In the Weeds: Are U.S. Health Care Companies Ready for a Legal Cannabis Market?

Three Potential Compliance Issues that Health Care Industry Participants Should Anticipate

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The trend of legalizing the distribution and use of medical cannabis in the United States has maintained momentum, positioning the industry for continued rapid growth that will have increasingly widespread regulatory and compliance implications across the health care sector. As of May 2019, 33 states and four territories, including the District of Columbia, have to some extent legalized cannabis for medical uses, and 13 other states permit access to oils high in cannabidiol (CBD) and low in tetrahydrocannabinol (THC), the main psychoactive component of cannabis. While the scope and exact requirements of such laws vary state to state, the accompanying regulatory schemes have called for significant and ongoing adaptation by most major health care players, including physicians, hospitals, and pharmaceutical companies.[1]

Despite the liberalization at the state level, federal law vis-à-vis the Controlled Substances Act (CSA) currently classifies cannabis, including its component parts, as an illegal "Schedule I" substance deemed to have no acceptable medical use.[2] This categorization, coupled with other federal statutes and regulations, has created an uncertain, disadvantageous, and even hostile environment for the integration of medical cannabis into the health care space. Due to these inherent compliance risks, most health care industry players, who already operate in a highly regulated environment, have either shied away or severely limited their interaction and involvement with medical cannabis.

Pending federal bills, including the Secure And Fair Enforcement (SAFE) Banking Act[3] and the Strengthening the Tenth Amendment Through Entrusting States (STATES) Act,[4] signal that the United States may now be at a tipping point for reforms that would align federal law more closely with the states and aim to disentangle

cannabis from federal criminal statutes altogether. With these pending pieces of legislation in mind, this article previews three potential compliance issues that health care industry participants should anticipate and prepare for: (1) the need to re-think policies for the use of medical cannabis onsite at hospital facilities; (2) the opening of pathways toward U.S. Food and Drug Administration (FDA) approval for new drugs and products; and (3) the increased attention that will be called for under federal health care privacy laws, such as the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations (collectively, "HIPAA").

Background—The Medical Cannabis Regulatory Enforcement Environment

Over the last several years, the federal government has not enforced the CSA against persons or entities complying with state cannabis laws. A 2013 U.S. Department of Justice (DOJ) memorandum issued by Deputy Attorney General James M. Cole (the "Cole Memo") identified eight enforcement priorities in reference to cannabis-related activities "that are particularly important to the federal government,"[5] and led the federal government not to enforce against state law compliant entities. On January 4, 2018, however, then Attorney General Jeff Sessions rescinded the Cole Memo, directing prosecutors instead to prosecute "marijuana activities" by following "the well-established principles that govern all federal prosecutors."[6] Attorney General William Barr has since testified in his confirmation hearing that he will not upset "settled expectations," "investments," or other "reliance interest[s]" arising as a result of the Cole Memo and that he does not intend to use federal resources to enforce federal cannabis laws in states that have legalized cannabis "to the extent people are complying with the state laws."[7]

While the DOJ has sent somewhat mixed messages, entities strictly complying with state medical cannabis laws have benefitted from additional protection at the federal level. Since 2014, federal spending bills have contained a provision[8] which has been interpreted to prohibit the DOJ and the U.S. Drug Enforcement Administration (DEA) from prosecuting anyone who strictly complies with a state medical cannabis law.[9] The provision was most recently extended through short-term appropriations legislation until September 30, 2019.[10] Notwithstanding the efforts to clarify and focus cannabis enforcement priorities, conflict remains both within sources of federal law and guidance as well as with state laws.

