REPORT OF THE BOARD OF TRUSTEES

B of T Report 30-A-19

Subject: Opioid Treatment Programs Reporting to Prescription Monitoring Programs (Resolution 507-A-18)

Presented by: Jack Resneck, Jr., MD, Chair

Referred to: Reference Committee B (Charles Rothberg, MD, Chair)

INTRODUCTION

At the 2018 American Medical Association (AMA) House of Delegates (HOD) Annual Meeting, the Medical Student Section introduced Resolution 507-A-18, asking that our AMA amend Policy D-95.980, “Opioid Treatment and Prescription Drug Monitoring Programs,” by deletion as follows:

Our AMA will seek changes to allow states the flexibility to require opioid treatment programs to report to prescription monitoring programs.

The resolution was ultimately referred. There was considerable testimony at the reference committee identifying numerous issues to both support and oppose the resolution. This report provides a current update of prescription drug monitoring programs (PDMPs), the privacy protections patients are afforded with respect to PDMPs, relevant federal laws governing opioid treatment programs (OTPs), highlights relevant AMA policy, and presents a recommendation.

DISCUSSION

Prescription drug monitoring programs

PDMPs are generally described as electronic interfaces that allow physicians and other authorized users to view a patient’s-controlled substance prescription history. Every state except Missouri has a PDMP, although some are more advanced than others. The AMA supports physicians registering for and using PDMPs as part of the clinical decision-making process.

At present, at least 44 states require physicians and other clinicians who prescribe controlled substances to query the PDMP under certain circumstances. These mandates range from requiring a query prior to prescribing any controlled substances every time a prescription for a controlled substance is issued to every six months or a year; to queries limited only to the prescribing of opioid analgesics and benzodiazepines.

Emerging data suggests that PDMPs have not led to reductions in opioid-related mortality as proponents have predicted. From 2014 and 2017, physicians’ and other health care professionals’ use of PDMPs increased from 61.4 million queries to more than 300.3 million queries; and registration to use a PDMP increased from 471,896 to more than 1.5 million registered users.\(^1\) Opioid-related mortality, however, has increased considerably. From 2012 to 2017, prescription opioid-related mortality increased from 11,134 to 14,495; heroin-related mortality increased from...
5,925 to 15,482; and illicit fentanyl-related mortality increased from 2,628 to 28,466. Meanwhile, there remains an unacceptable treatment gap for those with a substance use disorder (SUD) or co-occurring mental illness. According to the 2017 National Survey on Drug Use and Health (NSDUH) conducted by the U.S. Substance Abuse and Mental Health Services Administration, 92.3 percent of those age 12 and older received no treatment for an SUD; and 91.7 percent of those 18 and older received no treatment for a co-occurring mental illness and SUD.

Evaluation of PDMPs before 2012 found mixed results with respect to PDMP effects on opioid prescribing, reductions in morphine milligram equivalents (MME), per-capita opioid prescribing, mortality rates, and opioid-related admissions to the emergency department. A more recent, comprehensive study found that “PDMPs were not associated with reductions in drug overdose mortality rates and may be related to increased mortality from illicit drugs and other, unspecified drugs.” A prospective look at how PDMPs can impact the nation’s opioid epidemic found that “interventions such as prescription drug monitoring programs are unlikely to lead to major decreases in the number of deaths from opioid overdose in the near future.” These studies are not to suggest there is no role for PDMPs or that there is no other data showing positive effects of PDMPs—rather, that an overreliance on PDMPs to solve the nation’s opioid epidemic will not likely lead to widespread, positive impacts.

**PDMPs and privacy protections**

The AMA Code of Medical Ethics (the Code) states that “Protecting information gathered in association with the care of the patient is a core value in health care.” The Code further states that Patients need to be able to trust that physicians will protect information shared in confidence. They should feel free to fully disclose sensitive personal information to enable their physician to most effectively provide needed services. Physicians in turn have an ethical obligation to preserve the confidentiality of information gathered in association with the care of the patient.

