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PRESCRIPTION DRUG MONITORING PROGRAM INTEROPERABILITY STANDARDS

A REPORT TO CONGRESS

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> > Submitted to:

The Committee on Health, Education, Labor, and Pensions The Committee on Energy and Commerce



TABLE OF CONTENTS

EX	XECUTIVE SUMMARY	3
IN	TRODUCTION	3
Pu	JRPOSE AND STRUCTURE OF THE REPORT	3
FINDINGS IN THE REPORT		4
I.	BACKGROUND	6
	Introduction	6
	Purpose	7
	Structure of the Report	8
	Methods	8
	Prescription Drug Monitoring Programs	9
II.	REVIEW OF LITERATURE ON PDMP EFFECTIVENESS AND ASSESSMENT OF THE EXTENT PROVIDER UTILIZATION	of 10
III	. ASSESSMENT OF LEGAL, TECHNICAL, FISCAL, PRIVACY, AND SECURITY CHALLENGES	14
IV	. DISCUSSION OF CURRENT CHALLENGES FOR STATE PDMPS TO INCREASE PRODUCTION A DISTRIBUTION OF UNSOLICITED REPORTS	ND 17
v.	R ECOMMENDATIONS FOR ADDRESSING CHALLENGES THAT IMPACT INTEROPERABILITY O STATE PDMPS	F 20

EXECUTIVE SUMMARY

INTRODUCTION

The United States (U.S.) is in the midst of an unprecedented drug overdose epidemic. Drug overdose death rates have increased five-fold since 1980.¹ In 2009, drug overdose deaths outnumbered deaths due to motor vehicle crashes for the first time in the U.S. This increase has largely been fueled by the abuse of opioid analgesics such as oxycodone, hydrocodone, and methadone.² Opioid analgesics were involved in 30 percent of drug overdose deaths where a drug was specified in 1999, compared to nearly 60 percent in 2010. In fact, opioid analgesic-related overdose deaths now outnumber overdose deaths involving all illicit drugs combined.³

One of the most promising tools available to reverse the prescription drug abuse epidemic are prescription drug monitoring programs (PDMPs). PDMPs are state-run electronic databases used to track the dispensing of controlled prescription drugs to patients. PDMPs are designed to monitor this information for suspected abuse or diversion and can give a provider critical information regarding a patient's controlled prescription drug history. PDMPs are also used to identify providers who are contributing to patient risk and not providing appropriate care, serve as a surveillance tool to monitor dispensing and use trends, and evaluate the impact of state policies and programs designed to reduce abuse and overdose. As of June 2013, there were 47 operational PDMPs in the U.S.⁴

Although significant efforts have been directed to increase the implementation and enhancement of PDMPs in recent years, opportunities exist to increase utilization among providers and strengthen PDMPs through the use of health information technology (health IT).

PURPOSE AND STRUCTURE OF THE REPORT

This report was developed pursuant to Section 1141 of the Food and Drug Administration Safety and Innovation Act of 2012 (hereafter, referred to as FDASIA).⁵

Section 1141 of FDASIA requires the Secretary of the Department of Health and Human Services (HHS) to:

"submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on enhancing the interoperability of State prescription drug monitoring programs with other technologies and databases used for detecting and reducing fraud, diversion, and abuse of prescription drugs...The report shall include— (A) an assessment of legal, technical, fiscal, privacy, or security challenges that have an impact on interoperability; (B) a discussion of how State

¹ Warner M, Chen LH, Makuc DM, Anderson RN, Miniño AM. Drug poisoning deaths in the United States, 1980–2008. NCHS data brief, no 81. Hyattsville, MD: National Center for Health Statistics. 2011.

² Paulozzi L, Jones C, Mack K, Rudd R; Centers for Disease Control and Prevention (CDC). Vital signs: overdoses of prescription opioid analgesics—United States, 1999-2008. MMWR Morb Mortal Wkly Rep. 2011;60(43):1487-1492.

³ Centers for Disease Control and Prevention. WONDER [database]. Atlanta, GA: US Dept of Health and Human Services, Centers for Disease Control and Prevention; 2012. Available at <u>http://wonder.cdc.gov</u>. Accessed January 31, 2013.

⁴ Prescription Drug Monitoring Program Training and Technical Assistance Center, Program Status map. Available at

http://pdmpassist.org/pdf/pmpprogramstatus2013.pdf. Accessed June 2013.

⁵ Public Law 112-144. Food and Drug Administration Safety Innovation Act of 2012. Available at: <u>http://www.gpo.gov/fdsys/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf</u>

prescription drug monitoring programs could increase the production and distribution of unsolicited reports to prescribers and dispensers of prescription drugs, law enforcement officials, and health professional licensing agencies, including the enhancement of such reporting through interoperability with other States and relevant technology and databases; (C) any recommendations for addressing challenges that impact interoperability of State prescription drugs; and (D) an assessment of the extent to which providers use prescription drug management programs in delivering care and preventing prescription drug abuse."

The report is organized into an Executive Summary, followed by five sections. After the Executive Summary, the *first section* contains the purpose, structure, and methods of the report. The *second section* provides a review of the literature on PDMP effectiveness and an assessment of the extent to which providers use PDMPs. The *third section* highlights the current legal, technical, fiscal, privacy, and security challenges facing PDMP interoperability. The *fourth section* provides a discussion of how state PDMPs could increase production and distribution of unsolicited reports. Finally, the *fifth section* discusses recommendations to address the challenges currently facing PDMP interoperability.

FINDINGS IN THE REPORT

As described in the report, PDMPs face several challenges that currently limit their interoperability. The primary challenges center around two main areas: 1) legal and policy challenges; and 2) technical challenges. Addressing these challenges can greatly improve the ability of states to establish interoperability and leverage PDMPs to reduce fraud, diversion, and abuse of prescription drugs.

The following are recommendations to address identified challenges discussed in the report:

Address legal and policy challenges

- States should ensure that PDMPs do not restrict access to PDMP data for health care providers.
- States should consider implementing laws and policies to increase the use of PDMPs by prescribers, dispensers, and other authorized health care providers, such as requirements for prescribers and dispensers to register for the state PDMP.
- States should consider having authorizing legislation to send unsolicited reports to providers, licensing boards, regulatory and law enforcement agencies, and public and private insurers and pharmacy benefit managers.
- States should enable real-time access to PDMP data by health care providers. This information would be reported to the PDMP minutes after a prescription is filled and dispensed from the pharmacy.
- States, third-party intermediaries, and interstate data sharing hubs should identify the general scope of legal instruments that will facilitate the exchange of PDMP data via third-party intermediaries, and make available standardized templates for states to use on a shared PDMP resource website.

• States should ensure that PDMP laws, regulations, policies, and business agreements are developed in such a manner to mitigate privacy and security concerns.

