

A Legal and Ethical Analysis Advocating for the Inclusion of Methadone in State Prescription Drug Monitoring Programs *An Information Paper*

This information paper was created by members of the ACEP Ethics Committee,
August 2021

Objective Background

In an effort to curtail the misuse and abuse of opioid medications, in 2018 the ACEP Council and the Board of Directors adopted Amended Resolution 28(18): Inclusion of Methadone in State Drug and Prescription Databases. This resolution called for the end of prohibition and subsequent inclusion of methadone dispensed by Opioid Treatment Programs (OTPs) in state and federal prescription drug monitoring programs (PDMPs). In response to this resolution, however, concerns were raised regarding the unintended consequences that may occur as a result of the inclusion of methadone in PDMPs.

In response to these concerns, the Board asked the Ethics Committee to collaborate with the Medical-Legal Committee and the State Legislative/Regulatory Committee to review Amended Resolution 28(18). After careful consideration, the overwhelming majority of the members of all three Committees supported implementing the resolution. A vocal minority on the State Legislative/Regulatory Committee remained opposed to the resolution, however, largely based on concern about breaches of patient privacy and the potential repercussions of such breaches. In response to this continued opposition, the Board asked the Ethics Committee to develop an information paper to address legal, ethical, and privacy issues that may arise from the inclusion of methadone in PDMPs.

Background

Federal Regulations

The regulation of opioids and the treatment of opioid addiction has a long and complex history. The regulation of opioids began in 1914 with the Harrison Narcotics Act. This federal law regulated and taxed the importation, production, distribution, and physician prescription of opioids. With regard to physician prescribing practices, the act stated that a doctor could prescribe an opioid “in the course of his professional practice only”¹; however, the act did not provide further explanation of this clause. The Supreme Court later ruled, in *Webb v. United States* 249 U.S. 96, 99 (1919), that physicians could not prescribe opioids for the purposes of maintenance therapy for addiction, as at that time addiction was viewed as a moral failing or crime and not as a disease.

As the heroin epidemic accelerated in the 1960s, so did a shift in the approach to addiction from a punitive to a therapeutic approach.² The Narcotic Addict Rehabilitation Act of 1966 established a federal civil commitment program in response to evidence that oral methadone maintenance facilitated abstinence from heroin. Methadone treatment centers during the late 1960s largely operated under Investigational New Drug (IND) applications issued by the FDA. Methadone, however, remained controversial. Concerns were raised about inappropriate use, profiting, diversion, lack of regulation,

iatrogenic addiction, accidental overdose, and the use of methadone to control young black men, causing the FDA to tighten restrictions on INDs.²

Even during the War on Drugs, in 1971, the Nixon administration acknowledged the safety and efficacy of methadone maintenance therapy. To expand access to methadone therapy while minimizing perceived and real problems associated with its use, the Special Office for Drug Abuse Prevention worked with the FDA to develop a set of regulations. The regulations, promulgated in 1972, established the basic framework that still governs the use of methadone maintenance therapy, or similar agonist therapy. Among these regulations was the restriction of methadone availability to “medication clinics.” While their authors did not intend these regulations to limit the prescribing and dispensing of methadone to specialty clinics,³ this restriction was the origin of today’s Opioid Treatment Programs (OTPs). The regulations also established strict limitations on take-home doses to deter diversion and prevent potentially lethal ingestion by a child or other opioid-naïve person. Other regulations included restrictions on patient age, duration of therapy, and other eligibility criteria.

In 1970, Congress enacted the Controlled Substances Act (CSA), declaring that “the illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people.” (21 U.S.C.S. § 801). Federal regulation enacted under the CSA established five schedules for controlled substances based on the medical utility of the drug and its potential for abuse, misuse, or dependence. Schedule I substances are deemed to have no medical utility and are illegal in the US. Schedules II-V have medical utility, but have potential harms, and the regulations impose restrictions based on the level of perceived potential harm. In an amendment to the CSA, The Narcotic Addict Treatment Act (NATA) of 1974 established Drug Enforcement Agency (DEA) jurisdiction over the storage and security of medications used to treat addiction.² NATA also required practitioners and treatment sites to register with the DEA in order to prescribe controlled substances, and a separate registration for physicians to treat opioid addiction with Schedule II medications.

