REPORT OF THE BOARD OF TRUSTEES

B of T Report 9-N-21

Subject: Medical Marijuana License Safety (Resolution 219-A-19)

Presented by: Bobby Mukkamala, MD, Chair

Referred to: Reference Committee B

INTRODUCTION

At the 2019 Annual Meeting, the American Medical Association (AMA) House of Delegates (HOD) referred Resolution 219-A-19, "Medical Marijuana License Safety," introduced by the Oklahoma delegation, which asked:

> That our American Medical Association draft model state legislation to amend states' prescription drug monitoring programs to include a medical marijuana license registry.

Testimony on Resolution 219 raised numerous issues, including increasing legalization of medical and recreational cannabis; concerns about cannabis use by patients with—or without—a physician's knowledge; how medical marijuana license registries function in select states; and the potential intersection with and appropriate role(s) of a state prescription drug monitoring program (PDMP). This report provides relevant background and discussion, a review of relevant AMA policy and makes policy recommendations.

BACKGROUND

It is likely that any patient who sees a physician will be asked for a current list of any medications, supplements, herbal remedies or other substances being taken. This information is essential to ensure the physician has complete and accurate information that may be relevant to a patient's diagnosis and treatment options for any given ailment or disease.

The U.S. Food and Drug Administration (FDA) is charged with, among other things, reviewing new drug applications, including making recommendations about a drug's scheduling. The U.S. Drug Enforcement Administration (DEA) receives that recommendation and is charged with determining the drug's schedule or changing an existing drug's schedule. Cannabis (also referred to as marijuana or marihuana by DEA), contains the active ingredient delta-9-tetrahydrocannabinol (THC) and is a Schedule I controlled substance.[1] This means that under federal law, there is "no currently accepted medical use in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse." Other Schedule I substances include heroin, LSD, peyote, methamphetamine and Ecstasy.[2]

In testimony to Congress earlier this year, Douglas Throckmorton, MD, Deputy Director, Center for Drug Evaluation and Research, FDA, explained that the FDA has approved four products containing cannabinoids: Epidiolex (standardized, plant derived cannabidiol (CBD)), Marinol (dronabinol, synthetic THC), Syndros (dronabinol), and Cesamet (nabilone, a synthetic THC

derivative). These approved drug products are only available with a prescription from a licensed health care provider. Importantly, FDA has not approved any other cannabis, cannabis-derived or CBD products.

According to the National Conference of State Legislatures, more than 30 states allow for marijuana use by persons with certain medical conditions and an additional 14 states allow for recreational use of marijuana by adults.[3] In the "medical marijuana"[4] states, 29 states provide for the establishment of a patient registry and/or identification card, three states' provisions are pending and Washington does not have such a provision.[5] With respect to patient registries in "medical marijuana" states, it is common for states to require a considerable amount of personally identifiable information and other information, which may be made available to law enforcement and others. For example:

- California established a voluntary, web-based registry to allow law enforcement and the general public to verify the validity of a medical marijuana identification card for a patient. The registry is maintained by the California Department of Public Health.[6]
- Colorado's web-based registry allows patients to apply for an identification card as well as allows so-called "medical marijuana centers" to check whether a card has been revoked. It also has functionality to allow law enforcement to verify a card's validity among other features.[7]
- Ohio patients seeking medical marijuana must first have a certified physician submit information to the registry—after which the patient will receive an email prompting the patient to complete their application and pay a $50 fee.[8]
- North Dakota's patient registry requires patients to apply online, including uploading a photo, in which the state requires eyes to be open and indicates further that applicants should, "[a]void wearing dark, tinted glasses, hats or head coverings when taking the photo."[9]

These examples are not meant to be representative of all patient registries. Most patient registries also include information about whether the patient has a qualifying medical condition, which might include AIDS, amyotrophic lateral sclerosis, Alzheimer's disease, cancer, chronic traumatic encephalopathy, Crohn's disease, epilepsy or another seizure disorder, fibromyalgia, glaucoma, hepatitis C, inflammatory bowel disease, multiple sclerosis, pain that is either chronic and severe or intractable, Parkinson's disease, positive HIV status, post-traumatic stress disorder, sickle cell anemia, spinal cord disease or injury, Tourette's syndrome, traumatic brain injury and/or ulcerative colitis.

