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Prescription Drug Monitoring Programs

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Summary

In the midst of national concern over the opioid epidemic, federal and state officials are paying greater attention to the manner in which opioids are prescribed. Nearly all prescription drugs involved in overdoses are originally prescribed by a physician (rather than, for example, being stolen from pharmacies). Thus, attention has been directed toward better understanding how opioids are being prescribed and preventing the diversion of prescription drugs after the prescriptions are dispensed.

Prescription drug monitoring programs (PDMPs) maintain statewide electronic databases of prescriptions dispensed for controlled substances (i.e., prescription drugs with a potential for abuse that are subject to stricter government regulation). Information collected by PDMPs may be used to educate and inform prescribers, pharmacists, and the public; identify or prevent drug abuse and diversion; facilitate the identification of prescription drug-addicted individuals and enable intervention and treatment; outline drug use and abuse trends to inform public health initiatives; or educate individuals about prescription drug use, abuse, diversion, and PDMPs themselves.

As of February 2018, 50 states, the District of Columbia, and two territories (Guam and Puerto Rico) had operational PDMPs within their borders.

How PDMPs are organized and operated varies among states. Each state determines which agency houses the PDMP; which controlled substances must be reported; which types of dispensers (e.g., pharmacies) are required to submit data; how often data are collected; who may access information in the PDMP database (e.g., prescribers, dispensers, or law enforcement); the circumstances under which the information may (or must) be accessed; and what enforcement mechanisms are in place for noncompliance.

PDMP costs may vary widely, with startup costs that can range as high as $450,000 to over $1.5 million and annual operating costs ranging from $125,000 to nearly $1.0 million. States finance PDMPs using monies from a variety of sources including the state general fund, prescriber and pharmacy licensing fees, state controlled substance registration fees, health insurers' fees, direct-support organizations, state grants, and/or federal grants.

The federal government supports state PDMPs through programs at the Departments of Justice (DOJ) and Health and Human Services (HHS). Since FY2002, DOJ has administered the Harold Rogers Prescription Drug Monitoring Program, and in FY2017, DOJ incorporated this grant program into the new Comprehensive Opioid Abuse Program. HHS programs include National All Schedules Prescription Electronic Reporting (NASPER), State Demonstration Grants for Comprehensive Opioid Abuse Response, Opioid Prevention in States grants, State Targeted Response to the Opioid Crisis Grants, and various pilots and initiatives under the Office of the National Coordinator for Health Information Technology (ONC). Of note, NASPER last received appropriations (of $2.0 million) in FY2010.

State PDMPs vary with respect to whether or how information contained in the database is shared with other states. Federal policymakers have repeatedly emphasized the importance of enhancing interstate information sharing and the interoperability of state PDMPs. In 2011, the Obama Administration included efforts to increase interstate data sharing in its action plan to counter prescription drug abuse. In 2017, a presidential commission recommended, among other things, that the Trump Administration support legislation to require DOJ to fund a "data-sharing hub" and require states receiving federal grant funds to share PDMP data.

The available evidence suggests that PDMPs can be effective in reducing the time required for drug diversion investigations, changing prescribing behavior, reducing "doctor shopping," and reducing prescription drug abuse. Assessments of effectiveness should also take into consideration potential unintended consequences of PDMPs, such as limiting access to medications for legitimate use or pushing drug diversion activities over the border into a neighboring state. Experts suggest that PDMP effectiveness might be improved by increasing the timeliness, completeness, consistency, and accessibility of the data.

Policy issues that might come before Congress include the role of state PDMPs in federal efforts to combat prescription drug abuse, the role of the federal government in interstate data-sharing and interoperability, and the possible link between the crackdown on prescription drug abuse and the uptick in illicit opioid (e.g., heroin and illicit fentanyl) abuse. While establishment and enhancement of PDMPs enjoy relatively broad support, stakeholders express concerns about health care versus law enforcement uses of PDMP data (particularly with regard to protection of personally identifiable health information).

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Introduction

In the midst of national concern over the opioid epidemic and the large number of prescription opioid overdose deaths in the United States, federal and state officials are paying greater attention to the manner in which opioids are prescribed.[1] Prescription opioid-related overdose deaths dramatically increased from 1999 to 2010 in the United States in conjunction with increased opioid prescribing, and overdose deaths involving prescription opioids were five times higher in 2016 than in 1999.[2] Over the last year, the Trump Administration, Congress, state governments, and the private sector have all taken action to address prescription drug abuse. Initiatives range from state and private health care initiatives, such as limiting the number of pills in a prescription, to major legislation, such as the Comprehensive Addiction and Recovery Act (CARA; P.L. 114-198), which included many provisions to address prescription drug abuse.[3]

In 2016, an estimated 11.8 million individuals aged 12 or older (4.4% of this population) misused[4] opioids in the past year, including 11.5 million pain reliever misusers and 948,000

[1] Centers for Disease Control and Prevention, *Understanding the Epidemic*, August 2017, http://www.cdc.gov/drugoverdose/epidemic/index.html; The President's Commission on Combating Drug Addiction and the Opioid Crisis, *Final Report*, November 1, 2017, https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf; and The White House, *FACT SHEET: Obama Administration Announces Public and Private Sector Efforts to Address Prescription Drug Abuse and Heroin Use*, https://obamawhitehouse.archives.gov/the-press-office/2015/10/21/fact-sheet-obama-administration-announces-public-and-private-sector (hereinafter, *FACT SHEET: Obama Administration Announces Public and Private Sector Efforts to Address Prescription Drug Abuse and Heroin Use*). Prescription drugs of abuse are often divided into the categories of *pain relievers* (e.g., oxycodone), central nervous system *stimulants* (e.g., amphetamine), and central nervous system *depressants* (e.g., benzodiazepines). Pain relievers that are subject to abuse may be called *narcotics* or *opioids*. Central nervous system depressants may be further divided into *tranquilizers* (also called *anxiolytics*, used to reduce anxiety) and *sedatives* (also called *sedative-hypnotics*, used to induce sleep). The term *psychotherapeutics* is sometimes used to capture all of these categories.

[2] Gera P. Guy Jr., Kun Zhang, Michele K. Bohm et al., Centers for Disease Control and Prevention (CDC), *Vital Signs: Changes in Opioid Prescribing in the United States, 2006-2015*, Morbidity and Mortality Weekly Report (MMWR), July 7, 2017, https://www.cdc.gov/mmwr/volumes/66/wr/mm6626a4.htm; and CDC, *Prescription Opioid Overdose Data*, https://www.cdc.gov/drugoverdose/data/overdose.html.

[3] CVSHealth, "CVS Health Fighting National Opioid Abuse Epidemic With Enterprise Initiatives," press release, September 21, 2017, https://cvshealth.com/newsroom/press-releases/cvs-health-fighting-national-opioid-abuse-epidemic-with-enterprise-initiatives; CVS Caremark, *CVS Caremark® Opioid Quantity Limits Pharmacy Reference Guide*, 2018, https://www.caremark.com/portal/asset/Opioid_Reference_Guide.pdf; Walmart, *Walmart Introduces Additional Measures to Help Curb Opioid Abuse and Misuse*, May 7, 2018, https://news.walmart.com/2018/05/07/walmart-introduces-additional-measures-to-help-curb-opioid-abuse-and-misuse; and the Comprehensive Addiction and Recovery Act of 2016 (CARA; P.L. 114-198). For a review of state initiatives, see National Conference of State Legislatures, *Prevention of Prescription Drug Overdose and Abuse*, May 23, 2016, http://www.ncsl.org/research/health/prevention-of-prescription-drug-overdose-and-abuse.aspx.

[4] The National Survey on Drug Use and Mental Health (NSDUH) defines *misuse* as use in any way not directed by a doctor, including use without a prescription of one's own; use in greater amounts, more often, or longer than told to take a drug; or use in any other way not directed by a doctor. Misuse of over-the-counter drugs is not included. Terms such as *misuse*, *abuse*, *dependence*, and *addiction* are often used interchangeably with nonmedical use, although each term may have its own definition within a specific context.

heroin users.[5] Prescription painkillers—natural and semisynthetic opioids (e.g., oxycodone, hydrocodone, and morphine) are involved in more overdose deaths than any other opioid.[6]

Of the individuals who used prescription painkillers non-medically in 2016, more than half (53.0%) received the drugs from a friend or relative either for free, by purchase, or by stealing.[7] Aside from prescription painkillers such as oxycodone, other commonly abused prescription medications include benzodiazepines and amphetamine-like drugs.

Some academic and government experts link the crackdown on prescription drug abuse and the comparatively higher cost of prescription pain relievers on the black market to the uptick in heroin abuse.[8] The number of individuals aged 12 or older currently[9] using heroin (475,000 in 2016) has nearly tripled since 2002.[10] Like many prescription pain relievers, heroin is an opioid. Unlike prescription pain relievers, however, heroin is a Schedule I controlled substance under the Controlled Substances Act[11] and has no accepted medical use in the United States.

Most prescription drugs that are misused are *originally* prescribed by a physician (rather than, for example, being stolen from pharmacies); therefore, attention has been directed toward preventing the diversion of prescription drugs after the prescriptions are dispensed. Prescription drug monitoring programs (PDMPs) maintain statewide electronic databases of dispensed prescriptions for controlled substances. PDMP information can aid medical professionals and those in law enforcement in identifying patterns of prescribing, dispensing, or receiving controlled substances that may indicate abuse.[12]

For over a decade, the federal government has provided financial support for state-level PDMPs. In 2002, Congress established the Harold Rogers PDMP grant, administered by the Department of Justice (DOJ), to help law enforcement, regulatory entities, and public health officials analyze data on prescriptions for controlled substances. Three years later, Congress and the President enacted the National All Schedules Prescription Electronic Reporting Act of 2005 (NASPER)

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[5] Some reported use of both heroin and pain relievers, so the numbers will not total to 11.5 million. U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, *Results from the 2016 National Survey on Drug Use and Health: Summary of National Findings*, September 2017, https://www.samhsa.gov/data/sites/default/files/NSDUH-FFR1-2016/NSDUH-FFR1-2016.htm (hereinafter: *2016 National Survey on Drug Use and Health*).

[6] Rose A. Rudd, Noah Aleshire, and Jon E. Zibbell et al., Centers for Disease Control and Prevention, *Increases in Drug and Opioid Overdose Deaths—United States, 2000-2014*, Morbidity and Mortality Weekly Report (MMWR), January 1, 2016, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm.

[7] *2016 National Survey on Drug Use and Health*, Figure 34, https://www.samhsa.gov/data/sites/default/files/NSDUH-FFR1-2016/NSDUH-FFR1-2016.htm.

[8] Pradip K. Muhuri, Joseph C. Gfroerer, and M. Christine Davies, *Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States*, Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality, August 2013, http://www.samhsa.gov/data/2k13/DataReview/DR006/nonmedical-pain-reliever-use-2013.pdf; Theodore J. Cicero, Matthew S. Ellis, and Hilary L. Surratt, "Effect of Abuse-Deterrent Formulation of Oxycontin," *New England Journal of Medicine*, vol. 367, no. 2 (July 12, 2012), pp. 187-189; U.S. Department of Justice, National Drug Intelligence Center, *National Drug Threat Assessment 2003*, "Narcotics", January 2003, http://www.justice.gov/archive/ndic/pubs3/3300/pharm.htm; and U.S. Department of Justice, National Drug Intelligence Center, *National Drug Threat Assessment 2011*, August 2011, p. 37, http://www.justice.gov/archive/ndic/pubs44/44849/44849p.pdf.

[9] NSDUH defines "current" use as any use in the past 30 days.

[10] *Results from the 2016 National Survey on Drug Use and Health*.

[11] 21 U.S.C. §801 et seq.