Pending Federal Legislation—The Safe Banking Act, States Act, and More

Federal cannabis legislation may be approaching an inflection point. Industry observers believe that the SAFE Banking Act of 2019 has the best chance of passing this or next year. The SAFE Banking Act would "create protections for depository institutions that provide financial services to cannabis-related legitimate businesses and service providers for such businesses…"[11] Effectively, upon passage, no one in the cannabis industry conducting business consistent with state law would face uncertainty around federal anti-money laundering crimes. While the legislation would not fully harmonize federal and state laws (*e.g.*, the bill does not absolve cannabis companies from CSA violations or providers from inchoate liability under the CSA), it comes close to doing so. Increased legal certainty around federal law is likely to lead established players, including banks and public companies, to become more involved in the space.

Although less likely to pass in 2019, the STATES Act would go even further to align federal and state law.[12] The bill provides in relevant part that the provisions of the CSA, as applied to cannabis, "shall not apply to any person acting in compliance

with State law relating to the manufacture, production, possession, distribution, dispensation, administration, or delivery of marihuana." Even though cannabis would remain a Schedule I controlled substance, the STATES Act makes state legal cannabis activities federally permissible by creating a carve-out to the CSA (nullifying concerns about violations of the CSA, including inchoate offense liability for service providers). By allowing continued prohibition to be a choice by the individual states, the STATES Act does not fully legalize cannabis on a national level. Nonetheless, for fully compliant state regulated businesses, there would be no federal criminal risk.

These are also several other laws proposed at the federal level with the goal of eliminating the conflict between state and federal law. In early May, top congressional democrats announced they would be reintroducing legislation that would go even further than the STATES Act.[13] The proposed legislation, "Marijuana Freedom And Opportunity Act,"[14] would remove cannabis from the CSA altogether, a process known as descheduling. States would then have the ability to regulate cannabis as they see fit.

Three Compliance Concerns for Health Care Entities to Consider

These bills represent significant strides toward reconciling the divergence between deeply engrained federal law and the many constantly evolving bodies of state law. Although the precise fate of these laws remains uncertain, it is becoming increasingly more likely that at some point, federal law will become more permissive. When that happens, the barriers that have held the health care industry back will for the most part disappear or change significantly. Below, we briefly discuss three topics that the health care industry will have to face. Health care industry participants would be well served to consider and prepare for these issues sooner rather than later.

Hospital Onsite Use of Medical Cannabis

Should a hospital permit the presence and consumption of medical cannabis by inpatients? If so, where in the hospital would use and/or storage be authorized and in what forms of delivery? What role should physicians, nurse practitioners, and other facility staff play in oversight and administration? And, considering cannabis currently remains a Schedule I controlled substance under the CSA, what level of risk could the onsite use of medical cannabis pose to a hospital's federal funding, licenses, and programs, including its Medicare enrollment? These are just a few of the baseline questions hospitals and other providers are grappling with as state legalization and regulation of medical cannabis continues to mature. Not surprisingly, legal uncertainty has led many providers to mitigate risk by defaulting to outright prohibition, or in some cases, adopting an informal "don't ask, don't tell" approach.

The Centers for Medicare & Medicaid Services (CMS), despite being the single largest payer and one of the most important regulatory bodies in the U.S. health care system, has to-date been mostly silent and not issued specific guidance on medical cannabis matters. CMS does, however, require that providers contracting with and billing Medicare and Medicaid agree to "Conditions of Participation," pursuant to which such providers must certify their general compliance with all state and federal laws and regulations.[15] This, of course, includes compliance with the CSA. Accordingly, beyond Medicare and Medicaid not covering medical cannabis treatments, the use or even presence of cannabis in health care facilities runs the risk of financial penalties, lost federal funding, and the potential revocation of a provider's Medicare enrollment and other various categories of federal licenses and accreditations.