Nearly every state has a PDMP[10] that includes information about controlled substances dispensed to patients, as well physicians' and other health care professionals' controlled substances prescribing history. The pharmacist (or other dispenser) is typically required to submit certain information to the PDMP, as well. This typically includes a patient's name, date of birth, address, contact information, physician's DEA registration or National Provider Identifier, dose and quantity of the prescription and potentially a wide variety of information ranging from the site from which the prescription was issued, type of identification and whether the prescription was for a human or animal subject.[11]

Nearly every state has the ability to share PDMP data across state lines.[12] Nearly all PDMPs are administered by the state board of pharmacy. While there is some variation in state law and policy, most state PDMPs contain Schedule II-V information. This information is generally viewed as helpful clinical information for health care professionals. Encouraging physicians to register for

and use state PDMPs when clinically indicated was one of the first recommendations of the AMA Opioid Task Force (the Task Force) in 2015.[13]

DISCUSSION

Most physicians agree that PDMPs have the capability to provide relevant clinical information for physicians and other health care professionals as part of the clinical decision-making process. The Task Force identified many of the useful features of a state-based PDMP in its first recommendations in 2015.[14] The Task Force emphasized the need for PDMPs to be integrated into clinical workflow, including having the PDMP data easily accessible in the electronic health record (EHR) without having to perform multiple clicks, enter multiple passwords, close and open multiple screens and other time-consuming barriers to PDMP use. While this has occurred in some settings, and is improving in others, it is not the norm.

Despite the barriers to PDMP use, registration and use of state-based PDMPs has significantly increased. Registration increased to nearly 2 million physicians and other health care professionals in 2019—almost a 300 percent increase from 2014; and PDMP queries have increased more than 1,100 percent during the same time period to more than 739 million.[15] It is worth noting that while most states now have a legislative mandate to use a PDMP in certain circumstances, voluntary PDMP registration and use began to increase prior to those mandates taking effect.

What is less clear, however, is whether the increased registration and use has led to improved patient outcomes, reduced opioid- and drug-related mortality, an increase in referrals for treatment of a substance use disorder or any other potential benefits of a PDMP.[16] It is also not clear whether any state PDMP already includes information regarding cannabis use. As noted above, with only four exceptions, cannabis, cannabis-derived and cannabinoid products remain Schedule I controlled substances and are not included in any state PDMP law. Resolution 219-A-19 is accurate in the assumption that state laws would need to be changed to allow for a Schedule I controlled substance to be part of the information captured into a state PDMP.

Another possibility is to somehow merge the information that is contained in a medical marijuana patient registry with a state PDMP. The technical aspects of such an endeavor are beyond the scope of the report, but even a cursory review of state PDMPs and medical marijuana patient registries reveals that the underlying software development and database management appear to be different in most states, including the fact that the state pharmacy board is typically not the state agency that administers the medical marijuana patient registry.

In addition, it is not clear if merging PDMPs and medical marijuana patient registries would further allow law enforcement to make inquiries into a state PDMP. Not only does this raise potential conflicts with AMA policy as detailed below, but it is unclear what precisely would be entered into the PDMP. Proponents of including medical marijuana registry information suggest that physicians should have information that a patient has registered for and received authorization to possess, obtain or purchase medical marijuana. On the surface, this sounds like a reasonable position.