[12] Initiatives countering prescription drug abuse range from prevention and treatment to enforcement. These activities include scheduling chemicals used in certain prescription drugs, supporting public awareness campaigns, bolstering law enforcement, and providing assistance to states—in part through PDMPs. This report focuses on PDMPs.

requiring the Secretary of Health and Human Services (HHS) to award grants to states to establish or improve PDMPs. In 2016, CARA authorized PDMP activity under two grant programs administered by DOJ and HHS.

Congress has demonstrated a particular interest in facilitating interoperability among state-level PDMPs, as well as in establishing national programs.[13] Policymakers have focused on enhancing state-level databases and interstate information sharing, and some have suggested establishing a national system. Related issues that policymakers may consider are whether PDMPs and their interstate information-sharing platforms adequately protect personally identifiable and related health information, and whether they can ensure that patients with legitimate medical needs have access to prescriptions. Congress may also exercise oversight with respect to the role of PDMPs in the Administration's efforts to combat the prescription drug epidemic;[14] policymakers may assess the extent to which the relevant departments and agencies have taken steps to accomplish these PDMP-related goals.

This report provides an overview of PDMPs, including their operation, enforcement mechanisms, costs, and financing. It also examines the effectiveness of PDMPs and outlines federal grants supporting PDMPs. Finally, this report discusses relevant considerations for policymakers including interstate data sharing, interoperability, protection of health information, and the possible link between the crackdown on prescription drug abuse and rise in heroin abuse.

Prescription Drug Monitoring Programs (PDMPs)

PDMPs maintain statewide electronic databases of designated information on specified prescription drugs dispensed within the states. Data are made available to individuals or organizations as authorized under state law; these may include prescribers, law enforcement officials, licensing boards, or others. Possible uses of PDMPs include

- identifying or preventing drug abuse and diversion;
- facilitating the identification of prescription drug-addicted individuals and appropriate intervention and treatment;
- outlining use and abuse trends to inform public health initiatives; and
- educating individuals about prescription drug use, abuse, and diversion.[15]

In addition to uses of PDMPs aimed at drug abuse and diversion, an explicit goal of PDMPs is supporting access to controlled substances for legitimate medical use. This may best be understood by viewing PDMPs in comparison to earlier, paper-based programs called multiple-copy prescription programs. For example, in 1914 a New York state law required physicians to use state-issued, serialized, duplicate prescription forms for certain drugs.[16] Similarly, California

[13] These issues were addressed in Section 1141 of the Food and Drug Administration Safety and Innovation Act (P.L. 112-144).

[14] The President's Commission on Combating Drug Addiction and the Opioid Crisis, *Final Report*, November 1, 2017, https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf; and *FACT SHEET: Obama Administration Announces Public and Private Sector Efforts to Address Prescription Drug Abuse and Heroin Use*.

[15] The Prescription Drug Monitoring Program Training and Technical Assistance Center, *The Goals of Prescription Monitoring*; National Alliance for Model State Drug Laws, *Prescription Drug Monitoring Programs: A Brief Overview*, August 17, 2010.

[16] Scott M. Fishman et al., "Regulating Opioid Prescribing Through Prescription Monitoring Programs: Balancing Drug Diversion and Treatment of Pain," *Pain Medicine*, vol. 5, no. 3 (2004), pp. 309-324.

began a multiple-copy prescription program using triplicate forms for specified narcotics in 1939; it expanded to monitor all schedule II narcotics in 1972 and schedule II non-narcotics in 1981.[17] Studies of multiple-copy prescription programs found that many prescribers did not order the required prescription forms, rendering them unable to prescribe specified controlled substances even when medically appropriate.[18] In addition, the ability to check a patient's prescription history using an electronic PDMP might give prescribers more confidence when considering the use of drugs with high risk of abuse and prevent the prescribing of contraindicated medications.

As of February 2018, 50 states, the District of Columbia, and two territories (Guam and Puerto Rico) had operational PDMPs within their borders.[19]

Program Operation

The entity responsible for administering the PDMP varies by state and may be a pharmacy board, department of health, professional licensing agency, law enforcement agency, substance abuse agency, or consumer protection agency. Of the authorized state PDMPs (including the District of Columbia), most (40) are administered by either pharmacy boards or health departments.[20]

State laws determine which schedules of controlled substances are monitored under each program (see text box for a brief explanation of schedules), what information is to be submitted, the means by which dispensers or dispensaries submit the required information, and the time frame in which information must be submitted.

Schedules of Controlled Substances

The Controlled Substances Act (21 U.S.C. §801 et seq.) establishes schedules for controlled substances (including drugs), ranging from schedule I (most restrictive) to schedule V (least restrictive). Drugs on schedule I have no currently accepted medical use in the United States and are not available by prescription. Drugs with recognized medical uses are on schedules II through V, with each successive schedule representing a lower risk of abuse.

Each state also determines which entities dispensing prescriptions for controlled substances are required to submit data to the PDMP. Most states require retail pharmacies and dispensing practitioners (e.g., physicians and/or veterinarians) to submit data to the PDMP.[21] Some states also have statutory authority to require out-of-state, mail order, and Internet pharmacies to submit data to the PDMP regarding prescription or controlled drugs dispensed to residents of the state. For instance, if a patient in Alabama receives a prescription for a monitored drug from an out-of-state mail order pharmacy, the mail order pharmacy must report the prescription to the Alabama PDMP.[22]

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[17] Aaron M. Gilson et al., "Time Series Analysis of California's Prescription Monitoring Program: Impact on Prescribing and Multiple Provider Episodes," *Journal of Pain*, vol. 13, no. 2 (2012), pp. 103-111.

[18] Scott M. Fishman et al., "Regulating Opioid Prescribing Through Prescription Monitoring Programs: Balancing Drug Diversion and Treatment of Pain," *Pain Medicine*, vol. 5, no. 3 (2004), pp. 309-324.

[19] In July 2017, Missouri Governor Eric Greitens signed an executive order directing the Missouri Department of Health and Human Services to establish a PDMP. While St. Louis County, MO, already had an operational PDMP that incorporated other counties in Missouri, it is unclear if the *state* has an operational PDMP. CRS attempted to reach the Missouri Department of Health and Human Services to discuss this matter on January 31, 2018, but was referred to the St. Louis County PDMP.

[20] Research current through June 30, 2017. National Alliance for Model State Drug Laws (NAMSDL), *Prescription Drug Monitoring Program (PMP) Administering Agency*, 2017, http://www.namsdl.org.

[21] NAMSDL, *Reporting Requirements and Exemptions to Reporting, Compilation of Statutes*, May 2016, http://www.namsdl.org/prescription-monitoring-programs.cfm.

[22] NAMSDL, *States With Statutory Authority to Require Nonresident Pharmacies to Report to Prescription Monitoring*

Of note, information on medications (e.g., methadone or buprenorphine) dispensed at federally assisted drug treatment programs generally may not be reported to PDMPs without patient consent under federal privacy regulations (42 C.F.R. Part 2). These regulations place strict limitations on the disclosure, and redisclosure, of patient information created and maintained by such programs that identifies the individual patient as a drug abuser, or links the individual to the program.[23]

Access to information contained in the PDMP database is determined by state law and varies by state. The majority of states allow pharmacists and practitioners to access information related to their patients, and some also allow other entities—law enforcement, licensing and regulatory boards, state Medicaid Programs, state medical examiners, and research organizations—to access the information under certain circumstances.[24] State laws outline the procedures by which information from the PDMP may be accessed.

With respect to how the states identify and investigate cases of potential prescription drug diversion or abuse, PDMPs may be classified as *reactive* or *proactive*. In essence, "[s]tates with [r]eactive PDMPs ... generate solicited reports only in response to a specific inquiry made by a prescriber, dispenser, or other party with appropriate authority" while "[s]tates with [p]roactive PDMPs ... identify and investigate cases, generating unsolicited reports whenever suspicious behavior is detected."[25]

Interstate Information Sharing and Interoperability

State PDMPs vary widely with respect to whether or how information contained in the database is shared with other states. While some states do not have measures in place allowing interstate sharing of information, others have specific policies that govern sharing of information across state lines. These policies may be based on factors such as agreed-upon reciprocity between states, or whether a request stems from an ongoing investigation.[26] As of September 20, 2017, 43 states were engaged in interstate data sharing while 5 states were still implementing interstate data sharing.[27]

Researchers provided states with guidance in creating memoranda of understanding (MOUs) for interstate data exchange. Questions that states may consider when drafting an MOU include the following:[28]

- How is the information to be reported?
- How will the information be used by the relevant states?

Program, May 2016, http://www.namsdl.org/.

[23] See CRS In Focus IF10374, *Health Privacy: Updating Federal Protections for Patient Records at Substance Abuse Treatment Programs*.

[24] Researchers may be allowed de-identified data for analysis and research purposes. See PDMP Training and Technical Assistance Center, *Prescription Monitoring Frequently Asked Questions (FAQ)*, http://www.pdmpassist.org/content/prescription-drug-monitoring-frequently-asked-questions-faq.

[25] Ronald Simeone and Lynn Holland, *Executive Summary: An Evaluation of Prescription Drug Monitoring Programs*, Simeone Associates, Inc., http://www.namsdl.org/.

[26] National Alliance for Model State Drug Laws, *Interstate Sharing of Prescription Monitoring Database Information*, May 2016, http://www.namsdl.org.

[27] For a map depicting the interstate sharing of PDMP data, see http://www.pdmpassist.org/pdf/Interstate_Data_Sharing_20170920.pdf.

[28] Alliance of States With Prescription Monitoring Programs and Brandeis University's Training and Technical Assistance Center, *Memorandum Of Understanding: Writing Guide for States with Prescription Monitoring Programs*, funded through a grant (No. 2010-DG-BX-K088) from the Bureau of Justice Assistance.

- What are the guidelines on data retention?
- What are the state responsibilities in the event of a data breach?
- Are there measures in place for conflict resolution?
- What are the consequences of potential data misuse?

In addition, the Council of State Governments highlighted four areas as central to the success of interstate compacts regarding PDMPs and data sharing:

> **Education**—responsibility of providers, data integrity, training requirements (start up versus ongoing)[;]
>
> **Funding**—state funding, costs of data sharing, costs of operation[;]
>
> **Security and Access**—authorized users, authentication, audit trails, Internet access, vendor security, reporting, privacy, confidentiality, use of data[; and]
>
> **Technology**—data transfer and exchange, uniformity and standards, cost reduction, compatibility, quality/error correction[.][29]

Without funding, data sharing, and knowledgeable users actively participating in PDMPs, these programs cannot be effective.

Efforts are ongoing to facilitate information sharing using prescription monitoring information exchange (PMIX) architecture—an information exchange standard/nationwide framework that applies to PDMP systems, data sharing "hubs", such as RxCheck,[30] and other exchange partners or intermediaries.[31] The PMIX program is intended to enable the interstate exchange of PDMP information, providing information on an individual's prescription drug history to states participating in the information exchange. This information can help identify potential prescription drug abuse or diversion, and can help inform stakeholders such as law enforcement, health and human services, health practitioners, and public regulatory agencies. A state can participate in the PMIX program if it has

- legislation allowing it to share patient information with other states in real time,
- identified at least one other state as a partner in the information exchange, and
- either (1) established an MOU with their identified partner(s) in the information exchange or (2) ratified the Prescription Monitoring Interstate Compact.[32]

The infrastructure of the PMIX program is based on the National Information Exchange Model (NIEM), which is a "common vocabulary" used by the public and private sector to exchange

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[29] The Council of State Governments, National Center for Interstate Compacts, *Prescription Drug Monitoring Programs: Interstate Compact—National Advisory Panel*, November 5-6, 2009, http://www.csg.org/pubs/capitolideas/enews/enewsissue38/21stCenturyHandout.pdf.