Harness advances in health information technology (health IT)

- PDMPs should apply the latest advances in health IT to incorporate PDMP data directly into the workflow of prescribers and dispensers to enable timely access to their patients' controlled prescription drug history information at the point of care. Integrating with health IT makes PDMP data timelier and more easily accessible which encourages routine checking of the PDMP.
- HHS, working with the Bureau of Justice Assistance (BJA) within the Department of Justice (DOJ), should establish an initiative under the Standards & Interoperability (S&I) Framework to assess the current PDMP infrastructure (including interfaces, data formats, data transport and data security protocols) in use or available for use in connecting PDMPs to health information technology systems (e.g., electronic health records (EHRs) and health information exchanges (HIEs) and establishing interoperability.
- State PDMPs should implement interoperability standards that best support the information's use upon its exchange.
 - For information exchange from PDMPs to providers or pharmacists, states should work with relevant federal agencies and health care provider groups to harmonize and adopt standards best equipped to convey prescription information to meet their various clinical needs. For providers, this could include the use of PDMP data within EHRs for clinical purposes (e.g., to trigger clinical decision support, update medication history, or inform a health care provider's treatment plan). For pharmacists, this could include the use of PDMP data in a pharmacy system to inform pharmacists about previously dispensed prescriptions.
 - For information exchange between PDMPs (or government-to-government transactions, such as state-to-state notifications), states should continue to follow the National Information Exchange Model (NIEM) PDMP specification and the Prescription Monitoring Program Information Exchange (PMIX) Architecture supported by the Alliance of States with Prescription Monitoring Programs.
 - States should also be encouraged to utilize existing infrastructure to support data exchange with both private sector and government partners.⁶
- State PDMPs should implement single sign-on (SSO) capabilities that enable prescribers and dispensers to automatically access the PDMP by signing in to their health IT systems (e.g., EHRs), taking into account the level of trust in the credentialing and authentication process for the health IT systems.
- State PDMPs should automate the process of generating alerts to notify prescribers and dispensers of possible doctor shoppers. Automation helps to minimize costs and staff resources, while increasing the rate of notification. Health IT is key to automating this process and enabling PDMP data to be more readily available at the point of care.

⁶ National standards adopted for meaningful use and the PDMP initiative under the Standards and Interoperability (S&I) Framework from the SAMHSA/ONC Enhancing Access to PDMP Project can be referenced for more detailed information on this exchange use case (http://wiki.siframework.org/Prescription+Drug+Monitoring+Program+Initiative).

I. BACKGROUND

INTRODUCTION

The United States is in the midst of an unprecedented drug overdose epidemic. Drug overdose death rates have increased five-fold since 1980.⁷ In 2009, drug overdose deaths outnumbered deaths due to motor vehicle crashes for the first time in the U.S. Prescription drugs, especially opioid analgesics, have been increasingly involved in drug overdose deaths in the last decade.⁸ Opioid analgesics were involved in 30 percent of drug overdose deaths where a drug was specified in 1999, compared to nearly 60 percent in 2010. Between 1999 and 2010, over 125,000 people in the U.S. died from an overdose involving an opioid analgesic – far exceeding deaths from any other drug or drug class, licit or illicit, during this time period. In fact, opioid analgesic -related overdose deaths now outnumber overdose deaths involving all illicit drugs combined.⁹

In addition to overdose deaths, nonmedical use of prescription drugs – use without a prescription or use for the feeling or experience the drug caused – and the health and economic consequences associated with it are significant. In 2011, more than 14.5 million people 12 years and older reported nonmedical use of psychotherapeutic prescription drugs (pain relievers, sedatives, tranquilizers, and stimulants) in the past year.¹⁰ Rates of emergency department (ED) visits associated with pharmaceutical misuse or abuse increased 114 percent between 2004 and 2011 while rates for illicit drugs remained stable. By 2011, more than 1.4 million ED visits annually were related to the misuse or abuse of pharmaceuticals – with over 420,000 involving opioid analgesics and over 425,000 involving benzodiazepines.¹¹ Substance abuse treatment admissions for opioid analgesic results in over \$72 billion in medical costs each year.¹³ In many instances, public payers are responsible for covering the costs of prescription drug abuse.^{14,15}

Coinciding with the rise in opioid-related morbidity and mortality is an increase in opioid analgesic prescribing, primarily for chronic non-cancer pain.^{16,17,18} An analysis by the Centers for

⁷ Warner M, Chen LH, Makuc DM, Anderson RN, Miniño AM. Drug poisoning deaths in the United States, 1980–2008. NCHS data brief, no 81. Hyattsville, MD: National Center for Health Statistics. 2011.

⁸ Paulozzi L, Jones C, Mack K, Rudd R; Centers for Disease Control and Prevention (CDC). Vital signs: overdoses of prescription opioid analgesics—United States, 1999-2008. MMWR Morb Mortal Wkly Rep. 2011;60(43):1487-1492.

⁹ Centers for Disease Control and Prevention. WONDER [database]. Atlanta, GA: US Dept of Health and Human Services, Centers for Disease Control and Prevention; 2012. Available at <u>http://wonder.cdc.gov</u>. Accessed January 31, 2013.

¹⁰ Substance Abuse and Mental Health Services Administration. Results from the 2011 National Survey on Drug Use and Health: Detailed tables. In NSDUH Series H-41. Rockville, MD: Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. 2012.

¹¹ Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. *The DAWN Report:*

Highlights of the 2011 Drug Abuse Warning Network (DAWN) Findings on Drug-Related Emergency Department Visits. Rockville, MD. ¹² Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. *Treatment Episode Data Set* (*TEDS*): 2000-2010. National Admissions to Substance Abuse Treatment Services. DASIS Series S-61, HHS Publication No. (SMA) 12-4701. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2012.

¹³ Coalition Against Insurance Fraud. Prescription for peril: how insurance fraud finances theft and abuse of addictive prescription drugs. Washington, DC: Coalition Against Insurance Fraud; 2007. Available at <u>http://www.insurancefraud.org/downloads/drugDiversion.pdf</u>. Accessed October 2012.

¹⁴ Government Accountability Office. Medicaid: Fraud and abuse related to controlled substances identified in selected states. Washington, DC; 2009.

 ¹⁵ Government Accountability Office. Medicare Part D: Instances of questionable access to prescription drugs. Washington, DC; 2011.
¹⁶ Braden JB, Fan MY, Edlund MJ, Martin BC, DeVries A, Sullivan MD. Trends in use of opioids by non-cancer pain type 200-2005 among

Arkansas Medicaid and HealthCore enrollees: Results from the TROUP Study. J Pain. 2008;9(11):1026-1035.
¹⁷ Sullivan MD, Edlund MJ, Fan MY, DeVries A, Braden JB, Martin BC. Trends in use of opioids for non-cancer pain conditions 2000-2005 in commercial and Medicaid insurance plans: The TROUP Study. Pain. 2008;138(2):440-449.

Disease Control and Prevention (CDC) found that opioid analgesic sales increased four-fold between 1999 and 2010, and this was paralleled by an increase in opioid overdose deaths and substance abuse treatment admissions during the same time period.¹⁹ A similar trend was noted for rates of chronic nonmedical use of opioid analgesics, opioid sales, opioid overdose deaths, and substance abuse treatment admissions between 2002 and 2010.²⁰ Other studies have reported that increased opioid prescribing is associated with increased nonmedical use and ED visits.^{21,22}

The problem of prescription drug abuse and overdose is complex and multi-faceted. The prevalence and type of health consequences vary depending on age, gender, race, ethnicity, geography, socioeconomic factors, and diagnosed medical conditions. There are multiple drivers of the problem, and an effective response requires a multi-pronged, targeted, and sustained approach that must also balance the legitimate needs of patients and ensure that access to pain treatment is not unnecessarily restricted. One of the most promising tools available to reverse the prescription drug abuse epidemic and improve patient care is the prescription drug monitoring program (PDMP) – state-run electronic databases used to track the dispensing of controlled prescription drugs to patients.