Data does not exist, however, on how law enforcement currently uses medical marijuana patient registry information. Data also does not exist on what physicians might do with this information. The AMA Board of Trustees (the Board) is concerned that adding more information to a state PDMP without appropriate safeguards to ensure patient privacy could expose patients' personal health information to law enforcement in ways that could be detrimental. The mere existence of a patient's registration for medical marijuana should not be used as pretext for law enforcement to conduct unfettered searches in a patient's or physician's PDMP record.[17]

In addition to the concerns around increased law enforcement access to a PDMP, the Board notes that the existence of opioid prescriptions in a patient's PDMP report has resulted in myriad complications for patients, including non-consensual tapering, reports of physicians no longer prescribing opioids to such patients and patients subsequently not being able to find a physician willing to provide opioid therapy. Given that use of a legitimate medical prescription has become subject to intense scrutiny, stigma and negative consequences, the Board is concerned that adding information about a patient's authorization to use a Schedule I controlled substance could lead to similar negative consequences.

The other side to this argument is that medical diagnosis, treatment and management of disease are improved when the physician has access to all relevant information about his or her patient. This certainly includes whether a patient is using cannabis for medicinal or recreational use, as well as whether a physician has certified that a patient has one or more of the medical conditions that a state has determined qualify the patient to use cannabis for medicinal purposes. Data is not clear as to whether a patient's primary care physician is the one who is typically certifying the patient. If not, what happens when the primary physician—if reviewing new medical marijuana patient registry data—newly discovers that the patient has been certified for a serious medical condition? What effect(s) would this have on the patient-physician relationship? In addition to the above concerns, the Board notes that there is nothing currently preventing a physician from asking about these issues and that a fully functioning EHR could help resolve incomplete information about the patient's medical history.

While EHRs continue to improve, full integration with PDMPs remains a work-in-progress. In addition, the challenges with data integration would likely be increased significantly given that medical marijuana patient registry data are housed in agencies separate from those administering state PDMPs. It also is not clear what data would be integrated into a state PDMP from the registry. What would law enforcement's access be? Do the potential unintended consequences of listing patient's certification for medicinal cannabis outweigh the potential benefits for the physician and other health care professionals knowing that a patient has been certified? These are among the many questions for which clinical experience, medical evidence and objective data do not exist. Therefore, while the Board supports efforts to ensure physicians have all relevant information about their patients' potential use of cannabis for medicinal use, based on the above discussion and potential unintended consequences, it is premature to recommend developing model legislation.

AMA POLICY

AMA policy on the use of cannabis for medicinal use provides well-established balance for patient safety, autonomy and assurances for free and unfettered communication between the patient and his or her physician (Policy D-95.969, "Cannabis Legalization for Medicinal Use").

With appropriate patient privacy safeguards, the AMA also has strongly advocated in support of PDMPs sharing information on prescriptions for controlled substances among states (Policy H-95.947, "Prescription Drug Monitoring to Prevent Abuse of Controlled Substances"). This includes strong support for having PDMPs administered by, "a state agency whose primary purpose and mission is health care quality and safety rather than a state agency whose primary purpose is law enforcement or prosecutorial," to help ensure the information "is protected from release outside of the health care system" (Policy H-95.946, "Prescription Drug Monitoring Program Confidentiality").

The AMA has advocated for the benefits of PDMPs and "supports the voluntary use of state-based prescription drug monitoring programs (PDMP) when clinically appropriate." Recognizing the

workflow challenges, however, AMA policy simultaneously, "encourages states to implement modernized PDMPs that are seamlessly integrated into the physician's normal workflow, and provide clinically relevant, reliable information at the point of care" (Policy H-95.939, "Development and Promotion of Single National Prescription Drug Monitoring Program").

RECOMMENDATIONS

The Board recommends that the following be adopted in lieu of Resolution 219-A-19 and the remainder of the report be filed.

1. That our American Medical Association (AMA) support efforts to limit information about medical cannabis in states' prescription drug monitoring programs to only whether a patient has been certified to receive medicinal cannabis consistent with AMA principles safeguarding patient privacy and confidentiality; (New HOD Policy)

2. That our AMA continue its monitoring of state legislation relating to the inclusion of cannabis and related information in state PDMPs. (Directive to Take Action)

Fiscal Note: Less than $500.