With the political climate and pending federal legislation trending toward greater if not total deference to state law, however, hospitals should consider establishing medical cannabis policies and procedures carefully tailored to satisfy the regulatory regimes in their respective state jurisdictions. Health care organizations in a few states have offered model policies that may serve as useful starting points. For example, the Minnesota Hospital Association has published several templates designed to align with state law, including policies that outline how certain "qualified" patients might be verified for eligibility to receive the assistance of a nurse in administering or otherwise self-administer their own supply of medical cannabis.[16] Similarly, the Washington Health Care Association has published a model policy directed toward long-term care facilities,[17] while select Mayo Clinic facilities in Minnesota have established a process for certifying and dispensing to Minnesota residents with certain qualifying conditions in the Minnesota medical cannabis program.[18]

The varying approaches to handling the risk of uncertainty where CMS regulations potentially stand at odds with state law are indicative of legal quagmires that are likely to be addressed and resolved through the STATES Act or similar legislation. Clear guidelines as to when a health care facility would be jeopardizing its accreditation status and access to federal funding will allow hospitals and other providers the opportunity to build on existing model policies to construct or rebalance their own approach to inpatient-use of medical cannabis. In doing so, providers may soon have more freedom to shift away from technical compliance with competing bodies of law and focus on the health, rights, and interests of patients, as well as the providers' own financial and operational goals and circumstances.

FDA Regulatory Pathways for Cannabis Products

The FDA has not attempted to regulate, or enforce rules against, state medical cannabis programs, despite a clear authority to do so under federal law.[19] It has and continues to address, however, the budding market for CBD derived from hemp.[20] By understanding how the FDA has approached CBD in hemp, we can make predictions about how the FDA may react to certain cannabis derived extracts, once and if they become available outside of a state-regulated market. Cannabis dispensing organizations will need to "catch up" to these regulations to the extent they do not anticipate them.

The FDA has issued statements reminding the public of the FDA's continued authority "to regulate products containing cannabis or cannabis-derived compounds under the United States Federal Food, Drug, and Cosmetic Act (FDCA) and section 351 of the Public Health Service Act."[21] Under the FDCA, it is unlawful "to introduce food containing added CBD or THC into interstate commerce, or to market CBD or THC products, as, or in, dietary supplements, regardless of [the source of the substance]."[22] This is because, regardless of whether health claims are made, CBD (and THC) are active ingredients in FDA-approved drugs and have been the subject of public substantial clinical investigations. Therefore, the FDA's position has been that, prior to introduction into interstate commerce, any cannabis product, whether derived from hemp or otherwise, marketed with a disease claim (*e.g.*, therapeutic benefit, disease prevention) must first be approved by the FDA for its intended use through one of the drug approval pathways.

It seems that current political pressure caused a shift in the FDA's prohibitive position. As a result, the FDA has formed a working group to evaluate how best to regulate CBD products but has added that the working group will likely take a

number of years to develop and implement a new regulatory strategy, unless Congress passes CBD-specific legislation that forces it to act within a specified timeframe.[23] The agency has taken several steps in its continued evaluation of possible regulatory pathways for cannabis-containing and cannabis-derived products: (1) it has noticed a public hearing date, May 31, 2019, to discuss the safety, manufacturing, product quality, marketing, labeling, and sale of products containing cannabis or cannabis-derived compounds; (2) it has formed a high-level internal agency working group tasked with exploring potential pathways for the legal marketing of foods and/or dietary supplements containing CBD; (3) it updated FAQs on the FDA Web site related to this topic; and (4) it issued warning letters to three companies marketing CBD products using claims viewed as egregious and targeted at particularly vulnerable populations.[24]

The health care industry, especially drug manufacturers, has a vested interest in the outcome of this FDA action for several reasons. First, drug manufacturers already do and increasingly will have to compete with medical cannabis products, which may, due to an unusual regulatory history, have less restrictive barriers to approval under the FDCA, further disadvantaging competing therapies. Second, the FDA may set a precedent for certain products to be approved with less effort and expense than other products, an outcome that may or may not be welcome by industry participants. Therefore, regardless of whether or not any particular drug manufacturer has an interest or desire to participate in the cannabis industry post-legalization, decisions that will affect the regulatory landscape in the future are happening now.

