providers to check the PDMP when initially prescribing a controlled substance and at least annually thereafter, though many states have more stringent requirements. A 2018 study of private insurance claims revealed that comprehensive mandates (requiring that all providers check the PDMP before writing a new opioid prescription and to recheck at regular intervals thereafter) are associated with a significant reduction in the number of opioid prescriptions at high risk for unhealthy use and overdose (Bao et al. 2018). State mandates that were less prescriptive (i.e., only required that providers establish a PDMP user account or did not require regular PDMP checks) were less effective in reducing inappropriate opioid prescribing (Bao et al. 2018). As of December 2020, 46 States and one U.S. territory required providers to query the PDMP when prescribing an opioid and, in most cases, at regular intervals thereafter (exhibit 1). The Department of Health & Human Services' Indian Health Service (IHS) also has a mandatory PDMP query. The legal terms of these mandates as well as enforcement vary widely. Across States, there is significant regulatory variability, including the frequency with which the provider must check the PDMP, whether the mandate applies to all providers or only those writing controlled substance prescriptions in the ambulatory setting, whether pharmacists must also check the PDMP before dispensing, and which controlled substances require PDMP checks for example.

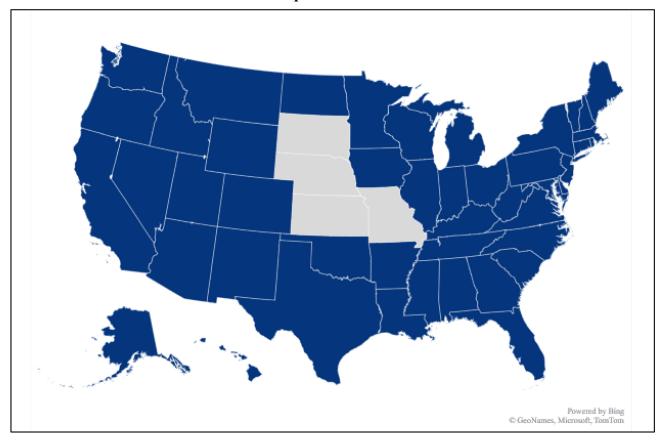


Exhibit 1. State and Territories with Requirements for Providers to Check PDMP

■ States with requirements for providers to check PDMP

Source: Prescription Drug Monitoring Program Training and Technical Assistance Center, www.pdmpassist.org. Last updated December 2020.

NOTE: Missouri does not have a statewide PDMP

Forty-five States and the District of Columbia authorize providers to delegate the checking of the PDMP to another member of his or her staff (PDMP Assist, 2020).⁵ The use of provider delegates is intended to reduce the burden on providers and to enhance the capacity of delegates to perform timely checks. A 2018 study found that legislation allowing office staff to check the PDMP on behalf of a provider reduced the probability of having three or more providers of opioids to the same patient over a 3-month period (Bao et al. 2018).

States vary in how they define providers, pharmacy staff, and delegates who can access the PDMP. Typically, providers include physicians, physician assistants, nurse practitioners, dentists, and podiatrists. The definition of "provider delegate" varies from state to state given state level control over licensure and accreditation resulting in variation in prescribing ability. Further, there are several health services professionals who might benefit from access to the PDMP but are prohibited by State legislation. Both behavioral health professionals without prescribing authority who may be involved in the diagnosis or treatment of an opioid use disorder. Additionally, psychologists and other licensed behavioral health providers often

⁵ The States that do not allow unlicensed delegates to access the PDMP are California, Iowa, Nebraska, South Dakota, and Washington.

supervise drug counselors and almost always lack access. Emergency medical services (EMS) personnel who are often first responders to an opioid-related crisis may have limited or no access to the PDMP, depending on State laws. An analysis of laws across all States and territories revealed 63 unique roles that define who has access to the PDMP. Future studies might consider whether there is a relationship between outcomes and which clinical roles have access to the PDMP. The PDMP access roles implemented by a majority of the States are listed in exhibit 2.

Exhibit 2. State Variation in PDMP Access Roles

PDMP Access Role	No. of States and Territories Allowing Access*
Pharmacist	53
Provider (Prescriber)	53
Law enforcement	52
Nurse practitioner	52
Physician assistant	51
Provider delegate	51
Licensing board	50
Pharmacist delegate	47
Medical Examiner	45

PDMP Access Role	No. of States and Territories Allowing Access*
Patient	42
Medicaid fraud and abuse analyst	33
Medical resident	33
Other PDMPs	32
Prosecutor	32
Researcher	31
Drug treatment provider	16
Coroner	5
Mental health therapist	1

Source: Leveraging Health IT and Prescription Drug Monitoring Programs to Address Substance Use Disorder and Opioid Use Disorder (LPASO) Landscape Assessment Report, June 2020. Updated Dec 2020.

Cross-State Access to PDMP Data

A 2014 report indicated that two-thirds of patients who procured prescriptions for controlled substances from multiple providers crossed State lines to do so (McDonald et al. 2014). Since 2014, multiple States have worked diligently to identify solutions to allow other States to access their PDMP data. As of August 2019, 49 States, Puerto Rico, and the District of Columbia support interstate data sharing with at least some contiguous States. In many cases, the data are shared with a larger number of States. States use different solutions to facilitate patient matching across State systems. Interstate exchange of PDMP data introduces several complexities, including variations across States in terms of data privacy laws, standards for data reporting, storage, and exchange, patient and provider identity management, and limitations on data access, integration, and sharing.

Volume of Providers Accessing the PDMP

The frequency with which providers check the PDMP before writing a controlled substance prescription varies substantially across States. Those with policies requiring that providers check the PDMP before writing a prescription for controlled substances have higher compliance rates

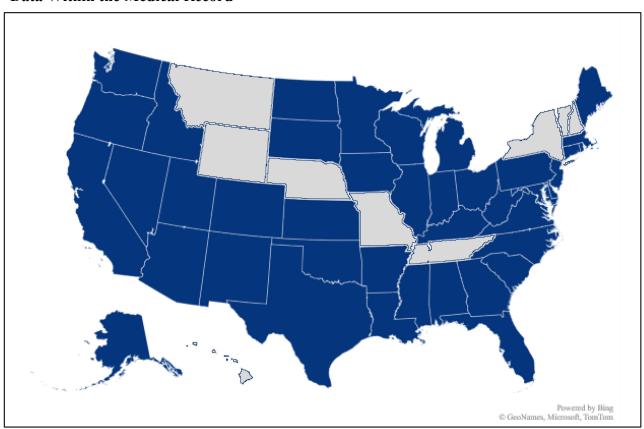
^{*}The denominator is 56 entities composed of 50 States; Washington, DC; and five U.S. territories.

in terms of accessing and using the PDMP (Bao et al. 2018), and has been shown to decrease the number of Medicare beneficiaries prescribed opioids and the number of claims (Pylypchuk, et al., 2021). States have undertaken different activities to increase provider use of the PDMP, including generating provider-specific reports on their prescribing history and sharing reports with State licensure boards.

Placement of PDMP Data within Medical Records

One of the biggest barriers to provider use of the PDMP is the level of effort associated with accessing the data. State statutory or regulatory language authorizing the integration of PDMP data into the EHR varies across States. Full integration of the PDMP with an EHR allows providers to rapidly check a patient's prescription history. However, it introduces challenges such as duplication of prescription history in a patient's medical record and concerns regarding access and redisclosure requirements, especially in States where the PDMP access and disclosure requirements are more stringent. As of 2020, 41 States authorize placement of PDMP data into an EHR (exhibit 3).

Exhibit 3. States With Statutory or Regulatory Language Authorizing Placement of PDMP Data Within the Medical Record



■ States with statutory or regulatory language authorizing placement of PDMP data within the medical record Source: Prescription Drug Monitoring Program Training and Technical Assistance Center, www.pdmpassist.org. Last updated December 2020.

NOTE: Missouri does not have a statewide PDMP

Another challenge associated with placing PDMP data in the EHR stems from the inconsistencies in patient-level information captured in the PDMP across States. While all PDMPs include patient name, State PDMPs vary in how the name is recorded, the inclusion of other personal identifiers, types of prescription data included, and fill dates. States that include more personally identifiable information in the PDMP might have more rigorous state level privacy protections. In these States, integration of the PDMP and the EHR requires satisfying both Federal and State access and disclosure requirements.

According to an ONC analysis of 2017 data from the American Hospital Association (AHA) Annual Survey, while 90 percent of acute care hospitals have an established process for clinicians to access the State's PDMP, approximately two-thirds do not have the PDMP integrated into their EHR system. As a result, before prescribing a controlled substance, these providers must log in through a separate system to access this information (exhibit 4). The AHA survey did not assess the ways in which logging in to a separate system affected the timeliness of accessing PDMP data or the frequency with which the PDMP data were checked by hospital providers. However, one research study of ambulatory care providers found that time spent accessing PDMP records when a separate login is required accounts for an extra 13 hours per year for providers practicing in States with mandated PDMP checks (Bachhuber et al. 2018).

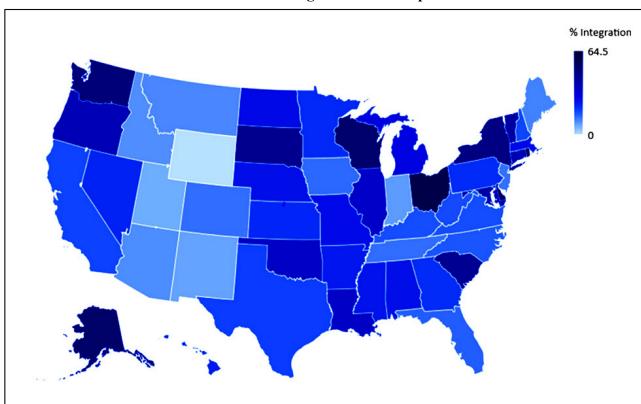


Exhibit 4. Nationwide Status of PDMP Integration into Hospitals

Source: Office of the National Coordinator, Leveraging Prescription Drug Monitoring Program and Health Information Technology for Addressing Substance Use Disorder and Opioid Use Disorder (LPASO) Landscape Assessment Report, June 2020.

NOTE. Based on 2017 AHA data.

NOTE: Missouri does not have a statewide PDMP; however, the St Louis operates a PDMP for the city and adjacent counties

Currently, no data exist on the percentage of ambulatory-based providers who can access the PDMP seamlessly through their EHR system. However, the 2017 National Electronic Health Records Survey found that only 28 percent of office-based physicians reported being able to integrate external data into their EHR system (Patel et al. 2019).

PDMP Privacy Protections

A group of physicians interviewed by the General Accounting Office (GAO 2020) reported that, in general, they have not encountered any significant challenges related to the security of data captured in the State PDMP. Physicians identified several features that increase data security, including registration, login, and password requirements, along with automatic log-outs and requirements for password changes. It is important to note, however, that although many of these features increased confidence in data security, they contribute to administrative burden, especially in busy practices where these steps to ensure data security can be time consuming.