[30] As of January 17, 2018, five states were actively using RxCheck as their interstate data sharing hub. Twelve additional states were either implementing interstate data sharing via RxCheck or planning to connect to RxCheck. See PDMP Training and Technical Assistance Center, *Interstate Data Sharing via RxCheck Hub*, http://www.pdmpassist.org/pdf/RxCheck_Hub_states_20180117.pdf.

[31] More information on PMIX can be found at http://www.pdmpassist.org and http://www.ijis.org. A pilot project between Kentucky and Ohio's PDMPs formed the springboard for the larger PMIX initiative. Through this pilot, a PMIX hub server was installed in Ohio, and Ohio and Kentucky signed an MOU for data exchange, see IJIS Institute, *Cross-Boundary Initiatives*, http://www.ijis.org.

[32] *Prescription Monitoring Information Exchange (PMIX) Architecture*, Brandeis University, Prescription Drug Monitoring Program Training and Technical Assistance Center, http://www.pdmpassist.org/content/prescription-drug-monitoring-information-architecture-pmix.

information.[33] To facilitate information security and data privacy, data are encrypted while passing through "hubs," and no data are actually stored on these hubs. PMIX allows for hubs to exist at the state and national levels, and it allows for hub-to-hub information exchange.[34]

With pharmaceutical industry support, the National Association of Boards of Pharmacy (NABP) developed a technology platform to facilitate interstate sharing of PDMP data, called InterConnect, which NABP committed to make compliant with PMIX architecture.[35]

Although there are no federal requirements for state PDMP interoperability and information sharing, Congress and the President enacted legislation that

- authorized the HHS Secretary, consulting with the Attorney General as appropriate, to "facilitate … the development of recommendations on interoperability standards" for interstate information exchange by states receiving specified federal grants to support their PDMPs;
- required the HHS Secretary, in so doing, to consider the PMIX standards; and
- required the HHS Secretary to submit "a report on enhancing the interoperability of [state PDMPs] with other technologies and databases used for detecting and reducing fraud, diversion, and abuse of prescription drugs."[36]

In 2013, HHS submitted its report to Congress on PDMP interoperability standards. In addressing legal and policy challenges, HHS recommended that states ensure that PDMPs do not restrict access to PDMP data for health care providers and enact laws and policies to increase use of PDMPs by health care providers, among other recommendations.[37] In addressing interoperability and technology issues, HHS recommended that state PDMPs implement interoperability standards "that best support the information's use upon its exchange," among other recommendations.[38] HHS stressed the importance of unsolicited reports from PDMPs to providers, licensing boards, regulatory and law enforcement agencies, and public and private insurers and pharmacy benefit managers.[39] The report also reviews literature on PDMP effectiveness and health provider use of PDMPs.

Over the past several years, federal grant funds have gone toward improving interoperability and information sharing between states, and there are reports of successful initiation and expansion of interstate information sharing. For example, SAMHSA funded PDMP integration and interoperability projects in nine states from FY2012 to FY2016 and released a report outlining challenges and successes.[40]

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[33] See the government website for the National Information Exchange Model (NIEM): https://www.niem.gov/.

[34] PDMP Training and Technical Assistance Center and Alliance of States With Prescription Monitoring Programs, *PMIX National Architecture Overview*, http://www.pdmpassist.org/pdf/PMIX%20National%20Architecture%20Overview.pdf.

[35] U.S. Department of Justice, Office of Justice Programs, Bureau of Justice Assistance, BJA Policy on Use of Harold Rogers Prescription Drug Monitoring Program (HRPDMP) Funding to Support Interstate Data Sharing Activities, May 30, 2012, https://www.bja.gov/Programs/PDMPPolicy.pdf. This supersedes interim policy guidance documentation dated March 21, 2012, and April 17, 2012.

[36] Section 1141 of the Food and Drug Administration Safety and Innovation Act (P.L. 112-144).

[37] U.S. Department of Health and Human Services, *Prescription Drug Monitoring Program Interoperability Standards*, A Report to Congress, September 2013, http://www.healthit.gov/sites/default/files/fdasia1141report_final.pdf.

[38] Ibid., pp. 5, 21. For specific recommendations, see the full report.

[39] Ibid., pp. 4, 17-18.

[40] Centers for Disease Control and Prevention, National Center for Injury Prevention and Control, Division of

Compliance and Enforcement Mechanisms

In ensuring that a given state's PDMP reflects comprehensive data from all relevant pharmacies, physicians, and other dispensaries, one principal concern is how to ensure that they are reporting prescription data to the program. The laws or rules governing consequences for failure to report data are determined by each state. For example, one consequence may be disciplinary action by the appropriate licensing board or commission. Another may be that failure to report information could trigger the PDMP program office to report the lapse in compliance to the PDMP governing agency, which may then refer the information to law enforcement.[41]

Program Costs

PDMP expenses involve startup costs, funds needed to operate and maintain the programs, and any monies used to enhance program operation and interoperability. Overall program costs can entail

- hardware such as servers;
- software to run the PDMP database and ensure information security;
- connectivity such that pharmacies and dispensaries can enter data, and prescribers and/or law enforcement officials can request and access data;
- staff to administer the PDMP and provide technical assistance; and
- overhead fees.

A 2009 evaluation by the Maryland Advisory Council on Prescription Drug Monitoring assessed existing state PDMPs on a range of factors including the costs associated with establishing and maintaining the programs.[42] The overarching finding was that costs vary widely, with program startup costs ranging from $450,000 to over $1.5 million. Further, based on available data from six operational PDMPs, the Maryland Advisory Council's evaluation indicates that annual operating costs range from $125,000 to nearly $1.0 million, with an average annual cost of about $500,000. The Maryland Advisory Council reported that

> [c]ost variations are affected by the frequency of data collection (e.g., daily, weekly, bi-weekly, monthly), the use of third party vendors for data collection and analysis, the number of prescriptions written and filled in the state, the number of drug schedules (II-V) and drugs of interest collected, and the use of official forms or other required collection and submission mechanisms.[43]

Unintentional Injury Prevention, *Integrating & Expanding Prescription Drug Monitoring Program Data: Lessons from Nine States*, February 2017, https://www.cdc.gov/drugoverdose/pdf/pehriie_report-a.pdf.

[41] See, for example, Florida's PDMP rule states that "[t]he program will file a complaint with the Department and refer to law enforcement any failure to report the dispensing of Schedules II – IV controlled substances." Rule 64K-1.004, https://www.flrules.org/gateway/RuleNo.asp?title=Prescription%20Drug%20Monitoring%20Program&ID=64K-1.004.

[42] Maryland Advisory Council on Prescription Drug Monitoring, *Maryland Advisory Council on Prescription Drug Monitoring Legislative Report*, December 31, 2009, p. 76, http://msa.maryland.gov/megafile/msa/speccol/sc5300/sc5339/000113/012000/012478/unrestricted/20100355e.pdf.

[43] Maryland Advisory Council on Prescription Drug Monitoring, *Maryland Advisory Council on Prescription Drug Monitoring Legislative Report*, December 31, 2009, pp. 76-77. An earlier (2002) evaluation of PDMPs by the Government Accountability Office (GAO) found similar reasons for variability in state costs for PDMP operation. These variations were driven by "differences in the PDMP systems implemented, the number of pharmacies reporting drug dispensing data, and the number of practitioners and law enforcement agencies seeking information from the systems."

A 2002 Government Accountability Office (GAO) evaluation of PDMP costs in Kentucky, Nevada, and Utah revealed findings similar to those presented by the Maryland Advisory Council. GAO noted a number of PDMP design and operational factors driving variations in state costs for running PDMPs. Specifically, these involved "differences in the PDMP systems implemented, the number of pharmacies reporting drug dispensing data, and the number of practitioners and law enforcement agencies seeking information from the systems."[44]

PDMP Financing

States finance the startup and operation of PDMPs through a variety of channels. PDMP financing often involves monies from the state general fund, prescriber and pharmacy licensing fees, state controlled substance registration fees, health insurers' fees, direct-support organizations, state or federal grants, or a combination thereof.[45] Guidelines for how states may fund PDMPs are outlined in each state's PDMP authorizing legislation. For example, Oregon's PDMP has a fund within the state treasury. This fund receives monies, in part, from a proportion of medical provider fees. These fees are paid to the appropriate medical board, and the board in turn transmits a portion of these fees to the PDMP fund. The Oregon Department of Human Services, which administers the PDMP, may also accept and deposit into the fund money from a variety of additional sources, including grants and donations.[46]

Some states prohibit the use of certain sources of funding, thus limiting the potential range of funding mechanisms. For instance, Florida law specifically prohibits the use of state funds or funds received—directly or indirectly—from prescription drug manufacturers to support the PDMP.[47] As such, the program receives funding from three sources: the Florida PDMP Foundation, Inc., an organization established in Florida law for the purpose of funding the PDMP; federal grants; and private grants.[48]

PDMP Effectiveness

The available evidence suggests that PDMPs are effective in some ways for both law enforcement and health care purposes; however, research on the effectiveness of PDMPs is limited, especially in the area of law enforcement. Experts suggest that PDMPs have the potential to be more effective.

Effectiveness Research

Research on PDMP effectiveness suggests that they have an impact on both law enforcement and health care. A 2002 GAO study found that "the time and effort required by law enforcement and regulatory investigators to explore leads and the merits of possible drug diversion cases" declined

[44] U.S. General Accounting Office, *Prescription Drugs: State Monitoring Programs Provide Useful Tool to Reduce Diversion*, GAO-02-634, May 2002, p. 3, http://www.gao.gov/assets/240/234687.pdf.

[45] Alliance of States With Prescription Monitoring Programs, *Prescription Monitoring Programs: Funding Mechanisms & Business Models*, National Legislation & Implementation Meeting 2010, 2010, p. 3, http://www.pdmpassist.org/pdf/PPTs/LI2010/PMP-FundingBusModels.pdf.

[46] Oregon PDMP statute (ORS 431.960 et seq.).

[47] Title XLVI, Section 893.055, Florida Statutes - Prescription Drug Monitoring Program.

[48] Florida Department of Health, *Funding the E-FORSCE Database*, http://www.floridahealth.gov/statistics-and-data/e-forcse/funding/index.html.

after PDMP implementation.[49] The study found that investigations of alleged doctor shoppers by Kentucky officials took an average of 156 days prior to PDMP implementation and 16 days after PDMP implementation (a 90% decrease). Nevada and Utah also reported decreases in investigation time of 83% and 80%, respectively. It is important to note that decreases in investigation time do not necessarily translate into less prescription drug abuse.

A 2012 review article summarized all peer-reviewed research articles about PDMPs published between 2001 and 2011, which amounted to 11 articles (not all of which addressed effectiveness).[50] The author concluded that PDMPs reduce "doctor shopping," change prescribing behavior, and reduce prescription drug abuse. For example, a 2006 federally funded study (included in the 2012 review article) found that PDMPs—especially ones that issue reports proactively—change prescriber behavior in a way that reduces the per capita supply of prescription pain relievers and stimulants, which in turn reduces the likelihood of abuse.[51] Another study published in 2012 (and therefore not included in the review article) found that while opioid abuse was increasing over time, the rate of increase was slower in states with PDMPs than in states without PDMPs.[52]

A 2014 briefing document from the Prescription Drug Monitoring Program Center of Excellence at Brandeis University (now called the PDMP Training and Technical Assistance Center) suggests that evidence shows PDMPs are "effective in improving clinical decision-making, reducing doctor shopping and diversion of controlled substances, and assisting in other efforts to curb the prescription drug abuse epidemic."[53] In 2015, the University of Kentucky Institute for Pharmaceutical Outcomes and Policy examined the effectiveness of mandatory enrollment of prescribers and dispensers in PDMPs in Kentucky and cited closures of non-physician-owned pain management facilities and a decrease (over 50%) in the number of individuals doctor shopping as two of several positive outcomes from mandatory reporting in Kentucky.[54]

Several more recently published articles reported positive results for prescription drug monitoring programs. In one article, researchers found that implementation of state PDMPs, in particular those with "robust characteristics,"[55] was associated with a modest reduction in opioid-related overdose deaths.[56] Another study found that states with prescription drug monitoring mandates

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[49] U.S. General Accounting Office, *Prescription Drugs: State Monitoring Programs Provide Useful Tool to Reduce Diversion*, GAO-02-634, May 2002, p. 3, http://www.gao.gov/assets/240/234687.pdf.