Medical Cannabis and HIPAA

The medical cannabis state programs raise questions about compliance with HIPAA's privacy protections.[25] There appears to be a misconception in the industry that because HIPAA is a federal law, and cannabis remains federally illegal, medical cannabis dispensaries are not subject to HIPAA. While this correlation is without merit (consider that these companies are still beholden to federal tax laws, for example), it is likely the case that the vast majority of medical cannabis dispensaries are not presently subject to HIPAA. In order for a dispensary (or any other entity) to be subject to HIPAA, the entity must meet the definition of a "covered entity" or a "business associate" as defined by the law.

A HIPAA-covered entity is defined as a health plan, health care clearinghouse, or health care provider who transmits any health information in electronic form in connection with particular transactions subject to HIPAA.[26] While a dispensary might meet the definition of a health care provider,[27] it most likely fails the second required component of the definition to be a covered entity; namely that the health care provider *transmit health information in electronic form in connection with particular transactions subject to HIPAA*.[28] Similarly, a dispensary is unlikely to meet the definition of a HIPAA business associate, which is generally any entity that performs a covered function or activity on behalf of a covered entity that involves the use or disclosure of protected health information (PHI).[29]

Nonetheless, from a policy perspective, medical cannabis should theoretically be subject to HIPAA. Doing so would serve to further protect the privacy, security, and confidentiality of dispensary customers. It also would place restrictions on how customers' information could be used and disclosed and would afford such customers additional rights regarding their identifiable information maintained by the dispensary. As noted by the U.S. Department of Health and Human Services (HHS), health care providers have a strong tradition of safeguarding private health information, and the consequences of not

doing so could cause significant negative outcomes for the patient.[30]

Once medical cannabis programs become federally legal, this question is likely to come to a head. Again, participants in the health care industry should have a vested interest in ensuring that medical cannabis facilities are subject to HIPAA and safeguard PHI, especially as those organizations become more connected to other health care institutions. Furthermore, health care industry lawyers are uniquely suited to help dispensing organizations come into compliance.

While many medical cannabis businesses have not focused on HIPAA requirements, they would be well served to reassess their operations so as to ensure compliance with HIPAA and state health privacy laws. The passage of something similar to the STATES Act would eliminate the veil of illegality, bringing in more institutional actors, including health care providers such as hospitals and nursing homes, who will already be HIPAA compliant and require any entities they associate with to do the same.

Conclusion

Some level of cannabis legalization or at least decriminalization, which used to seem impossible, now seems likely if not inevitable in the United States. The pending federal bills at the very least signal a directional change in federal politics, as more and more legislators appear ready to consider making changes to federal law. Furthermore, many different industries, including food, tobacco, and alcohol may enter the fray (and certain forward-thinking companies have already begun experimenting in Canada). The health care industry will inevitably more frequently and deeply be impacted directly and indirectly by the cannabis industry and the increased use of cannabis for health and wellness. Indeed, health care providers are uniquely positioned to and should provide leadership on the issue.