When the DEA was established as the law enforcement agency tasked with combatting drug trafficking and unlawful distribution, the Secretary of Health, Education, and Welfare (now Health and Human Services) retained responsibility for setting standards and regulations pertaining to the treatment of addiction. The 1972 drug enforcement regulations were modified in 1980, 1989, and 1993.² The following three-tiered approach to methadone oversight persists today: 1) the FDA’s general requirements for establishing safety, efficacy, and quality of pharmaceuticals; 2) the DEA’s requirements for registration and licensing; and 3) the Department of Health and Human Services (DHHS) Secretary’s regulations delegating authority to the FDA to set regulations on how and when methadone may be prescribed.⁴ In 1995, the Institute of Medicine (IOM) advocated for revision of the overly restrictive regulations in order to realize the full benefits of methadone treatment. The IOM described methadone not just as a treatment for addiction, but part as part of an approach to complex public health issues related to drug use, including violent crimes, HIV, and hepatitis that affect the community as a whole.

The IOM attributed the lack of modernization of the regulations in part due to bureaucratic inertia. In the 1990s, as buprenorphine became recognized as an effective treatment, its improved safety profile prompted the development of new legislation, the Drug Addiction Treatment Act of 2000 (DATA 2000), which is beyond the scope of this paper.

State Prescription Drug Monitoring Programs

The goal of state PDMPs is similar to that of federal regulations – to reduce the misuse, abuse, or inappropriate prescription of controlled substances. PDMPs are not a novel entity; New York implemented a state PDMP in 1918, followed by California in 1939. Today, all states have some form

of PDMP, with Missouri being the last state to establish one in 2017. PDMPs, in their present form, are electronic databases that collect data from pharmacies and healthcare providers that dispense controlled substances. State laws dictate who can access the information contained within a PDMP.

The U.S. Supreme Court's landmark 1977 decision in *Whalen v. Roe* addressed the balance between the state's interest in tracking individuals' prescription information and patient rights to confidentiality of personal health information.⁵ In order to implement a more effective PDMP, the New York legislature enacted a new law requiring that Department of Health employees record patient identification, prescription information, and other personal data. The plaintiffs in the case argued that the law was unconstitutional because it violated individual privacy rights, would deter patients from seeking treatment, and would further stigmatize addiction. On appeal, the U.S. Supreme Court ruled that the state's policing effort to protect the health of the public by monitoring the use of prescription drugs with addiction and misuse potential was a reasonable exercise of power. That public health responsibility justified restrictions on patient rights to confidentiality. In subsequent cases, most courts, applying *Whalen's* balancing test, have continued to rule in favor of the state. While individuals have a right to privacy in their medical records, this right is not absolute.⁵

The primary functions of PDMPs today are promote patient safety and coordinate care. PDMPs promote safe prescribing practices by enabling providers to identify potential drug-drug interactions with controlled substances that other providers have prescribed. Querying the PDMP may also help identify patients who need screening for substance use disorders and linkage to care. States vary in the scope of information contained in PDMPs, who has access to the information, the timeliness and accuracy of the information, how and when unsolicited reports are generated, querying requirements for prescribers, and interstate sharing, among other aspects.⁶

Until recently, medications administered by OTPs were not included in PDMPs. Federal confidentiality requirements under 42 C.F.R. Part 2 protect patient information received or acquired by federally-assisted substance abuse programs. These regulations provide a layer of protection in addition to the privacy safeguards implemented by the Health Insurance Portability and Accountability Act privacy rules. On August 14, 2020, a final rule amended 42 CFR Part 2 to allow OTPs to send patient information to the PDMP, but patients must first consent to the release of this information.