Standards for PDMP Data Exchange

Several technology standards are used to support PDMP data sharing. The National Council for Prescription Drug Programs (NCPDP) SCRIPT® standard allows providers to share prescription data across systems, and a few PDMPs rely on or translate this standard as needed for exchange. NCPDP has also developed a Prescription Drug Monitoring Programs Reporting Standard. The American Society for Automation in Pharmacy (ASAP) Prescription Monitoring Program Web Service Standard and the ASAP Standard for Prescription Monitoring Programs allow pharmacy systems to report dispensed controlled substance prescriptions to PDMPs, while the National Information Exchange Model (NIEM) and the Prescription Monitoring Information Exchange (PMIX) National Architecture are used to support data exchange across State lines. Most providers and pharmacists, and all of those participating in the Medicare program, currently use the NCPDP SCRIPT® standard version 2017071 to support electronic prescribing.

Fast Healthcare Interoperability Resources (FHIR®) is a standard that is rapidly being deployed to accelerate data exchange. To expedite sharing of clinical data, ONC is funding a multistage project to support interoperability by mapping the NCPDP SCRIPT® Standard Version 2017071, 2015 ASAP Prescription Monitoring Program Web Service Standard version 2.1A, and PMIX standards to HL7® FHIR® R4. Through this work, ONC continues to build the US Meds Prescription Drug Monitoring Program FHIR® Implementation Guide. Once the project is complete, this will enable the seamless, secure exchange of data between EHRs and other clinical data systems including pharmacies and State PDMPs, as well as interstate data sharing across PDMPs.

Technical and policy requirements governing management of the PDMP differ across States. As a result, sharing data across State lines requires a data-sharing agreement that reconciles terms and conditions for data sharing. Most States use one or both of two national hubs to facilitate the sharing of PDMP data across State lines:

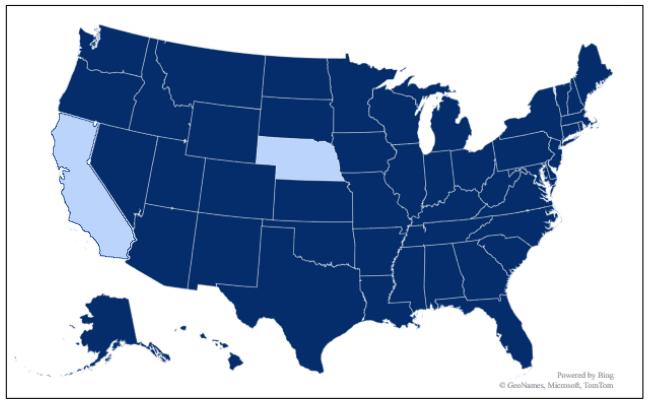
⁶ Accessible at http://build.fhir.org/ig/HL7/FHIR-ONC-Meds/pdmp.html.

- <u>PMP Interconnect</u> is owned by the National Association of Boards of Pharmacy, developed in partnership with Appriss, Inc., and currently includes 51 participating States and Territories.
- RxCheck was developed using Federal funds from the Bureau of Justice Assistance in the Department of Justice and currently connects 43 States to support PDMP data sharing. Another four States are in the process of onboarding to use RxCheck, and four States are in the process of developing a memorandum of understanding to permit use of RxCheck (ONC 2020 and CDC updates).

Because RxCheck leverages open, non-proprietary standards and technology to exchange PDMP data safely and securely across state lines, its adoption and use offers a number of advantages over proprietary solutions. These include: (1) it reduces the need to create multiple, disparate system interfaces between state PDMPs; and (2) it allows for the exchange and full integration of discrete data into EHRs for medication reconciliation, allergy checks, and other forms of clinical decision support. Proprietary solutions do not typically allow for discrete data integration. These systems enable a prescriber to view patient medication histories on a secure website, but the data is not accessible for any other purposes, be it clinical or administrative. RxCheck also supports the use of innovative technology such as FHIR®-based APIs and SMART on FHIR® technology.

Exhibit 5a identifies States that are connected to PMP Interconnect and exhibit 5b identifies States that are connected—or are in the process of connecting—to RxCheck to support interstate data sharing.

Exhibit 5a. States Using PMP Interconnect to Share Data with Other States



■ Connected ■ Not connected

Source: Office of the National Coordinator, Leveraging Prescription Drug Monitoring Program and Health Information Technology for Addressing Substance Use Disorder and Opioid Use Disorder (LPASO) Landscape Assessment Report, June 2020. Updated Dec 2020.

NOTE: Missouri does not have a statewide PDMP

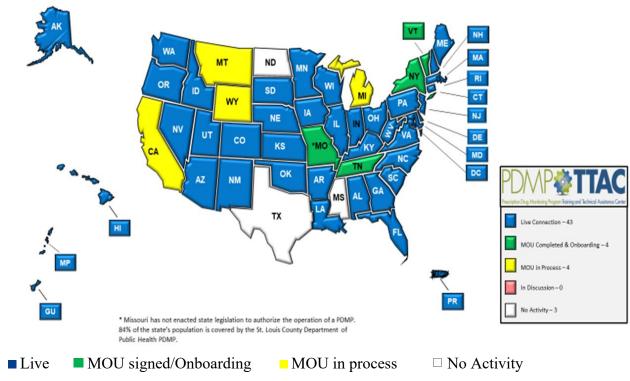


Exhibit 5b. States Using RxCheck to Share Data with Other States

Source: CDC data provided 12/10/2020.

NOTE: Missouri does not have a statewide PDMP; however, the St Louis operates a PDMP for the city and adjacent counties

CDC's Overdose Data to Action (OD2A) cooperative agreement seeks to increase the timeliness and comprehensiveness of PDMP data. States applying for funding are required to maintain an active connection to RxCheck. Ensuring access to the RxCheck hub is available at low or no cost to States and can help address disparities. Specifically, RxCheck allows health systems and hospitals that lack resources to pay for connection fees and/or are located in under-resourced areas within a State, to integrate PDMP data within their clinical workflow at low or no cost. The OD2A awards include an enhancement that can be used to cover vendor fees associated with connecting and maintaining their connection to RxCheck. States also can continue to use proprietary solutions, such as PMP Interconnect as their technology of choice, provided they are able to respond to interstate data requests that are received through RxCheck.

Use of 100 Percent Federal Medicaid Match to Advance State PDMPs

Section 5042 of the SUPPORT Act offered States a 100 percent Federal match of Medicaid dollars ("Federal match") for quarters during fiscal years 2019 and 2020 for approved design, development, and implementation investments to accelerate the establishment or augmentation of a qualified PDMP. States seeking the Federal match were required to submit an APD outlining the manner in which the funds would be employed to achieve the objectives of the SUPPORT Act. CMS worked collaboratively with CDC to issue sub-regulatory public guidance in the form of a published set of Frequently Asked Questions⁷ and clarified that any State applying for these funds was required to coordinate with CMS to secure approval of its APD. Additionally, States were required to confirm that all proposed activities would

Requirements for the 100 Percent Federal Medicaid Match for PDMP Investments

- Submit APD.
- Outline activities and associated costs.
- Describe how funding will help the State align with SUPPORT Act.
- Exchange PDMP data with contiguous States.
- Obtain CMS approval.

Source: CMS Federal Policy Guidance, 2019.

be completed by September 30, 2020, the date the 100 percent enhanced Federal match would expire. States also were required to have agreements in place to facilitate the secure exchange of qualified PDMP data with contiguous States.

In the next section, we describe the total amount of funds approved by CMS for the Federal match authorized under the SUPPORT Act, the State agencies operating the PDMPs supported by these funds, mandates within these States for PDMP access and use, and strategies outlined in the approved APDs for meeting qualified PDMP requirements in these States.

Approved Funding

A total of 14 States and one territory (hereinafter referred to as "States") applied and were approved for the 100 percent enhanced Federal match made available under Section 5042 of the SUPPORT Act to fund the integration or enhancement of their State's Medicaid information system and the State PDMP. Approvals occurred on a rolling basis between summer 2019 and summer 2020. Across the 15 States approved for this Federal match, the average (median) funding request was \$6 million reflecting a large volume of smaller (less than \$10 million) requests. The value of State-approved APDs totaled \$170,669,792 and ranged from just under \$1.5 million (New Jersey) to \$51 million (Nebraska). Exhibit 6 provides a list of the States, the funds approved for the 100 percent enhanced Federal match, and the date of CMS approval. Given the limited time to implement the activities described in the approved plans, several States did not spend the full sum.⁸

⁷ See https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/faq051519.pdf.

⁸ The final dollar figure spent by states was not available at the time of this report.

Exhibit 6. States Approved for 100 percent enhanced Federal Match for Investments in PDMP, Approved Funds and Date of CMS Approval (n = 15)

State	Approved Funds	Approval Date
Alaska	\$5,595,593	March 24, 2020
Colorado	\$4,996,630	February 10, 2020
Connecticut	\$3,253,639	February 5, 2020
Idaho	\$12,537,088	December 19, 2019
Illinois	\$3,261,492	December 19, 2019
Indiana	\$18,229,175	March 24, 2020
Kentucky	\$40,573,159	March 6, 2020
Maine	\$7,668,163	March 9, 2020
Maryland	\$6,377,900	September 24, 2019
Nebraska	\$51,000,000	October 1, 2019
New Jersey	\$1,453,000	April 16, 2020
New Mexico	\$6,065,640	April 2, 2020
Puerto Rico	\$5,225,283	March 31, 2020
Rhode Island	\$5,787,320	December 19, 2019
Washington	\$11,212,798	July 9, 2019

Source: Approved State advance planning documents submitted by State Medicaid agencies for the 100 percent Federal match for PDMPs under the SUPPORT Act

The small number (15) of States that applied for the 100 percent enhanced Federal match may be attributed to several factors. First, States had to invest time and resources in developing and refining an additional APD, requiring coordination across State agencies. Furthermore, the funds for this Federal match had to be expended before the end of fiscal year (FY) 2020. A number of States applied for Federal resources available through other funding vehicles, such as grants available from CDC and DOJ. Under 42 C.F.R. §433.112, States can qualify for a 90 percent enhanced Federal match for the design, development, and installation of their PDMP, and a 75 percent Federal match for ongoing operations of portions of a State's PDMP that support Medicaid uses under 42 C.F.R. § 433.116. One advantage of these alternative funding opportunities is that there is no expiration date by which these funds must be expended. For activities that received approval for the 100 percent enhanced Federal match authorized under section 5042 of the SUPPORT Act, some ongoing efforts may qualify for the 75 percent Federal match beginning in FY 2021. CMS can authorize a 90 percent Federal match for State implementation efforts to integrate their Medicaid systems with the State's PDMP.

Operating State Agency

Within each State that received the 100% Federal match, there is variability in which department operates the PDMP. Five States with approved APDs operate their PDMP out of the State department of health; four State PDMPs are managed by the State board of pharmacy; in two States, the PDMP is managed by the State's substance abuse agency; and the remaining State PDMPs are housed within the professional licensing agency, consumer protection agency, law enforcement agency, or office of the inspector general (exhibit 7). This contrasts somewhat with the national picture whereby the pharmacy board operates the PDMP in nearly one-half (n = 20) of all States, followed closely by the department of health (n = 18). Even though a PDMP is operated by one specific State agency, another State entity may oversee the PDMP. For example, in Idaho, the pharmacy board and an advisory council oversee the PDMP, even though it is housed in the department of public health. Coordination with the State Medicaid agency can be challenging when the PDMP is not housed in the department of health.