Endnotes

1. For example, in all states that have legalized medical cannabis, doctors need to identify and certify or recommend patients to relevant programs (see, *e.g.*, Florida (Fla. Stat. Ann. § 381.986(4)), describing physician certification); some states additionally require employment of a physician to supervise the activities of a medical cannabis dispensing organization (*e.g.*, Florida (Fla. Stat. Ann. § 381.986(8)(b)(9))); and some states require that the cannabis be dispensed by a pharmacist (*e.g.*, Connecticut, (CT ADC §21a-408h(b)(B)), Minnesota (Minn. Stat. Ann. § 152.29, subd. 3) and New York (10 NYCRR § 1004.12)).
2. 21 U.S.C 801 *et seq*. Until recently, hemp (defined by the U.S. Government as Cannabis sativa L. with a THC concentration of not more than 0.3 percent on a dry weight basis) and hemp's extracts were illegal Schedule I controlled substances, along with cannabis generally, under the CSA (except mature stalks, fiber produced from the stalks, oil or cake made from the seeds, and any other compound, manufacture, salt derivative, mixture, or preparation of such parts). In December 2018, the U.S. government changed the legal status of hemp. The Agriculture Improvement Act of 2018, Pub.L. 115-334 (the "Farm Bill"), removed hemp and extracts of hemp, including CBD, from the CSA schedules. Accordingly, the production, sale, and possession of hemp or extracts of hemp, including CBD, no longer violate the CSA.
3. SAFE Banking Act of 2019. H.R. 1595, 116th Cong. § 1 (2019), *www.congress.gov/bill/116th-congress/house-bill/1595*.
4. Strengthening the Tenth Amendment Through Entrusting States Act, H.R. 2093, 116th Cong. § 1 (2019), *available at www.congress.gov/bill/116th-congress/house-bill/2093/text*.
5. *See* Memorandum from James M. Cole, Deputy Att'y Gen., to U.S. Atty's, 1 (Aug. 29, 2013), *www.justice.gov/iso/opa/resources/3052013829132756857467.pdf*.
6. Jefferson B. Sessions, III, U.S. Dep't of Justice, Memorandum for All U.S. Att'ys re: Marijuana Enforcement (Jan. 4, 2018), *available at www.justice.gov/opa/press-release/file/1022196/download*.
7. *See* Attorney General William Barr Confirmation Hearing, *available at www.c-span.org/video/?456626-1/attorney-general-nominee-william-barr-confirmation-hearing* ("My approach to this would be not to upset settled expectations and the reliance interest that have arisen as a result of the Cole Memorandum and investments have been made and so there has been reliance on it, so I don't think it's appropriate to upset those interests.").
8. The provision, now called the Joyce Amendment (previously the Rohrabacher Amendment), states: "None of the funds made available under this Act to the Department of Justice may be used, with respect to any of the [states with medical cannabis programs], to prevent any of them from implementing

their own laws that authorize the use, distribution, possession, or cultivation of medical marijuana." Consolidated Appropriations Act, 2019, Pub. L. No. 116-6, § 537, *available at www.govtrack.us/congress/bills/116/hr21/text*.