In a 2011 guidance letter, the Substance Abuse and Mental Health Services Administration (SAMHSA) encouraged OTPs to query PDMPs prior to dispensing medications to improve patient safety; this letter stated that OTPs could not disclose information to the PDMPs unless an exception applied that was consistent with federal regulations, however.⁷ In the 2020 amendment to 42 CFR Part 2, SAMHSA states that, in response to the public health crisis created by opioid misuse, abuse, and overdose, they no longer believe that the aforementioned policy to be advisable. SAMHSA takes the stance that the omission of OTP data from PDMPs is detrimental to patient safety and increases the potential risks of overdose and death. It proposes inclusion of OTP data in the PDMP to improve coordination of care among providers, patient safety, and overall patient care by incorporating more accurate and comprehensive data into medical decision making. The amendment requires that the patient's written consent be obtained prior to disclosing patient data by an OTP, that the written consent is specific to the PDMP and distinct from disclosures for care coordination in § 2.33. The rule also states that SAMHSA will consider future revisions to § 2.36 as needed, to allow for modernization, as may be needed in future. As PDMPs are state-specific, it is up to each state to modernize and update the processes required for this change.

Parallel Public Health Benefits: Methadone and Other Opioids

PDMPs are a recognized tool for public health and prescribers alike, critical in the management of the

opioid crisis. With increased awareness of controlled substance misuse, abuse, and diversion, there has been increased attention to ensuring that prescriptions for high risk substances are appropriate. The following benefit of PDMPs are not widely debated:

- 1) they monitor for and limit “doctor shopping”;
- 2) they support licensing boards in reviewing licensee’s practices and investigating of inappropriate prescribing or dispensing;
- 3) they reduce inappropriate prescription of opioids and controlled substances; and
- 4) they generate data to help identify concerning public health trends in specific medications, locations, or demographics.⁸

For regulatory and investigatory bodies, these databases provide a public health surveillance tool to monitor and respond to adverse trends.⁹ For the individual prescriber, reviewing a particular patient’s PDMP allows for a better understanding of potential drug-drug interactions (based on prescription of other high-risk medications that the patient may not have disclosed) and potential patterns of abuse (based on recently filled prescriptions that conflict with the patient’s stated need for a new controlled medication). Identification of a pattern of misuse may warrant an open discussion about risk-reduction strategies and referrals to substance use disorder treatment programs.

All of these can be best characterized as efforts to either reduce public harm (by responding to inappropriate prescribing patterns and analyzing problematic trends) or improve care for individual patients (by avoiding duplicative prescriptions and addressing misuse or diversion in real-time).

These are the conceptual *goods* that a PDMP might bring to the care of patients and the public at large. Growing evidence is showing that the database is effective at achieving these goods. Utilization of these programs has been associated with decreased prescriptions from multiple providers, decreased substance abuse admissions, and an increase in substance use disorder treatment.¹⁰ This experience indicates that these benefits of a robust PDMP are not theoretical but of legitimate practical value.

Each of these widely recognized values of effective PDMPs applies to methadone in the same way it applies to every other opioid registered on the databases. Although methadone has a role in substance use disorder treatment through medication-assisted treatment, it is also recognized as posing a “particularly high risk for overdose death.”¹⁰ As a recent SAMSHA provider briefing highlights quite dramatically, “Methadone is involved in about one-third of deaths related to opioid pain relievers, even though only two percent of pain reliever prescriptions are for this medication.”¹⁰ Despite its various uses, methadone’s pharmacological properties as an opioid and identical, if not higher, risk for misuse and diversion place it clearly within the appropriate purview of a PDMP. In short, all of the benefits that PDMPs offer also support including methadone within their databases.

From De-stigmatization to Normalization

Many of the arguments against the inclusion of methadone in PDMP databases are deeply rooted in stigma. First, a segment of healthcare professionals and society at large still maintain that opioid dependence is a moral weakness or willful choice, and therefore shameful.¹¹ Second, some believe that methadone is simply substituting one opioid for another.¹² In this model, the patient retains the addiction and thus the shame.

Some healthcare professionals and policy makers want to maintain the prohibition against PDMP inclusion of methadone in order to protect patients from judgment or other negative repercussions. They assert that inclusion of methadone into PDMP databases could allow law enforcement, employers, and non-physician healthcare professionals to access records of methadone administration, and that such

availability could have harmful legal or social ramifications.¹³ In believing that this *could* happen, they may be correct. These opponents, however, fail to recognize that continuing the secrecy around methadone simply perpetuates its misguided stigma. *The real problem is not that including methadone in PDMP databases may increase transparency and thus knowledge of methadone treatment, but rather that there are any negative ramifications at all to a patient receiving methadone treatment.* To address this problem, health care professionals must advocate for methadone to be considered exactly what it is: a medication that treats a disease.