Exhibit 7. State/Territorial Agency in Charge of SUPPORT Act-Funded PDMPs (n = 15)

State Agency	Number	States
Department of Health	5	IL, MD, NE, RI, WA
Board of Pharmacy	4	AK, CO, ID, NM
Substance Abuse Agency	2	ME, PR
Professional Licensing Agency	1	IN
Consumer Protection Agency	1	CT
Law Enforcement Agency	1	NJ
Office of Inspector General	1	KY

Source: Approved State Advance Planning Documents submitted by State Medicaid agencies for the 100 percent Federal match for PDMPs under the SUPPORT Act and discussions with State Medicaid staff.

State Mandates PDMP Access

Across these 15 States, the State mandates for checking the PDMP vary widely. Ten States approved for the 100 percent enhanced Federal match have a State mandate requiring that providers check the PDMP; however, the individuals required to check and the timing and frequency with which they must check vary (exhibit 8) (Pew Charitable Trusts 2018b). For example, Connecticut, Indiana, and Maine require that providers check the PDMP at the time of any new opioid prescription and every 90 days thereafter for as long as the patient continues the medication. In contrast, Illinois requires that the provider check the PDMP only at the time of the initial prescription. Alaska requires that the provider check every 30 days, whereas Colorado and Washington require a check when a patient is enrolling in an opioid treatment program or at the time the individual is enrolling in a worker's compensation program. Some State mandates pertain only to prescriptions written by ambulatory care providers, whereas other States (for example, Rhode Island, Indiana, and Washington) specify certain non-ambulatory healthcare settings in which the PDMP must also be checked before writing a new prescription for an opiate.

Exhibit 8. State Mandates and Requirements for Accessing the PDMP* (n = 15)

Frequency of Check	States	
At time of initial Rx (Ambulatory)	AK, CO, CT, IL, IN, KY, ME, MD, NJ, NM, RI, WA	
Regular intervals**	AK, CO, CT, IN, KY, ME, MD, NJ, NM, RI	
No State mandate	ID, NE, PR	

Source: Prescription Drug Monitoring Training and Technical Assistance Center. Available at https://pdmpassist.org/.

State Status with Respect to Qualified PDMP Requirements

Under the SUPPORT Act, States are required to establish a "qualified prescription drug monitoring program." The legislation outlined a set of requirements that must be met in order to meet this definition. These are detailed in exhibit 9.

Exhibit 9. Qualified PDMP Requirements Under Section 5042 of the SUPPORT Act

Qualified Prescription Drug Monitoring Program

- 1. Provider access to the following patient-level information over the past 12 months:
 - a. Prescription drug history
 - b. Number and type of controlled substances prescribed and filled
- 2. Name, location, and contact information for each provider that prescribed a controlled substance over the past 12 months
- 3. PDMP data integrated into provider workflow
- 4. Interoperability agreements for sharing PDMP data with contiguous States

Optional: Support data sharing with State Medicaid program.

At the time their APD was submitted, not all 15 States met the complete set of requirements. Most States guaranteed provider access to patient-level information on prescription drug history, but several States did not have the capability to track whether prescriptions were filled as fill data and prescribing data are almost always separate data sources. All States had information on providers who had prescribed controlled medicines in the past year but could not attest that the contact information was still accurate. Most State plans included specific language about using the 100 percent enhanced Federal match to update their PDMP to meet these criteria. Many States proposed using funds to support the integration of PDMP data into the provider workflow. This integration process included working with health systems, the State's health information exchange(s) (HIE[s]), provider EHR systems, and e-prescribing systems. Next, we present specific details on each of these criteria for the States approved for the 100 percent enhanced Federal match.

^{*} Data reflect States with a mandate that applies to all providers and at least all initial opioid prescriptions. Additional States may have a mandate that does not include these requirements.

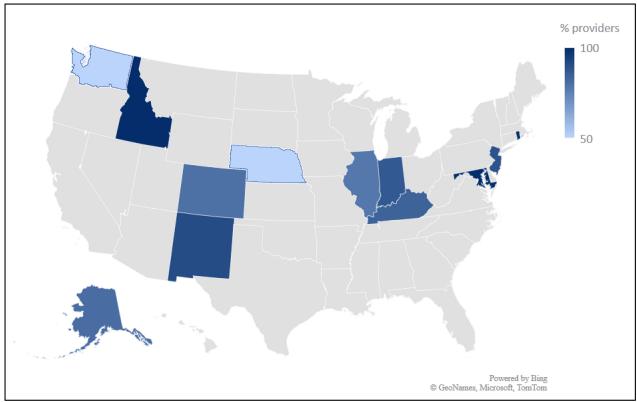
^{**} Typically, a State mandate requiring ongoing checks of the PDMP specifies that providers (or their delegates) check the PDMP every 90 days for patients continuing to receive specified medications.

PDMP Access for Providers

State mandates are not always effective in ensuring that providers are regularly accessing the PDMP. Inconsistent use of the PDMP is further compounded by the variation across States in how providers are defined, which impacts the ability to perform an accurate comparison across States. Despite State mandates, not all providers within a State register for an account, and fewer regularly check the PDMP. Additionally, many States do not have a process for verifying whether all providers with the authority to prescribe controlled substances have established an account or whether they are checking the PDMP when prescribing opioids.

For example, although Connecticut mandates that providers check the PDMP when prescribing a controlled substance, many providers are still not registered with an account to access the PDMP. In Indiana, nearly 80 percent of all providers have a PDMP account, whereas 100 percent of all Maryland and Rhode Island providers have accounts. In Nebraska, only 55 percent of providers have an account. The map in exhibit 10 illustrates the estimated percentage of providers approved to prescribe controlled substances that have an account in the State PDMP for the 15 States approved for the 100 percent enhanced Federal match.

Exhibit 10. Percentage of Providers with an Established PDMP Account across States Approved for 100 percent Enhanced Federal Match, by State (n = 15)



Data for CT, ME, and PR was not available.

Source: Approved State Advance Planning Documents submitted by State Medicaid agencies for the Federal match under the SUPPORT Act and individual communication with selected States.

PDMP Integration Status

An issue brief authored by the U.S. Department of Health and Human Services (HHS) Assistant Secretary for Planning and Evaluation and released in March 2020 clarified the distinction

between data sharing and data integration. Although the ability to access data from multiple sources is important, the ultimate goal is to integrate "outside data into a workflow that allows the user to draw needed insights from the data without additional effort" (HHS 2020). Throughout this report, we use the term "integration" to refer to data that are shared (interoperable) but also incorporated into the provider's work stream (integrated) to support effective use of data on PDMP. Streamlined access to PDMP data reduces provider burden and has been shown to increase the frequency with which providers actively use the PDMP data to inform their prescribing behavior (CDC 2017). In 2018, CMS issued a letter to State Medicaid Directors encouraging integration of PDMP data into EHRs to "limit provider burden and improve interstate Health Information Exchange (HIE)" (CMS 2018).

At the time of applying for the SUPPORT Act funds, about half of the States approved for the 100 percent enhanced Federal match had integrated their PDMP data with their State's HIE (exhibit 11). Some States reported having integrated the PDMP with some provider EHR systems as well. For example, Rhode Island has integrated the PDMP with EHRs for two of the largest hospital systems in the State. Almost all States' APDs included plans to use the funds to advance their integration efforts, by either establishing or enhancing integration between their PDMP and State HIE or facilitating integration between the PDMP and provider EHRs.

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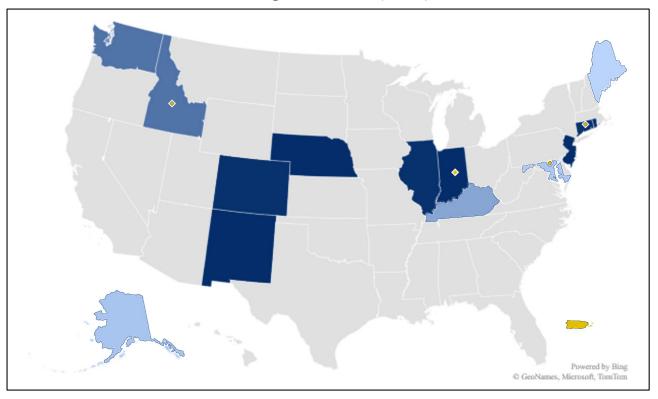
Exhibit 11. States Approved for 100 percent Enhanced Federal Match with Integration Between Their PDMP and HIE (n = 15)

Source: Approved State Advance Planning Documents submitted by State Medicaid agencies for the 100 percent enhanced Federal match under the SUPPORT Act and Prescription Drug Monitoring Training and Technical Assistance Center. Available at https://pdmpassist.org/.

Integration with Other States

Prior to the passage of the SUPPORT Act, all States that were approved for the 100 percent Federal match could exchange data with contiguous States, and most were able to exchange PDMP data with additional, noncontiguous States (exhibit 12). The number of States with which PDMP data could be exchanged ranged from 6 to 47 States and territories.

Exhibit 12. Number of Other States with Which States Approved for the 100 percent enhanced Federal Match Can Exchange PDMP Data (n = 15)



 \square 0–10 \square 11–20 \square 20–30 \square 31+ \square Military Health Service

Source: Approved State Advance Planning Documents submitted by State Medicaid agencies for the 100 percent enhanced Federal match for PDMPs under the SUPPORT Act and Prescription Drug Monitoring Training and Technical Assistance Center. Available at https://pdmpassist.org/.

NOTE. Number of States with which Puerto Rico can exchange data was not available.

Plans for Use of the 100 Percent Enhanced Federal Match

An analysis of the approved State APDs revealed commonalities in State plans. Proposed uses for funding were categorized into four key domains: (1) Planning; (2) System Integration; (3) Infrastructure Development; and (4) Enhancements, Data, and Analytics. Exhibit 13 provides a high-level summary of the key activities proposed within each of these categories and indicates those States planning to undertake these efforts using the 100 percent enhanced Federal match.