As PDMP systems have evolved outside the health IT ecosystem, significant barriers to interoperability have resulted. For example, one of the current technical barriers to interoperability is the lack of standard methods to exchange and integrate data from PDMPs to health IT systems, so that it can be used in a timely and convenient manner. Currently, prescribers and dispensers must either interrupt their workflow and log on to a separate system to access the PDMP or write or dispense prescriptions without consulting the PDMP. In response, HHS is working with colleagues in the BJA and the Alliance of States with Prescription Drug Monitoring Programs along with the PDMP Center of Excellence and the PDMP Technical Training and Assistance Center, both located at Brandeis University, and other stakeholders to facilitate the development of recommendations and practices to improve PDMP to health IT connectivity and integration.

PURPOSE OF THE REPORT

This report was developed pursuant to Section 1141 of the Food and Drug Administration Safety and Innovation Act of 2012 (hereafter, referred to as FDASIA).²³

Section 1141 of FDASIA requires the Secretary of HHS to:

¹⁸ Food and Drug Administration. Risk Evaluation and Mitigation Strategies (REMS) for Extended-Release and Long-Acting Opioid Analgesics Briefing Material. 2010. Available at

http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM217510.pdf

¹⁹ Paulozzi LJ, Jones C, Mack K, Rudd R; Centers for Disease Control and Prevention (CDC). Vital signs: overdoses of prescription opioid pain relievers—United States, 1999-2008. MMWR Morb Mortal Wkly Rep. 2011;60(43):1487- 1492.

 ²⁰ Jones CM. Frequency of prescription pain reliever nonmedical use: 2002-2003 and 2009-2010. Arch Intern Med. 2012;172(16):1265-1267.
²¹ Wisniewski AM, Purdy CH, Blondell RD. The epidemiologic association between opioid prescribing, non-medical use, and emergency department visits. J Addict Dis. 2008;27(11):1-11.

²² Braden JB, Russo J, Fan MY, et al. Emergency department visits among recipients of chronic opioid therapy. Arch Intern Med 2010;170:1425-32.

²³ Public Law 112-144. Food and Drug Administration Safety Innovation Act of 2012. Available at: <u>http://www.gpo.gov/fdsys/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf</u>

"submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on enhancing the interoperability of State prescription drug monitoring programs with other technologies and databases used for detecting and reducing fraud, diversion, and abuse of prescription drugs...The report shall include— (A) an assessment of legal, technical, fiscal, privacy, or security challenges that have an impact on interoperability; (B) a discussion of how State prescription drug monitoring programs could increase the production and distribution of unsolicited reports to prescribers and dispensers of prescription drugs, law enforcement officials, and health professional licensing agencies, including the enhancement of such reporting through interoperability with other States and relevant technology and databases; (C) any recommendations for addressing challenges that impact interoperability of State prescription drug monitoring programs in order to reduce fraud, diversion, and abuse of prescription drugs; and (D) an assessment of the extent to which providers use prescription drug management programs in delivering care and preventing prescription drug abuse."

STRUCTURE OF THE REPORT

The report is organized into an Executive Summary, followed by five sections. After the Executive Summary, the *first section* contains the purpose, structure, and methods of the report. The *second section* provides a review of the literature on PDMP effectiveness and an assessment of the extent to which providers use PDMPs. The *third section* highlights the current legal, technical, fiscal, privacy, and security challenges facing PDMP interoperability. The *fourth section* provides a discussion of how state PDMPs could increase production and distribution of unsolicited reports. Finally, the *fifth section* discusses recommendations to address the challenges currently facing PDMP interoperability.

METHODS

The report was developed by the Office of the Assistant Secretary of Health (OASH), the Office of the National Coordinator for Health Information Technology (ONC), the Substance Abuse and Mental Health Services Administration (SAMHSA), and the Centers for Disease Control and Prevention (CDC). Information contained in the report comes from three main sources: 1) Workgroup recommendations and pilot project findings conducted as part of the ONC/SAMHSA *Enhancing Access to PDMPs using Health IT* (the "*Enhancing Access*") project (see additional information below on this project); 2) information provided by the Prescription Drug Monitoring Program Center of Excellence at Brandeis University, the Training and Technical Assistance provider on PDMPs for the BJA that is also located at Brandeis University; and 3) a review of the available literature on PDMPs.

Enhancing Access Project

ONC, in collaboration with SAMHSA, CDC, and the Office of National Drug Control Policy (ONDCP), launched the *Enhancing Access* project in 2011. This 18-month effort was designed to improve timely access to PDMP data by prescribers and dispensers by exploring ways to

integrate PDMP data into existing technologies (e.g., EHRs, HIEs, and pharmacy dispensing systems) which are part of the normal clinical workflow.

As part of the *Enhancing Access* project, work groups comprised of stakeholders from the PDMP and clinical community were convened to identify challenges and recommend solutions to increase timely use of PDMP data. The work groups developed a set of recommendations critical to increasing PDMP use and moving toward greater integration with health IT, such as automating unsolicited reporting, providing real-time access to PDMP data to providers, and integrating access to PDMP data into the clinical workflow. The *Work Group Report* summarizing the findings, recommendations, and work group artifacts was finalized and published on the ONC website in August 2012.²⁴

The *Enhancing Access* project also conducted pilot studies²⁵ designed to test the feasibility of leveraging health IT and information exchange to improve timely access to PDMPs at the point of care and the point of dispensing. The pilots tested linkages between state PDMPs and health IT systems, and the results demonstrated the value that increased access to state PDMP data has at the point of care. For example, pilot participants reported that the new functionality streamlined their clinical workflows, made PDMP data easier to access, and helped improve clinical decision making.

Additionally, the PDMP Standards & Interoperability (S&I) Initiative²⁶ was launched as part of the *Enhancing Access* effort to bring together the PDMP and health IT communities to evaluate data format standards for exchanging patient information between PDMP and provider EHR systems. This S&I initiative sought input on how best to both describe and exchange this data, starting from the PDMP Work Group recommendations released in August 2012.

PRESCRIPTION DRUG MONITORING PROGRAMS

PDMPs are state-based electronic databases that track the dispensing of controlled substances in a state. They are designed to monitor this information for suspected abuse or diversion (i.e., the channeling of the drug into an illegal use) and to give providers critical information regarding their patients' controlled prescription drug history. This information can have a direct impact on reducing a patient's risk for overdose and provides an opportunity to intervene and refer patients for substance use disorder treatment, when necessary.

The first PDMP was created in 1939 in California. In 1992, only 10 operational programs existed. As of June 2013, there are 47 operational programs.²⁷ PDMPs receive data on dispensed controlled substances from pharmacies and in some states from physicians or other providers who dispense controlled substances directly from their office. This information is then compiled in the PDMP database and made available to prescribers, dispensers, and other authorized users

²⁴ http://www.healthit.gov/sites/default/files/work_group_document_integrated_paper_final.pdf

²⁵ http://www.healthit.gov/PDMP

²⁶ The S&I Framework is an open forum and collaborative community, with participation from key stakeholders in the public sector and private industry, <u>http://wiki.siframework.org/Prescription+Drug+Monitoring+Program+Initiative</u>, <u>http://wiki.siframework.org/Prescription+Drug+Monitoring+Program+Initiative</u>.

