Minimizing the Risks in Prescribing, Dispensing, and Administering Controlled Substances

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Despite many articles, educational materials, and opinions written on compliance and legal implications of prescribing, administering, and dispensing controlled substances, it still remains the number one reason for disciplinary actions across the nation. The DEA cases against physicians are also not declining in numbers. This presentation focuses on the "hot-areas" in the controlled substance arena as applicable to physicians, as well as new trends, laws, and practices affecting their practice of prescribing and administering controlled substances.

1. DEA registration.

While federal requirements of the DEA registration are not a new (the law has been in effect since 2007), a question of new registration often comes up in the context of opening another practice within or outside the state of practice, during a merger, or affiliation with a hospital.

Physicians must remember that a separate registration is required for every principal place of business, unless a physician is only prescribing at a second location.[1] If a physician maintains supplies of controlled substances, administers, or directly dispenses controlled substances at the second location, a separate registration must be obtained.[2] If the second location is outside of the state of the DEA's registration, a physician may obtain a separate registration or may modify the existing registration to change the address.[3]

In case of a new employment, no separate registration is required for an agent or employee of any registrant acting in the usual course of the employment.[4] If a physician works for a hospital and the hospital assigns a specific internal code number for the tracking purposes, a physician need not obtain a separate individual DEA registration.[5] Also, a physician can administer or dispense under another physician's registration as an employee or an agent but must be licensed individually to prescribe.[6]

[1] 21 C.F.R. § 1301.12(b)(3)
[2] 21 U.S.C. § 823(f)
[3] 21 C.F.R. § 1301.51
[4] 21 C.F.R. § 1301.22(c)
[5] For guidance on assigning separate registration codes, see 21 CFR 1301.22(c)
[6] 21 CFR 1301.22

2. *DEA Audits and Orders to Show Cause.*

The DEA may inspect routinely without a formal complaint to verify that the registrant is keeping proper records of controlled substances and to ensure that the registrant complies with the Controlled Substances Act.

Healthcare clients often want to know what the chances are of being audited by the DEA, who is on the DEA's radar and a potential target of the investigations. While it is difficult to predict if a physician will be investigated by the DEA in a near future, physicians must keep in mind that some registrants are of more interest to the DEA than others. For example, the DEA prepares a yearly list of the registrants to be audited during the prospective calendar year. Often the focus is on physicians with prior non-compliance records, physicians who administer or dispense controlled substances, and physicians specializing in pain management.

The DEA's agents are allowed to review and copy all records and reports, obtain samples, and examine security features. In addition, the agents may create a mirror image of the physician's computer data to analyze whether the practitioner properly prescribes, handles, and orders controlled substances, and whether proper recordkeeping requirements are observed. Inspection, however should not extend to (1) any financial data, (2) sales information (besides shipment data), and (3) pricing data – unless the owner or the agent-in-charge consents in writing.[7] Before the audit, the Diversion Investigator is required to state the purpose, present the credentials and a written notice of inspection. In addition, the investigator must obtain a written statement of informed consent to the search or obtain a warrant.

The DEA inspections are extremely stressful and potential consequences can be devastating. For Schedule II diversion, a provider can receive up to 20 years in prison and if physicians are prosecuted under the Controlled Substances Act, they must inform their licensing boards and often face disciplinary proceedings. This makes it extremely important that practitioners have readily available policies and procedures addressing the DEA inspections and know exactly (1) what could be said and what should never been discussed with the DEA agents, (2) their rights of refusing to be interviewed, and procedural rights in any collection of evidence against them, (3) what providers are obligated to disclose and what the DEA agents should not be reviewing, (4) and most importantly, their attorney's contact information to whom they can turn for assistance and guidance (the attorney should be contacted as soon as possible to minimize any potential exposure and further expenses).

If during or after the audit, the DEA determines that a physician does not substantially comply with the Controlled Substances Act, it will start a disciplinary action against the physician and may refer the matter to the Department of Justice for criminal prosecution. If, on the other hand, the DEA discovers minor recordkeeping insufficiencies, such as an inventory process that needs improvement, clerical mistakes and security deficiencies, it may forego any disciplinary action but issue a letter of admonition and enter into a memorandum of understanding (MOU) with the physician. Often the memorandum of understanding places a restriction on the physician's ability to administer or dispense controlled substances. For example, if the DEA discovers inventory shortage but determines that there was no diversion (software malfunction, sloppy recordkeeping), it may prohibit the physician from administering

[7] 21 CFR 1316

or dispensing controlled substances for a certain period of time. Therefore, the effect of the MOU should not be underestimated and providers should take advantage of every single opportunity to negotiate the terms of the MOU, because often it has the same effect as the suspension from the DEA registration.