Exhibit 13. Approved Activities for States Approved for 100 Percent Enhanced Federal Match

State Activity Authorized for 100 Percent Enhanced Federal Match	N	States
Planning and Development		
Develop and test use cases	5	AK, CT, CO, NM, RI
Develop patient-matching algorithm	2	KY, CT
Perform gap analysis	4	ID, IL, IN, NE
Procure information technology vendor (either for PDMP or as add-on)	2	AK, CO
Integration		
Establish or expand integration with HIE	9	AK, CT, CO, IL, ME, NJ, PR, RI, WA
• Enhance Patient matching (includes master index)	7	AK, CO, IN, KY, ME, MD, NE
Establish or expand integration with EHRs	8	CT, IL, IN, ME, MD, NE, PR, RI
Develop application programming interface	7	KY, CT, CO, ID, IN, ME, MD
Enhance intrastate integration	6	CT, CO, IN, MD, NE, NJ
• Expand access to other providers (e.g., behavioral health, long-term care, EMS) and/or other Federal health systems (U.S. Department of Veterans Affairs, U.S. Department of Defense, Indian Health Service)	5	CT, ID, IN, ME, NE
Integrate e-Rx	3	IN, ME, NE
Implement Patient Unified Lookup System for Emergencies (PULSE)	3	CT, NE, PR
Infrastructure		
Upgrade technology	8	AK, CT, CO, IN, ME, MD, NE, NM
Establish or renew licenses	4	CT, CO, ID, NM
Data and Analytics		
Develop or improve analytic infrastructure (data aggregation, visualization) and data reporting (trends, provider-specific reports)	10	CT, CO, ID, IN, ME, MD, NJ, PR, RI, WA
• Implement decision support (e.g., alerts, risk scores)	9	AK, CT, CO, ID, ME, MD, NE, PR, RI
Other		
Increase staff capacity (including consultants)	10	AK, KY, CO, IL, IN, ME, NE, NM, PR, RI
Conduct provider outreach/education	7	AK, CO, ID, IN, MD, PR, RI

State Activity Authorized for 100 Percent Enhanced Federal Match	N	States
• Expand access to non-clinician entities (e.g., law enforcement, managed care organizations, Medicaid, authorized State agencies)	6	AK, CT, ID, IN, ME, NE

Source: Approved State Advance Planning Documents submitted by State Medicaid agencies for the Federal match for PDMPs under the SUPPORT Act.

Planning and Development

Two-thirds of State plans described activities that would support planning and development efforts. These included a gap analysis to identify and prioritize changes such as developing road maps, designing and testing use cases, and examining system requirements to compare alternative systems and vendors. Some States planned to redesign their PDMP processes, including identifying workflow barriers, improving data timeliness, and expanding PDMP access to additional providers. A few States proposed developing new models in collaboration with other States.

Integration

All States described plans to improve data integration. As exhibit 13 shows, most States planned to improve integration between the PDMP and the State HIE. A few States also sought to integrate PDMP data with providers' EHRs. About one-quarter of the States proposed to enhance their interstate integration, either by expanding the number of States with which data are exchanged or improving the quality of the data exchanged between States.

Several States described plans to collaborate with peer States either to leverage established integration systems or to collaborate in cross-State efforts focused on improving integration. One specific example was the establishment and implementation of an algorithm to improve patient matching both within and across State lines. Several States planned to integrate the PDMP with e-prescribing systems to increase the timeliness and accuracy of data.

Some States planned to enable PDMP access for non-ambulatory providers including delegates, EMS, and behavioral health and long-term care providers. Some APDs included plans to connect with patient-level data from other Federal health systems. One State proposed to use its Federal match to integrate the PDMP with the State Medicaid Enterprise System. More than one-half of the approved States proposed developing an application programming interface; most of these interfaces use FHIR® standards. Three States proposed development of a Patient Unified Lookup System for Emergencies (PULSE). 10

Infrastructure

Only about one-half of the State APDs referenced plans to use the 100 percent enhanced Federal match to enhance their existing infrastructure. All these States described plans to upgrade their technology either by augmenting existing systems or by soliciting bids for new contracts

⁹ Federal health systems referenced included the Department of Defense, the Department of Veterans Affairs, and the Indian Health Service.

¹⁰ More information about PULSE is available at https://www.hhs.gov/cto/projects/ems-to-hie-innovation/index.html.

including PDMP products, technology platforms, hardware, and software. Some States requested funds to cover the short-term (through 2020) cost of software licenses and user fees. Several States proposed enhancing their systems' infrastructure to support innovative strategies such as electronic approval of new account requests or generating audit logs to track provider compliance. Others proposed using the 100 percent enhanced Federal match to transition the PDMP to a cloud-based infrastructure, develop a statewide provider directory, or update user agreements and data governance.

Data and Analytics

All but two States planned to use the 100 percent enhanced Federal match to optimize the use of PDMP data. Most States planned to develop a framework to support data storage and analytics, including establishing a data warehouse and conducting analyses. Several States proposed developing regular data reports ranging from internal audit reports and statewide trending reports to reports shared directly with providers. States also discussed using advanced analytics to develop notification and alert systems, design predictive models for at-risk patients, generate individual patient risk scores, and employ clinical decision support algorithms. Some plans proposed the development of new performance measures, data visualization tools, and prospective claims reviews as well as employment of machine learning. One State proposed using the 100 percent enhanced Federal match to augment State investments in establishing a neonatal alcohol syndrome registry.

Other

Almost all States planned to use some of the money to support staffing needs including hiring new staff, increasing current staff time supporting the PDMP, and hiring consultants. Numerous States planned to support outreach and education to providers, including enrollment and awareness of the new PDMP functions such as reports and alerts. Several States proposed expanding access of PDMP data as allowable to nonclinical entities such as law enforcement, fraud and abuse, the State Medicaid agency, and other authorized State agencies.

Outcome Measures

The SUPPORT Act required that States report a set of outcome measures to HHS. These measures included the percentage of covered providers¹¹ that check the PDMP before prescribing a controlled substance¹² and aggregated trends related to the dispensing of controlled substances. While the SUPPORT Act provided examples, it did not specify the required aggregate measures. In 2019, CMS and CDC collaborated to identify a standardized set of five measures that States were encouraged to use to study outcomes associated with State PDMP utilization (CMS 2019). These measures were drawn from research that demonstrated comprehensive State PDMP mandates reduced opioid prescribing as well as opioid-related inpatient stays and emergency department visits (Wen et al. 2019). However, not all States were able to report these consensus measures for a variety of reasons, including difficulty calculating some measures because of the method by which the State PDMP data are captured. CMS tracks

¹¹ The providers included in the statutory definition of "covered provider" (codified in section 1944(h)(3) of the Social Security Act) varies by State but typically include all individuals with a license to prescribe controlled substances to patients.

¹² Determinations of which controlled substances must be reported varies by State. Most States require prescribers to report category II–IV opioids.

which States report the consensus measures and the measures being used by States that have elected to define their own measures. CMS will review whether States meet the measure-reporting requirement to qualify for future Federal funding.

Several State APDs approved for the 100 percent enhanced Federal match provided information on the measures that the State planned to report by the end of 2020 (exhibit 14). Not all States included this information in their plans; therefore, the table does not include a total count or list of the States.

A few States planned to produce provider-specific reports tracking key measures. Some States proposed creating online dashboards accessible by authorized entities. One State planned to analyze data looking at patient characteristics including demographics, ZIP code, and payer type.

Exhibit 14. Measures Reported by States Approved for Federal Match

Measures	
Multiple provider prescription events	Total opioid prescriptions
Number of prescriptions by provider	Total pharmacies dispensing opioids
Number of medications dispensed by provider and by pharmacy	Long-acting opioids
Number of prescriptions at patient level/number of unique providers at patient level	History of opioid overdose
Volume and quantity of morphine milligram equivalents prescribed per patient	Emergency department admissions
Patients prescribed both opioids and benzodiazepines	Data or privacy breach
Types of controlled substances prescribed	Naloxone history

Source: Approved State Advance Planning Documents submitted by State Medicaid agencies for the 100 percent Federal Medicaid match for PDMPs under the SUPPORT Act.

In the next section, we describe challenges related to implementing the PDMP requirements specified in the SUPPORT Act. These challenges were identified through conversations with the 15 States that were approved for the 100 percent enhanced Federal match.

State Challenges Implementing Qualified PDMP Requirements Under the SUPPORT Act

Establishing a State database that meets the definition of a qualified PDMP under the SUPPORT Act requires a significant investment of time and resources. Some States have been developing their PDMP for more than a decade, yet others are still in the early stages of this endeavor. In this section, we describe some of the challenges faced by States approved for the Federal match made available in Section 5042 of the SUPPORT Act that hinder their ability to establish, expand, and optimize their PDMP.

Patient Matching

States identified patient matching as the largest challenge faced by PDMPs across the country. Patients with common names, misspelled names, multiple names, and multiple entries create challenges in patient identification within one system, but even more so across multiple systems. Each State employs its own patient-matching algorithms; as a result, even contiguous States employ different strategies to match patients who may be dispensed prescriptions for controlled substances across State lines. In fact, patient-matching algorithms vary across the entire PDMP ecosystem, where PDMPs, pharmacy information systems, electronic health records, and other intermediaries apply a different approach to matching and linking patient records. This challenge is compounded by variations in data content, format, and quality collected by pharmacies and clinicians. Different pharmacies throughout the State may not have the same information on a patient, for example, yet each pharmacy reports on that patient to the same PDMP, creating a situation where the PDMP must reconcile multiple records for the same patient to one longitudinal record.

Further complicating these efforts, State HIEs employ their own patient-matching algorithms, which often do not align with the one employed by the State PDMP. Although HIEs have access to a larger variety and number of demographic data elements, which enables the development of more complex patient-matching algorithms, PDMPs can access only limited information, thus hindering the ability to reliably identify and link patient records. Therefore, even if the State's HIE patient algorithms are more robust, they may not be able to be operationalized to support patient matching for the PDMP. Patient matching is further complicated by the reality that many larger, multistate health systems have negotiated contracts with private companies that use proprietary patient matching algorithms. Many providers rely on the vendor's algorithms and approach for patient matching and thus do not use the one developed and employed by the HIE and are unable to align approaches across systems. Without a common patient matching approach, many PDMPs are unable to always detect multiple prescriptions written for a single patient, or they find that the systems they rely on frequently produces inaccurate matches between patients.

A few non-State entities have developed their own patient-matching solutions. States use different systems and may not have the resources to invest in a proprietary product or pay ongoing licensing fees. The NCPDP is working with Experian to develop a universal patient identifier that could be transmitted within transactions using NCPDP standards.

Patient matching increases the burden on staff who support State PDMP efforts. One small State pointed out that in a single month, staff identified 12,000 duplicate records in their PDMP. In most States, it is the job of one employee to regularly review the potential duplicates identified by their patient matching algorithms, adjudicate whether the duplicate records are a true or false positive match, disregard false positives, and merge or link those records determined to be a true match into one complete record. This is a time consuming process that detracts State employees from their work supporting PDMP operations. Furthermore, false positives are amplified when sharing across State lines. While States can identify and reconcile most duplicate records within the State PDMP, there is no way to know precisely why interstate data queries do not successfully link all patient records, even those known to be shared across States.

In the past 7 years, several key reports have addressed the ways in which improved patient matching and identification can improve treatment in a multitude of scenarios, including through the PDMP. In 2014, ONC published its Patient Identification and Matching Final Report (Morris et al. 2014). In 2018, the Pew Charitable Trusts published the report titled "Enhanced Patient Matching Is Critical to Achieving Full Promise of Digital Health Records" (Pew Charitable Trusts 2018a). In 2019, the U.S. Government Accountability Office published the report "Approaches and Challenges to Electronically Matching Patients' Records Across Providers" (U.S. Government Accountability Office 2019). One additional report to Congress on this topic is expected from ONC as a deliverable of the FY 2020 Federal budget. The research on this topic provides supporting solutions and acknowledges the intrinsic challenges.

