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Implications of the Medical Marijuana Law for Health Care Providers

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Special to the Legal

In April 2016, Pennsylvania enacted ground-breaking legislation on medical marijuana production and distribution that will have a far-reaching impact on the health care industry in this state, the Medical Marijuana Act, 35 P.S. Section 10231.101. The act authorizes a medical marijuana program for patients suffering from serious medical conditions, and will be implemented by regulations under development by the Pennsylvania Department of Health (DOH). The program is expected to take 18 to 24 months to implement from passage of the act.

To date, the DOH has issued for industry comment (but not formally published in the Pennsylvania Bulletin) temporary rules regarding permits for growing/processing medical marijuana. The DOH also has published regulations implementing a temporary safe harbor



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program to enable parents or caregivers of minors with a "serious medical condition" to obtain medical marijuana from outside of the commonwealth to administer to the minor, see 28 Pa. Code 1131. Rules for dispensaries and details on the process for caregivers and adult patients to access medical marijuana are still to come. The last regulations to be developed will relate to physician registration, which is required for physicians to recommend medical marijuana to adult patients.

Although many of the regulations are still under development and will be many months in the making, the new laws already have had an impact on medical practice. As we discuss below, both the act and the regulations must be viewed within the context that marijuana remains a Schedule I substance under the federal Controlled Substances Act (CSA) and is defined as a drug having a high potential for abuse, no currently accepted medical use in treatment in the United States, and lacking

accepted safety for use of the substance under medical supervision.

CANNABIS PHARMACOLOGY

We start with an explanation of what marijuana is and how it might be beneficial in medical applications. Marijuana is a term used to identify preparations made from *Cannabis sativa* or from *Cannabis indica*, equatorial plants. Marijuana contains more than 400 chemicals, including at least 100 cannabinoids. CBD and THC are the common terms for two naturally occurring cannabinoids in the cannabis plant.

Marijuana acts through cannabinoid receptors of which two primary subtypes have been identified—CB1 and CB2. The CB1 receptor is localized to the brain regions that are critical for neurologic and psychological functions, and has been implicated in seizure threshold modulation. The CB2 receptor is under investigation and may be useful in treatment of inflammation and pain. CBD, the nonpsychoactive component of the marijuana plant, binds to a receptor which mediates pain, perception, inflammation, and body temperature. CBD thus may be beneficial for pain resulting from inflammation. CBD has also been investigated as having therapeutic utility in a number of neurologic conditions including intractable seizures, although its mechanism of action in that arena is not established.

CBD has demonstrated a half-life of 18 to 33 hours after smoking and two to five days after oral administration. THC and the related

compound delta-8-THC are felt to be the primary psychoactive compounds found in the plant. After smoking marijuana, THC is absorbed and rapidly delivered to the brain. Peak blood levels occur 10 to 30 minutes after smoking, and active metabolites may prolong the duration of psychological effects. The estimated biological half-life of THC is 10 to 13 days.

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Some side effects of marijuana include drowsiness, dizziness, fatigue, disorientation, mental sedation, balance issues, respiratory issues, dry mouth, giddiness, short-term memory loss, hunger, and anxiety. In Pennsylvania, usage has been limited by statute initially to pills, oils, gels, creams, ointments, tinctures, liquids and nonwhole plant forms for administration through vaporization or nebulization, while smoking is prohibited.

Patients can qualify for medical cannabis if they have a “serious medical condition” such as cancer, HIV/AIDS, amyotrophic lateral sclerosis, Parkinson’s disease, Multiple Sclerosis, epilepsy, inflammatory bowel disease, PTSD,

neuropathies, Huntington’s disease, Crohn’s disease, intractable seizures, glaucoma, autism, sickle cell anemia, damage to the nervous tissue of the spinal cord with objective neurological indication of intractable spasticity, and severe chronic or intractable pain of neuropathic origin, or if conventional therapeutic intervention and opiate therapy is contraindicated.

Products packaged by a grower/processor or sold by a dispensary are only to be identified by the name of the grower/processor, the name of the dispensary, the form and species of medical marijuana, the percentage of tetrahydrocannabinol and cannabidiol contained in the product and any other labeling required by the DOH.

PHYSICIAN CERTIFICATION

Because medical marijuana is a Schedule I drug, it cannot be “prescribed.” Under the act, to receive medical marijuana, a patient with a serious medical condition must receive a “certification” to use medical marijuana from a physician who has registered with the Board of Health and has completed a four-hour course. The physician certification must include a determination that “the patient is likely to receive therapeutic or palliative benefit from the use of medical marijuana.”

Although physician certification for adult patients is not yet available because DOH has not yet designed the physician registry, DOH has created a “safe harbor” process for minor patients to lawfully obtain medical marijuana from outside of

Pennsylvania. Pursuant to temporary regulations issued in June, a parent, guardian, or caregiver of a minor suffering from a “serious medical condition” may administer medical marijuana to the child upon receiving a safe harbor letter from the DOH. An application for a safe harbor letter must include, among other items, a statement from a physician that the minor suffers from a serious medical condition.

