How High is the Risk to Your Organization? Risk Management and Medical Marijuana

By Yulian Shtern, Esq., Elizabeth Kase, Esq., Hindi Mermelstein, M.D., and Carolyn Reinach Wolf, Esq.

Abstract

Marijuana, cannabis sativa, is a pharmacologically active plant that can alleviate a number of distressing symptoms caused by a wide variety of serious medical conditions. Its use, even when legalized by state law, is fraught with legal and medical challenges. The New York Compassionate Care Act ("CCA") regulates the distribution and use of medical marijuana for New York State physicians, health care providers, institutions, and patients. In this article we will present an overview of the law, its risks, liabilities and applications from both the legal and medical perspective.

Introduction

New York's medical marijuana program went into effect earlier this year. It is considered by many to be the most restrictive marijuana program in the United States. The CCA governs various aspects of medical marijuana use, cultivation, dispensing and consumption. New York's CCA also establishes guidelines on the dosages and strengths of medical marijuana, the qualifying symptoms and conditions, and requirements for physicians to become eligible to certify patients for medical marijuana consumption.

In addition to New York's regulatory restrictions, practitioners, risk-managers and institutions must also navigate through the contradictory Federal legal system. Notwithstanding the legalization of marijuana in 23 states and its growing acceptance among the medical community, the Federal Government still categorizes marijuana as a Schedule I controlled substance. This means that the production, sale or use of marijuana, whether recreationally or medically, will violate the Federal Controlled Substances Act of 1970.[1] Though Federal prosecutions have been few and far between, this legal dichotomy can add to the risk management and compliance concerns for many health care providers and institutions.

While the demand from the patient community remains high, to date few patients have obtained medical marijuana in New York State. The complexities of implementation of the CCA have contributed to the hesitation of medical practitioners, health care providers and institutions to participate. This creates a *de facto* situation that threatens access to treatment for the very patients the law sought to help. With the growing acceptance and presence of marijuana in medicine, it is imperative for providers, risk managers and hospital management to identify and address the various risk areas and liabilities associated with medical marijuana.

The Medicine of Medical Marijuana

Marijuana contains more than 60 pharmacologically active substances. They interface with receptors located throughout the body with the highest concentration of receptors contained in the brain and spinal cord. The clinical effect depends on which active element of the plant is prevalent in a particular strain. For example the euphoria that is associated with marijuana is related to the THC9 component. Accordingly, the potency of medical marijuana is measured based on the ratio of THC9 to cannabinoid components. An individual's response to any form of marijuana is dependent on several factors including the specific preparation, dose, patient characteristics and total treatment regimen.

As with all biologically active agents, there can be adverse effects. Like alcohol, marijuana commonly produces mild cognitive impairment and affects judgment. Many patients may be taking other medications such as pain medicines or muscle relaxants that can amplify these effects and increase the risk of machine operated accidents. Marijuana can also acutely affect blood pressure and cardiac function, which for medically compromised populations, can increase the risk of hazardous conditions. Chronic use of marijuana can have more severe sequelae such as the neurocognitive effect of amotivation. The pulmonary damage from smoking marijuana, common in recreational use, may supersede that of tobacco cigarettes. Therefore, the New York medical marijuana program does not permit smoking marijuana products. In vulnerable populations, including the young or those at high risk for developing serious psychiatric illnesses, the use of marijuana can alter brain function, hasten the onset of illness and may affect overall outcomes.

If a physician determines that a patient can benefit from medical marijuana, completing the required New York State forms with the patient can serve as a springboard to an enhanced discussion regarding the newly available products. Good assessment, shared treatment planning and decisions making, careful follow up and documentation are the tenets of good medical care and are applicable to this area as well.

The CCA limits access to medical marijuana to those patients who are diagnosed with severe, debilitating or life threatening conditions as defined by New York State law. At present, they include cancer, HIV positivity or AIDS, amyolateral sclerosis, Parkinson's disease, Huntington's disease, multiple sclerosis, damage to the spinal cord resulting in intractable spasticity (confirmed), epilepsy, inflammatory bowel disease, and neuropathy. In addition, the patient must suffer from cachexia (wasting syndrome), pain (severe or chronic), nausea (severe), seizures, or muscle spasms (severe or persistent). While the CCA limits provider registration to only those physicians who treat such conditions, in practice, patients who suffer from such conditions and symptoms are usually under the care of a wide variety of practitioners in a wide variety of specialties.