The DEA also may issue an immediate suspension order, if in its opinion the physician is not substantially complying with the Controlled Substances Act and presents an imminent danger to the public health and safety. Under this scenario, the investigator often requests that the physician surrenders the DEA registration during the audit. Surprisingly, many physicians do surrender their registration immediately, fearing further criminal prosecution or more aggravated consequences. However, the physician can surrender the DEA registration at a later stage and the scope of consequences of relinquishing it on the spot can potentially be enormous: from employment issues to Medical Board's disciplinary actions.

If no immediate termination is sought but the DEA issues an Order to Show[8] cause, a physician should request a hearing or prepare a settlement agreement within 30 days of the service. If no agreement is reached and the matter goes to a hearing, the physician is looking at a process that often lasts over a year or two. Therefore, all the consequences must be carefully weighted and an experienced healthcare counsel should be available to assist in preparation for the hearing, developing a strategy, or drafting a settlement agreement (and to minimize any collateral consequences with the Medical Board). For example, there could be several reasons to continue with a hearing: to preserve the DEA registration, obtain evidence for the underlying criminal case[9], or argue an important point of the practice (cases on medical cannabis).

Prescribing controlled substances via TeleHealth:

Physicians are very cautious when prescribing controlled substances via TeleHealth and rightly so, due to the Ryan Haight Online Pharmacy Consumer Protection Act, which prohibits prescribing controlled substances via internet (including TeleHealth) without a valid prescription. A valid prescription for controlled substances must be issued in the usual course of professional practice with at least one in-person medical evaluation – this presents a problem in the TeleHealth context. Aware of this requirement, many physicians completely shun away from writing controlled substance prescriptions via TeleHealth means. The Act, however, has several important exceptions applicable to TeleHealth:

(1) when treatment is performed in a hospital or clinic where the patient is physically located and the practitioner is licensed in the State in which the patient is located (or licensing exemption applies);
(2) treatment is performed while the patient is in the physical presence of a licensed healthcare practitioner acting in accordance with applicable State law;

[8] A must-read recent opinion on this issue: Wesley Pope, M.D.; Decision and Opinion, 82 Fed. Reg. 14944-14985, 2017 Mar 23.

[9] There is no right to discovery during an administrative process, and because the DEA often seizes all the evidence, it is hard to prepare the case. For more discussion on the administrative hearing strategy, see Kelly Downer, "Registrants in Light of Recent DEA Enforcement Actions." Physician Organizations p.16 Volume 16, Issue 1, April 2013. Also for a discussion on discovery rights under the APA procedure, see Nicholas Sychak, 65 Fed. Reg. 75959-75961 (Dec. 5, 2000).

(3) the physician using TeleHealth is acting on behalf of the Indian Health Service or is working for an Indian tribe;
(4) the physician is using TeleHealth technologies during a public health emergency;
(5) the practice of TeleHealth is being conducted by practitioner who has obtained from the Administrator a special registration under 21 U.S.C. 311(h);
(6) when a physician is using TeleHealth during a medical emergency for treating Department of Veteran Affairs' employees and contractors.[10]

As seen from these exceptions, none of them apply to direct-to-patient scenarios many physicians use or plan to use via mHealth and TeleHealth technologies. This really limits the development of TeleHealth and services that physicians may provide through such technologies. The American Telemedicine Association (ATA) urged the DEA to open a special registration process allowing physicians to prescribe controlled substances via TeleHealth without the need for an in-person medical evaluation.[11] In 2016, the DEA agreed with the ATA's arguments and announced that it had started working on the new rules that would allow physicians to prescribe controlled substances via TeleHealth without in-person medical evaluations. The DEA should finalize the rules sometime in 2017.

In addition to Ryan Haight Act, physicians must consider their state rules on prescribing controlled substances by means of TeleHealth. For example, some states prohibit prescribing controlled substances via TeleHealth, while some expressly allow it or simply silent on the issue, and some allow prescribing only for certain medical conditions. States allowing physicians prescribing through TeleHealth without in-person evaluations often limit the circumstances when such practice is allowed, often mirroring the Ryan Haight Act.[12]

New Developments in State PDMP Laws.

Currently all states[13] – with the exception of Missouri – require physicians prescribing Schedules II-IV to be registered with their state PDMP and report prescribing and dispensing no later than 7 days after the fact. Many states have updated their PDMPs in 2016 or early 2017. For example, California's new Controlled Substance Utilization Review and Evaluation System (CURES) was updated in 2016 to CURES 2.0 and now features messaging between providers, alerts when the aggregate level of controlled substances prescribed or dispensed exceeds certain threshold, and improved real-time information update.