[50] Julie Worley, "Prescription Drug Monitoring Programs, a Response to Doctor Shopping: Purpose, Effectiveness, and Directions for Future Research," *Issues in Mental Health Nursing*, vol. 33, no. 5 (2012), pp. 319-328. Note: The GAO study was not included, because it was not published in the peer-reviewed literature.

[51] Ronald Simeone and Lynn Holland, *An Evaluation of Prescription Drug Monitoring Programs*, Simeone Associates, Inc., No. 2005PMBXK189, September 1, 2006, http://www.simeoneassociates.com/simeone3.pdf. This study was commissioned by the U.S. Department of Justice (DOJ), Office of Justice Programs (OJP), Bureau of Justice Assistance (BJA).

[52] Liza M. Reifler et al., "Do Prescription Monitoring Programs Impact State Trends in Opioid Abuse/Misuse," *Pain Medicine*, no. 13 (2012), pp. 434-442.

[53] Prescription Drug Monitoring Program Center of Excellence at Brandeis (now called the PDMP Training and Technical Assistance Center), *Briefing on PDMP Effectiveness*, updated September 2014, p. 3.

[54] Patricia R. Freeman, Amie Goodin, and SuZanne Troske, et al., *Kentucky House Bill 1 Impact Evaluation*, Kentucky House Bill 1 Impact Evaluation, Prepared for The Kentucky Cabinet for Health and Family Services, March 2015.

[55] Robust characteristics include monitoring greater numbers of drugs with abuse potential and updating PDMP data at least weekly.

[56] Using an interrupted time-series analysis, the authors found that a state's implementation of a PDMP was associated with an average reduction of 1.12 opioid-related overdose deaths per 100,000 population in each state in the year after implementation. States whose programs had "robust characteristics" had greater reductions in deaths, compared to states whose programs did not have these characteristics. See Stephen W. Patrick, Carrie E. Fry, and Timothy F. Jones

were associated with a 9% to 10% reduction in population-adjusted numbers of Schedule II opioid prescriptions received by Medicaid enrollees and similar reductions in Medicaid spending on these prescriptions.[57] A third study reported no associations between PDMP implementation and nonmedical initiation/abuse of opioids, but did report a significant association between PDMP implementation and a reduction in "doctor shopping."[58]

Research shows that PDMPs may have positive effects beyond their intended purpose. For example, when accessing information from a PDMP, a prescriber or dispenser may identify a patient who is receiving legitimate prescriptions for multiple controlled substances and who is therefore at risk of harmful drug interactions.[59] PDMPs may also enable prescribers to monitor their own U.S. Drug Enforcement Administration (DEA) number to determine whether someone else is using it to forge prescriptions.[60]

Limitations of the Research

Research regarding PDMP effectiveness is limited, at least in part, by the difficulties inherent in conducting such research. Challenges in conducting high-quality research on PDMP effectiveness include (but are not limited to) (1) defining effectiveness, (2) accounting for differences among PDMPs, and (3) considering potential confounding factors.

To study effectiveness, researchers must first define effectiveness in a way that can be systematically measured as a study outcome. Almost all PDMPs are statewide programs; thus, researchers look for outcome measures for which statewide data are available. Some outcomes that have been measured in research on PDMP effectiveness are shipments and sales of controlled substances, benzodiazepine use in a Medicaid population, opioid consumption, substance abuse treatment admissions, drug overdose mortality, and multiple provider episodes (i.e., doctor shopping).[61] One drawback of using opioid consumption as an outcome measure is that it includes both nonmedical use of opioids and medically appropriate use of opioids to manage pain. A limitation of using a count of substance abuse treatment admissions is that it fails to capture substance abuse that goes untreated. Each of these measures presents only a portion of the picture of prescription drug diversion and abuse.

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et al., "Implementation Of Prescription Drug Monitoring Programs Associated With Reductions In Opioid-Related Death Rates," *Health Affairs*, vol. 35, no. 7 (July 2016), pp. 1324-1332.

[57] A reduction in opioid prescriptions may or may not be viewed as a positive effect. This association was observed largely with mandates of registration in PDMPs and not with mandates of use. See Wen Hefei, Bruce R. Schackman, and Brandom Aden et al., "States With Prescription Drug Monitoring Mandates Saw A Reduction In Opioids Prescribed To Medicaid Enrollees," *Health Affairs*, vol. 36, no. 4 (April 2017), pp. 733-741.

[58] Mir M. Ali, William N. Dowd, and Timothy Classen et al., "Prescription drug monitoring programs, nonmedical use of prescription drugs, and heroin use: Evidence from the National Survey of Drug Use and Health," *Addictive Behaviors*, vol. 69 (June 2017), pp. 65-77.

[59] Some states may see this as an intended purpose of creating a PDMP. Jeanmarie Perrone and Lewis S. Nelson, "Medication Reconciliation for Controlled Substances—An 'Ideal' Prescription-Drug Monitoring Program," *New England Journal of Medicine*, vol. 366, no. 25 (2012), p. 2341-2343.

[60] Ibid.

[61] See summaries of several studies conducted between 2001 and 2011 in Julie Worley, "Prescription Drug Monitoring Programs, a Response to Doctor Shopping: Purpose, Effectiveness, and Directions for Future Research," *Issues in Mental Health Nursing*, vol. 33, no. 5 (2012), pp. 319-328; see also Liza M. Reifler et al., "Do Prescription Monitoring Programs Impact State Trends in Opioid Abuse/Misuse," *Pain Medicine*, vol. 13, no. 3 (2012), pp. 434-442; and Aaron M. Gilson et al., "Time Series Analysis of California's Prescription Monitoring Program: Impact on Prescribing and Multiple Provider Episodes," *Journal of Pain*, vol. 13, no. 2 (2012), pp. 103-111.

Studies that compared states with and without PDMPs and/or before and after implementation of a PDMP vary in the degree to which they account for differences among PDMPs. For example, despite evidence that proactive PDMPs are more effective than reactive PDMPs, most studies do not distinguish between proactive and reactive PDMPs.[62] Another difference that may influence PDMP effectiveness is which drugs are required to be reported to the PDMP, ranging from only those prescription drugs with the highest potential for abuse to all prescription controlled substances plus other drugs of concern. Research generally focuses on those controlled substances that are included in all of the PDMPs being examined. Differences in PDMPs over time may also influence effectiveness. For example, some states have transitioned from paper-based systems for monitoring prescriptions for controlled substances to the electronic PDMPs used today. Effectiveness studies have generally not accounted for such transitions over time, classifying two different systems as the same PDMP. Accounting for these and other differences between PDMPs may shed light on factors that influence effectiveness.

Researchers also contend with factors that may confound study results, both when comparing outcomes across states and when comparing outcomes over time. For example, the baseline rate of prescription drug abuse may vary across states. The authors of a previously referenced study noted that the likelihood of abuse was actually higher in states with PDMPs than in states without PDMPs, but that proactive PDMPs inhibited the rate of increase in prescription drug abuse.[63] A PDMP may be part of a larger effort to reduce prescription drug diversion and abuse, in which case other initiatives may be responsible for any change in the outcome. A seemingly unrelated event, such as an economic downturn or upturn, may also affect the outcome. These considerations, among many others, impede the ability of researchers—and therefore policymakers—to draw conclusions about the effectiveness of PDMPs.

Potential Unintended Consequences

PDMPs may have unintended consequences beyond reducing prescription drug diversion and abuse.[64] Prescribers may hesitate to prescribe medications monitored by the PDMP—even for appropriate medical use—if they are concerned about potentially coming under scrutiny from law enforcement or licensing authorities.[65] Studies of paper-based prescription monitoring programs that preceded the electronic PDMPs found that many prescribers did not order the required prescription forms, rendering them unable to prescribe specified controlled substances. Their concerns may lead prescribers to replace medications that are monitored by the PDMP with medications that are not monitored by the PDMP, even if the unmonitored medications are inferior in terms of effectiveness or side effects.

Like prescribers, patients may fear coming under scrutiny from law enforcement if they use medications monitored by the PDMP, even if they have a legitimate medical need for the

[62] Proactive PDMPs send out unsolicited reports to authorized users, while reactive PDMPs send solicited reports.

[63] Ronald Simeone and Lynn Holland, *An Evaluation of Prescription Drug Monitoring Programs*, Simeone Associates, Inc., No. 2005PMBXK189, September 1, 2006, http://www.simeoneassociates.com/simeone3.pdf.

[64] Most of the unintended consequences identified in this section are discussed in Scott M. Fishman et al., "Regulating Opioid Prescribing Through Prescription Monitoring Programs: Balancing Drug Diversion and Treatment of Pain," *Pain Medicine*, vol. 5, no. 3 (2004), pp. 309-324.

[65] Some have indicated that doctors hesitate to prescribe due to fear of scrutiny. See M. Mofizul Islam and Ian S. McRae, "An inevitable wave of prescription drug monitoring programs in the context of prescription opioids: pros, cons and tensions," *BMC Pharmacology & Toxicology*, vol. 15 (August 16, 2014); and Linda A. Johnson,"Americans Are Filling Fewer Prescriptions for Opioids Amid Rising Fear of Addiction," *TIME*, April 19, 2018.

medications.[66] Patients may worry about changes in prescribing behavior, which may limit their access to needed medications. Patients may worry about the additional cost of more frequent office visits if prescribers become more cautious about writing prescriptions with refills. Patients may also have concerns about the privacy and security of their prescription information if it is submitted to a PDMP.

Another potential unintended consequence of a state PDMP is that it may push drug diversion activities over the border into a neighboring state.[67] A GAO study, completed in 2002, identified evidence of this spillover across state lines.[68] This concern is one of the reasons interstate data sharing and interoperability have become priorities. Similarly, a PDMP may push drug diversion activities into a neighboring state with a PDMP that does not monitor as many medications. In any of these cases, the effectiveness of the PDMP may be offset by unintended consequences.

An additional possible unintended consequence of state PDMP activity may be an uptick in the abuse of nonprescription opioids such as heroin and illicit fentanyl. As mentioned, some academic and government experts link the comparatively higher cost of prescription drugs and the crackdown on prescription drug abuse to the recent rise in heroin abuse.[69]

A PDMP may also have positive unintended consequences. For example, when accessing information from a PDMP, a prescriber or dispenser may identify a patient who is receiving legitimate prescriptions for multiple controlled substances and who is therefore at risk of harmful drug interactions.[70] PDMPs may also enable prescribers to monitor their own U.S. Drug Enforcement Administration (DEA) number to determine whether someone else is using it to forge prescriptions.[71]

Potential to Increase Effectiveness

In 2012, the PDMP Center of Excellence at Brandeis University (now called the PDMP Training and Technical Assistance Center) published PDMP best practices and evaluated the quality of

[66] M. Mofizul Islam and Ian S. McRae, "An inevitable wave of prescription drug monitoring programs in the context of prescription opioids: pros, cons and tensions," *BMC Pharmacology & Toxicology*, vol. 15 (August 16, 2014).

[67] Given that all states now have an operational PDMP within their borders, this may not be as much of a concern, but it is possible that a similar effect may be found with neighboring states that have varying mandates of use, etc.