 ²⁷ Prescription Drug Monitoring Program Training and Technical Assistance Center, Program Status map. Available at http://pdmpassist.org/pdf/pmpprogramstatus2013.pdf.

typically through a Web-based portal. PDMPs are housed in various agencies within states. Currently, 39 state PDMPs are housed in a state health department, single state authority on drugs and alcohol, or board of pharmacy; 7 in a law enforcement or public safety agency; 2 in a professional licensing agency; and 1 in a consumer protection agency.²⁸

PDMPs serve many purposes in addition to their clinical role. They are used to identify providers who are contributing to patient risk and not providing appropriate care, serve as a surveillance tool to monitor dispensing and use trends, assist in investigating drug diversion, and are used to evaluate the impact of state policies and programs designed to reduce abuse and overdose.²⁹ PDMPs were originally designed as passive systems where authorized users were required to solicit information from the PDMP. However, in recent years, many PDMPs have moved towards proactive use of the data via unsolicited reporting.³⁰ Unsolicited reporting, also called proactive reporting, is a product of a PDMP where the prescription information is analyzed by PDMP staff and questionable activities are then reported to appropriate personnel based on thresholds established by the PDMP.³¹ Recipients of these reports include prescribers, pharmacists, investigative agencies, and licensure boards. A 2011 survey conducted by the PDMP Center of Excellence at Brandeis University of 38 states found that 30 state PDMPs were authorized to provide unsolicited reports to medical providers, yet only 16 were actually doing so. A smaller number were also providing such reports to law enforcement agencies (eight) and licensing boards (seven).³²

II. REVIEW OF LITERATURE ON PDMP EFFECTIVENESS AND ASSESSMENT OF THE EXTENT OF PROVIDER UTILIZATION

REVIEW OF THE LITERATURE ON PDMP EFFECTIVENESS

The literature on the impact of PDMPs on the abuse of opioid analgesics is increasing. Research consistently suggests that PDMPs reduce the prescribing of Schedule II opioid analgesics.^{33,34} However, one study indicated there were compensatory increases in the prescribing of Schedule III opioids and no change in total prescribing in states with PDMPs compared to those without one.³⁵ Another study found that states with PDMPs had lower substance abuse treatment rates for opioids from 1997 to 2003 compared to states with PDMPs.³⁶ A more recent analysis based

²⁸ National Alliance for Model State Drug Laws. "Prescription drug abuse, addiction, and diversion: overview of state legislative and policy initiatives.<u>http://www.namsdl.org/IssuesandEvents/NAMSDL%20With%20the%20National%20Safety%20Council%2C%20Part%201%2C%</u> 20State%20PMP%2C%2012%20July%202013.pdf

²⁹ Executive Office of the President of the United States. 2011. "Epidemic: Responding to America's Prescription Drug Abuse Crisis." http://www.whitehouse.gov/sites/default/files/ondcp/policy-and-research/rx_abuse_plan.pdf.

³⁰ Prescription Drug Monitoring Programs: An Assessment of the Evidence for Best Practices. Sept 20, 2012.

http://www.pewhealth.org/uploadedFiles/PHG/Content_Level_Pages/Reports/PDMP%20Update%201-31-2013.pdf ³¹ The Alliance of States with Prescription Monitoring Programs. PMP Acronyms & Terms. <u>http://www.pmpalliance.org/content/pmp-acronyms-terms</u>

 ²² Prescription Drug Monitoring Programs: An Assessment of the Evidence for Best Practices. Sept 20, 2012.
<u>http://www.pewhealth.org/uploadedFiles/PHG/Content_Level_Pages/Reports/PDMP%20Update%201-31-2013.pdf</u>

 ³³ Simeone R, Holland L. Washington, D.C.: U.S. Dept. of Justice, Office of Justice Programs2006 2006. http://www.simeoneassociates.com/simeone3.pdf

³⁴ Curtis LH, Stoddard J, Radeva JI, Hutchison S, Dans PE, Wright A, et al. Geographic variation in the prescription of schedule II opioid analgesics among outpatients in the United States. Health Serv Res. 2006 2006;41:837-55.

³⁵ Paulozzi L, Kilbourne E, Desai H. Prescription drug monitoring programs and death rates from drug overdose. Pain Medicine. 2011;12:747-54. ³⁶ Reisman RM, Shenoy PJ, Atherly AJ, Flowers CR. Prescription opioid usage and abuse relationships: an evaluation of state prescription drug

³⁰ Reisman RM, Shenoy PJ, Atherly AJ, Flowers CR. Prescription opioid usage and abuse relationships: an evaluation of stat monitoring program efficacy. Substance Abuse: Research and Treatment. 2009;3(SART-3-Shenoy-et-al):41.

on data from poison control centers from 2003 to 2009 concluded that PDMPs were associated with lower annual increases in opioid misuse/abuse.³⁷

Comparisons of PDMPs with and without certain features have been made. PDMPs with proactive or unsolicited reporting (sending alerts to providers and/or pharmacists when a patient meets or exceeds a threshold for suspected questionable activity such as doctor shopping) are associated with lower substance abuse treatment rates.³⁸ A recent randomized trial of use of proactive reporting by an insurer (similar to proactive PDMP reporting) suggests such reporting reduces the number of opioid prescribers and pharmacies as well as the number of opioid prescriptions among patients whose providers were proactively sent notifications.³⁹ PDMPs in states that required use of serialized prescription forms for controlled substances were associated with overall lower drug overdose mortality rates.⁴⁰

In a study of PDMP use in an ED, the ED clinicians' review of PDMP data changed their clinical management in 41 percent of cases. Of these cases, 61 percent received fewer or no opioids than the clinician originally planned to prescribe prior to reviewing the PDMP data, and 39 percent received more opioid medication than previously planned because the clinician was able to confirm the patient did not have a recent history of opioid use.⁴¹ Additional studies have also demonstrated the usefulness of PDMPs for surveillance purposes.^{42,43,44}

The non-peer reviewed literature on PDMPs suggests that proactive reporting reduces doctor shopping by increasing awareness among providers about at-risk patients and subsequently changing their prescribing behaviors.^{45,46,47} Surveys indicate that prescribers find the PDMP to be a useful tool and in many cases have altered their prescribing after reviewing a PDMP report.^{48,49,50,51} Public safety officials have endorsed the utility of PDMPs.^{52,53} A 2002 GAO report concluded that PDMPs are a useful tool to reduce drug diversion.⁵⁴

department prescribing behaviors. Ann Emerg Med. 2009 2009;doi:10.1016/j.annemergmed.2009.12.011.

³⁷ Reifler L, Droz D, Bailey J, Schnoll S, Fant R, Dart R, et al. Do prescription monitoring programs impact state trends in opioid abuse/misuse? Pain Medicine. 2012;13(3):355-6.

³⁸ Reisman RM, Shenoy PJ, Atherly AJ, Flowers CR. Prescription opioid usage and abuse relationships: an evaluation of state prescription drug monitoring program efficacy. Substance Abuse: Research and Treatment. 2009;3(SART-3-Shenoy-et-al):41.

³⁹ Gonzalez A, Kolbasovsky A. Impact of a managed controlled-opioid prescription monitoring program on care coordination. Am J Manag Care. 2012;18(9):516-24.

 ⁴⁰ Paulozzi L, Kilbourne E, Desai H. Prescription drug monitoring programs and death rates from drug overdose. Pain Medicine. 2011;12:747-54.
⁴¹ Baehren DF, Marco CA, Droz DE, Sinha S, Callan EM, Akpunonu P. A statewide prescription monitoring program affects emergency

⁴² Katz N, Panas L, Kim M, Audet AD, Bilansky A, Eadie J, et al. Usefulness of prescription monitoring programs for surveillance---analysis of Schedule II opioid prescription data in Massachusetts, 1996--2006. Pharmacoepidemiol Drug Safety. 2010 2010;19:115-23.