Consider the case of HIV testing. What other laboratory tests in the hospital require a separate consent? HIV was once considered a shameful, stigmatized disease, but today, it has touched all segments of society and has made huge gains in de-stigmatization. HIV tests can be ordered without separate consent. There are television commercials for HIV treatments. But before that could happen, it had to just be considered a disease, not a sin.

Potential for Security Breaches

In today's age of constant threats by internet hackers, breaches of security are a very real concern. PDMPs are operated at the state level by governing bodies within the state department of health, and PDMP access is dependent upon individual state laws. Confidentiality rules, such as password requirements, are in place, but, as with all things stored on a computer system, there is potential for unintended outsider access. Despite HIPAA laws pertaining to the security of health records, there have been instances of large-scale hacking of protected health information. In 2014, when an employee of Anthem insurance mistakenly opened a phishing e-mail, records of almost 80 million patients were accessed. In 2009, a hacker illegally accessed 35 million prescription records in the State of Virginia's PDMP.

There is also the concern for inappropriate access, such as when someone accesses the medical records of a patient with whom they have no treatment relationship or in excess of what is needed for care. This inappropriate access can be by an employee at a physician's office or hospital, such as a medical records clerk, a nurse or even another physician. While there are many examples of this occurring in relation to famous or well-known people, there is risk to any individual. Out of curiosity, or perhaps more nefarious reasons, hospital or clinic employees may seek information without medical necessity. This scenario has led to the firing of many employees through the years for illegally accessing records of professional athletes, musicians, and actors. If curiosity has led individuals to access medical data inappropriately, it is reasonable to suspect that something similar may happen with PDMPs.

Another potential breach of information found in the PDMP is indirect access to the results of a physician's query. After checking the PDMP, physicians will often put their findings into a patient's electronic chart in an effort to explain further treatment or prescription use. Out of necessity, patients' medical records are shared with a variety of people. This may include lawyers involved in a legal case regarding the patient or physician, insurance and coding / billing companies, worker's compensation investigators, and others not related to the PDMP finding. Review of a patient's chart may reveal incidental PDMP information. An example of this would be an employer who was given the patient's record as part of a worker's compensation claim. In addition to information regarding the injury, there could be results from a PDMP search done by the physician. The employer may misinterpret this information and intentionally or unintentionally use it against the employee. Of note, however, these potential breaches of confidentiality apply to all medications in the PDMP and not are not unique to methadone. Furthermore, while there are incidences of security breaches, they are uncommon and have not been used to justify calling the PDMP into question for other medications.

Law Enforcement

All states allow law enforcement access to their PDMPs, but the degree of access and criteria for access vary by state. Law enforcement access to PDMPs is based on having an “active investigation” in 28 states, while 21 states have more stringent requirements of needing a search warrant, court order, or subpoena.¹⁴ The Pennsylvania PDMP authorizes access to prescribers, dispensers, the attorney general’s office (on behalf of law enforcement), designated Commonwealth personnel, and medical examiners or county coroners. The state of Washington’s PDMP is solely funded by law enforcement agencies. Important considerations include that law enforcement access to the PDMP may deter patients from seeking medical treatment, including substance abuse treatment, for fear of stigmatization, and may make physicians reluctant to prescribe opioids even when medically indicated because they are being “watched.” To mitigate these concerns, PDMP should maintain a tightly regulated process for appropriate access. Law enforcement access, however, does not necessarily mean that privacy and confidentiality will be violated. The Pennsylvania PDMP’s privacy and confidentiality statement notes that the HIPAA privacy rule and state law protect patient privacy and that prescription information is confidential and not subject to the act of February 14, 2008 P.L.6, No. 3 Right-to-Know-Law.¹⁵