[68] U.S. General Accounting Office, *Prescription Drugs: State Monitoring Programs Provide Useful Tool to Reduce Diversion*, GAO-02-634, May 2002, p. 3, http://www.gao.gov/assets/240/234687.pdf.

[69] Pradip K. Muhuri, Joseph C. Gfroerer, and M. Christine Davies, *Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States*, Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality, August 2013, http://www.samhsa.gov/data/2k13/DataReview/DR006/nonmedical-pain-reliever-use-2013.pdf; Theodore J. Cicero, Matthew S. Ellis, and Hilary L. Surratt, "Effect of Abuse-Deterrent Formulation of Oxycontin," *New England Journal of Medicine*, vol. 367, no. 2 (July 12, 2012), pp. 187-189; U.S. Department of Justice, National Drug Intelligence Center, *National Drug Threat Assessment 2003*, "Narcotics", January 2003, http://www.justice.gov/archive/ndic/pubs3/3300/pharm.htm; and U.S. Department of Justice, National Drug Intelligence Center, *National Drug Threat Assessment 2011*, August 2011, p. 37, http://www.justice.gov/archive/ndic/pubs44/44849/44849p.pdf.

[70] Some states may see this as an intended purpose of creating a PDMP. Jeanmarie Perrone and Lewis S. Nelson, "Medication Reconciliation for Controlled Substances—An "Ideal" Prescription-Drug Monitoring Program," *New England Journal of Medicine*, vol. 366, no. 25 (2012), p. 2341-2343.

[71] Ibid.

evidence supporting each best practice candidate.[72] Most of the best-practice candidates were supported by the weakest of five possible levels of evidence:[73]

1. randomized controlled trial or meta-analysis (0 best-practice candidates)
2. observational study with comparison groups (2 best-practice candidates)
3. observational study without comparison group (6 best-practice candidates)
4. case study or written documentation of expert opinion (6 best-practice candidates)
5. accumulated experience and/or key stakeholder perceptions (21 best-practice candidates)

A PDMP is essentially a source of information; its effectiveness depends largely on the quality of the information and how the information is used.[74] The quality of PDMP information depends on its timeliness, completeness, accuracy, and consistency. Expert recommendations to enhance data quality include

- collecting data at the point of sale (in real time);
- monitoring all prescribed controlled substances and other drugs of concern;
- integrating electronic prescribing technology;
- sharing data between states;
- standardizing the content across states;
- identifying the person picking up the prescription (which may be someone other than the patient, such as a family member); and
- linking prescription records for an individual (to avoid confusion if, for example, an address changes or a name is spelled differently).

For PDMP information to be well used, it must be accessible. A survey of prescribers found that the most common reason given for not using a PDMP was the time required to access it (73%); two other reasons—difficulty navigating the web portal (29%) and forgetting the password (28%)—may contribute to the amount of time required to access PDMP information. More than a third of survey respondents (39%) felt that accessing PDMP information would not change their prescribing practices for their patients, although research suggests PDMP information changes prescribing behavior. Relatively small numbers of respondents reported that lack of computer availability (9%) or never having applied for access (11%) were barriers to using a PDMP.[75] Expert recommendations to enhance data use include

- providing easy online access;

[72] Prescription Drug Monitoring Program Center of Excellence (now called the PDMP Training and Technical Assistance Center), *Prescription Drug Monitoring Programs: An Assessment of the Evidence for Best Practices*, September 20, 2012.

[73] In this list, best-practice candidates supported by more than one level of evidence are assigned to the strongest level of evidence.

[74] See Prescription Drug Monitoring Program Center of Excellence (now called the PDMP Training and Technical Assistance Center), *Prescription Drug Monitoring Programs: An Assessment of the Evidence for Best Practices*; and (2) Jeanmarie Perrone and Lewis S. Nelson, "Medication Reconciliation for Controlled Substances—An "Ideal" Prescription-Drug Monitoring Program," *New England Journal of Medicine*, vol. 366, no. 25 (2012), p. 2341-2343.

[75] Jeanmarie Perrone and Lewis S. Nelson, "Medication Reconciliation for Controlled Substances—An "Ideal" Prescription-Drug Monitoring Program," *New England Journal of Medicine*, vol. 366, no. 25 (2012), p. 2341-2343.

- issuing automated, unsolicited reports; and
- increasing participation through education and promotional campaigns.

Experts recommend making PDMP information available for research and public health purposes, which would require permitting access by designated nonprescribers (e.g., researchers and medical examiners). An example of a public health use of PDMP information is to identify patients for enrollment in special programs: Washington state used its PDMP to select Medicaid enrollees for a Patient Review Coordination Program, which decreased emergency department visits, physician visits, and prescriptions (resulting in an average savings of $6,000 per patient per year).[76] PDMP data may also be analyzed to identify geographic areas where interventions (such as increased law enforcement attention or establishment of a substance abuse clinic) are most needed. Carefully controlled access to de-identified data for research and public health purposes may yield other uses.

Federal Programs that Support State PDMPs

The federal government supports state PDMPs through programs at the Departments of Justice (DOJ) and Health and Human Services (HHS). Since FY2002, DOJ has administered the Harold Rogers Prescription Drug Monitoring Program, and in FY2017, DOJ incorporated this grant program into the new Comprehensive Opioid Abuse Program. HHS programs include the National All Schedules Prescription Electronic Reporting (NASPER), State Demonstration Grants for Comprehensive Opioid Abuse Response, Opioid Prevention in States grants, and various pilots and initiatives under the Office of the National Coordinator for Health Information Technology (ONC).

Harold Rogers PDMP—Comprehensive Opioid Abuse Grant Program

From FY2002 to FY2016, the Harold Rogers PDMP was a discretionary, competitive grant program administered by the U.S. Department of Justice (DOJ), Office of Justice Programs (OJP), Bureau of Justice Assistance (BJA). It was created to help law enforcement,[77] regulatory entities, and public health officials analyze data on prescriptions for controlled substances. In FY2017, DOJ incorporated the Harold Rogers PDMP into the new Comprehensive Opioid Abuse Grant Program, which was created under Section 201 of the Comprehensive Addiction and Recovery Act (CARA; P.L. 114-198). Prescription drug monitoring activities were authorized as a purpose area of the program.[78]

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[76] Washington state update presented at Harold Rogers PDMP National Meeting, Washington, DC, June 4-6, 2012.

[77] Law enforcement uses of PDMP data include (but are not limited to) investigations of physicians who prescribe controlled substances for drug dealers or abusers, pharmacists who falsify records in order to sell controlled substances, and people who forge prescriptions. See U.S. Department of Justice, Drug Enforcement Administration, Office of Diversion Control, http://www.deadiversion.usdoj.gov.

[78] Specifically, Section 201 of CARA states, "From amounts made available to carry out this part, the Attorney General may make grants to States, units of local government, and Indian tribes, for use by the State, unit of local government, or Indian tribe to provide services primarily relating to opioid abuse, including for any one or more of the following... (6) In the case of a State, developing, implementing, or expanding a prescription drug monitoring program to collect and analyze data related to the prescribing of schedules II, III, and IV controlled substances through a centralized database administered by an authorized State agency, which includes tracking the dispensation of such substances, and providing for interoperability and data sharing with each other such program in each other State, and with any interstate entity that shares information between such programs." Prescription drug monitoring is one of 10 purpose areas for this program listed in statute.

Grant Purpose Areas

The program assists states (including U.S. territories and federally recognized tribal governments) in the planning, implementation, and enhancement of their PDMPs. This involves

- facilitating the exchange of information among states using technical solutions compliant with PMIX architecture;
- developing a training program for system users;
- assessing the efficiency and effectiveness of existing PDMPs and related initiatives;
- enhancing collaboration between law enforcement, prosecutors, treatment professionals, medical community members, and pharmacies to create a comprehensive PDMP strategy; and
- other authorized activities under the Comprehensive Opioid Abuse Grant Program.[79]

The Comprehensive Opioid Abuse Grant Program also offers training and technical assistance grants to promote the use of PDMPs.[80]

Appropriations

The Harold Rogers PDMP began receiving federal funding in FY2002 through the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act, 2002 (P.L. 107-77). While the program itself has never been authorized in statute, funding for the program was provided to DOJ each year through the annual appropriations process. Annual appropriations information is listed in **Table 1**. In FY2017, DOJ incorporated the Harold Rogers PDMP into the new Comprehensive Opioid Abuse Grant Program, and $14 million was appropriated for prescription drug monitoring as part of the broader DOJ "Opioids Initiative." In FY2018, the Consolidated Appropriations Act, 2018 (P.L. 115-141) more than doubled the amount for prescription drug monitoring[81] and provided $30 million for this purpose.

Table 1. Harold Rogers PDMP—Comprehensive Opioid Abuse Grant Program Funding through FY2018

(In millions of dollars)

Fiscal Year	Appropriation
2002	$2.00
2003	$7.50
2004	$7.00
2005	$10.00

[79] U.S. Department of Justice, Office of Justice Programs, Bureau of Justice Assistance, *Comprehensive Opioid Abuse Site-based Program FY2017 Competitive Grant Announcement*, pp.17-18, https://www.bja.gov/Funding/CARA17.pdf (hereinafter, *Comprehensive Opioid Abuse Site-based Program FY 2017 Competitive Grant Announcement*).

[80] See U.S. Department of Justice, Office of Justice Programs, Bureau of Justice Assistance, *Comprehensive Opioid Abuse Program Training and Technical Assistance (TTA) Program FY 2017 Competitive Grant Announcement*, https://www.bja.gov/Funding/COAPTTA17.pdf.

[81] Appropriations statute specifies that funds can be used to monitor scheduled listed chemical products in addition to prescription drugs.

Fiscal Year	Appropriation
2006	$7.50
2007	$7.50
2008	$7.05
2009	$7.00
2010	$7.00
2011	$5.80
2012	$7.00
2013	$6.51
2014	$7.00
2015	$11.00
2016	$13.00
2017[a]	$14.00
2018[a]	$30.00

Source: FY2002 data from P.L. 107-77; FY2003 data from P.L. 108-7; FY2004 data from P.L. 108-199; FY2005 data from P.L. 108-447; FY2006 data from P.L. 109-108; FY2007 data from P.L. 110-5; FY2008 data from P.L. 110-161; FY2009 data from P.L. 111-8; FY2010 data from P.L. 111-117; FY2011 data are based on CRS analysis of the text of P.L. 112-10; FY2012 data from P.L. 112-55. FY2013 data were provided by the Department of Justice. FY2014-FY2018 data were taken from the joint explanatory statements to accompany P.L. 113-76, P.L. 113-235, P.L. 114-113, P.L. 115-31 and P.L. 115-141.

a. In FY2017, DOJ incorporated the Harold Rogers PDMP into the new Comprehensive Opioid Abuse Grant Program. In FY2017, $14 million was appropriated to monitor prescription drugs and scheduled listed chemical products as part of the broader appropriation for "comprehensive opioid abuse reduction activities." In FY2018, $30 million was appropriated to monitor prescription drugs and scheduled listed chemical products again as part of the broader appropriation for "comprehensive opioid abuse reduction activities."

National All Schedules Prescription Electronic Reporting Act of 2005 (NASPER)

The NASPER PDMP grant was a formula grant administered by HHS, Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT).[82] NASPER grants were last funded in FY2010. NASPER was first authorized by the National All Schedules Prescription Electronic Reporting Act of 2005 (P.L. 109-60, NASPER), which amended the Public Health Service Act to require the Secretary of HHS to award grants to states[83] to establish or improve PDMPs. It was amended and reauthorized under Section 109 of the Comprehensive Addiction and Recovery Act of 2016 (CARA, P.L. 114-198). Since FY2010, funds have not been specifically appropriated for this program.