REFERENCES

1. U.S. Drug Enforcement Administration. Controlled Substances by CSA Schedule. Available at https://www.deadiversion.usdoj.gov/schedules/orangebook/e_cs_sched.pdf
2. U.S. Drug Enforcement Administration. Schedule I Controlled Substances. Available at https://www.deadiversion.usdoj.gov/schedules/
3. State Medical Marijuana Laws. National Conference of State Legislatures. Last updated Oct. 16, 2019. Available at https://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx
4. Disclaimer: While AMA policy makes a clear distinction between cannabis for medicinal use and the recreational use of marijuana, for the purposes of this report, "medical marijuana" will be used throughout as it is how state policy commonly uses the term to refer to cannabis for medicinal use.
5. Id.
6. California Department of Public Health Medical Marijuana Identification Card Program. Available at https://www.cdph.ca.gov/Programs/CHSI/Pages/MMICP.aspx
7. Colorado Department of Health & Environment. Medical Marijuana Registry. Available at https://www.colorado.gov/pacific/cdphe/medicalmarijuana
8. Ohio Medical Marijuana Control Program "How to obtain medical marijuana." https://www.medicalmarijuana.ohio.gov/
9. North Dakota Medical Marijuana Program. Patient Application Instructions. Available at https://mmregistration.health.nd.gov/static/web/InstructionsPatients.pdf
10. While Missouri (at the time of this report was written) does not have a statewide PDMP, St. Louis County operates a PDMP that was "launched in 2017 with 14 participating jurisdictions. Currently, 75 jurisdictions are participating in the program, and these 75 jurisdictions cover 85% of the state's population." Last accessed February 14, 2020. https://pdmp-stlcogis.hub.arcgis.com/
11. *See,* for example, Appendix A of the "Michigan Automated Prescription System Data Submission Guide for Dispensers." Available at https://www.michigan.gov/documents/lara/MI_Data_Submission_Dispenser_Guide_v2.3_656381_7.pdf
12. National Association of Boards of Pharmacy PMP Interconnect®. https://nabp.pharmacy/initiatives/pmp-interconnect/
13. *See* AMA Opioid Task Force fact sheet. "Thinking of prescribing an opioid? Did you check your state prescription drug monitoring program? 2015. Available at https://www.end-opioid-epidemic.org/wp-content/uploads/2017/05/15-0398-opioid-one-physician.pdf
14. AMA Opioid Task Force. "Thinking of prescribing an opioid? Did you check your state prescription drug monitoring program?" 2015. Available at https://www.end-opioid-epidemic.org/wp-content/uploads/2017/05/15-0398-opioid-one-physician.pdf
15. Fact sheet: Physicians' and health care professionals' use of state prescription drug monitoring programs surpass 739 million queries—more than 10 times the queries in 2014. AMA Opioid Task Force. https://end-overdose-epidemic.org/wp-content/uploads/2020/07/AMA-Fact-Sheet-PDMP-use-and-registration-increase-2014-2019-FINAL.pdf
16. It is beyond the scope of this report to detail the research, data and other information concerning effects of PDMPs, but this is an area well-discussed in previous BOT reports, including BoT Report 30-A-19; BoT Report 7-I-18; BoT Report 12-A-18; BoT Report 13-A-17; and BoT Report 3-I-16
17. *See,* for example. CMA tells California Supreme Court it must protect patient data in CURES. November 2, 2015. November 02, 2015. https://www.cmadocs.org/newsroom/news/view/ArticleId/27453/CMA-tells-California-Supreme-Court-it-must-protect-patient-data-in-CURES. The AMA joined CMA in filing an amicus brief emphasizing that patients have a basic right to privacy of their medical information and records. The AMA and CMA argued that access to PDMPs by non-health care individuals should be limited to those instances in which there is probable cause that an unlawful act or a breach of the standard of care may have occurred.