⁴³ Wilsey BL, Fishman SM, Gilson AM, Casamalhuapa C, Baxi H, Lin TC, et al. An analysis of the number of multiple prescribers for opioids utilizing data from the California prescription monitoring program. Pharmacepidemiol Drug Saf. 2011;20(12):1262-1268.

⁴⁴ Wilsey BL, Fishman SM, Gilson AM, Casamalhuapa C, Baxi H, Zhang H, et al. Profiling multiple provider prescribing of opioids, benzodiazepines, stimulants, and anorectics. Drug Alcohol Depend. 2010;112:99-106.

⁴⁵ PDMP Center of Excellence, "Trends in Wyoming PMP prescription history reporting: evidence for a decrease in doctor shopping?" 2010, http://www.pmpexcellence.org/sites/all/pdfs/NFF_wyoming_rev_11_16_10.pdf

⁴⁶ PDMP Center of Excellence, "Nevada's Proactive PMP: The Impact of Unsolicited Reports" October, 2011 http://www.pmpexcellence.org/sites/all/pdfs/nevada_nff_10_26_11.pdf

⁴⁷ P Kreiner of the PDMP Center of Excellence communication to MA PMP regarding preliminary analysis of baseline survey.

⁴⁸ Alliance of States with Prescription Monitoring Programs, "An Assessment of State Prescription Monitoring Program Effectiveness and Results" Version 1, 11.30.07, http://pmpexcellence.org/pdfs/alliance_pmp_rpt2_1107.pdf

⁴⁹ Kentucky Cabinet for Health and Family Services and Kentucky Injury Prevention and Research Center, 2010 KASPER Satisfaction Survey, http://chfs.ky.gov/NR/rdonlyres/BDC0DFC9-924B-4F11-A10A-5EB17933FDDB/0/2010KASPERSatisfactionSurveyExecutiveSummary.pdf

⁵⁰ Lambert D. Impact evaluation of Maine's prescription drug monitoring program. Muskie School of Public Service, University of Southern Maine: Portland, Maine, March, 2007.

⁵¹ Communication from LA PMP to PDMP Center of Excellence.

⁵² GAO Report GAO-02-634: "Prescription drugs. State monitoring programs provide useful tool to reduce diversion," 2002, http://www.gao.gov/new.items/d02634.pdf

Based on a review of both peer-reviewed and non-peer-reviewed studies, the Prescription Drug Monitoring Program Center of Excellence at Brandeis University concluded that PDMPs should implement best practices such as interoperability with other states, real-time data reporting and access, proactive or unsolicited reporting, and accessibility for all healthcare providers, licensure boards, and law enforcement (in appropriate circumstances, e.g., active investigation or subpoena).⁵⁵ Robust evaluations of PDMPs to identify the most effective aspects of PDMPs are needed. Researchers should account for differences among PDMPs as well as other co-occurring interventions in any future analyses.

PROVIDER USE OF PDMPs

Currently, there is no central resource to track provider use of PDMPs in every state. A recent report from the Prescription Drug Monitoring Program Center of Excellence at Brandeis University provides important insight into this issue.⁵⁶ In the report, 28 operational state PDMPs that received funding from the BJA's Harold Rogers Prescription Drug Monitoring Program grant program provided information on a number of PDMP metrics, including provider registration and use of PDMPs from January 2009 to June 2012. In general, the report found that provider use of PDMPs has increased in recent years, although use varies significantly by state. It is also worth noting that several states (e.g., New York and Kentucky) have now passed laws mandating registration and/or use of the state PDMP.

Prescriber registration rates, defined as the proportion of prescribers who issued at least one controlled substance prescription in the prior three months who had registered to use the PDMP. ranged from 1 percent (in newly operational states) to 82 percent (Figure 1). The median registration rate was 35 percent. The majority of states examined in the report have experienced a steady increase in registration rates, which appeared to continue to increase for four or more years after implementation of Web-based access to the PDMP.

In addition to information on prescriber registration, rates of solicited reports provide insight into prescriber use of PDMPs. Solicited reports are those reports requested by individual prescribers for a specific patient. Of the 22 grantee states where trend data were available, there was substantial growth in the number of solicited reports requested by prescribers. On average, there was a 400 percent increase in solicited reports in these states among prescribers between 2009 and 2012 (Figure 2). Among the 21 states providing data for January – June 2012, a total of over 4.1 million solicited reports were sent to prescribers.

⁵³ PDMP Center of Excellence. Perspective from Kentucky: using PMP data in drug diversion investigations. May, 2011.

http://www.pmpexcellence.org/sites/all/pdfs/NFF_kentucky_5_17_11_c.pdf ⁵⁴ U.S. General Accounting Office. Prescription Drugs: State Monitoring Programs Provide Useful Tool to Reduce Diversion. Washington, DC: U.S. General Accounting Office; 2002. Report No. GAO-02-634.

⁵⁵ Prescription Drug Monitoring Program Center of Excellence, Brandeis University. An assessment of the evidence for best practices. 2012. Available at http://www.pdmpexcellence.org/sites/all/pdfs/Brandeis PDMP Report final.pdf.

⁵⁶ Prescription Drug Monitoring Program Center of Excellence, Brandeis University. Bureau of Justice Assistance: Prescription Drug Monitoring Program Performance Measures Report: January 2009 through June 2012. 2013.





Figure 2. Percent change in number of solicited reports in select states from January - December 2009 to July 2011 - June 2012*



*Ratio of July 2011-June 2012 to January-December 2009. When 2009 or July 2011-June 2012 reports were missing, the earliest and/or latest available 12 months of reports were used to compute percent change.

Although PDMP use by providers has been increasing in recent years, especially among systems that have upgraded to provide Web-based access and states that have promoted use of the PDMP, there remains significant underutilization of this important clinical tool in many states. Efforts such as integration into clinical workflow, establishing interoperability, and policies requiring mandatory registration and/or use show promise to further increase utilization of PDMPs by providers.

III. ASSESSMENT OF LEGAL, TECHNICAL, FISCAL, PRIVACY, OR SECURITY CHALLENGES THAT HAVE AN IMPACT ON INTEROPERABILITY WITH OTHER TECHNOLOGIES AND DATABASES USED FOR DETECTING AND REDUCING FRAUD, DIVERSION, AND ABUSE OF PRESCRIPTION DRUGS

LEGAL AND POLICY CHALLENGES

Many of the legal and policy challenges facing PDMPs stem from differences in the state statutes that authorize PDMPs. In some states, users that may benefit the greatest from access to PDMPs do not have authority to access this data. For example, in Pennsylvania, prescribers and dispensers are not granted access to the PDMP. In many states, authorized users cannot delegate access to the PDMP to their assistants due to state law or organizational policy. In addition, organizational policy can serve as a barrier to PDMP use for authorized users. For example, some pharmacies have instituted policies that prevent their employees from accessing PDMP data in the pharmacy. PDMP data can give pharmacists a more complete picture about an individual's medication history because it is inclusive of multiple pharmacy networks and smaller stand-alone pharmacies.

The time requirement for reporting prescription data from the pharmacy to the PDMP is also determined in statute. Data transmissions generally occur weekly, bi-weekly, or in a small number of states, monthly. This variation in reporting frequency from state to state can affect the consistency of data reported across state lines. Moreover, the reporting period for PDMP data directly affects the currency of the data. Thus, less frequently reported results lead to limited information being available to providers, contributing to provider perception that the information in the PDMP is not useful, and ultimately affects their interest in utilizing the PDMP. In addition, there is currently no law or policy that specifies a standard set of data elements to capture in all PDMP reports. This lack of standardization makes integration with EHRs and other health information technologies challenging and potentially creates the need for multiple standards and mapping across different systems that have asymmetric data requirements.