Grant Purpose Areas

The two objectives of NASPER are to (1) foster the establishment of state-administered PDMPs that providers can access for the early identification of patients at risk for addiction in order to

[82] Unless otherwise noted, all information in this section on NASPER comes from 42 U.S.C. §280g-3.

[83] For purposes of NASPER, the term "State" is defined at 42 U.S.C. §280g-3(m)(8) to mean as "each of the 50 States, the District of Columbia, and any commonwealth or territory of the United States."

initiate appropriate interventions, and (2) establish a set of best practices for new PDMPs and improvement of existing PDMPs.

Appropriations

The NASPER Act of 2005 authorized appropriations for NASPER for FY2006-FY2010. The program was funded in FY2009 and FY2010. The final continuing resolution for FY2011 (P.L. 112-10) specifically prohibited the funding of NASPER.[84] Section 109 of CARA authorized appropriations for NASPER for FY2017-FY2021; however, no funds have been appropriated for the program. In FY2018, while no funds were *specifically* appropriated for NASPER, Congress directed the Centers for Disease Control and Prevention (CDC) to promote the use of PDMPs, including implementation of activities described in NASPER as part of its opioid prescription drug overdose (PDO) prevention activity.[85] Annual authorizations of appropriations and actual appropriations are listed in **Table 2**.

To be eligible for NASPER grant funding, states must meet certain requirements, such as having legal authority to implement PDMPs. All states that submit applications and meet the requirements receive grants noncompetitively. The amount awarded to each state is defined by a two-part formula:[86]

1. Each state receives a base amount of 1% of the total funding (i.e., $20,000 in FY2010).
2. The remaining amount is distributed according to the ratio of the number of pharmacies in the individual state to the number of pharmacies in all states with approved applications.

The HHS Secretary may adjust a state's allotment after taking into consideration the budget cost estimate for its PDMP. Thirteen states received grants under NASPER in FY2010, the last year of funding.[87]

Table 2. National All Schedules Prescription Electronic Reporting Act of 2005 (NASPER) Funding through FY2018

(In millions of dollars)

Fiscal Year	Authorization of Appropriation	Appropriation
2006	$15.00	$0.00
2007	$15.00	$0.00
2008	$10.00	$0.00
2009	$10.00	$2.00
2010	$10.00	$2.00
2011	NA	$0.00
2012	NA	$0.00

[84] Department of Defense and Full-Year Continuing Appropriations Act, 2011 (P.L. 112-10 §1815(a)(2)).

[85] Explanatory text to accompany P.L. 115-141.

[86] 42 U.S.C. §280g-3(a)(2)

[87] U.S. Department of Health and Human Services, *TAGGS - Tracking Accountability in Government Grants System*, http://taggs.hhs.gov/AdvancedSearch.cfm.

Fiscal Year	Authorization of Appropriation	Appropriation
2013	NA	$0.00
2014	NA	$0.00
2015	NA	$0.00
2016	NA	$0.00
2017	$10.00	$0.00
2018	$10.00	$0.00[a]

Sources: Authorizations of appropriations for FY2006-FY2010 from P.L. 109-60, and authorizations of appropriations for FY2017 (through FY2021, not shown) are from P.L. 114-198. Appropriations for FY2006-FY2010 are from SAMHSA's *Justification of Estimates for Appropriations Committees* for FY2011. Appropriations for subsequent years are from P.L. 112-10, P.L. 112-74, P.L. 113-6. P.L. 113-76, P.L. 113-235, P.L. 114-113, P.L. 115-31, and P.L. 115-141.

Note: NA = not authorized.

a. In FY2018, while no funds were *directly* appropriated for NASPER, Congress directed the Centers for Disease Control and Prevention to promote the use of PDMPs, including implementation of activities described in NASPER. This direction was provided under the heading "Opioid Prescription Drug Overdose (PDO) Prevention Activity," for which Congress appropriated $475.58 million. See Division H of the explanatory text to accompany the Consolidated Appropriations Act, 2018 (P.L. 115-141).

Although NASPER is not currently funded, HHS continues to support state PDMPs through other programs. For example, since 2015, the CDC has awarded funding to some states for PDO prevention activities, including efforts to improve access to PDMPs and the timeliness of PDMP data.[88]

Program Comparison

Table 3 provides an overview and comparison of the Harold Rogers PDMP and the NASPER PDMP. Basic information is provided on program legislation, administering agencies, program objectives, grant types, authorization of appropriations, and actual appropriations.

Table 3. Comparison of the Harold Rogers PDMP - Comprehensive Opioid Abuse Grant Program and NASPER

	Harold Rogers[a]	NASPER
Legislation	Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act, 2002 (P.L. 107-77); and the Comprehensive Addiction and Recovery Act of 2016 (P.L. 114-198).	National All Schedules Prescription Electronic Reporting Act of 2005 (P.L. 109-60), amended by the Comprehensive Addiction and Recovery Act of 2016 (P.L. 114-198)
Administering Agency	U.S. Department of Justice (DOJ), Office of Justice Programs (OJP), Bureau of Justice Assistance (BJA)	U.S. Department of Health and Human Services (HHS), Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT)

[88] HHS, CDC, *Prescription Drug Overdose Prevention for States*, https://www.cdc.gov/drugoverdose/states/state_prevention.html.

	Harold Rogers[a]	NASPER
Program Objectives	Help states to plan, implement, and enhance their PDMPs.	Two objectives: 1. Foster the establishment of state-administered PDMPs that providers can access for the early identification of patients at risk for addiction in order to initiate appropriate interventions. 2. Establish a set of best practices for new programs and improvement of existing programs.
Grant Types	Discretionary, competitive grants for states that have a pending or enacted enabling statute or regulation requiring the submission of controlled substance prescription data to an authorized state agency. Cities, counties, or regions within states that do not have an enabling state statute requiring the submission of PDMP data to an authorized state agency are eligible to apply under certain conditions.	Formula grant program in which each state with an approved application receives funding according to the following two-part formula: 1. Each state receives a base amount of 1% of the total funding. 2. The remaining amount is distributed according to the ratio of the number of pharmacies in the individual state to the number of pharmacies in all states with approved applications. The HHS Secretary may adjust the amount allocated to a state, after taking into consideration the estimated cost of the state's PDMP.
Authorization of Appropriations	From FY2002 to FY2016, the program itself was not authorized in statute while funding for the program was provided to DOJ each year since FY2002 through the annual appropriations process. In FY2017, DOJ incorporated the Harold Rogers PDMP into the new Comprehensive Opioid Abuse Grant Program, which was authorized at $103.00 million per year for FY2017-FY2021.	Authorizes to be appropriated $15.00 million per year for FY2006-FY2007, $10.00 million per year for FY2008-FY2010, and $10.00 million per year for FY2017-FY2021.
Appropriations	Appropriated $2.00 million in FY2002, $7.50 million in FY2003, $7.00 million in FY2004, $10.00 million in FY2005, $7.50 million in FY2006, $7.50 million in FY2007, $7.05 million in FY2008, $7.00 million in FY2009, $7.00 million in FY2010, $5.8 million in FY2011, $7.00 million in FY2012, $6.51 million in FY2013, $7.00 million in FY2014, $11.00 million in FY2015, $13.00 million in FY2016, $14.00 million in FY2017, and $30.00 million in FY2018.	No funds were appropriated for FY2006-FY2008; appropriated $2.00 million per year in FY2009 and FY2010; funding prohibited in final continuing resolution for FY2011; no funds were appropriated for FY2012-FY2018.

Source: CRS summary of information from the following sources:
For the Harold Rogers PDMP, CRS summary of U.S. Department of Justice, Bureau of Justice Assistance, *Comprehensive Opioid Abuse Grant Program*, https://www.bja.gov. For appropriations, see source list for **Table 1**. For authorization, see Section 109 of the Comprehensive Addiction and Recovery Act of 2016 (P.L. 114-198).

For NASPER authorization, see CRS summary of the National All Schedules Prescription Electronic Reporting Act of 2005 (P.L. 109-60); Section 109 of the Comprehensive Addiction and Recovery Act of 2016 (P.L. 114-198); and SAMHSA's *Justification of Estimates for Appropriations Committees* for FY2011. For appropriations, see source list for **Table 2**.

a. While DOJ incorporated the Harold Rogers PDMP into the new Comprehensive Opioid Abuse Grant Program, it is still generally referred to as the Harold Rogers PDMP.

Other Programs

Other federal programs that are explicitly used to support PDMPs include Opioid Prevention in States, PDMPs and Health Information Technology (IT), State Demonstration Grants for Comprehensive Opioid Abuse Response, and State Targeted Response to the Opioid Crisis Grants—all of which are administered by HHS.

Opioid Prevention in States

Opioid Prevention in States (OPIS) is the umbrella term for all opioid grants administered by CDC. The OPIS grants fall under CDC's Center for Injury Prevention and Control. Among the OPIS grant programs, two require states to use funds for PDMPs: the Prevention for States (PfS) grants and the Data-Driven Prevention Initiative (DDPI). Since 2015, CDC has awarded PfS funding to some states for prescription drug overdose prevention activities, including efforts to improve access to PDMPs and the timeliness of PDMP data.[89] Since 2016, CDC has awarded DDPI funding to some states and the District of Columbia to help them with opioid-related data collection and analysis; strategies to change behaviors driving prescription opioid abuse; and overdose prevention programs.[90]

These individual grant programs are not explicitly authorized in statute. The CDC Center for Injury Control and Prevention conducts activities authorized under numerous provisions, including general public health authorities of the HHS Secretary. The most directly relevant is Public Health Service Act (PHSA) Section 392, which broadly authorizes CDC to provide assistance to states and localities for injury prevention and control, but does not include an explicit authorization of appropriations. According to CDC's FY2019 budget request, the PfS and DDPI grant awards together were funded at $72 million in both FY2017 and FY2018.[91]

PDMPs and Health IT

The Office of the National Coordinator for Health Information Technology (ONC) has undertaken efforts to support the integration of PDMPs with health IT and to enhance clinician access to PDMP information using health IT. These efforts included a series of pilots, in collaboration with SAMHSA, from 2011 to 2013 to test different approaches to increasing provider access to PDMP information through health IT. In addition, ONC has undertaken an initiative to develop approaches to the challenge of a lack of uniform standards for sharing PDMP data with health IT systems such as electronic health records (EHRs) and health information exchanges.

Although ONC has directed funding to support these efforts beginning as early as 2011, they are not specifically authorized in statute and instead appear to be carried out under general statutory authorities for ONC in Title XXX of the PHSA. Both the FY2016 and the FY2017 ONC Congressional Budget Justifications requested $5 million in each of those years for efforts to support PDMP and Health IT integration under the broader budget category of Policy Development and Coordination.[92] These funds were to be used for activities including technical

[89] HHS, CDC, *Prevention for States*, https://www.cdc.gov/drugoverdose/states/state_prevention.html.

[90] HHS, CDC, *Data-Driven Prevention Initiative (DDPI)*, https://www.cdc.gov/drugoverdose/foa/ddpi.html.

[91] HHS, CDC, *Justification of Estimates for Appropriation Committees* for FY2019, p. 221. The FY2018 amount presented was based on the annualized FY2017 continuing resolution. These were not line items in the CDC FY2017 operating plan.

[92] HHS, ONC, *Justification of Estimates for Appropriations Committee* for FY2017, https://www.healthit.gov/sites/default/files/final_onc_cj_fy_2017_clean.pdf, p. 30; and HHS, ONC, *Justification of Estimates for Appropriations Committee* for FY2016, https://www.healthit.gov/sites/default/files/ONC-FY2016-budget-justification.pdf, pp. 26-27.

assistance for state PDMPs with HIT integration; challenge awards to design and use HIT to access PDMPs in clinical settings; and further adoption of electronic prescribing of controlled substances. The FY2018 and FY2019 ONC Congressional Budget Justifications do not specifically mention anything about efforts related to PDMPs.