Vendor Costs

The second most frequently cited challenge associated with developing and upgrading a State's PDMP is the associated costs of contracting with vendors—some of which were not covered under the Federal match, and others of which are related to ongoing costs to support sustainability. Multiple States have established contracts with a specific software vendor that supports data analytics, including real-time provider queries. Both PDMPs and providers must independently support vendor-related costs. Although these contracts can support system integration and patient matching, the solution is expensive and can be cost-prohibitive for smaller health systems or independent providers. Vendors also charge for individual customization or system enhancements, which are often required to tailor the solution according to State regulation, existing EHR and related infrastructure, and clinical or other priorities. Even after the State has purchased the system and paid for customization, the vendor charges annual licensing fees.

Other vendor-related challenges include understanding and negotiating the company's procurement and contract language. Some States pay lawyers to help negotiate these terms which requires additional financial investment. One State discovered that a private company was prohibiting certain connections, including to the State HIE. Such a practice could be considered information blocking under the 21st Century Cures Act.

Vendor contracts can range from 2 to 5 years, and State procurement laws can make it difficult, if not impossible, to replace a system or vendor mid-contract. Given the limited time States had to use the Federal match, many States had to work with their existing system and vendor to make the necessary changes, often at the sacrifice of cost, quality, or usability. State procurement practices also can favor established vendors who are familiar with procurement processes or who

can emphasize their experience working in other States, regardless of whether the systems are in fact, meeting user needs.

Time

Staff time and availability inhibited States' ability to fully operationalize their PDMP. States noted that even if they have the financial capital to employ proprietary systems with algorithms to support patient matching and the capacity to support data integration with EHRs and other health IT, the timeline challenges delayed each step in developing and executing the plan for use of the Federal match. These delays included hiring and onboarding new staff, procuring supplies, authoring, and revising the APD for final approval, and securing stakeholder input. Furthermore, States pointed out that they had intended to use some of the funds for strategic planning to ensure that the final plan reflected the collective perspectives of stakeholders. The need to expedite efforts inhibited the ability to thoroughly evaluate different vendors or determine, whether to continue with the current vendor, or select a new one.

Alternative Funding Sources

Several States elected not to apply for the Federal match and instead relied on grants from other Federal agencies that do not require funds to be expended within a specific time frame. CDC has invested millions of dollars to improve, enhance, and maximize PDMPs through investments at the Federal, State, and local levels. In 2017, CDC awarded States nearly \$30 million through the Prevention for States program to support effective prevention of opioid deaths through public health information, including enhanced PDMP functionality. ¹³

In September 2019, CDC released a cooperative agreement called Overdose Data to Action (OD2A) to provide funding for State, territorial, county, and city health departments to generate high-quality, comprehensive data on overdose morbidity and mortality. ¹⁴ Through this funding opportunity, CDC has awarded \$301 million in new funding to 47 States in addition to the District of Columbia, Puerto Rico, and 16 city and counties to enhance and maximize PDMPs. Required strategies include universal PDMP use among providers, integration of more timely data, active data management by providing unsolicited reports to providers regarding their prescribing history, increasing PDMP usability and accessibility, and improving intrastate and interstate operability.

The BJA within DOJ has also offered States millions of dollars to improve their PDMPs. Unlike the Federal match authorized under the SUPPORT Act, these grant dollars are not time limited. Additionally, CDC and DOJ cooperative agreements and grants do not require any investment by the States. Finally, in response to the COVID-19 pandemic, several staff who were slated to support implementation of the activities in the approved APD were diverted to address pandemic-related State activities, threatening the State's ability to complete the work described in the APD within the specified timeline.

¹³ More information on CDC's Prevention for States program is available at https://www.cdc.gov/drugoverdose/states/state prevention.html

¹⁴ More information on CDC's Overdose to Action is available at https://www.cdc.gov/drugoverdose/od2a/index.html

Comprehensiveness of Data

The data contained in the PDMP are not necessarily comprehensive. Often, key data are not reported to the PDMP, or data in existing fields are missing or unreliable. For example, if the individual is in temporary housing or is experiencing homelessness, their record in the PDMP may not reflect the individual's current and correct place of residence. Thus, it is not possible to accurately determine with 100% certainty the residential neighborhoods with the highest rates of individuals who are prescribed and dispensed controlled substances. Often, PDMPs can accurately track data only from those pharmacies that dispense the highest volume of controlled prescriptions. As a result, efforts to adequately deploy resources, such as community outreach and establishment of outpatient treatment centers, are hampered.

Most PDMPs do not collect information on why the pain medication was prescribed. As a result, patients with chronic or deteriorating conditions may not receive appropriate pain management. Several stakeholders pointed out that this issue could be effectively resolved by effectively integrating the PDMP data into a patient's medical record. An additional strategy may be to harmonize the required use of diagnostic codes (i.e., ICD-10) in prescription data across all relevant PDMP standards, or coordinate with pharmacy systems, industry groups, and other stakeholders on improve data capture and quality, including medication-related indications.

Federal health programs such as those offered by the DOD and the VA contribute to the challenge of accurately capturing all opioid prescriptions in the PDMP. The DOD has its own PDMP, which does not share data with the States and territories. Therefore, prescriptions covered by the DOD are not captured in the PDMP of the State in which the individual and his or her dependents reside. The VA uses a postal service to deliver prescriptions. Thus, the PDMP captures the location of the mail-order pharmacy that fills the prescription rather than the pharmacy that is closest to the patient's residence. As a result, the numbers of opioid prescriptions are artificially inflated in some counties, affecting the effective deployment of resources. One State noted that its State-funded NARCAN® vans are not being deployed to the neighborhoods in which they are likely to be most beneficial.

State Coordination

Several States expressed frustration with silos at the State level. As noted, the PDMP in many States is located outside the State department of health, in which the Medicaid agency is housed. In some States, the PDMP is "owned" by one entity but housed in another part of the State government. To use authorized CMS funds, the Medicaid agency must establish an interagency agreement or another fund-transfer mechanism so that the funds can be used by the department within the State that owns and operates the PDMP. This creates additional burden, which may impede States' ability to take advantage of Medicaid funds for PDMP enhancement.

Even in States in which the PDMP is located within one umbrella agency with Medicaid, some States cited challenges in coordinating across divisions or in gaining executive support for necessary changes. State politics also create unnecessary barriers. While cross-department coordination introduces challenges within a State, it may also introduce challenges for cross-State coordination, given that one State agency must coordinate with a different entity that controls the PDMP in an adjacent State. One stakeholder recommended that all PDMPs be managed out of the State's health department.

PDMP Data Integration with Medicaid Data

While a few States have successfully integrated the PDMP data with Medicaid data, for most States, this is still a work in progress. Barriers to this integration are often driven by State privacy laws, which limit the ability of Medicaid agency staff to access certain data fields in the PDMP. States must ensure that they address both Federal and State requirements with regard to data privacy and security protections. In response, one State has developed a separate, secure portal in which relevant, data are uploaded, making those data accessible to Medicaid staff. As a result, even in States in which integration between the PDMP and Medicaid agency has occurred, there may be no record of those Medicaid beneficiaries who are personally paying to fill their prescriptions.

Qualified PDMP Requirements

States commented on the need for clarification regarding interpretation of specific language in the SUPPORT Act. For example, one State was not sure how to interpret the Federal requirement that providers need to access the qualified PDMP data in "close to real time." This could be broadly interpreted and fails to consider variation in the ability of pharmacy providers to report this information to the PDMP. For example, small and rural pharmacies may batch uploads rather than submit the data on a daily basis or more frequently.

States also sought clarification on the length of the look-back period for reporting the percentage of covered providers checking the PDMP before prescribing (e.g., 6 months or 12 months). For example, States that are already calculating this information over a 6-month period, time and resources will be required to restructure their PDMP reporting system to accommodate a longer look-back period. Typically, CMS uses the regulatory process to address questions of this nature; however, there was insufficient time for CMS to conduct notice-and-comment rulemaking in sufficient time to guide states in their use of the 100 percent Federal match before it ceased to be available from October 1, 2020.

States pointed out that their PDMP is not currently structured to comply with some of the requirements of a qualified PDMP and indicated that they would need to completely reconfigure their systems to meet the statutory requirements for a qualified PDMP as added by the SUPPORT Act. For example, one State PDMP aggregates data at the practice level. This limits the State's ability to track and report data at the provider level. Another State indicated that its system does not collect certain data fields and that capturing this information would require the development of new data sources, standards and systems.

The next section describes creative, innovative, and/or highly effective strategies for optimizing the use of the PDMP. These promising practices were identified through a review of the APDs for those States approved for the Federal match as well as through conversations with State representatives.

Promising Practices in PDMP Implementation

The SUPPORT Act legislated that the Report to Congress include a section on best practices. At the time of this report, States had not fully implemented the activities approved for the Federal match. Given the lack of available data to evaluate the impact of these investments on patient safety, this section highlights several promising practices that States have undertaken. Some of these could be expanded to other States to improve the safe prescribing of controlled substances.

Internal State Coordination

At least one State established a partnership with other agencies within the State to improve communication and coordination while reducing data silos. Given that the PDMP may be housed in one part of the State government but used by other State entities, facilitating collaboration and an open dialogue can help overcome administrative barriers to data access and use. States have also identified the need to secure buy-in and support from community-level stakeholders. To this end, one State initiated a series of stakeholder engagement meetings. These discussions helped inform the State's APD application and has been valuable in ensuring that the PDMP is optimized to effectively meet the needs of multiple parties.

Collaboration Across States

States have employed several innovative approaches to collectively leverage their experiences and resources in building, enhancing, and operationalizing the PDMP. The best example of this interstate partnership is the New England States Consortium Systems Organization (NESCSO), a nonprofit organization governed by the New England States' health and human services agencies and the University of Massachusetts Medical School. ¹⁵ NESCSO members facilitate information exchange to identify collaboration opportunities, investigate collaborative approaches such as multistate purchasing and joint applications for Federal funding, and coordinate regional workshops and meetings to share best practices.

CMS has encouraged cross-State partnerships by hosting regional, multistate gatherings and engaging in group and individual discussions with State representatives at national meetings. CMS senior staff and project officers review and discuss the State's strategy, progress, and address questions. Through these conversations, CMS has facilitated collaboration across States to share materials, discuss lessons learned, and expand the use of existing resources. Some States also sponsored summits attended by representatives from contiguous States and those in other States with an interest in partnering and sharing their lessons learned. As a result of these cross-State conversations, States have advised one another on strategies for overcoming State legislative barriers, building strategic plans informed by the efforts of others, and refining and coordinating patient-matching algorithms and approaches. In some cases, States have developed open-source or low-cost products that can be used by other States as an alternative to expensive commercial products.

CDC Funding

States have used CDC cooperative agreements to augment available resources targeting PDMP development and enhancements. One State explained that all its PDMP investments are funded

¹⁵ More information is available at https://nescso.org/.

completely through grants and cooperative agreements from CMS and CDC. Another State indicated that it plans to use CDC's ongoing sustainability funding to help offset licensing costs when the funds from the Federal match are no longer available.