The PDMP Training and Technical Assistance Center (TTAC) has state-specific information for sending solicited and unsolicited reports to law enforcement agencies.¹⁶ Because of variability in state PDMPs, there is concern about compromises to patient and provider privacy, and some argue for legislation creating a national standard to help regulate privacy and security protections for individuals whose information is captured in these databases. CA CURES allows law enforcement to be pre-registered users that can gain access to the electronic system in real time without making a request.⁵ The 2005 *Douglas v Dobbs* decision used a “balancing test” to weigh an individual expectations of privacy in their controlled substance prescriptions against state interests in monitoring the use of dangerously addictive drugs.⁵ Almost all court cases have been unwilling to find a violation to privacy based on this balancing test between individual and state. In 2012 and 2014, Oregon asserted 4th amendment protections for right to privacy, but law enforcement agencies including the DEA successfully argued that individuals are not protected when information is held by a third party, such as a PDMP.⁵ States may exercise “police power” to protect and promote public health, safety and general welfare. With most states allowing law enforcement access, there is the potential for PDMPs to be considered more a tool of the police than for patient safety. Maintaining a balance between enforcing laws and protecting the rights and health of individuals is a challenge for law enforcement and provides an opportunity for community-based policing where police can collaborate with community members to respond effectively to public health goals for this vulnerable population.

Privacy concerns are also a potential problem when it comes to insurance companies. In theory, information about a patient’s use of controlled substances could be valuable to insurance companies who could deny coverage to individuals deemed at risk. Insurers, however, already have access to substance use disorder treatment information, so including methadone information in the PDMP may not change what is known. The PDMP TTAC has state-specific information regarding PDMP practices in sending solicited and unsolicited reports to public and private insurance entities.¹⁷ An additional concern regarding companies who are self-insured is that self-insured health insurance plans may access employee’s prescriptions to monitor use and costs of the plan.⁵ Third-party doctrine, that holds that information that is voluntarily given to a third parties may be accessed by the US government without a warrant, may include hospitals and health insurers. In the Oregon vs DEA cases supported that third-party doctrine overrides privacy expectations. Under HIPAA, health plans are considered covered entities like doctor’s offices and pharmacies and may disclose personal health information when required by law or for health oversight activities. Some claim that this exception is general enough that it could apply to PDMPs, but others argue that PDMPs are not considered covered entities and so fall out of scope of federal or state privacy standards.

Effective integration of healthcare systems and PDMPs requires exchange of patient health care information. The National Heroin Task Force, which consists of law enforcement officers, doctors, public health officials, and education experts, convened in 2015 to develop strategies to mitigate harms related to heroin use.¹⁸ They reported that integration and coordination of health care for substance use disorders and mental health can lead to better outcomes and address disparities. Public health approaches such as Minnesota's 2012 State Substance Abuse Strategy involve coordination across federal, state, and local levels in order to: 1) create comprehensive community structures that strengthen prevention and intervention; 2) interrupt cycles of substance use, crime, and incarceration; and 3) expand support for recovery, among other aspects.¹⁸ PDMPs can be integral to inter-agency collaboration of relevant stakeholders to allow sharing of information to improve treatment and patient safety without compromising privacy and confidentiality.

Recommendations and Conclusions

We contend that the primary objective of the PDMP is patient safety. Secondary objectives are improving coordination of care and decreasing misuse, diversion, and irresponsible prescribing patterns. These objectives can only be maximally achieved if the database is complete and includes methadone. As our nation continues to fight the COVID-19 pandemic and recover from the widespread social, economic, and mental health consequences that will persist in its aftermath, it is a moral imperative of the healthcare system to advocate for patient safety measures. The CDC reports that in Chicago's Cook County, during the 11-week stay-at-home order, weekly opioid overdose deaths rose from a relatively stable pre-pandemic average of 22.6 to 43.3. In the subsequent 18 weeks after the stay-at-home order was lifted, the mean declined to 31.2, which the report states is concerning as it may indicate continued upward trend in opioid overdose deaths.¹⁹ The pandemic has led to interruptions in healthcare, including substance abuse treatment, and disruptions in living situations. As people shift their lives, the places they live, and their healthcare, coordination of care is needed to maintain patient safety and minimize unnecessary healthcare spending.