Another legal/policy challenge is related to use of third-parties to transmit data between states. Data sharing among state PDMPs via third-party intermediaries is still a nascent and growing practice that requires significant coordination, cooperation, and standardization. This new area poses several legal and policy challenges for states. There are a number of legal hurdles to forming data sharing agreements with other states and the various entities responsible for transmitting data across state lines. Specific issues include maintaining patient privacy and authenticating that requestors of the data have the authority to access the data.

FEDERAL HEALTH CARE SYSTEM CHALLENGES

Prescribers and dispensers who practice within federal health care systems such as the Department of Veterans Affairs (VA), Department of Defense (DoD), and Indian Health Services (IHS), face a unique set of policy challenges with respect to PDMPs. Differences in state authorizing and federal statutes have contributed to difficulties in including prescription data in state PDMPs and sharing PDMP data with federal prescribers and dispensers who practice in these agencies. However, efforts are underway to address some of these barriers. At this time, IHS has agreed to memoranda of understanding with 17 states, allowing their dispensers to submit dispensing data to the PDMP and for their prescribers and dispensers to access PDMP data.⁵⁷ The VA recently published an Interim Final Rule that allows VA sites to contribute data to certain state PDMPs. ⁵⁸ Individual VA sites are currently testing software designed to submit data to certain state PDMPs. Since states are not using a single universal version of data transaction software, the VA must customize to each state's software requirements prior to implementation. Additionally, federal sites must account for all disclosures to state PDMPs. This poses another technical challenge as software and infrastructure are needed to address this requirement.

Single state licensure is another policy challenge further limiting the use of PDMPs in federal health care systems. For example, federal employees are only required to hold a license in one state and the state in which they hold the license may not be the state in which they practice. If the federal employee is practicing in a state that restricts PDMP access to only those prescribers and dispensers licensed in that state, a significant patient safety issue may exist if the federal employee cannot query the PDMP prior to prescribing or dispensing.

TECHNICAL CHALLENGES

There is a lack of common technical standards, vocabularies, and system-level access controls to allow PDMPs to share computable information with the EHR and pharmacy systems that prescribers and dispensers use to support automated queries and reporting. No formal standards or specifications exist for sharing a PDMP report electronically with a prescriber or dispenser. In addition, some states are not yet equipped to initiate interstate exchange of data as they are still in the implementation/enhancement phase of establishing their PDMPs.⁵⁹ In addition to data transmission standard challenges, there are currently multiple options available to PDMPs for sharing data with other states, some of which include the use of data sharing intermediaries, or hubs. Specifically, three interstate PDMP data-sharing exchanges are in operation today: the Prescription Monitoring Program Interconnect (PMPi), RxCheck, and RxSentry. These solutions are converging on existing common standards and conformance to the PMIX National Architecture,⁶⁰ which will enable nationwide query and reporting capability. However, these standards were created primarily to support sharing among PDMP systems and the incorporation

⁵⁷ Indian Health Services, "Indian Health Services Status Update" 2013, http://www.pdmpassist.org/pdf/PPTs/North_2013/3_IHS_Update_Gunderson.pdf

 ⁵⁸ Dept. of Veterans Affairs, "Disclosures to Participate in State Prescription Drug Monitoring Programs", 78 Fed. Reg. 9589, February 11, 2013.
⁵⁹ PDMP Center of Excellence, "Prescription Drug Monitoring Programs: An Assessment of the Evidence for Best Practices" 2012,

http://www.pdmpexcellence.org/sites/all/pdfs/Brandeis_PDMP_Report_final.pdf

⁶⁰ PDMP Training & Technical Assistance Center: Brandeis University, "Prescription Drug Monitoring Program Information Architecture" http://www.pdmpassist.org/content/prescription-drug-monitoring-information-architecture-pmix

of additional user groups such as dispensers and prescribers typically requires modification or enhancement to the process and specifications.

The final technical challenge deals with the current manner in which providers and pharmacists access PDMP data - usually by leaving their normal workflow and accessing a standalone Webbased portal. This inefficient process discourages some providers from accessing this data. For PDMP data to maximally impact provider and pharmacist clinical decision making, they need to have relevant PDMP information when interacting with patients. Prescribers and dispensers have limited time to retrieve and view this information, and they want to obtain it at the right point in the clinical workflow to help inform complex, controlled-substance prescribing decisions. The use of standalone Web portals that are not integrated into clinical work via EHRs or pharmacy systems is a barrier to maximal use of PDMPs.

Pilots integrating PDMPs into EHR and pharmacy systems have shown great benefits for prescribers and dispensers, such as streamlined clinical workflows, timely access to PDMP data, and improved clinical decision making. The success of the pilots and the growing concerns over the rise in prescription drug misuse and overdose, prompted the Health IT Policy Committee (HITPC) – a federal advisory committee that advises ONC on federal health IT policy issues, including how to define the "meaningful use" of EHRs for the purposes of the Medicare and Medicaid EHR Incentive Programs - to explore opportunities to increase the clinical adoption of PDMPs. The HITPC sought public comment on whether EHR certification could enable and support streamlined access to PDMP data. Feedback from the public indicated general support for a new EHR certification criterion, with many commenters stating that streamlined PDMP access was a critical tool for patient care and clinical decision making. The HITPC and ONC will continue to explore the possibility of including such a requirement for certification in future rulemaking.

FISCAL CHALLENGES

Many PDMPs face significant fiscal challenges, and insufficient funding is often cited as a barrier to implementing best practices.⁶¹ PDMP expenses involve implementation, maintenance, and enhancement costs which may or may not include the following: hardware (e.g., servers); software to run the PDMP database and ensure information security; connectivity to submit and access data; PDMP administrative and technical assistance staff; and overhead fees.⁶²

Consistent funding is needed to enable a stable platform for PDMPs to operate, implement new technologies, and maintain sufficient staffing levels. Moreover, adequate funding facilitates data access for authorized users, implementation of interoperability between PDMPs, and effective analysis of prescription information.⁶³

State PDMPs are funded from a variety of sources (i.e., state general fund, prescriber and pharmacy licensing fees, state controlled substance registration fees, health insurers' fees, directsupport organizations, state or federal grants). The state's PDMP authorizing statute usually

⁶¹ PDMP Center of Excellence, "Prescription Drug Monitoring Programs: An Assessment of the Evidence for Best Practices" 2012, http://www.pdmpexcellence.org/sites/all/pdfs/Brandeis_PDMP_Report_final.pdf
⁶² Research Service, "Prescription Drug Monitoring Programs" 2013, <u>http://www.fas.org/sgp/crs/misc/R42593.pdf</u>

⁶³ PDMP Center of Excellence, "Prescription Drug Monitoring Programs: An Assessment of the Evidence for Best Practices" 2012, http://www.pdmpexcellence.org/sites/all/pdfs/Brandeis PDMP Report final.pdf

defines how its PDMP will be funded.⁶⁴ Funding continues to pose a significant challenge to many state PDMPs. Some states are prohibited from receiving funds from certain entities or leveraging fees such as licensure fees to support the PDMP. BJA recently released a technical assistance document on funding options for state PDMPs developed by the Prescription Drug Monitoring Program Training and Technical Assistance Center.⁶⁵ This document provides helpful tips to states on ways that other states have supported their PDMP's funding.