PDMP Access for EMS Personnel

Several States already allow EMS staff access to the PDMP. Maryland is working with EMS jurisdictions throughout the State to bring data about prior overdose events into the PDMP database so that it can be accessed in the field (Monica 2019). In several States, EMS teams use PDMP data to perform overdose fatality reviews to review drug-related overdose deaths to identify opportunities to be more proactive in providing treatment and social services (Pew Charitable Trusts 2020). Timely access to this information can save lives by ensuring that patients get appropriate care and, when suitable, receive therapeutic medications such as naloxone. Some States plans discussed development of a PULSE system that allows providers, including EMS staff, access to an individual's key health information at the time of an emergency. Unfortunately, alerts and PULSE systems require cross-State agreements, and some States have legal restrictions that encumber the ability to establish this type of system. For EMS providers operating in communities that cross State borders or those working in metropolitan areas with a high volume of commuters, a lack of EMS access to PDMP data for individuals who reside in other States can be particularly harmful as it prevents informed clinical decision making.

In the next section of this report, we highlight a subset of States that have employed novel approaches to optimizing their PDMP. The information presented next was derived from the APDs submitted for the Federal match, conversations with representatives from the State, and conversations with contractors hired by the State to support their PDMP implementation efforts.

State Models of Promising Practices to Maximize Effectiveness of PDMPs

The SUPPORT Act legislation required CMS to produce a report on State models of promising practices. However, given the requirement that the report be produced by October 2020, it is not possible to evaluate which practices generated the intended positive outcomes. In the discussion that follows, we highlight three States that have employed promising and innovative approaches to maximize the effectiveness of their PDMPs to support patient safety.

Colorado

Before passage of the SUPPORT Act, Colorado established a PDMP work group composed of representatives from their two HIEs; the University of Colorado; and multiple State agencies, including the Department of Regulatory Agencies, Office of Medicaid, Office of Technology, Office of Behavioral Health, and Department of Public Health and Environment. The work group has been supporting cross-agency alignment while also considering how the State's PDMP can be enhanced to better support safe prescribing practices. The diverse membership provides a broad perspective that reflects input from stakeholders with different roles and responsibilities related to addressing opioid use in the State. Colorado also operates the Colorado Consortium for Prescription Drug Abuse Prevention which includes a PDMP Workgroup, a separate oversight entity that works with the State Department of Regulatory Agencies. Although these two work groups serve distinct roles, they regularly collaborate and facilitate open communication.

As a result of these collaborative efforts, Colorado was well positioned to develop a proposal to use the SUPPORT Act funds to establish a road map for optimizing the PDMP. As part of the plan, the State identified several priority investments to further these efforts. For example, the Colorado State Health Information Exchange (CORHIO), one of the State HIEs, is developing a FHIR®-enabled application programming interface that will help improve patient access to PDMP data. The Federal match will help support and continue these efforts. CORHIO is also planning to incorporate within its HIE data on social determinants of health. Integration of these data will be helpful for providers treating patients prescribed opioids; individuals with lower socioeconomic status are significantly more likely to suffer from an opioid fatality (Altekruse et al. 2020).

Colorado has integrated its PDMP data with the State's online service through which residents can apply for public assistance programs. The funds provided through the Federal match will be used to support efforts initiated by the Medicaid agency to develop a provider-facing tool that supports e-prescribing. The State is developing a risk algorithm that uses data from both the PDMP and the HIE to help providers identify patients who may be at higher risk for an opioid use disorder.

Nebraska

Nebraska views the PDMP as a public health and patient safety tool. Because of a unique and expansive State law, its PDMP captures all prescription medications dispensed in the State—not just controlled substances, as in others. This law enables the State to support safe prescribing practices by flagging potentially dangerous drug combinations, such as opioids and benzodiazepines prescribed in tandem. State leadership acknowledged that this approach helps

reduce adverse drug events; however, they recognized several challenges that had to be negotiated. These include managing an increasingly large and complex database; effectively implementing reliable data quality checks; and acknowledging the strain that these efforts place on vendors, including excessive time and testing whenever any changes or updates are made to the system.

Through optimized use of its data analytics platform, Nebraska can identify within 24 hours whether the volume of prescriptions for a specific type of medication has increased. This information has been used to support disease surveillance, including the ability to track infectious diseases such as COVID-19 and seasonal influenza. The data also can help identify communities with higher rates of chronic disease based on the number and types of prescriptions that are dispensed. Further, this information can be used to track chronic disease management by determining whether routine medications are not being filled. These data can be used to detect communities in which higher rates of acute incidents are likely to occur because of poor disease management. The State has also employed the data to track and target education about the importance of antibiotic stewardship.

In 2018, Nebraska hosted a SUPPORT Act summit with contiguous States and other interested States to discuss the ways in which their PDMP is structured and to share their lessons learned with other States. These include developing additional functionalities that can be leveraged by other States and establishing a portal to share data fields from the PDMP with the State's Medicaid agency.

A portion of Nebraska's Federal match from CMS was used to make enhancements to RxCheck, a hub used by a growing number of States (see exhibit 5) to support interstate PDMP data exchange. These features will improve patient matching, data quality and accuracy, provider compliance, and comprehensiveness of information that is available across State lines. By leveraging its CMS Federal match, Nebraska has made significant investments to expand the capacity to benefit patients across the State and the nation.

Rhode Island

Rhode Island's PDMP captures data on nonscheduled drugs that have been implicated in prescription drug abuse. All pharmacists must be enrolled in the PDMP to track their dispensing patterns. The State is also collaborating with DOD and VA to link their respective PDMP data. Each provider receives a customized report on his or her prescribing behavior related to key metrics.

Rhode Island's strategic plan has served as a model for other States. With extensive planning, the State was able to coordinate SUPPORT Act-funded activities with other existing Federal grants, maximizing available resources and building an ambitious road map for improvements. The State has led coordinated submissions for Federal funding to support PDMP efforts across New England, facilitating interstate coordination and increased efficiencies. As a result of a series of stakeholder meetings involving direct users, pharmacists, and other key constituencies, Rhode Island is considering ways to allow access to PDMP data for health insurance payers for specific use cases, such as patient care management. Stakeholders also suggested increasing transparency regarding the ways in which the PDMP is being used for compliance, prescription tracking, and other purposes. Aggregated information would be shared with health insurers or provider organizations.

The State is also considering methods for consolidating measures across States, including tracking the volume of Rhode Island residents who fill their prescriptions in another State. These measures will help identify those States in which greater cross-State PDMP integration is needed.

In the section that follows, we present insights from consultations with key stakeholders regarding the effectiveness of PDMPs and opportunities to enhance their utility.

Consultations with Key Stakeholders

AIR conducted interviews and discussions with the National Association of Medicaid Directors, pharmacy benefit managers, managed care entities, clinicians, patient advocates, and subject matter experts. The findings provide valuable insights and perspectives on PDMPs, their benefits, limitations, and opportunities to more effectively operationalize and use them to better support care coordination and patient safety.

Benefits

Several individuals pointed out that PDMPs have been an effective tool to reduce the number of opioids prescribed in the United States. PDMPs have improved care coordination by providing clinicians information to make informed decisions. Both providers and pharmacy benefit managers find the PDMP useful for tracking patients who are using multiple providers or pharmacies. Therefore, the PDMP can reduce inappropriate use of opioids that can result in patient harms, including overdose.

Enhanced Clinical Care. Providers, pharmacy benefit managers, and payers commented on the role PDMPs can play in empowering providers and pharmacists to provide appropriate education and treatment. PDMPs enable pharmacists to play an active role in the patient's care, including ensuring safety and providing education and information about opioid-related risks. Providers reported that the PDMP (1) allows them to make more informed decisions and engage in valuable discussions related to the effectiveness of current pain medications; (2) enables them to initiate discussions related to non-opioid or non-pharmacological medications or modalities for treatment of pain; and (3) provides essential information to effectively treat new patients who are experiencing pain. The information captured in the PDMP is especially valuable to ensure appropriate treatment for patients who come from other States or who are switching providers as the new provider may not have access to the patient's medical record at the time of the first consult. One provider indicated that the PDMP discourages patients from seeking care from multiple providers and pharmacies when they realize that their prior prescriptions are tracked across multiple States.

Experts noted that, in some States, the PDMP has been highly used, particularly in States with robust systems that are fully integrated into the State's HIE. The PDMP greatly reduces provider burden while generating a more comprehensive picture of the patient including previous prescriptions, diagnoses, and medical history. It increases the provider's confidence to make informed decisions about patient care by providing additional safeguards. Additionally, many States generate regular reports from the PDMP that inform quality improvement efforts.

Population Health. PDMP data have been used to support community-based initiatives. Public health experts have used the data to identify and target resources to areas with high rates of opioid prescriptions. Insurers have indicated that the PDMP has benefitted their members by

facilitating increased care coordination and access to behavioral health and social services. Some States have given law enforcement access to the PDMP to help identify areas where people may be selling illegal drugs or medications that may be laced with fentanyl. Other States have developed electronic alert systems to identify patients at risk of an opioid-use disorder or patients who have experienced an adverse event associated with an opioid prescription. One health information technology expert pointed out that PDMPs can play a critical role in addressing social determinants of health and improving the overall health of a community.

Challenges and Limitations

Despite these benefits, several individuals cautioned that PDMPs are not being used or leveraged

effectively to achieve their intended objective and, therefore, have not realized their full potential. In some States, law enforcement officials use the PDMP data as evidence to prosecute people who may have an opioid use disorder. Advocates and health information technology experts criticized this approach, arguing that PDMP

"[There is an] overreliance on inappropriate solutions.... [A PDMP] can't be implemented at [the] expense of improving the quality of prescribing and identifying and implementing other measures to support patients with chronic pain needs or substance use disorder."

data should be used to support patient safety and public health by preventing overdoses and providing individuals with access to appropriate treatment options and ongoing support.

Below, we outline key barriers identified through stakeholder interviews that impede the effective use of PDMPs and may compromise their capacity to improve patient safety and population health.

Medicaid Agency Access. First and foremost, stakeholders commented on challenges related to access. Despite congressional encouragement, a few State Medicaid agencies still do not have access to the PDMP data. While significant Federal funding to support the enhancement of the State PDMP comes through Medicaid, frequently the PDMP is managed by another State agency. This creates challenges in effectively leveraging these funds to invest in upgrades and enhancements to the PDMP when it is owned and operated out of a different agency. In several States, the agency overseeing the PDMP may have limited technical resources and not be well versed in clinical data and the workflow standards of the provider community. Furthermore, internal silos at the State level may create coordination challenges and introduce unnecessary obstacles. One individual cited a disagreement across State agencies related to data use that occurred several years ago but still hinders establishing a constructive partnership. In this State, the PDMP data are manually exchanged with the State's Medicaid agency.

Even when there are strong relationships between these State agencies, technological challenges hinder the ability to integrate the PDMP with Medicaid data. According to the National Association of Medicaid Directors, States with the highest rates of PDMP use have established strong relationships across State agencies and with the entity that runs the State HIE. However, States often lack the funds to effectively support interoperability between the PDMP and the State HIE.