While the potential for a privacy breach is a valid concern, it has long been established by the courts that state public health responsibilities can outweigh these potential risks with the application of a balancing test. The potential privacy risks already exist for the other medications on the PDMP and have not been significant enough to call the programs into question. The change that needs to occur is a de-stigmatizing of treatment for substance use disorders, not a forgoing of potentially lifesaving protections, that also serve the goal of de-stigmatization. If there is a fear of repercussions from employers, insurance companies, or other entities, explicit policies should address protections to prevent such repercussions and protect the rights of persons adhering to substance use treatment plans. Treating substance use disorders differently than other diseases perpetuates shame and stigma. The future of substance use disorder treatments should incorporate a movement from de-stigmatization to normalization around therapies, such as methadone, for substance use disorders.

References

1. Terry CE. The harrison anti-narcotic act. *Am J Public Health*. 1915 Jun;5(6):518.
2. Jaffe JH, O'Keefe C. From morphine clinics to buprenorphine: regulating opioid agonist treatment of addiction in the United States. *Drug Alcohol Depend*. 2003 May 21;70(2 Suppl):S3-11.
3. Jaffe JH. The history and current status of opiate agonist treatment. 1997:19-25.
4. Institute of Medicine (US) Committee on Federal Regulation of Methadone Treatment, Rettig RA, Yarmolinsky A, eds. *Federal Regulation of Methadone Treatment*. Washington (DC): National Academies Press (US); 1995.

5. Simek CP. Do Prescription Drug Monitoring Programs Compromise Patient Privacy By Remaining Outside Federal and Most States' Privacy Standards? *J Health Care Finance*. 2019;46(1).
6. American Society of Addiction Medicine. Public Policy Statement on Prescription Drug Monitoring Programs (PDMPs). 2018.
7. Clark H. *Dear Colleague Letter* 2011. https://www.samhsa.gov/sites/default/files/programs_campaigns/medication_assisted/dear_colleague_letters/2011-colleague-letter-state-prescription-drug-monitoring-programs.pdf
8. Hopkins DR. The Fundamentals of PDMP Operations, 2017.
9. Substance Abuse and Mental Health Services Administration. Prescription Drug Monitoring Programs: A Guide for Healthcare Providers. *In Brief*. 2017;10(1)
10. Briefing C. Mandating PDMP participation by medical providers: current status and experience in selected states.
11. White WL. Long-term strategies to reduce the stigma attached to addiction, treatment, and recovery within the City of Philadelphia (with particular reference to medication-assisted treatment/recovery). *Philadelphia: Department of behavioral health and mental retardation services*. 2009.
12. Woo J, Bhalerao A, Bawor M, et al. “Don’t judge a book by its cover”: a qualitative study of methadone patients’ experiences of stigma. *Subst Abuse*. 2017 Mar 23;11:1178221816685087.
13. Madera JL. In: Pallone GWaF, editor. 2018.
14. The PEW. Policy Changes Could Bolster Prescription Drug Monitoring Programs. <https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2020/04/policy-changes-could-bolster-prescription-drug-monitoring-programs>
15. Pennsylvania Department of Health. Patient Information Accessed May 18 2021. <https://www.health.pa.gov/topics/programs/PDMP/Pages/Patients.aspx>
16. Prescription Drug Monitoring Program Training and Technical Assistance Center. PDMPs Authorized and Engaged in Sending Solicited and Unsolicited Reports to Law Enforcement Entities. Accessed May 18 2021. https://www.pdmpassist.org/pdf/Law_Enforcement_Entity_Table.pdf.
17. Prescription Drug Monitoring Program Training and Technical Assistance Center. Accessed May 18, 2021. https://www.pdmpassist.org/pdf/Insurance_Entity_Table.pdf.
18. Substance Abuse and Mental Health Services Administration. Health care systems and substance use disorders. *Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health [Internet]*. US Department of Health and Human Services; 2016.
19. Mason M, Welch SB, Arunkumar P, et al. Notes from the Field: Opioid Overdose Deaths Before, During, and After an 11-Week COVID-19 Stay-at-Home Order—Cook County, Illinois, January 1, 2018–October 6, 2020. *MMWR Morb Mortal Wkly Rep*. 2021 Mar 12;70(10):362-63.