The Lack of Education and Training Resources Available

Traditionally physicians and other health care providers have had little, if any, training regarding cannabis and the endocannabinoid system. There is also a gap in the reference material available to physicians on this subject. The lack of education and resources impedes the ability of practitioners to gain comfort in recommending medical marijuana. Practitioners are also generally unfamiliar with the pharmacology, indications, contraindications, and potential drug interactions of marijuana use.

The void in education and resources concerning marijuana is somewhat attributable to the lack of research conducted due to marijuana's classification as an illicit substance under Federal law. Since the enactment of the Comprehensive Drug Abuse Prevent and Control Act in 1970, the Federal Government has classified marijuana as a Schedule I controlled substance, which in turn placed extraordinary burdens on efforts to research marijuana. These burdens exist even to this day. Prospective marijuana researchers must receive approval from four Federal administrative entities: the Food and Drug Administration ("FDA"), the National Institute of Drug Abuse ("NIDA"), the Department of Health and Human Services ("HHS") and the Drug Enforcement Agency ("DEA").[2] This restrictive process of obtaining Federal approval has deterred and even prevented research into marijuana.

Within the past decade, there has been a growing body of research from around the world reflecting increased acceptance of marijuana in medicine, with a few of the studies included in standard medical literature. Such research has expanded the educational resources available to physicians who recommend medical marijuana in the United States. However, such research has its limitations, as it is based on observations made from foreign grown strains of marijuana or restricted federally produced plant-products, which may have differing effects from marijuana products available in New York. In addition, such research has not made its way into mainstream medical educational training courses or reference books. Thus, the education and resources for physicians who may recommend marijuana remains limited.

To address this fundamental limitation, New York State mandates physicians who wish to participate in the medical marijuana program to complete a specific state-sanctioned educational course. The mandatory educational course is four hours in duration and its content includes the pharmacology of marijuana, contraindications, side effects, adverse reactions, overdose prevention, drug interactions, dosing, routes of administration, risks and benefits, warnings and precautions, and abuse and dependence. While this requirement helps to ensure that physicians who certify patients are well-educated on medical marijuana, other professionals who may treat the same patient are under no legal obligation to complete similar training. Accordingly, such practitioners may lack adequate expertise to understand how marijuana can affect the patient and their recommended treatment plan.

Standards of Care and Professional Liability Issues

The integration of marijuana into the field of medicine raises serious professional liability questions. What degree of negligence liability does a hospital and/or a physician face for adverse patient outcomes that stem from the medical use of marijuana? What steps can be taken to mitigate liability? How will your current professional liability insurance carriers react to your medical marijuana policies? Do you have a duty to notify your carriers? Will your carriers cover any marijuana related incidents or will they disclaim coverage due to marijuana's legal status? Do you need supplemental or gap insurance coverage?

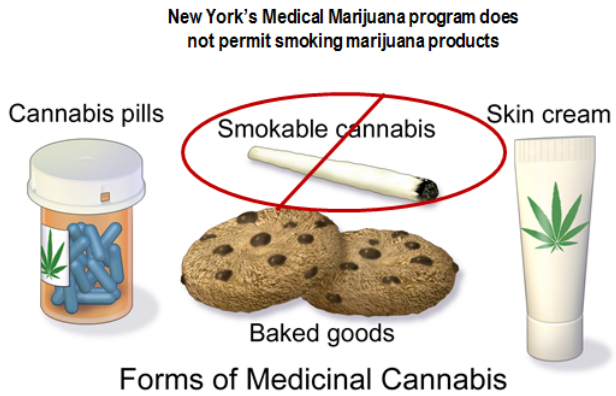
The answers to these questions are unclear as medical marijuana programs around the nation are relatively new and there have been few professional liability cases decided on the topic. In addition, there is little to no guidance as to the accepted standards of medical care, a key component in analyzing a medical malpractice action, with respect to medical marijuana.