The physician certification process raises a number of questions for providers, including:

- Does the physician have a reasonable basis for concluding that medical marijuana is appropriate for the patient? Physicians who certify the use of medical marijuana for patients must base certification on a determination that “the patient is likely to receive therapeutic or palliative benefit from the use of medical marijuana.” While some research exists regarding the therapeutic benefits of medical marijuana, physicians may be hampered by the lack of a robust field of research regarding the benefits and risks of marijuana administration, and the effects of different dosages, strains, and varieties of medical marijuana.

- What risk management guidelines are appropriate?

It is not yet clear what kind of professional liability physicians may be exposed to for certifying medical use of marijuana for patients because they will not be “prescribing” medical marijuana. Nevertheless, hospitals and physician practices should develop risk-management guidelines to reduce the possibility of a lawsuit or

disciplinary action, and ensure compliance with the act, including requirements that the physician conduct a clinical visit with the patient before the initial written certification, the physician document the patient’s medical history and the existence of a serious medical condition in the medical record before certifying medical marijuana use, the physician provide certification only for patients under the physician’s continuing care for the serious medical condition, the physician review the patient’s controlled substance history using the prescription drug monitoring program, and the patient’s progress be monitored so that the physician can satisfy his ongoing obligation to notify the DOH if medical marijuana would no longer be therapeutic or palliative. Hospitals also may develop a specific disclosure form indicating that the risks of medical marijuana, including any potential for addiction, were discussed with the patient. Hospitals should confirm that any physician who provides medical marijuana certification does not have a direct or economic interest in a medical marijuana organization, does not accept, solicit, or offer any form of remuneration to certify a patient, other than accepting a fee for service with respect to the examination of the patient, and does not advertise his or her services as a practitioner who can certify a patient to receive medical marijuana.

- Does hospital- and physician-purchased professional liability insurance cover a physician’s certification for medical marijuana use?

Hospitals and physicians should evaluate whether the applicable insurance covers a physician’s certification for medical marijuana use, given that medical marijuana is not FDA-approved, and whether additional insurance should be purchased.

In addition, all health care providers need to carefully evaluate the potential federal criminal risk exposure, as discussed below.

MEDICAL MARIJUANA RESEARCH

The act also provides funding and infrastructure for medical marijuana research within the commonwealth. First, it creates a state-funded and administered process, wherein DOH will maintain a database of patients receiving medical marijuana for treatment of each of the serious medical conditions enumerated in the act, and will petition FDA and DEA for approval of a research protocol to study the impact of medical marijuana on the condition, once the database grows to a certain size. DOH will then partner with a vertically integrated health system and university to conduct the study. Second, DOH may approve up to eight permits for “clinical registrants,” which will be authorized to grow medical marijuana for research purposes and dispense it for research purposes to an academic clinical research center with which it has a contractual relationship.

The act’s research provisions present an enormous opportunity for universities and other research

entities within the commonwealth, but not without risk. In August, DEA denied a petition to reclassify medical marijuana from its Schedule I status, expressing its view that medical marijuana still lacks demonstrable medical value. (See DEA, Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81 Fed. Reg. 53767 (Aug. 12) (to be codified at 21 CFR Ch. II); Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81 Fed. Reg. 53688 (Aug. 12) (to be codified at 21 CFR Ch. II)). At the same time, however, DEA also announced a policy change to permit growers of medical marijuana to apply for registration to provide marijuana for research purposes. (See DEA policy statement, Applications to Become Registered under the Controlled Substances Act to Manufacture Marijuana to Supply Researchers in the United States, 81 Fed. Reg. 53846 (Aug. 12) (to be codified at 21 CFR Part 1301)). This announcement shifted a decades-long policy of permitting only one entity—the University of Mississippi—to grow marijuana for research purposes.

Marijuana's Schedule I status also means that research involving the substance requires a special DEA registration and a federal review of the research protocol through the investigational new drug application process. Research entities seeking to conduct research involving marijuana will need to be prepared to navigate the federal marijuana research regulatory scheme and to assure stakeholders and institutional review boards that research into

marijuana's medical utility is worth the investment, notwithstanding DEA's less than enthusiastic view.

THE ENFORCEMENT LANDSCAPE

In recent DEA policy statements from August 2016, the federal government reaffirmed marijuana's ongoing status as a Schedule I illegal controlled substance under the CSA. Nevertheless, in the past few years, the U.S. Department of Justice (DOJ) has informally decriminalized some marijuana-related conduct through the issuance of guidance documents. The DOJ, in particular, has announced that its objectives in enforcing the criminal statutes are:

- Preventing the distribution of marijuana to minors;
- Preventing the revenue from the sale of marijuana from going to criminal enterprises, gangs, and cartels;
- Preventing the diversion of marijuana from states where it is legal in some form to other states;
- Preventing state-authorized marijuana activity from being used as a cover or pretext for the trafficking of other illegal drugs or other illegal activity;
- Preventing violence and firearm use in the cultivation and distribution of marijuana;
- Preventing drugged driving and other adverse public health consequences associated with marijuana use;
- Preventing the growing of marijuana on public lands; and
- Preventing marijuana possession or use on federal property.