9. *See United States v. McIntosh*, 833 F.3d 1163 (9th Cir. 2016). Three caveats are important to note. First, the Ninth Circuit's decision may be persuasive for, but is not binding on, other federal appellate courts. Therefore, another appellate circuit court could interpret the Rohrabacher provision's scope differently, although district courts in other circuits have adopted the Ninth Circuit's interpretation. Second, most courts considering the issue have decided that the criminal defendant, not the government, has the burden to prove strict compliance with state law. *See United States v. McIntosh*, No. 14-cr-00016 (N.D. Cal. Mar. 20, 2017); *United States v. Daleman*, No. 1:11-CR-00385, 2017 WL 1256743 (E.D. Cal. Feb. 17, 2017); *United States v. Gentile*, No. 1:12-cr-00360, 2017 WL 1437532 (E.D. Cal. Apr. 24, 2017); *but see United States v. Samp,* No. 16-cr-20263, 2017 WL 1164453 (E.D. Mich. Mar. 29, 2017) (burden of proof on government). Third, the Ninth Circuit noted in the *McIntosh* opinion that the Rohrabacher provision protects against prosecution only while the provision is in place; if it were not continued at any point, the DOJ could prosecute any past conduct within the statute of limitations. *McIntosh*, 833 F.3d at 1179 n.5. *see also United States of Am. v. Marin All. for Med. Marijuana*, 139 F. Supp. 3d 1039 (N.D. Cal. 2015), *appeal dismissed* No. 15-17486 (9th Cir. Apr. 12, 2016).
10. *See supra* n.8.
11. SAFE Banking Act of 2019. H.R. 1595, 116th Cong. § 1 (2019), *www.congress.gov/bill/116th-congress/house-bill/1595*.
12. Strengthening the Tenth Amendment Through Entrusting States Act, H.R. 2093, 116th Cong. § 1 (2019), *available at www.congress.gov/bill/116th-congress/house-bill/2093/text*.
13. Kyle Jaeger, *Top Congressional Democrats Announce Bill To Federally Deschedule Marijuana*, MARIJUANA MOMENT (May 9, 2019), *www.marijuanamoment.net/top-congressional-democrats-announce-bill-to-federally-deschedule-marijuana/*.
14. *See* Rick Schettino*, Marijuana Freedom and Opportunity Act introduced to federally decriminalize cannabis, www.potnetwork.com/news/marijuana-freedom-and-opportunity-act-introduced-federally-decriminalize-cannabis*.
15. 42 C.F.R. § 482.25.
16. Durkin M., *Medical marijuana . . . in the hospital? As states legalize marijuana, hospitals develop policies on inpatient use*. ACP Hospitalist. January 2017. *acphospitalist.org/archives/2017/01/marijuana-policies-hospital.htm*.
17. Minnesota Hospital Associate, Medical Cannabis Template Policy (June 17, 2015), *available at www.mnhospitals.org/Portals/0/Documents/patient-safety/MedCannabis/Medical%20Cannabis%20Documentation.pdf*.
18. Washington Health Care Association, Draft Medical Marijuana Policy, *available at www.whca.org/files/2013/04/sample-medical-marijuana-policy.pdf*.
19. As previously stated, entities that are only involved in the medical side of the cannabis industry have federal protection under the Joyce Amendment (previously the Rohrabacher-Farr Amendment), which prevents the DOJ from spending money to prosecute those in strict compliance with state medical cannabis laws. This does not apply to the FDA, which is not restricted in this fashion.
20. *See supra* n.2.
21. *Statement from FDA Commissioner Scott Gottlieb, M.D., on signing of the Agriculture Improvement Act and the agency's regulation of products containing cannabis and cannabis-derived compound*, dated Dec. 20, 2018, *available at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm628988.htm*.
22. *Id.*
23. Links to Gottlieb's prepared testimony and to a video of the committee hearing can be found here: *www.appropriations.senate.gov/hearings/review-of-the-fy2020-budget-request-for-the-fda*. Even though Gottlieb has stated multiple times that congressional action would be needed for a speedy solution, congressional observers believe that the current 116th Congress is not likely to act on CBD regulation.
24. *Statement from FDA Commissioner Scott Gottlieb, M.D., on new steps to advance agency's continued evaluation of potential regulatory pathways for cannabis-containing and cannabis-derived products*, *available at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm635048.htm*.
25. The Health Insurance Portability and Accountability Act of 1996. Pub. L. 104-191. Stat. 1936; 45 C.F.R. Part 160 and Subparts A and E of Part 164.
26. 45 C.F.R. § 160.103.
27. A health care provider means a provider of medical or health services (as defined in Section 1861(s) or Section 1861(u) of the Social Security Act) and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business. 45 C.F.R. § 160.103.
28. HIPAA-covered transactions include the following types of information transmission: (1) health care claims or equivalent encounter information; (2) health care payment and remittance advice; (3) coordination of benefits; (4) health care claim status; (5) enrollment and disenrollment in a health plan; (6) eligibility for a health plan; (7) health plan premium payments; (8) referral certification and authorization; (9) first report of injury; (10) health claims attachments; (11) health care electronic funds transfers (EFT) and remittance advice; and (12) other

transactions that the Secretary of HHS may prescribe by regulation. 45 C.F.R. § 160.103.

29. 45 C.F.R. § 160.103.
30. *Why is the HIPAA Privacy Rule needed?, www.hhs.gov/hipaa/for-professionals/faq/188/why-is-the-privacy-rule-needed/index.html*.

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