While "the jury is still out" as to the accepted standards of care, there are certain guidelines that can be deduced from existing medical and legal literature. For instance, medical literature suggests that a practitioner who recommends marijuana simply to accede to patient demands does not comport with ethical and medical standards of care:

> [s]imply acceding to patient demands for a treatment on the basis of popular advocacy, without comprehensive knowledge of an agent, does not adhere to the ethical standards of medical practice... [and] any recommended therapy requires proof of concept by sound scientific study that attests to both efficacy and safety.[3]

In addition, it is a criminal offense in New York and certain other states to recommend medical marijuana with reasonable grounds to know that a patient has no medical need for it or will not be using it to treat a qualifying serious medical condition.[4] Such an offense is punishable as a felony and can lead to negligence *per se* liability.

We can also look to cases and standards of care established in other states, which have a relatively longer history of sanctioned medical marijuana use. For instance, the Medical Board of California issued a press release, setting forth accepted medical standards when recommending marijuana.[5] The Medical Board stated that 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 factors: (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; and (6) proper record keeping and maintenance thereof that supports the decision to recommend the use of marijuana for medical purposes.[6]



Forms of Medicinal Cannabis

Risk managers and hospital executives would be wise to address these issues with their liability insurance carriers and review their insurance contracts carefully. Several liability insurance companies in the United States have already included exclusionary language in their contracts or their policies and procedures, specifically excluding "non-FDA approved medications or devices."[7] To address this lack of coverage, several companies have explored offering a supplemental or gap insurance policy specifically covering marijuana related professional liability. These issues and potential solutions should be explored to avoid gaps in coverage.

Insurance Eligibility and Reimbursement Issues

It is clear that Medicare, Medicaid and most health insurance companies have refused to pay for the costs of medical marijuana. Marijuana's status as a Schedule I substance makes it medically unnecessary by definition and thus non-reimbursable by third-party payors. In furtherance of this long-standing policy, New York and several other states enacted statutory provisions allowing insurers to freely refuse to provide coverage for medical marijuana.[8]

However, it is unclear whether any other items or services associated with a medical marijuana certification or recommendation will also be excluded from reimbursement. If a patient comes in for an office visit and subsequently receives a recommendation by his or her treating physician, can the hospital or physician bill for the evaluation? What if a physician orders laboratory tests for a patient using medical marijuana to monitor how the patient is responding to marijuana? Do the laboratory tests become excluded from coverage?

Hospitals and providers will have to determine whether certifying patients for medical marijuana use will jeopardize their ability to seek reimbursement from third-party payors and their continued eligibility to participate in government programs and grants.

Regulatory Compliance and Enforcement Risks

Physicians and institutions may not be comfortable with the medical marijuana program. Marijuana has been culturally treated as taboo in the United States and remains a Schedule I controlled substance. Physicians cannot legally "prescribe" marijuana, but, rather may only "recommend" it with guidelines as to type, potency and dosing. However, the dispensaries and the New York State Department of Health exercise considerable control over the products that are ultimately developed and dispensed to end-users. The marijuana products in New York may be inconsistent, as they are separately produced by five different companies and without the FDA-like quality control standards in place. New York State has also issued strict adverse event reporting rules for physicians, adding to the other regulatory burdens.

Marijuana's status as an illicit drug under Federal law raises potential risk areas for an organization's compliance efforts. Hospitals are required to certify compliance with all Federal and state law during various events, particularly when submitting claims for reimbursement to Medicare or Medicaid[9] or in its cost reports. In addition, hospitals must adhere to strict requirements to maintain their DEA and other narcotics licenses. Hospital risk managers, compliance personnel and attorneys will need to scrutinize whether the hospital's participation in a medical marijuana program will impact its compliance efforts.

It is unclear whether institutions will receive the same protection as physicians for "recommending" marijuana. In 1996, following the enactment of the first medical marijuana program in California, the Federal Government threatened that it would prosecute physicians for participating in the program with penalties including revocation of their DEA licenses and denial of participation in Medicare and Medicaid.[10] In response to this declaration, several physicians filed a lawsuit in U.S. District Court in the Northern District of California.[11] In *Conant v. Walters*, these physicians successfully argued that the physicians' recommendations are protected by the First Amendment to the United States Constitution. The Court recognized the significance of the doctor-patient relationship and the need under the First Amendment to protect physicians' opinions with respect to the care and treatment required for a particular patient. In furtherance of this First Amendment right, the Court prohibited the Federal Government from prosecuting physicians solely for the expression of their medical opinions.