PRIVACY AND SECURITY CHALLENGES

PDMP interoperability poses new challenges for patient privacy and data security because, in some cases, individuals and entities other than the providers and pharmacists who created the patient data are given access to it. In addition, the need to accurately identify and verify the credentials of those accessing the PDMP data across state lines requires appropriately defined and mutually agreeable administrative and technical safeguards to ensure patient health information is protected when it is shared outside of a state's PDMP.

PDMP reports contain individually identifiable health information (IIHI) that should be safeguarded in accordance with established policies and procedures protecting the privacy and security of the information. Information in the PDMPs must be stored and protected with administrative, technical, and physical safeguards to ensure that the confidentiality, integrity, and availability of patient prescription drug data is maintained. For example, PDMP administrators should implement access controls to ensure that unauthorized persons cannot access IIHI that is maintained in the PDMP's electronic database. States should ensure that uses and disclosures of PDMP data, and the safeguards for securing such data, are consistent with the requirements of applicable federal and state laws. PDMPs should also consider adopting policies that conform to the well-established fair information practice principles.⁶⁶ Additionally, to prevent misuse of patient and prescriber information, states should consider providing appropriate training for those authorized to access the PDMP data on maintaining the confidentiality of prescription records.

IV. DISCUSSION OF CURRENT CHALLENGES FOR STATE PDMPS TO INCREASE PRODUCTION AND DISTRIBUTION OF UNSOLICITED REPORTS

BACKGROUND ON UNSOLICITED REPORTS

Unsolicited reporting, also known as proactive reporting, is a product of a PDMP where the prescription information is analyzed by PDMP staff and questionable activities are then reported to appropriate personnel based on thresholds established by the PDMP.⁶⁷ Recipients of these "proactive reports" sent by state PDMPs include prescribers, pharmacists, investigative agencies, and licensure boards.

 ⁶⁴ Congressional Research Service, "Prescription Drug Monitoring Programs" 2013, <u>http://www.fas.org/sgp/crs/misc/R42593.pdf</u>
⁶⁵ PDMP Training and Technical Assistance Center, "Funding Options for Prescription Drug Monitoring Programs" 2013, <u>http://www.pdmpassist.org/pdf/PDMP_Funding_Options_TAG.pdf</u>

⁶⁶ Office of the National Coordinator for Health Information Technology, "Nationwide Privacy and Security Framework For Electronic Exchange of Individually Identifiable Health Information." December 15, 2008. <u>http://www.healthit.gov/sites/default/files/nationwide-ps-framework-5.pdf</u>

⁶⁷ The Alliance of States with Prescription Monitoring Programs. PMP Acronyms & Terms. <u>http://www.pmpalliance.org/content/pmp-acronyms-terms</u>

Unsolicited reports can serve several functions such as the following: to inform prescribers and pharmacists that patients may be abusing or diverting controlled substances; to help prescribers make better decisions about prescribing controlled substances, thus improving patient care; to provide an opportunity to intervene and refer patients for substance use disorder treatment when appropriate; and to inform potential end users about the PDMP and its value. Reports sent to investigative agencies and licensure boards can assist in targeting drug diversion reduction efforts and ensuring safe, effective, and legal practice by healthcare professionals.

Unsolicited patient reports are triggered by a predefined set of parameters in the PDMP systems to indicate that a patient has exceeded some threshold for obtaining too many prescriptions within a specific time-frame. Historically, unsolicited reports were sent to providers via fax or postal mail, which were often not timely enough to inform the patient-provider interaction. Recent pilot projects which leveraged health IT to increase efficiency of unsolicited reporting have demonstrated great utility.

The Enhancing Access to PDMPs using Health IT project led by ONC and SAMHSA conducted a pilot in Kansas which directly addressed some of the efficiency issues through the use of health IT. This pilot automated the unsolicited reporting process for the PDMP by converting it to an electronic process so that PDMP data can be made more readily available to providers. The pilot used an open source intermediary that manipulated a large electronic document containing all of the alert letters generated for providers based on the thresholds set for that state. In Kansas, the PDMP administrator historically printed and mailed the document in hard copy – a time consuming and cumbersome process resulting in a large burden on the small PDMP staff. Technology now converts the document into individual electronic files with associated email addresses. An intermediary then used DIRECT⁶⁸ to securely send these files to their intended recipient directly in their EHR system, which subsequently placed the unsolicited reports into the physicians' clinical workflow.⁶⁹ Another pilot conducted in Indiana demonstrated how providing unsolicited reports for "at-risk" patients through secure electronic messaging could improve prescriber awareness of potential prescription drug abuse. The Indiana PDMP provided weekly "person of interest (POI)" alerts to prescribers at ambulatory clinics based on a defined "at-risk" threshold of prescription drugs obtained by a given patient. Prior to the pilot, POI alerts were sent to prescribers via regular email or postal mail if one of their patients exceeded a given threshold. The new design enabled patient information to be shared in a more secure and timely manner.⁷⁰

⁶⁸ The Direct Project was created to specify a simple, secure, scalable, standards-based way for participants to send authenticated, encrypted health information directly to known, trusted recipients over the Internet. Source: <u>http://www.healthit.gov/policy-researchers-</u> implementers/direct-project

⁶⁹ Enhancing Access to PDMPs using Health IT, "Connecting for Impact: Integrating Health IT to PDMPs to Improve Patient Care"2013. http://www.healthit.gov/PDMP

⁷⁰ Enhancing Access to PDMPs using Health IT: "Using Direct Messaging to Send Secure, Unsolicited Patient-at-Risk Alerts" 2012. http://www.healthit.gov/sites/default/files/indiana-2_pdmp_pilot_study.pdf

CURRENT CHALLENGES FOR UNSOLICITED REPORTS

Legislative Restrictions on Unsolicited Reports

To date, most states are authorized to send unsolicited reports to either prescribers, pharmacists, licensing boards, law enforcement, or a combination of these entities.⁷¹ Some, but not all, PDMPs are authorized to send unsolicited reports to prescribers and pharmacists, and a smaller number are authorized to send unsolicited reports to law enforcement investigators and licensing boards. While these states are authorized to send unsolicited reports, available information suggests that many are not doing so.

A 2011 survey of 38 states conducted by the PDMP Center of Excellence at Brandeis University found that 30 state PDMPs were authorized to provide unsolicited reports to medical providers, yet only 16 were actually doing so. A smaller number were also providing such reports to law enforcement agencies (eight) and licensing boards (seven).⁷²

Data Transaction Standards

Currently, there are a variety of methods to define and deliver unsolicited reports such as through fax or postal mail. This leads to significant data access and interoperability issues for interstate information exchange. The many variations in how unsolicited reports are sent reduce interoperability and slow the development of effective interstate data sharing. Software developers need clear technical guidance on how to capture, store, transmit, and present data to the diverse set of stakeholders in a user-friendly and meaningful format as well as on how to implement systems that can effectively access the desired data.

Unsolicited Reporting Thresholds

Thresholds used to generate unsolicited reports are typically set by pharmacy boards or other state agencies and vary widely among states. There are currently no standard criteria for identifying patients on whom unsolicited reports should be sent. In some cases, these thresholds correspond to funding reporting metrics (e.g., the BJA's required performance measures for states receiving funding under the Harold Rogers PDMP grant program), but frequently they represent the judgment of specific state authorities.