Some states,[14] declaring a war on opioid abuse, now require physicians to review new patients' substance history via PDMP before they prescribe controlled substances within 24 hours prior to prescribing.[15] Failure to do so may trigger disciplinary actions even if no improper

[10] To ease the reading of the Act, the author has simplified this TeleHealth exceptions. The exceptions, however, are very narrow and must be followed to the letter. For the full text, see 21 CFR 1300.
[11] The complete letter submitted to the DEA, may be found at: https://www.healthcarelawtoday.com/wp-content/uploads/sites/15/2017/03/ATA-Ryan-Haight-Letter-Oct-6-2015.pdf (accessed April 25, 2017).
[12] Such states are Ohio (Rule 4731-11-09 and 7331-11-01), Delaware, Florida (limited to psychiatric disorders, Florida Admin. Code 64B8-9.0141), New Hampshire, and West Virginia.
[13] For an interactive map of the nation-wide PDMPs, go to: http://www.pdmpassist.org/pdf/PDMPProgramStatus.pdf (last accessed April 27, 2017).
[14] More and more states across country are moving in this direction: Kentucky, N.J., Indiana, Virginia, Ohio, Maryland, Wisconsin, Massachusetts (10 states in total).
[15] Cal. SB 482

prescribing occurred. In addition, a prescriber who does not verify PDMP shows a lack of due diligence and may potentially face negligence-type law suits.

For the existing patients, physicians must review patients' substance history periodically (at least once every four months in California), if the substance remains a part of the treatment of the patient. Some exceptions apply. For example, California's exempts hospice-patients, on-site administration, surgical procedures, and if the quantity of the controlled substance does not exceed a non-refillable 5-day supply.[16] California law also exempts physicians from civil or administrative liability arising from any false, incomplete, inaccurate, or misattributed information submitted to or relied upon in CURES database with reasonable care and in good faith for any resulting failure of the CURES database to accurately or timely report that information.[17]

Research shows that states that recently enacted this laws requiring physicians to review substance history prior to prescribing, have experienced decline in drug abuse.[18]

Data accumulated in PDMP is available to appropriate state and federal agencies, law enforcement, and regulatory boards for disciplinary, civil, or criminal purposes. But when should PDPM be reviewed for such purposes? When a government suspects overprescribing? May it be used against a prescriber when no controlled substances are involved in the underlying disciplinary, civil, or criminal case? California Supreme Court is expected to answer these questions shortly and to determine whether the Medical Board of California violated patients' informational privacy rights in their controlled substances prescription records when the Board obtained that data from CURES during a disciplinary investigation of the physician not involving controlled-substances.[19] The physician in this case argues that the Board must obtain a warrant or an administrative subpoena demonstrating a good cause prior to searching and reviewing the records of his patients. The court of appeal decided – on balancing patients' right to privacy against state's interest in protecting public health – that state's practice of reviewing CURES to pursue an individual does not amount to an impermissible invasion of patients' state constitutional right to privacy, as there are sufficient safeguards to prevent unwarranted public disclosure and unauthorized access to CURES data.

Louisiana Supreme court also tackled a similar issue on two occasions and held that the Fourth Amendment requires a search warrant before a search of prescription and medical records for criminal investigative purposes.[20]

Marijuana Dilemma for Physicians: "legal-but-not-entirely-legal-status.[21]"

More and more states legalize medical and recreational marijuana while federal law still continues to classify it as a Schedule I drug with a high potential for abuse and no currently

[16] Id.
[17] Id.
[18] The report is available: http://californiahealthline.org/news/cures-controversy-rekindled/ (accessed April 26, 2017)
[19] Lewis v Superior Court of Los Angeles County, 226 Cal.App.4th 933 (2014).
[20] State v. Brock, 210 So. 3d 276, 277 (La. 2017), State v. Skinner, 10 So. 3d 1212, 1218 (La. 2009)
[21] Erwin Chemerinsky, Jolene Forman, Allen Hopper & Sam Kamin, Cooperative Federalism and Marijuana Regulation, 62 UCLA L. Rev. 74, 113 (2015).

accepted medical use. Therefore, no prescription may be written for a Schedule I drug under the federal law, and such substances are subject to production quotas by the DEA. Physicians in states that had legalized medical cannabis, may only recommend marijuana, with no recommendation as to the dosage, refills, or length of use.

Many recommending physicians are concerned about any potential DEA's audits or investigations into their practice. And yes, the DEA may threaten a physician's DEA registration as aiding and abetting in obtaining illegal drug under the federal law. On a number of occasions, however, the U.S. Department of Justice highlighted that the priority is not on individuals in strict compliance with state laws but on individuals presenting threat to public safety, such as those supplying cannabis to minors, drugged driving, etc.[22]

Nevertheless, recently the DEA has cancelled registrations of two Colorado doctors specializing in recommending medical marijuana to their patients.[23] In these cases, however, the doctors lost their licenses to practice medicine due to a large number of medical marijuana recommendations authorizing high plant counts. Doctors were each accused of recommending hundreds of patients to grow or possess more than the standard six plants per patient as allowed under the state law. The DEA has published a notice in the Federal Register explaining that the revocation was a consequence of the state license suspension.[24]