While the *Conant v. Walters* decision protects physicians' opinions, it does not offer a blanket protection from the Federal Government. Following the *Conant v. Walters* decision, the Federal Government successfully prosecuted patients and other individuals involved in the medical marijuana industry.[12] Under President Barack Obama's administration, Federal enforcement against marijuana program participants has decreased.[13] The United States Attorney General's office issued several policy memos, essentially requiring Federal prosecutors to prioritize their resources and to avoid investigating individuals and entities that follow the strong and effective regulatory and enforcement systems implemented under state law.

To date, there have not been any significant enforcement efforts against hospitals that participated in a state's medical marijuana program. However, significant risks of enforcement can arise, depending on the degree that the hospital participates in such a program, the hospital's compliance with the respective state regulatory enforcement scheme and the safeguards that the hospital puts in place. Such risks include enforcement actions from the DEA and the Centers for Medicare and Medicaid Services for non-compliance with regulatory and legal requirements.

Conclusion

We anticipate that as the research and support for the legalization of marijuana progresses, the political and legal atmosphere will also adapt to alleviate some of the risk areas identified in this article. In March of 2015, Congress made initial steps to solve some of these problems, when Senators Corey Booker (D-NJ), Rand Paul (R-KY) and Kirsten Gillibrand (D-NY) co-sponsored the Compassionate Access, Research Expansion and Respect States (CARERS) Act of 2015. The CARERS Act was a monumental bi-partisan bill that would, among other things, reclassify marijuana from Schedule I to Schedule II, allowing for its prescription and use under Federal Law. While the CARERS Act was not enacted into law, it showed promising support from members of the Democratic and Republican parties, giving hope to patients and providers around the nation. While we wait for the inevitable reconciliation between Federal and state law, it is an opportune time to become more educated about the legal and medical issues surrounding medical marijuana.

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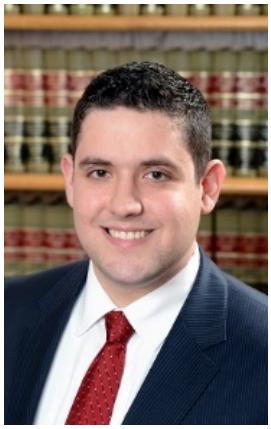
About the Authors



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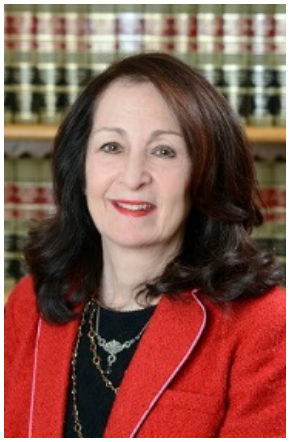
Hindi Mermelstein, M.D. is a board certified psychiatrist with many years of experience. Dr. Mermelstein holds additional boards in both geriatric psychiatry and psychosomatic medicine. Her clinical practice is focused on complex patients, many of whom suffer from serious medical illnesses and struggle with significant symptoms such as pain. In addition, Dr. Mermelstein has extensive experience in administrative, regulatory and legal issues for physicians and other health care providers both in outpatient and hospital settings with experience consulting to and collaborating with non-medical entities. The medical practice of Medical Marijuana, particularly since the enactment of the New York Compassionate Care Act, has been for her, an area of keen interest and active engagement.



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President's Message Continued……

Congratulations to Lesli Giglio and Gehan Soliman on tremendous success with the fundraising committee. Their tireless efforts make it possible for AHRMNY to produce our programs at a reasonable cost. We also appreciate the efforts of our Treasurer, Rob Marshall and Assistant Treasurer Dylan Braverman for their efforts to make sure our finances are maintained in a professional manner.

The Publications Committee under Linda Foy and Ruth Nayko continue to put out a product that is well regarded at the national level and continues lead in quality peer reviewed articles on cutting edge topics important to the risk management community. The "Risky Business" column and "Member Spotlight" have proven to be popular additions.

The nominating committee has been working to prepare for elections later this spring.

We look forward to a terrific annual meeting at our new venue, the Holiday Inn Midtown located at 57th Street between 9th and 10th Avenues. Mary Steffany and the Education Committee have been hard at work producing what will be an exceptional event featuring group events and four break-out sessions on June 3, 2016. We look forward to seeing you there!

I wish to thank the board and emeritus members, as well as the membership, for your support and involvement during my term.

Best Regards,

Robert D. Martin
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