In a recent letter to the United States Office of Civil Rights, the AMA stated that the first step of any ultimately successful privacy framework, legislative or regulatory, places the patient first. Each entity seeking access to patients’ most confidential medical information must pass the stringent test of showing why its professed need should override individuals’ most basic right in keeping their own information private—something that technology can help physicians accomplish in a minimally burdensome way. Moreover, citizens deserve a full and open discussion of exactly who wants their private medical information and for what purpose. Only then may the true balancing of interests take place. These are the ground rules of AMA policy and they should be the ground rules for the federal debate regarding data privacy.

With respect to PDMPs, the AMA has significant privacy concerns about law enforcement and other non-health care entities using a PDMP because of the personal health information (PHI) contained within a PDMP. PHI may include a patient’s controlled substance prescription history, which can potentially cause someone to learn a patient is being treated for gender dysphoria, a substance use disorder, mental illness, HIV/AIDS or other medical condition that has historically been subject to stigmatization. The AMA believes that an appropriate balance between law enforcement access and a patient’s right to privacy occurs when law enforcement obtains a court-issued warrant or other judicially authorized access. That occurs, however, in fewer than 20 states. Only four states have granted authority for third-party payers other than Medicaid access to PDMPs despite third-party payer state legislative efforts.
In the courts, the AMA and nine state medical societies argued to the Ninth Circuit Court of Appeals against the United States Drug Enforcement Administration efforts to access the Oregon PDMP with only an administrative warrant that “patients have a basic right to privacy of their medical information. That privacy should be honored unless there is meaningful waiver by the patient or a strong countervailing public health or safety interest, and then only with stringent safeguards.” The AMA and California Medical Association also argued against unfettered access to patients’ prescription information in *Lewis v. Medical Board of California*, where “a Medical Board of California investigator testified that the board routinely obtains confidential prescribing records from [the California PDMP] for all patients of physicians subject to medical board investigations, even where the complaint is unrelated to the patients or the physician’s prescribing practices.”

Additionally, before enacting a law requiring that police and prosecutors obtain warrants before searching in sensitive patient information in the state’s prescription monitoring database, Massachusetts allowed police and prosecutors to view patient medical records without warrants nearly 11,000 times—or about 20 times per day—between August 2016 and March 2018.

Unauthorized access also can occur when law enforcement inappropriately pressures pharmacists to query a PDMP without judicial oversight. The American Pharmacists Association counsels that:

> The information in PDMP reports is personal and private. Patients expect that pharmacists will maintain the confidentiality of this information, and this is a key aspect of the professional relationship of trust between pharmacists and patients.

Unauthorized access and inappropriate use of an individual’s person health information can have devastating effects, such as occurred to a Utah firefighter whose PDMP information was accessed and misinterpreted at multiple steps during several year long legal battle. Ultimately, all charges were dismissed, but not before the damage had been done.

Notwithstanding the legal requirements, case law and news items noted above, states generally have strong protections regarding the unauthorized use of information within a PDMP. While important work is being done to remove stigma and regard SUD as a medical condition like any other, the fact remains that illicit substance use is illegal, which is decidedly unlike any other medical issue. Inappropriate disclosure of SUD data can result in consequences exponentially more harmful to a patient than the improper disclosure of his or her hypertension (e.g., loss of housing, loss of child custody, discrimination from medical professionals, loss of benefits or loss of employment, among others). Any discussion of increasing the exchange of SUD information must contemplate the potential for such outcomes.

The AMA supports the refinement of PDMPs and development and implementation of technology that assists physicians with sharing information on prescriptions for controlled substances among states. AMA also calls for appropriate balance when the information in question relates to patients who receive treatment in an OTP—patients who often experience a much higher degree of stigmatization and prejudice than other patients with a chronic medical disease.