In addition, the federal case law establish that the DEA's policy threatening to punish physicians for communicating with their patients about the medical use of marijuana is invalid. For example, in *Conant v. Walters*, the 9th Cir. Court held that the DEA may not revoke physicians' registrations merely for recommending medical marijuana as provided under the state law.[25] The case also upheld the injunction prohibiting the DEA from conducting an investigation of a physician based solely on the physician's recommendation of medical marijuana.[26]

While the majority of states with medical marijuana laws prohibit disciplining a physician for recommending cannabis for treatment of a serious medical condition, the Medical Board can and does take disciplinary action against physicians who fail to comply with accepted medical standards when recommending cannabis. The Boards in these states outline the standard of care applicable to such recommendations. For example, California Medical Board stated in a precedential decision that "the mere receipt of a complaint that the physician is recommending marijuana for medical purposes will not generate an investigation absent additional information indicating that the physician is not adhering to accepted medical standards."[27] These accepted standards are the same as any reasonable and prudent physician would follow when recommending or approving any other medication, and include the following:

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[22] 2009 Ogden Memorandum, available at https://www.justice.gov/archives/opa/blog/memorandum-selected-united-state-attorneys-investigations-and-prosecutions-states and 2013 Cole Memorandum: https://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf (accessed on April 29, 2017).

[23] Gentry Reeves Dunlop, M.D.; Decision and Order, 82 Fed. Reg. 8432-8433 (Jan. 25, 2017) and Janet Carol Dean, M.D. Decision and Order, 82 Fed. Reg. 9224-9226 (02/03/2017).

[24] Janet Carol Dean, M.D. Decision and Order, 82 Fed. Reg. 9224-9226 (02/03/2017).

[25] Conant v. Walters, 309 F.3d 629 (9th Cir. 2002)

[26] Id.

[27] Precedential Decision No. MBC-2007-02-Q (against Tod H. Mikuriya, M.D.), California Medical Board.

1. History and an appropriate prior examination of the patient.
2. Development of a treatment plan with objectives.
3. Provision of appropriate consent including discussion of side effects.
4. Periodic review of the treatment's efficacy.
5. Consultation, as necessary.
6. Proper record keeping and maintenance thereof that supports the decision to recommend the use of marijuana for medical purposes.[28]

In other words, if physicians use the same care in recommending marijuana to patients as they would in recommending any other dangerous drug, they would not be subject to discipline with the Medical Boards (according to the California Board's position taken in the above cited precedential decision). The problem, however, is that most of cannabis recommendations take place under the following circumstances:

(1) no prior relationship exists between the patient and physician;
(2) the recommender is not a specialist in treating the underlying condition; and
(3) no follow-up appointments are scheduled.

This makes physicians prone to licensing issue, violation of ethical duties; and negligence-style type of cases.

American Medical Association also developed guidelines for physicians to follow when recommending medical cannabis (which mirror California requirements). In addition, many healthcare players are creating their own policies and procedures on cannabis. For example, many hospitals strictly prohibit the possession and use on their premises, while others started working with the patients on cannabis use and the admitted physician is to make a choice whether continued use of cannabis during the admission will benefit the patient. Some hospitals have shifting rules: allowing cannabis for certain patients only (cancer, pediatrics). As more states legalize medical and recreational cannabis, we will see more pressure on the federal government to revise its existing law on marijuana and possibly more leeway to the states in administering their own cannabis programs.

Conclusion

Prescribing, administering, and dispensing controlled substances will continue to be a hot area in the healthcare law. We will continue seeing tension between the state and federal law on the subject of cannabis and more investigations (including undercover) by the Boards into physicians' practices recommending medical cannabis. We will also see more states toughening up their PDMP laws (and hopefully Missouri will join the pack) and taking diversion very seriously, disciplining providers for overprescribing or not verifying PDMPs. The federal government also is likely to increase the amount of civil penalties against healthcare providers for violating the Controlled Substances Act.[29] On the other hand, we are likely to have the new DEA's regulations for prescribers utilizing TeleHealth technologies prescribing controlled substances, which may help reach often critical patients in access-problem areas.

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[28] Id. at 36.

[29] See, United States v. Appalachian Regional Healthcare, Inc., No. 5:16-cv-00132-JMH, E.D. Ky., 2017 U.S. Dist. LEXIS 47694, March 30, 2017

But, honestly, it is unclear why despite so much awareness and compliance materials available, some healthcare practices still do not make compliance with the state and federal controlled substances acts as one of their priorities. Every legal counsel to a healthcare practice should start to pave the way to compliance with reviewing policies and procedures on dispensing, prescribing, and administering controlled substances. Problems uncovered in these policies often lead to other underlying issues, such as false claims, regulatory compliance, and even kickbacks.