The DOJ places responsibility for pursuing criminal conduct involving marijuana on state and local authorities—"The department's guidance ... rests on its expectation that states and local governments that have enacted laws authorizing marijuana-related conduct will implement strong and effective regulatory and enforcement systems that will address the threat those state laws could pose to public safety, public health, and other law enforcement interests," (Cole Memorandum at 2.). The DOJ's expectation that state and local governments will be at the forefront of addressing law enforcement concerns may have influenced Pennsylvania legislators, who included a provision in the act that holds a physician criminally liable for "intentionally, knowingly, or recklessly certifying a person as being able to lawfully receive medical marijuana or otherwise providing medical marijuana to a person who is not lawfully permitted to receive medical marijuana."

Interestingly, the DOJ's authority to enforce the CSA was recently restricted by a federal appeals court when it upheld the Congressional spending fund limitations imposed on DOJ through an omnibus appropriations bill for 2015 in *United States v. McIntosh*, 2016 U.S. App. LEXIS 15029 (9th Cir. Aug. 16). Congress had legislated that the DOJ could not use appropriated funds to prevent states that had passed medical marijuana legislation from using their own state laws to authorize the use, distribution, possession, or cultivation of

medical marijuana. The U.S. Court of Appeals for the Ninth Circuit took Congress' words one step further and held that the DOJ could not use "spending funds from relevant appropriations acts for the prosecution of individuals who engaged in conduct permitted by State Medical Marijuana Laws and who fully complied with such laws.

As a practical matter for physicians in Pennsylvania, strict compliance with state laws in connection with participating in a medical marijuana practice and avoiding the types of criminal conduct specified by the DOJ in its guidance documents may well provide strong legal defenses for an individual accused of violating federal, but not state, offenses involving marijuana certification. Although the decision of the Ninth Circuit in *McIntosh* is not binding precedent in the Third Circuit, it will likely be instructive.

IMPLICATIONS FOR HEALTH CARE EMPLOYERS

Medical marijuana also has implications for health care providers in their roles as employers. While the act prohibits retaliation "solely on the basis of [an] employee's status as an individual who is certified to use medical marijuana," it certainly recognizes the possibility that employees who are "under the influence of medical marijuana" can be restricted from performing certain duties. Specifically, the act allows employers to prohibit medical marijuana users from "performing any duty which could result in a public health or safety risk," while they are under the

influence. Likewise the act provides that a "patient may be prohibited by an employer from performing any task which the employer deems life-threatening, to either the employee or any of the employees of the employer." This is in keeping with the requirement of the Americans with Disabilities Act (ADA) and its state analogues that employees must be fit for duty, that is, employers are not required to allow employees to work when they are impaired. The difficulty, of course, will be in trying to determine whether and when an employee is "under the influence," of medical marijuana, and under what circumstances it is appropriate to restrict an employee's duties. While the act specifies that employers can discipline employees "for working under the influence of medical marijuana when the employee's conduct falls below the standard of care normally accepted for that position," the standard of care concept is capacious and not easily susceptible to a bright line definition.

Given that medical marijuana is being used to treat various medical conditions that qualify as disabilities under the ADA and serious health conditions under the Family and Medical Leave Act, the use of medical marijuana will be inextricably intertwined with issues of reasonable accommodation and medical leaves. This is complicated by the fact that marijuana remains illegal under the CSA and the ADA provides that any employee or job applicant who is "currently engaging" in the illegal use of drugs is not a "qualified individual

with a disability," and therefore is not entitled to protection under the ADA. While the act specifically provides that an employer is not required to accommodate medical marijuana use on employer premises, it does not speak to the broader issue of accommodating medical marijuana use for disabled employees. And of course the legalization of medical marijuana complicates employee drug testing and creates potential liability risks if employees are (unbeknownst to their employers) impaired by their medical marijuana use at work.

CONCLUSION

Medical marijuana offers the potential for significant relief of symptoms for patients with a wide range of intractable illnesses. However, neither its medical benefits nor its associated physiologic risks are well understood at this time. Pennsylvania's new legislation, once the regulations are finalized, will enable health care providers to conduct medical research, and to prescribe medical marijuana for a variety of conditions under state law. However, given how much remains to be learned about its pharmacologic properties, and certainly in light of its continued status as a Schedule I controlled substance, health care providers must proceed carefully and with a full appreciation of the attendant legal risks. •