Interstate Access. Challenges of data sharing across States is another impediment to the effective use of PDMPs. Although most States have access to data from contiguous States, States may not have access to data from all States, and one State did not have an operational PDMP as of 2020. Furthermore, politics are involved in data coordination across State agencies. Intrastate data sharing is challenging when the PDMP is not located within the State Medicaid agency. Housing the PDMP in a different agency across each State introduces significant challenges for interstate

"The sooner all States can synchronize [data] and become more [consistent in how they are] used, the sooner the opioid epidemic will be managed and we can address root causes and work toward whole patient health." sharing, as the data that are shared differs depending on the type of agency where the data originate. States use different vendors to support their PDMP, which hinders innovation, interoperability, and discourages an open marketplace.

Workflow Barriers. Providers who can access the PDMP through the patient's electronic record or the State HIE are much more likely to use the data. When the PDMP is not integrated into the State HIE or the individual provider's EHR, it creates a workflow barrier that can compromise the frequency with which the PDMP is accessed. However, according to one subject matter expert, the entities that oversee the PDMP often lack the strategic and technical visioning to identify barriers to data sharing and to support automation. States are still working to standardize a format that can interoperate with all providers' EHRs. One provider reported that her health system claims that the PDMP is integrated into the EHR; however, this just means that she can click on a link in the EHR which will take her to a separate State PDMP login screen. Furthermore, the acceptance of PDMPs varies from State to State, which makes it difficult to ensure that they are being adequately used and checked even when data from the PDMPs in other States are accessible.

Usability. When providers need to log into separate systems, especially when checking the PDMP or PDMPs across multiple States, time is taken away from direct patient care. Some physicians confess that they do not have the time to check the PDMP and assume that the pharmacist will check it. However, this depends on how busy the pharmacist is, as well as technical capacity, system integration, PDMP enrollment, PDMP training, and workflow optimization to support PDMP checks at pharmacies. Alternately the pharmacist may assume that the prescriber already checked it.

Incomplete Information. To effectively manage patients who have been diagnosed with a substance use disorder, providers need to understand the full patient, including data on diagnoses, hospitalizations, emergency room visits, the multiple providers involved in the

patient's care, and the patient's behavioral health needs. If effectively integrated with the patient's medical record, PDMPs can help to identify the need for better care coordination and can be used to begin a dialogue with the patient about options to effectively manage the patient's pain.

"The [PDMP's] value is not [in] finding multiple prescribers but rather [having access to] comprehensive information about people being prescribed [opioids] to better inform clinical decision making at the point of care."

In most cases, PDMP data does not include the reason for the patient's prescription. One reason for this is that reporting standards only support optional inclusion of diagnosis or indication, and

so even if this information is known to the pharmacy who dispensed the controlled medication, it is not included in the report to the PDMP. Providers who treat patients with chronic health needs, like musculoskeletal disorders for example, may be inaccurately flagged if they continue prescribing opioids to patients who may have legitimate reasons for ongoing use. The PDMP fails to consider disease progression, so clinicians are forced to make decisions based on the initial pain assessment of a patient who may have a deteriorating condition. Stakeholders argued that the PDMP should not be implemented at the expense of improving the quality of care. One large health insurer reported that its providers were "acutely aware of the PDMP" and, therefore, hesitant to continue to prescribe opioids at all, resulting in patients being denied the medication they may need to treat their condition.

Unintended Effects. One individual pointed out that several negative consequences have resulted from the use of PDMPs. Patients may feel like they cannot switch doctors because they will be seen as "doctor shopping" even if they are dissatisfied with the quality of the provider's care. Individuals with pain may change medications every few weeks or months even if the other medications are not as effective. Patients who are denied needed pain medications may turn to street drugs, which increase the risk of overdose. Individuals living with pain may also turn to marijuana, which, even if legal, is not regulated. Patients with legitimate pain who cannot get adequate relief are more likely to suffer from depression and have increased rates of suicide. The PDMP can be perceived to force providers to push people into interventions that may be suboptimal and can lead to unintended harms. One advocate referenced the fungal meningitis

outbreak that affected patients in 21 States. Many affected patients received epidurals to manage their pain because they were denied an opioid prescription. As a result, these injections exposed them to a lifethreatening illness.

"Not all drugs are bad and not all people who are using drugs are bad. We are not making good use of the tools we have."

PDMPs employ risk algorithms that do not account for community and population demographics. For example, residents in rural communities tend to be older and experience higher rates of disabilities. Efforts to reduce inappropriate prescribing in rural areas have reduced access for residents in these communities with chronic pain. Many primary care providers are reluctant to prescribe opioids, which forces patients to seek care from specialists. The reluctance of primary care providers to prescribe controlled substances has affected entire health systems in rural communities as patients are forced to seek treatment in urban areas, which can be more difficult for rural residents to access.

Data Quality. The PDMP was initially designed to track medication use by individuals suspected to have a substance use disorder. It was never tested or optimized for reliability or validity in a more general patient population that includes individuals experiencing chronic pain and illness. As a result, it cannot differentiate which patients are misusing drugs and which patients have a legitimate need for longer term use of opioids to manage their pain.

Stakeholders also commented on the quality and utility of the data. Because the PDMP is housed and managed by different agencies across the United States, the data reported by one State varies from another State, making it difficult to match patients accurately across State lines.

Furthermore, clinicians can make errors, and several individuals recalled instances where data

were incorrectly entered into the PDMP. When the provider noticed the error, they could correct it only by closing out of the system and then logging in again. In at least one case, the provider just entered a new (correct) record without deleting the prior (incorrect), thereby creating a duplicate

"[There is a] lack of quality, comprehensiveness, [and] consistency of information that can be channeled through [PDMPs] to inform clinicians."

record that must be reconciled by the PDMP. A patient advocate pointed out that although individuals have access to their medical record, they cannot access the information about them that is recorded in the PDMP. As a result, they are not given the opportunity to review and validate the accuracy of the information or correct any data errors.

"We can look at numbers all day long, but what we are really doing is making people sicker without capturing that information." Furthermore, States generate measures from the PDMP that may not be useful or meaningful to providers. One provider reported that she never looks at measures

for morphine milligrams equivalents and did not understand why PDMP reports include data on which patients paid cash for their medicine. Without a clear understanding of the measures, confidence in the reliability of the data, and the ability to capture and exchange the reason the medication was prescribed (for acute or chronic pain), providers cannot use PDMP measures effectively to inform their decision making.

Optimizing the PDMP

When asked about how the PDMP might be enhanced to meet its intended purpose more effectively, stakeholders offered several valuable insights. Some of these recommendations require the investment of additional resources, other recommendations require changes in State legislation, and still others require education and outreach.

Interoperability. Stakeholders talked about the importance of integrating the PDMP data into the EHR and enhancing interoperability with other health data, including the State HIE and cancer and vaccine registries. Workflow barriers could be minimized by streamlining provider identity authentication across States and establishing a

"Providers who have easy access into the system are able to have confidence in the care they are providing the patient....
[W]hen providers have confidence in the systems they use, it becomes like another limb to them, thus adoption is easier."

single sign on system. One provider suggested that having data aggregated by region would help, particularly for providers practicing on State borders, to reduce the need to log into multiple State PDMPs.

Broader Access. Increasing access to individuals without prescribing authority will increase the usability of the PDMP. Giving delegates access to the PDMP will reduce the burden on clinical providers while increasing the frequency with which it is checked. Providing access for behavioral health providers, social workers, outpatient treatment programs, correctional health facilities, ambulances, paramedics, and emergency medical personnel will improve care coordination and increase the ability to provide appropriate treatment during unplanned

"Providing access to more individuals who have a hand in care can help evolve the care coordination and the social determinants picture in many States. Working together to provide...the best access to information is going to change the way we provide healthcare, proactively rather than reactively. I think [the] PDMP is a wonderful tool, but standardization and widespread adoption will propel the use of the PDMP further and help to stop the opioid epidemic."

situations. One health information technology expert envisions a future when the PDMP will be fully integrated into the clinical workflow with automated electronic clinical decision support tools to help providers effectively use these data in combination with the patient's comprehensive health data.

State Mandates. A pharmacy benefit manager and a health information

technology expert commented on the importance of establishing State mandates to increase the frequency with which the PDMP is accessed. Providers practicing in States with mandates are significantly more likely to access the PDMP before prescribing a controlled substance.

Housed in Health Department. One individual strongly recommended that all States mandate that the PDMP is managed by the State department of health. Transferring management to the health department would minimize internal politics, streamline the use of Federal dollars channeled through Medicaid agencies to support PDMP enhancements, and facilitate better interoperability across State lines.

All Prescription Database. A handful of States have augmented their PDMP to improve population health and patient safety. One State PDMP captures all prescription medications, and two other States have recently mandated expanding the PDMP to capture all prescriptions. Another State PDMP tracks the use of medical marijuana. A single database that tracks all prescriptions, including medical marijuana, can improve chronic disease management by flagging potentially contraindicated drugs or drugs with a higher likelihood of generating an adverse event. For example, many States are interested in tracking potential inappropriate use of benzodiazepines, stimulants, and other drugs of concern such as gabapentin. Expanding the PDMP to include all prescriptions could advance antibiotic stewardship efforts and improve tracking of compounded substances by documenting exactly what is in the compound and in what amounts. A prescription drug database can be useful to standardize quality measures and support pay-for-performance efforts.

Quality Improvement. PDMPs should be optimized to support performance management by providers, payers, and health systems. The data should be synthesized and reported back to payers and health systems to characterize prescribing patterns across systems of care. Data can be used more broadly across individual States and regions to track where more resources should be allocated and establish services to support communities with higher rates of opioid use. The data can be used to disseminate norms and best practices and to support benchmarking.

Education and Training. All stakeholders remarked on the importance of enhanced education for health systems, payers, providers, and patients. Health systems can monitor the prescribing patterns of its clinicians and offer training and technical assistance. Payers can work with providers to use data to track progress in terms of patient safety as well as increase access to care management programs for patients. For providers, it is necessary to have clear guidelines for when to check the PDMP and what to check for (e.g., patients seeking care from multiple providers and pharmacies). Providers could benefit from technical assistance to support data reporting, submission, and interpretation. Providers should communicate with each patient to discuss the dangers of opioids, the risk of addiction, and non-opioid or non-pharmacological pain options, including living with pain and balancing medications with non-prescription treatments like acupuncture. Providers should use PDMP data to consider a more balanced approach to pain management, which includes a dialogue between the provider and the patient to determine the best options to manage pain. Patients need to take a more active role in the process by communicating with doctors and sharing if they have a history of substance misuse. Furthermore, pharmacists should be empowered to check the PDMP and alert the prescriber if anything stands out. Finally, there needs to be better public outreach so that patients know that providers and pharmacists are required to check the PDMP and that accountability is enforced at the State level.

Research and Data Quality. To improve data reliability and validity, one stakeholder recommended establishing an audit trail. An audit trail may support efforts towards improving data accuracy by identifying errors. Other respondents recommended conducting an evaluation to determine whether the PDMP as designed is working effectively or has created unintended consequences. Finally, the effectiveness of the PDMP could be enhanced by working with Medicaid, the State HIE, and other social service agencies to develop predictive analytics to distinguish between potential abusers and individuals who are using opioids safely to manage their pain.