State Demonstration Grants for Comprehensive Opioid Abuse Response

The State Demonstration Grants for Comprehensive Opioid Abuse Response were newly authorized for FY2017 by the Comprehensive Addiction and Recovery Act of 2016 (CARA, P.L. 114-198). CARA amended the PHSA by adding a new Section 548 requiring the HHS Secretary to "award grants to States, and combinations of States, to implement an integrated opioid abuse response initiative."[93] A state's response initiative may include "establishing, maintaining, or improving" a PDMP, as well as other elements such as efforts to provide education, and prevent and treat opioid abuse. PHSA Section 548 specifies that the HHS Secretary, in awarding these grants, shall give priority to a state meeting certain conditions, including several related to PDMPs (e.g., a state that ensures the capability of sharing PDMP data with other states).

PHSA Section 548 authorizes to be appropriated $5 million for the state demonstration grants for each of FY2017-FY2021. The state demonstration grants were not funded in FY2017 and FY2018.[94]

State Targeted Response to the Opioid Crisis Grants

SAMHSA's State Targeted Response to the Opioid Crisis Grants were newly authorized by the 21st Century Cures Act (Division A of P.L. 114-255; see Section 1003). One of several authorized purpose areas is improving state prescription drug monitoring programs. In FY2018, $1 billion was provided to SAMHSA for this grant program.[95]

Selected Policy Issues

Role of PDMPs in Federal Efforts to Address Prescription Drug Abuse

The VA and PDMP Participation

Federal agencies that provide health care have faced some challenges in working with state PDMPs. For example, before the Department of Veterans Affairs (VA) could contribute prescription data to state PDMPs, a statutory change was necessary to authorize the VA Secretary to disclose relevant information; this change occurred in the Consolidated Appropriations Act, 2012 (P.L. 112-74, Title II, Section 230). Since then,

[93] P.L. 114-198, §601.

[94] P.L. 115-31 and P.L. 115-141.

[95] See "Division H-Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2018," *Congressional Record*, vol. 164 (March 22, 2018), p. H2702.

In 2011, in response to the "epidemic"[96] of prescription drug abuse, the Obama Administration released an action plan.[97] This plan, from the Office of National Drug Control Policy (ONDCP), outlined four primary areas that may reduce the abuse of prescription drugs: educating individuals on the safe use of prescription drugs and risks involved in abusing them; implementing prescription drug monitoring programs (PDMPs) in the states and encouraging information sharing; developing programs for proper drug disposal; and providing law enforcement with tools to enforce proper prescribing practices and disband "pill mills."[98]

> the VA has worked state by state to be able to contribute data to each state's PDMP.
>
> The VA has also worked state by state to enable VA prescribers to query each state's PDMP because, for example, some state PDMP laws may restrict registration to prescribers who are licensed in the state, and some VA prescribers are licensed in a state other than where they work for the VA. In October 2016, the VA issued a policy establishing minimum requirements for VA providers to query state PDMPs under specified circumstances such as prior to initiating therapy with a controlled substance (VHA Directive 1306).

As part of this plan, the Administration outlined actions to improve the functioning of state PDMPs and increase interstate PDMP operability and communications. Specific actions offered included

- working with states to establish effective PDMPs by encouraging research on PDMP effectiveness and means to improve PDMP effectiveness;
- supporting the NASPER reauthorization;
- ensuring that the Department of Veterans Affairs (VA)[99] and the Department of Defense (DOD)[100] are authorized to share patient information with state PDMPs;
- encouraging federally funded health care programs to provide controlled substance prescription information to the state PDMPs (in states where they operate health care facilities or pharmacies);
- exploring the feasibility of reimbursing prescribers for checking PDMPs before writing controlled substance prescriptions to patients covered under insurance plans;

[96] According to the National Survey on Drug Use and Health (NSDUH) in 2010, estimates of persons aged 12 and over who currently used "prescription-type psychotherapeutic drugs" nonmedically (7 million or 2.7 % of this population) were similar to estimates in 2009 (7 million, or 2.8% of this population) and in 2002 (6.3 million, or 2.7% of this population). See SAMHSA, *Results from the 2010 National Survey on Drug Use and Health: Summary of National Findings*, p. 1. The Obama Administration pointed to statistics such as initiation of drug use, how people accessed prescription pain relievers, youth use of prescription drugs (at the time it was the second most-abused category of drugs after marijuana), and rising prescription drug abuse among active duty servicemembers.

[97] Office of National Drug Control Policy, *Epidemic: Responding to America's Prescription Drug Abuse Crisis*, 2011.

[98] "Pill mill" is a term used to describe a doctor, clinic, or pharmacy that is prescribing or dispensing narcotics inappropriately or for nonmedical reasons. They may be disguised as independent pain-management centers. They tend to open and shut down quickly to evade law enforcement.

[99] The Consolidated Appropriations Act, 2012 (P.L. 112-74) authorized the VA Secretary to share prescription information with state PDMPs.

[100] According to Department of Defense, *Report to Congress: Medication Management for Physically and Psychologically Wounded Armed Forces Members In Fiscal Year 2011-2012*, RefID: 6-B74CA6F, March 14, 2012, "DoD providers can access PDMPs for controlled substance prescription histories before generating prescriptions for controlled substances…. The military specific response to this challenge includes work by the PharmacoVigilance Center to apply the lessons learned and apply it to the military where relevant." The report does not indicate whether DOD dispensers contribute information to state PDMPs; however, if servicemembers fill prescriptions at retail pharmacies in the private sector (in a state with a PDMP), the prescriptions would be reported just like any others.

- evaluating programs that require certain doctor shoppers or drug abusing individuals to use one doctor and one pharmacy;
- evaluating the potential for state PDMPs to reduce Medicare and Medicaid fraud;
- issuing a final rule from DEA on electronic prescribing of controlled substances;
- increasing the use of "Screening, Brief Intervention, and Referral to Treatment" programs to identify and prevent prescription drug abuse;
- identifying how health information technologies can enhance prescription drug information;
- testing the usefulness of the Centers for Disease Control and Prevention's surveillance system to generate measures of prescription drug abuse;
- assessing the use of the Drug Abuse Warning Network to better understand prescription drug abuse at the community level;
- expanding DOJ's efforts to enhance interstate PDMP interoperability, particularly though the PMIX program; and
- evaluating existing databases with information on prescription drug access, use, misuse, and toxicity to improve their utility and as new sources of data.[101]

While this plan was never updated, the Obama Administration released a fact sheet in October 2015 outlining its public and private sector efforts to address both prescription drug abuse and heroin use.[102] This fact sheet noted that President Obama had issued a memorandum to federal departments and agencies directing two essential elements in combating this problem: prescriber training and improving access to treatment. It went on to describe private sector efforts, which included the National Association of Boards of Pharmacy enhancing access to PDMP data to thousands more physicians and pharmacists in Arizona, Delaware, Kentucky, and North Dakota in 2016. It also went on to describe public sector efforts, which included the federal government expanding access to PDMP data throughout federal agencies.[103]

In 2017, President Trump established the President's Commission on Combating Drug Addiction and the Opioid Crisis, which has issued a report outlining recommendations to combat the opioid crisis. Among its recommendations, the commission issued two that were specific to PDMPs:

> 12. The Commission recommends the Administration's support of the Prescription Drug Monitoring (PDMP) Act to mandate states that receive grant funds to comply with PDMP requirements, including data sharing. This Act directs DOJ to fund the establishment and maintenance of a data-sharing hub.
>
> 13. The Commission recommends federal agencies mandate PDMP checks, and consider amending requirements under the Emergency Medical Treatment and Labor Act (EMTALA), which requires hospitals to screen and stabilize patients in an emergency department, regardless of insurance status or ability to pay.[104]

[101] The White House, *Epidemic: Responding to America's Prescription Drug Abuse Crisis*, 2011, pp. 6-7.

[102] The White House, *FACT SHEET: Obama Administration Announces Public and Private Sector Efforts to Address Prescription Drug Abuse and Heroin Use*, https://obamawhitehouse.archives.gov/the-press-office/2015/10/21/fact-sheet-obama-administration-announces-public-and-private-sector.

[103] Ibid.

[104] The President's Commission on Combating Drug Addiction and the Opioid Crisis, *Final Report*, November 1, 2017, pp. 53-54, https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf.

In regard to Recommendation #12, the Prescription Drug Monitoring Act of 2017 (H.R. 1854; S. 778) would, if enacted, require states receiving PDMP grant funds from DOJ or HHS[105] to comply with specified requirements, including a requirement to share their PDMP data with other states. Under the proposed legislation, DOJ and HHS may withhold grant funds from states that fail to comply. It also would direct DOJ to award a grant under the new Comprehensive Opioid Abuse Grant Program to establish and maintain an interstate data-sharing hub.

Supporting PDMPs is just one component in the overall federal effort against prescription drug abuse. Research on PDMP effectiveness has yielded sometimes inconclusive results on a number of desired outcomes, though research findings suggest that PDMPs may contribute to reduced doctor shopping and prescription drug abuse. As such, policymakers may want to assess the extent to which federal agencies' PDMP-related efforts have accomplished the Administration's goals to reduce illicit prescribing activities and prescription drug abuse.

Balancing Stakeholder Concerns

While establishment and enhancement of PDMPs (such as interstate data sharing and real-time data access) enjoy broad support,[106] some stakeholders express concerns about health care versus law enforcement uses of PDMP data, particularly with regard to protection of personally identifiable health information.

Law Enforcement Use of PDMP Data[107]

Research has demonstrated that PDMPs save law enforcement officials time in investigations, *if law enforcement officials have access to PDMP information*. Concerns about potential law enforcement uses of PDMP data have been expressed by stakeholder organizations representing prescribers. The American Medical Association (AMA), a professional association of more than 200,000 physicians, supports the use of PDMPs and recommended that PDMPs be housed in health-related agencies (rather than law enforcement agencies).[108] AMA further recommends that information from PDMPs "be used first for education of the specific physicians involved prior to any civil action against these physicians."[109] The American Society of Addiction Medicine (ASAM), one of several national medical specialty societies under the AMA umbrella, likewise expresses concern about the use of PDMP data for purposes other than health care: "[L]aw enforcement, the judiciary, corrections professionals, employers, and others outside of the health care system should not be granted access to PDMP data except via the means available to them to

[105] Specifically, the bill references the Harold Rogers Prescription Drug Monitoring Program established under the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act, 2002 and the controlled substance monitoring program under Section 399O of the Public Health Service Act.

[106] For example, the Pharmaceutical Research and Manufacturers of America (PhRMA)—the industry group representing pharmaceutical research and biotechnology companies—supports PDMPs and recommends assessing their effectiveness and exploring enhancements. PhRMA, *Prescription Drug Abuse*, http://www.phrma.org/prescription-drug-abuse.

[107] CRS Legislative Attorney Brian Yeh contributed to the legal discussion in this section.

[108] American Medical Association, *H-95.946 Prescription Drug Monitoring Program Confidentiality*, AMA Policy Statements, https://policysearch.ama-assn.org/policyfinder/detail/prescription%20drug%20monitoring%20program?uri=%2FAMADoc%2FHOD.xml-0-5325.xml.