Further, even if a patient receiving care in an OTP authorized the disclosure of prescription information to be entered into a PDMP, it is unclear how that authorization would protect the patient against further re-disclosure. That is, proponents of removing OTP privacy and disclosure protections suggest that the PDMP already has sufficient safeguards against unauthorized use, but as noted above, that is not actually the reality. In addition, the patient privacy and consent provisions of relevant federal law (often referred to as Part 2) allow for a case-by-case
determination by the patient to whom disclosure may be made. Thus, while the patient may authorize and provide specific consent for disclosure to other health care professionals who treat the patient, any authorized user of a PDMP could view the OTP patient’s prescription history once it is entered into the PDMP. Until a PDMP has much more advanced controls and sufficient privacy protections for OTP users, entering a patient’s prescription history into the PDMP would almost certainly mean widespread disclosure well beyond those involved in the patient’s care. It should further be emphasized that Part 2 written consents prohibit the recipient from further disclosure of the information. In other words, it would be neither operationally feasible nor legally logical to send information to a PDMP—the PDMP would not be allowed to redisclose it to anyone, regardless of whether they are authorized to access the PDMP, absent additional written patient consent. That is key because PDMPs are not set up to prevent re-disclosure. As explained at the outset of this report, they are databases that contain considerable information and can be accessed by any authorized user.

**OTPs and PDMPs**

Part 2 does not permit information about a patient in an OTP to be entered into the PDMP without the patient’s specific consent, even if the OTP dispenses medication. The rationale for this rule is that identifying individuals with an SUD could lead to discrimination against the individual, and part of the original purpose of Part 2 was a decision by lawmakers to promote and protect individuals seeking SUD treatment. The AMA supports this rationale and has heard from front line clinicians who agree that identifying patients who receive SUD treatment could have a chilling effect on patients seeking care. Adopting policy that requires OTPs to report to PDMPs would necessitate a change to the statute underlying Part 2. Most stakeholders who support such a change want OTPs (and other practice settings to which Part 2 applies) to disclose information in accordance with the Health Insurance Portability and Accountability Act (HIPAA)—that is, in a less-restricted manner. HIPAA allows disclosure of a patient’s health information without a patient’s consent for treatment, payment and health care operations (TPO) purposes, as defined by HIPAA. Purportedly, to address concerns that patients will maintain control over how their information is shared, proponents of changing Part 2 to allow OTPs to enter information into PDMPs claim that patients diagnosed with an SUD will still have the “same consent requirements” when his or her information is disclosed for TPO purposes as any other patient does under HIPAA. However, while patients may be asked for consent to share their information for TPO purposes under HIPAA, patient consent is not required. This is a critical distinction, and if Part 2 is changed, would immediately change patients’ privacy protections for the hundreds of thousands of patients currently receiving care in an OTP.

Changing Part 2 to require OTPs to report to PDMPs would effectively remove the very privacy protections that were created to encourage SUD treatment. Indeed, 113 patient advocacy groups have stated that such a change will discourage individuals struggling with addiction from seeking treatment if they know that their information will not be protected. The 2017 NSDUH reported that among the top reasons for those with an SUD not receiving treatment: “Might Cause Neighbors/Community to Have Negative Opinion;” “Might Have Negative Effect on Job;” and “Did Not Want Others to Find Out.” At a time when the nation’s opioid epidemic is worse than ever, policymakers must balance greater access to information with potential effects of undermining patient privacy when attempting to increase access to care. Given the lack of data showing the benefits of additional information or use of the PDMP to mitigate the epidemic’s harms, the AMA believes that the balance clearly edges toward patient privacy as opposed to
opening the door to adverse effects on patients who receive—or might be deterred from seeking—
care in an OTP.