Insights from the Pandemic. As the COVID-19 pandemic has unfolded, it has diverted the focus of public health officials away from the opioid epidemic. However, several individuals noted that opioid use disorder continues to be a problem and reported higher rates of adverse events due to restricted access to medication-assisted treatment. States need additional funds to improve the PDMP and address behavioral health needs, especially considering the pandemic's impact on mental health. One provider applauded some of the relaxed restrictions for telehealth that were authorized under the public health emergency declaration. Allowing the use of telemedicine for first encounters and for the prescription of controlled substances has increased the number of patients seeking medications for opioid use disorder because it reduces travel time and assuages the fear of being seen by peers at a substance use disorder clinic.

In the final section that follows, we highlight lessons learned that could inform future Federal and State investments to optimize the use of PDMPs to improve medication safety at the State and national levels.

Lessons Learned

Discussions with States and key stakeholders highlighted areas in which legislative changes at the Federal or State level could facilitate State PDMP efforts.

Extended Timeline for Expending Funds Approved for Federal Match

States suggested that the U.S. Congress consider extending the timeline by which the funding for the Federal match must be expended. Procedural steps to secure the funding delayed any implementation efforts. These steps included: (1) stakeholder meetings to identify priorities, (2) internal team meetings to review this input, (3) collaboration with other State agencies engaged in the State PDMP, (4) drafting of the APD request, (5) revisions to the APD based on CMS feedback, and (6) delays due to the diversion of staffing resources to address the COVID-19 pandemic. Many States did not receive CMS approval to proceed until spring 2020. As a result, these States had less than 12 months to implement the activities outlined in their APD. Even once approved, efforts to implement the plan were stymied by challenges related to recruitment, procurement, and interagency memoranda of understanding. Several States proposed performing pilot tests and investing time to engage in strategic planning. However, without an extended period, these States will not have time to implement the results of these efforts. An extended timeline also would provide more time for CMS to operationalize the details of the funding, such as establishing a shared understanding on key terms in the legislation that lacked specificity (as noted) and identifying a standardized set of measures that all States could collect and report. Additionally, more time would afford CMS the capacity to create tools to measure States' progress and outcomes vis-à-vis their proposed objectives outlined in the APD.

National Data Standards

PDMP data integration across States has been a significant challenge, as highlighted previously in this report. Although States are collaborating to improve patient matching to support data exchange, it was noted that these collaborative efforts would benefit from Federal guidance on data content and exchange standards. Many States that are collecting the same information are capturing these data differently, resulting in challenges with data sharing, aggregation, and cross-State analysis. One cautionary note, however, is that developing national standards should be performed in partnership with the States to minimize disruption and build upon existing State efforts.

Clarification of Requirements for a Qualified PDMP

Several States expressed confusion regarding how to interpret some of the language in the SUPPORT Act legislation. For example, several States sought clarification on whether the required look-back period encompassed 12 months. One State already had established a 6-month look-back period and noted that expanding this time frame to 12 months would require a significant investment in resources.

Another point of confusion concerned interpretation of the language regarding who is authorized to check the PDMP. State laws vary significantly regarding which individuals have access to the PDMP. Even among those States that have a State mandate, considerable differences exist in terms of which providers must check the PDMP, along with whether or not they can delegate this

responsibility to a professional colleague. Some States require reporting class II–IV controlled substances, while others afford more latitude regarding the data that must be reported to the PDMP. At least one State wanted to also include prescriptions for medical marijuana, which is a schedule I controlled drug. States sought guidance on the types of medications that must be captured in the PDMP including class V medications, benzodiazepines, or other controlled substances, such as prescription amphetamines. Another State felt that the legislation was unclear with regards to how to address pharmacists who submit the data rather than the prescriber. A lack of clarity regarding these and other components of the legislation may result in unanticipated issues related to tracking and enforcing compliance.

Flexibility in Use of Federal Funds

Several Federal agencies have offered States opportunities to apply for funding to support PDMP development. These include, but are not limited to, CMS, CDC, and DOJ. Some of these opportunities include restrictions on funding, which impede the State from focusing on its State-specific priorities. Multiple funding streams also make it difficult for States to coordinate activities internally, and some States may be reluctant to pursue available funding because of the challenges associated with coordination and reporting. Federal coordination of funding opportunities to support PDMP operations would help optimize State investments by reducing the number of applications they must submit, standardizing how the funding can be used, and minimizing the need to manage multiple funding streams.

Most State PDMPs employ commercial products. As discussed earlier, these are expensive but offer several advantages, such as established patient-matching and verification algorithms, analytic platforms, and data validation checks. The ongoing use of these products requires licensing fees. Furthermore, some PDMP vendors charge additional licensing fees for essential add-on services, such as integrated access within provider EHRs. A few States included the costs of these fees in their APD request for the Federal match. After September 2020, States that have integrated their qualified PDMP with their existing Medicaid data systems, will be eligible for a 75 percent Federal Medicaid match to cover these licensing fees but would be responsible for the other 25 percent of these ongoing costs, which may present a hardship given limited budgets.

Identification of State Legislation That Impedes PDMP Development and Use

Some State legislative mandates, including data privacy laws, have created barriers to effectively developing and implementing PDMPs. These include restricting access to the PDMP to certain user types (such as physicians or other clinical providers), limiting health plan (including State Medicaid agencies or Medicaid managed care organizations) access to PDMP data, prohibiting use of PDMP data for licensing or State board disciplinary action, and limiting the sharing of data with other States. Further, behavioral health professionals without prescribing authority who are involved in the diagnosis or treatment of a patient—as well as EMS providers—often do not have access to the PDMP. These restrictions also create challenges with interstate data sharing because States generally will impose their regulatory restrictions on data shared with or received by other States.

States noted a common challenge related to delegate access, which is crucial to the inclusion of PDMP data in clinical workflows, as it allows medical assistants or other authorized users to pull records and prepare them for busy clinicians. Many States will prohibit delegates from other

States to access patients' records. Additionally, as noted, State legislation often dictates the State agency or program responsible for administering the PDMP, which has led to challenges with communication, coordination, and policy development. Some States have succeeded in working with their State legislatures to address these challenges; however, this effort takes time and delays activities. An analysis of State laws that may impede PDMP efforts would help identify these unintended barriers at the State level as well as decipher policies from other States that could be adopted to remove these impediments.

Coordination with Federal PDMP Programs

Several Federal health programs operate their own PDMP, including, the DOD and VA. Data from State residents receiving services from these Federal programs may not also be reported to the State PDMP. Each State must establish its own separate agreement with each of these programs to share data on relevant controlled prescriptions. In some cases, the state may need to incur configuration costs to exchange data with providers for federal programs in their state, or state Medicaid providers wishing to exchange data with non-Medicaid providers in the state connected to these other programs may need to incur costs.

As described, the VA mails prescriptions to patients from centralized pharmacy dispensing sites. As a result, the PDMP shows the ZIP code of the location from which the prescription was mailed, rather than the recipient's address or nearest pharmacy. This makes it difficult to identify which residents in a State are taking opioids and other controlled substances that were not filled by a local pharmacy, thus impeding efforts to use PDMP data to target resources to communities with high volumes of individuals taking controlled substances. Research has shown that mandates that do not include well-defined criteria on both prescribing data and prescription fill data are not nearly as effective in addressing opioid misuse and preventing avoidable negative events.

Comprehensive State Mandates

A number of States have enacted laws to encourage and promote greater use of the State PDMP. These laws include mandates for providers to check the PDMP and authority for them to delegate the task of checking the PDMP to other office staff (Bao et al. 2018). However, there is a great deal of inconsistency across States that have enacted one or more of these policies.

Comprehensive State mandates that require all clinical providers, across all settings, to check the PDMP upon initial prescription of an opioid and at least every 90 days thereafter, along with legislation that allows a delegate to check the PDMP on the provider's behalf, can significantly reduce the risk of opioid misuse and overdose. State legislatures should consider either adopting a State mandate or increasing the comprehensiveness of existing State mandates to ensure that they include all providers across the healthcare system, support the use of delegates, and require regular checks. States should also enact policies to ensure accountability for compliance with the State mandate.

Funding for State Collaboration

Collaboration with peer States has proven very effective in communicating best practices, leveraging limited resources, and increasing efficiencies. Organizations like NESCSO serve as

models for interstate coordination and partnership, not only for PDMP issues but also for a variety of State and regional information technology issues.

At a CMS meeting of States in both the Northwest and the Midwest, participants agreed that they would value the opportunity to coordinate efforts, learn from one another, and leverage joint resources. For these efforts to be successful, however, one State needs to invest its own limited resources to take the lead in facilitating the efforts. States need resources to allow staff to participate in meetings and contribute to jointly produced products. Federal funding to support these cross-State collaborations could increase efficiencies while also establishing more robust PDMPs.

Increased Integration Between PDMP and EHRs

Improving the workflow to enable providers to check the PDMP through the EHR system during the time of the patient encounter and/or when prescribing a controlled substance has been shown to be effective in increasing provider compliance with checking the PDMP (Bao et al. 2018). Supporting State efforts to integrate PDMP data with provider EHRs across all healthcare settings, including ambulatory and inpatient care, will reduce the burden on providers and increase the likelihood of providers complying with guidelines and regulations to check the PDMP before writing new prescriptions or refilling existing prescriptions for opioids.

Best Practices on Increasing Enrollment and Use of PDMP

While some States have successfully enrolled all providers to use the PDMP, other States are experiencing challenges. The Federal government can help overcome these obstacles by conducting a case study of those States that have been the most successful and the ways in which they addressed the challenges that other States have encountered. Additional collaboration and coordination are needed between State medical boards, NPPES, State PDMPs, and credentialing offices to facilitate PDMP registration at the time of medical license renewal and provide technical assistance for healthcare provider directory solutions. This information will be useful for improving public health by ensuring that PDMPs are broadly used by all providers.

Enhanced Education and Training for Providers, Payers, and Patients

Improving education and training on how to effectively use the PDMP and its limitations can improve patient safety, clinical care, and coordination. Health systems can review prescribing patterns and provide technical assistance to physicians. Payers can work with healthcare practitioners to track key metrics while increasing access to care management programs. Providers need training on when to check the PDMP, what to check for, steps to increase data accuracy, how to interpret performance measures, and best practices in effectively communicating with patients. ¹⁶ Patients must take a more active role by communicating with their providers and sharing their behavioral health history. Furthermore, pharmacists should be further empowered to check the PDMP and alert the provider if anything stands out.

Evaluation of Impact of PDMPs

Finally, concerns remain about the quality of the data that are captured in the PDMP as well as whether the expanded use of PDMPs has unintended negative consequences. Optimizing the use

¹⁶ CDC developed a set of 16 QI measure based on the 12 recommendations within its Guideline for prescribing opioids for chronic pain: https://www.cdc.gov/drugoverdose/prescribing/qi-cc.html.

of the PDMP requires ensuring that the system has a positive impact on patient safety and population health and that the data are reliable. Through data audits, it may be possible to detect erroneous data. A formal analysis will help to identify best practices that can be adopted by other States while also confirming that the PDMP achieves its intended goals yet does not foster unanticipated, and potentially harmful, consequences.

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