[109] American Medical Association, *H-95.947 Prescription Drug Monitoring to Prevent Abuse of Controlled Substances*, AMA Policy Statements, https://policysearch.ama-assn.org/policyfinder/detail/prescription%20drug%20monitoring%20program?uri=%2FAMADoc%2FHOD.xml-0-5325.xml.

secure access to other personally identifiable health information."[110] The fact that PDMPs contain personally identifiable health information raises concerns about privacy and data security. Both AMA and ASAM stress the need to subject PDMP information to the same standards applied to other patient records.[111]

In recent years, to investigate violations of the federal Controlled Substances Act (CSA), the DEA has demanded access to certain PDMP data without a court order or search warrant, a practice that has caused some controversy[112] and been subject to court challenge.[113] The CSA contains a provision, 21 U.S.C. §876, that authorizes the DEA to issue administrative subpoenas (without prior court approval) to obtain documents that the agency finds are "relevant or material" to an investigation involving controlled substances.[114] The DEA may also seek judicial enforcement of such subpoenas "to compel compliance" with the requests for evidence.[115] In 2012, the Oregon Department of Justice filed a lawsuit against the DEA[116] in federal court seeking a declaratory judgment that, pursuant to state law,[117] the DEA must obtain "a valid court order" in order to access patient and physician records contained in the Oregon PDMP.[118] The DEA argued that the CSA's administrative subpoena provision preempts Oregon's statutory requirement.[119] Agreeing with the DEA, the U.S. Court of Appeals for the Ninth Circuit held that the CSA[120] preempted[121] the Oregon law because the provisions are in "positive conflict ... so that the two cannot consistently stand together."[122]

In another federal case, a Utah district court upheld the DEA's exercise of its administrative subpoena power to access the state's PDMP database,[123] despite a Utah state law requirement that law enforcement officers may obtain such information only "pursuant to a valid search

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[110] American Society of Addiction Medicine (ASAM), *Public Policy Statement on Measures to Counteract Prescription Drug Diversion, Misuse and Addiction*, January 25, 2012, http://www.asam.org/advocacy/find-a-policy-statement/view-policy-statement/public-policy-statements/2012/01/26/measures-to-counteract-prescription-drug-diversion-misuse-and-addiction.

[111] American Medical Association, *H-95.946 Prescription Drug Monitoring Program Confidentiality*, AMA Policy Statements, https://policysearch.ama-assn.org/policyfinder/detail/prescription%20drug%20monitoring%20program?uri=%2FAMADoc%2FHOD.xml-0-5325.xml; and ASAM, *Public Policy Statement on Measures to Counteract Prescription Drug Diversion, Misuse and Addiction*, January 25, 2012, http://www.asam.org/advocacy/find-a-policy-statement/view-policy-statement/public-policy-statements/2012/01/26/measures-to-counteract-prescription-drug-diversion-misuse-and-addiction.

[112] Christian Gaston, "Oregon Sues DEA Over Access to Patient Drug Records," *The Oregonian*, November 30, 2012, http://www.oregonlive.com/politics/index.ssf/2012/11/oregon_sues_dea_over_access_to.html.

[113] This paragraph and the following one were authored by CRS Legislative Attorney Brian Yeh.

[114] 21 U.S.C. §876.

[115] 21 U.S.C. §876(c).

[116] Or. Prescription Drug Monitoring Program v. DEA, 998 F. Supp. 2d 957 (D. Or. 2014).

[117] Or. Rev. Stat. §431A.865(2)(a)(G) (2017).

[118] Or. Prescription Drug Monitoring Program v. DEA, 860 F.3d 1228, 1230 (9th Cir. 2017).

[119] Pursuant to the Supremacy Clause of Article VI of the U.S. Constitution, Congress has the power to preempt, or override, state law. U.S. Const. art. VI, cl. 2. The Controlled Substances Act contains a preemption provision codified at 21 U.S.C. §903.

[120] 21 U.S.C. §876.

[121] *Or. Prescription Drug Monitoring Program*, 860 F.3d at 1236.

[122] Ibid., quoting 21 U.S.C. §903.

[123] United States Dep't of Justice v. Utah Dep't of Commerce, No. 2:16-cv-611-DN-DBP, 2017 U.S. Dist. LEXIS 118470 (D. Utah 2017).

warrant."[124] Though the court first observed that the Supremacy Clause resolves the conflict between the conflicting federal and state laws at issue,[125] Utah asserted that the DEA's use of the CSA's administrative subpoena provision is not a "valid exercise of national power" because the Fourth Amendment's protections against unreasonable search and seizure require a search warrant to access the PDMP data.[126] The court disagreed with the state,[127] ruling that the DEA's subpoena authority is a valid exercise of national power "that does not offend the Fourth Amendment" because the pharmaceutical industry is a highly regulated one in which "physicians and patients have no reasonable expectation of privacy from the DEA" in the records stored in Utah's PDMP.[128]

Privacy of Individually Identifiable Health Information and PDMPs

PDMPs have elicited numerous concerns about patient privacy, including issues around the scope and breadth of authorized access to collected health information as well as the potential for unauthorized access or breaches. While PDMPs are seen as a valuable source of information in the effort to address improper prescribing of controlled substances, concerns exist about the potential deterrent effect on timely access to needed medication due to fears that sensitive health information will be shared with PDMPs, and may be subsequently legally disclosed or accessed through a breach.[129]

PDMPs have varying requirements with respect to the security and authorized use and disclosure of their stored information. These uses and disclosures are regulated by state law. PDMPs also receive protected health information (PHI) from pharmacists and other health care providers (HIPAA covered entities) who are subject to the federal HIPAA Privacy Rule.[130] In addition, individually identifiable health information that is generated pursuant to treatment at substance abuse facilities is subject to stricter privacy requirements established by the "Part 2" rule.[131]

The HIPAA Privacy Rule governs covered entities' (health care plans, providers and clearinghouses) and their business associates' use and disclosure of PHI. The rule describes multiple situations in which covered entities may use or disclose PHI, while all uses and disclosures of PHI by covered entities or business associates that are not expressly permitted under the rule require the individual's prior written authorization. Generally, covered entities may share PHI between and among themselves for the purposes of treatment, payment or healthcare operations, with few restrictions (and specifically, without out the individual's authorization).[132]

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[124] Utah Code Ann. §58-37f-301(2)(m) (LexisNexis 2017).

[125] *United States Dep't of Justice,* 2017 U.S. Dist. LEXIS 118470, at *16.

[126] Ibid. at *17.

[127] The Utah Attorney General's Office reportedly decided not to appeal the district court's decision. See Lindsay Whitehurst, "Utah to Obey Order for DEA Drug Database Search," *The Salt Lake Tribune*, August 22, 2017, https://www.sltrib.com/news/2017/08/22/utah-to-obey-order-for-dea-drug-database-search/.

[128] *United States Dep't of Justice,* 2017 U.S. Dist. LEXIS 118470, at *22. However, the court noted that Utah still has the authority to require a search warrant for *state and local* law enforcement officers and prosecutors to access the PDMP. Ibid. at *22.

[129] MM Islam, IS McRae, "An inevitable wave of prescription drug monitoring programs in the context of prescription opioids: pros, cons and tensions," BMC Pharmacological Toxicology, vol. 15, 2014.

[130] Protected health information is defined as individually identifiable health information that is transmitted by electronic media; maintained in electronic media; or transmitted or maintained in any other form or medium (45 C.F.R. §106.103).

[131] PHSA Section 543 (42 U.S.C. §290dd-2); 45 C.F.R. Part 2.

[132] 45 CFR §164.506

Certain other uses and disclosures (e.g., sharing PHI with family members and friends) are permitted, but require the covered entity to give the individual the opportunity to object or agree to the PHI's use or disclosure.[133]

The HIPAA Privacy Rule also recognizes that PHI may be useful in other circumstances aside from health care treatment and payment for a given individual. For this reason, the rule lists a number of "national priority purposes" for which covered entities may disclose PHI without an individual's authorization or opportunity to agree or object.[134] PDMPs can receive PHI from covered entities under authority of one or more of these exceptions. Relevant exceptions include disclosures required by law—in this case, state PDMP laws; disclosures for public health activities; or disclosures for health oversight activities.

A PDMP is not a HIPAA covered entity, nor is it generally a business associate as defined by HIPAA, and in these cases the HIPAA requirements and standards for maintaining the security and privacy of the PHI—or for its re-disclosure—that apply to HIPAA covered entities would not apply to PDMPs. Although HIPAA may not apply, privacy and security requirements for PDMPs are still enumerated under state law.

Stricter privacy requirements—commonly known as the "Part 2" rule—apply at the federal level to individually identifiable patient information received or acquired by federally assisted substance abuse programs.[135] The "Part 2" rule allows such programs to disclose information with patient consent or pursuant to exceptions in regulation; however, in the case of PDMPs, it prohibits re-disclosure of information without patient consent. The requirement for consent may be a logistical deterrent to the submission of this information to PDMPs. In addition, since PDMPs are designed to share information with registered users, the "Part 2" rule's prohibition on re-disclosure without patient consent discourages federally assisted substance abuse programs from contributing to PDMPs' information about controlled substances dispensed for the treatment of opioid addiction (i.e., methadone or buprenorphine) due to concerns that authorized re-disclosures of the data could not be prevented.

Federal Role in Interstate Information Sharing and Interoperability

Federal policymakers have repeatedly emphasized the importance of enhancing interstate information sharing and the interoperability of state systems. The PDMP component of the Obama Administration's 2011 action plan to counter prescription drug abuse included efforts to improve the functioning of state PDMPs and increase interstate PDMP operability and communications. In 2013, HHS published a congressionally mandated report on PDMP interoperability standards for interstate exchange of PDMP information.[136] In November 2017, a presidential commission recommended, among other things, that the Trump Administration support legislation to require DOJ to fund a "data-sharing hub" and require states receiving federal grant funds to share PDMP data.[137]

[133] 45 CFR §164.508, 45 CFR §164.510

[134] 45 CFR §164.512

[135] Stricter state privacy law may also apply on a state by state basis.

[136] HHS, *Prescription Drug Monitoring Program Interoperability Standards*, September 2013, https://www.healthit.gov/sites/default/files/fdasia1141report_final.pdf. The report was mandated by Section 1141(c) of P.L. 112-144

[137] The President's Commission on Combating Drug Addiction and the Opioid Crisis, *Final Report Draft*, November 1, 2017, p. 13, https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf.

The Rise in Illicit Opioid Abuse

In 2014, then-Attorney General Holder called the rise in heroin abuse "a sad but not unpredictable symptom of the significant increase in prescription drug abuse we've seen over the past decade."[138] While then-Attorney General Holder did not cite increased monitoring of prescription opioids and enforcement activities as a reason for the rise in heroin abuse, others have stated that the crackdown on prescription drug abuse may have led users to turn to heroin, a cheaper alternative to prescription drugs that may be more easily accessible to some who are seeking an opioid high.[139]

Policymakers may debate whether increased scrutiny and monitoring of prescription drug activity has unintentionally contributed to the increase in heroin abuse; and if this is the case, how might the government address this issue, if at all.

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[138] U.S. Department of Justice, *Attorney General Holder, Calling Rise in Heroin Overdoses 'Urgent Public Health Crisis,' Vows Mix of Enforcement, Treatment*, Justice News, March 10, 2014, http://www.justice.gov/opa/pr/2014/March/14-ag-246.html.

[139] Pradip K. Muhuri, Joseph C. Gfroerer, and M. Christine Davies, *Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States*, Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality, August 2013, http://www.samhsa.gov/data/2k13/DataReview/DR006/nonmedical-pain-reliever-use-2013.pdf; Theodore J. Cicero, Matthew S. Ellis, and Hilary L. Surratt, "Effect of Abuse-Deterrent Formulation of Oxycontin," *New England Journal of Medicine*, vol. 367, no. 2 (July 12, 2012), pp. 187-189; U.S. Department of Justice, National Drug Intelligence Center, *National Drug Threat Assessment 2003*, "Narcotics", January 2003, http://www.justice.gov/archive/ndic/pubs3/3300/pharm.htm; and U.S. Department of Justice, National Drug Intelligence Center, *National Drug Threat Assessment 2011*, August 2011, p. 37, http://www.justice.gov/archive/ndic/pubs44/44849/44849p.pdf.

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