In other cases, thresholds used reflect the PDMP's limited resources to generate such reports. That is, thresholds are set high to identify persons most likely involved in doctor shopping and thereby minimizing the number of unsolicited reports that would be generated.⁷³ Some studies suggest the utility of including factors other than the number of prescribers and the number of pharmacies in a specified period as criteria for identifying questionable activity or likely doctor

⁷¹ National Alliance for Model State Drug Laws. "Unsolicited PMP Reports/Info to Prescribers, Pharmacists, Law Enforcement and Licensing Entities". 2012, http://www.namsdl.org/library/8574600F-19B9-E1C5-311C406CE9768073/

⁷² Prescription Drug Monitoring Programs: An Assessment of the Evidence for Best Practices. Sept 20, 2012.

http://www.pewhealth.org/uploadedFiles/PHG/Content_Level_Pages/Reports/PDMP%20Update%201-31-2013.pdf

⁷³ Prescription Drug Monitoring Programs: An Assessment of the Evidence for Best Practices. Sept 20, 2012. http://www.pewhealth.org/uploadedFiles/PHG/Content_Level_Pages/Reports/PDMP%20Update%201-31-2013.pdf

shopping.⁷⁴ No studies have yet evaluated the effects of using different criteria within the same state. Additional research is needed to examine the current criteria used to trigger unsolicited reports and validate the criteria for questionable activity.

Automation of Unsolicited Reports and Integration into Clinical Workflow

Findings suggest that unsolicited reports can serve important functions in providing new information to providers to guide their clinical practice and investigative and regulatory agencies to identify criminal or inappropriate prescribing and dispensing. The quality and usefulness of unsolicited reports greatly depends on their timeliness and accessibility to providers. However, in many cases the current use of unsolicited reports is not conducive to prescriber and pharmacists' clinical workflow, making them less valuable for clinical decision making.

These reports are typically unanticipated by the recipients and are currently delivered through a variety of methods, including fax or postal mail, which typically do not occur frequently enough to support clinical decision making. Generation and delivery of these reports can be resource intensive and time-consuming, resulting in the information being received days, weeks, or even months after the patient encounter, and the prescription called into question by the report has already been dispensed.

A number of PDMPs are moving to electronic alerts – e-mails with a code or patient ID, which, when clicked on produces a report from the PDMP. Such alerts greatly reduce resources needed by the PDMP for unsolicited reporting, but still require the recipient to log on to the PDMP and retrieve the report.

V. RECOMMENDATIONS TO ADDRESS CHALLENGES THAT IMPACT INTEROPERABILITY OF STATE PRESCRIPTION DRUG MONITORING PROGRAMS IN ORDER TO REDUCE FRAUD, DIVERSION, AND ABUSE OF PRESCRIPTION DRUGS

As highlighted throughout the document, PDMPs face several challenges that currently limit interoperability and the maximum utility of PDMPs. The primary challenges center around two main areas: 1) legal and policy challenges; and 2) technical challenges. Addressing these challenges can greatly enhance the ability of states to establish interoperability and leverage PDMPs to reduce fraud, diversion, and abuse of prescription drugs. The following set of recommendations was developed to address the challenges identified throughout this report. Many of the recommendations are consistent with current PDMP best practices such as those identified in the Prescription Drug Monitoring Program Center of Excellence (COE), Brandeis University white paper on PDMP best practices released in September 2012. This white paper examined the current evidence for PDMP best practices and proposes research on how PDMPs can continue to increase their effectiveness.

⁷⁴ Prescription Drug Monitoring Programs: An Assessment of the Evidence for Best Practices. Sept 20, 2012. http://www.pewhealth.org/uploadedFiles/PHG/Content_Level_Pages/Reports/PDMP%20Update%201-31-2013.pdf

Address legal and policy challenges

- States should ensure that PDMPs do not restrict access to PDMP data for health care providers.
- States should consider implementing laws and policies to increase the use of PDMPs by prescribers, dispensers, and other authorized health care providers, such as requirements for prescribers and dispensers to register for the state PDMP.
- States should consider having authorizing legislation to send unsolicited reports to providers, licensing boards, regulatory and law enforcement agencies, and public and private insurers and pharmacy benefit managers.
- States should enable real-time access to PDMP data by health care providers. This information would be reported to the PDMP minutes after a prescription is filled and dispensed from the pharmacy.
- States, third-party intermediaries, and interstate data sharing hubs should identify the general scope of legal instruments that will facilitate the exchange of PDMP data via third-party intermediaries, and make available standardized templates for states to use on a shared PDMP resource website.
- States should ensure that PDMP laws, regulations, policies, and business agreements are developed in such a manner to mitigate privacy and security concerns.

Harness advances in health information technology (health IT)

- PDMPs should apply the latest advances in health IT to incorporate PDMP data directly into the workflow of prescribers and dispensers to enable timely access to their patients' controlled prescription drug history information at the point of care. Integrating with health IT makes PDMP data timelier and more easily accessible which encourages routine checking of the PDMP.
- HHS, working with the Bureau of Justice Assistance (BJA) within the Department of Justice (DOJ), should establish an initiative under the Standards & Interoperability (S&I) Framework to assess the current PDMP infrastructure (including interfaces, data formats, data transport and data security protocols) in use or available for use in connecting PDMPs to health information technology systems (e.g., electronic health records (EHRs) and health information exchanges (HIEs) and establishing interoperability.
- State PDMPs should implement interoperability standards that best support the information's use upon its exchange.
 - For information exchange from PDMPs to providers or pharmacists, states should work with relevant federal agencies and health care provider groups to harmonize and adopt standards best equipped to convey prescription information to meet their various clinical needs. For providers, this could include the use of PDMP data within EHRs for clinical purposes (e.g., to trigger clinical decision support, update medication history, or inform a health care provider's treatment plan). For pharmacists, this could include the use of PDMP data in a pharmacy system to inform pharmacists about previously dispensed prescriptions.
 - For information exchange between PDMPs (or government-to-government transactions, such as state-to-state notifications), states should continue to follow

the National Information Exchange Model (NIEM) PDMP specification and the Prescription Monitoring Program Information Exchange (PMIX) Architecture supported by the Alliance of States with Prescription Monitoring Programs.

- States should also be encouraged to utilize existing infrastructure to support data exchange with both private sector and government partners.⁷⁵
- State PDMPs should implement single sign-on (SSO) capabilities that enable prescribers and dispensers to automatically access the PDMP by signing in to their health IT systems (e.g., EHRs), taking into account the level of trust in the credentialing and authentication process for the health IT systems.
- State PDMPs should automate the process of generating alert to notify prescribers and dispensers of possible doctor shoppers. Automation helps to minimize costs and staff resources, while increasing the rate of notification. Health IT is key to automating this process and enabling PDMP data to be more readily available at the point of care.

PDMPs are one of the most promising tools available to help reduce prescription drug abuse and overdose. The recommendations contained in this document outline the steps that need to be taken to address the identified challenges and improve the interoperability of PDMPs. Implementing these recommendations will greatly enhance the utility of PDMPs to improve the legitimate use of controlled substances, while mitigating the prescription drug abuse epidemic.

⁷⁵ National standards adopted for meaningful use and the PDMP initiative under the Standards and Interoperability (S&I) Framework from the SAMHSA/ONC Enhancing Access to PDMP Project can be referenced for more detailed information on this exchange use case (<u>http://wiki.siframework.org/Prescription+Drug+Monitoring+Program+Initiative</u>).