AMA POLICY

AMA policy strongly supports patient privacy and confidentiality protections in all areas of health
care. This includes calling for “safeguards and protections of state databases by limiting database
access by non-health care individuals to only those instances in which probable cause exists that an
unlawful act or breach of the standard of care may have occurred” (Policy H-95.946, “Prescription
Drug Monitoring Program Confidentiality”). AMA policy also makes clear that the AMA
“considers PDMP data to be protected health information, and thus protected from release outside
the healthcare system unless there is a HIPAA exception or specific authorization from the
individual patient to release personal health information, and recommends that others recognize that
PDMP data is health information” (Policy H-95.945, “Prescription Drug Diversion, Misuse and
Addiction”). The AMA also “supports legislation and regulatory action that would authorize all
prescribers of controlled substances, including residents, to have access to their state prescription
drug monitoring program.” (Policy H-95.927, “Universal Prescriber Access to Prescription Drug
Monitoring Programs”). Despite the impression given by the title of the policy, the AMA broadly
supports physicians using PDMPs only “when clinically appropriate” as well as sharing information
“within the safeguards applicable to protected health information.” AMA policy also calls for using
PDMPs as part of the effort to identify and reduce “multiple provider events” that can occur when
patients receive multiple controlled substance prescriptions from multiple pharmacies or other
dispensers in a short time frame to help ensure continuity of care.” (Policy H-95.928, Model State
Legislation “Promoting the Use of Electronic Tools to Mitigate Risk with Prescription Opioid
Prescribing”).

Finally, as noted throughout this report, AMA policy regarding patients’ rights to privacy and
confidentiality of their personal health information is robust. (Policy H-315.983, “Patient Privacy
and Confidentiality”). A strong, representative sample includes provisions that state:

there exists a basic right of patients to privacy of their medical information and records, and
that this right should be explicitly acknowledged; That patients’ privacy should be honored
unless waived by the patient in a meaningful way or in rare instances when strong
countervailing interests in public health or safety justify invasions of patient privacy or
breaches of confidentiality, and then only when such invasions or breaches are subject to
stringent safeguards enforced by appropriate standards of accountability.

It goes on to state that in such instances that “breaches of confidentiality are compelled by concerns
for public health and safety, those breaches must be as narrow in scope and content as possible,
must contain the least identifiable and sensitive information possible, and must be disclosed to the
fewest possible to achieve the necessary end.” Finally, AMA Policy H-315.983, “Patient Privacy
and Confidentiality,” states that:

Employers and insurers should be barred from unconsented access to identifiable medical
information lest knowledge of sensitive facts form the basis of adverse decisions against
individuals,” and that “[t]he fundamental values and duties that guide the safekeeping of
medical information should remain constant in this era of computerization. Whether they are in
computerized or paper form, it is critical that medical information be accurate, secure, and free
from unauthorized access and improper use.
RECOMMENDATION

The Board of Trustees recommends that Resolution 507-A-18 not be adopted and the remainder of this report be filed.

Fiscal Note: Less than $500.

REFERENCES


4 Young Hee Nam, PhD; Dennis G. Shea, PhD; Yunfeng Shi, PhD; and John R. Moran, PhD. “State Prescription Drug Monitoring Programs and Fatal Drug Overdoses.” The American Journal of Managed Care, May 26, 2017. Available at https://www.ajmc.com/journals/issue/2017/2017-vol23-n5/state-prescription-drug-monitoring-programs-and-fatal-drug-overdoses


8 PDMPs Authorized and Engaged in Sending Solicited and Unsolicited Reports to Public and Private Insurance Entities, The Prescription Drug Monitoring Program Training and Technical Assistance Center (PDMP TTAC) at Brandeis University. Available at http://www.pdmpassist.org/pdf/Insurance_Entity_Table_20180801.pdf


16 https://www.childwelfare.gov/pubPDFs/drugexposed.pdf
17 https://www.ncbi.nlm.nih.gov/pubmed/23490450
21 45 CFR 164.506(b)(1).
23 See Table 5.54B – Detailed Reasons for Not Receiving Substance Use Treatment in Past Year among Persons Aged 18 or Older Classified as Needing But Not Receiving Substance Use Treatment at a Specialty Facility and Who Felt a Need for Substance Use Treatment in Past Year: Percentages, 2017. National Survey on Drug Use and Health. Available at https://www.samhsa.gov/data/sites/default/files/cbhsq-reports/NSDUHDetailedTabs2017/NSDUHDetailedTabs2017.htm#tab5-46A