Medical Marijuana

Practical Considerations for Addressing Patient Expectation for Use of Medicinal Marijuana in the Hospital Inpatient Setting
A 52-year-old male patient, Mr. Green, suffers from recurrent brain tumors that cause debilitating symptoms on a daily basis, including excruciating chronic headaches and loss of appetite. Looking for a solution from this pain and suffering, he has collaborated with various physicians on different medication options including a Food and Drug Administration (FDA)-approved version of synthetic cannabis, but these options did not manage his symptoms satisfactorily. In accordance with the law in his state, several years ago the patient obtained a physician recommendation and identification card that allowed him to obtain marijuana to manage his symptoms. The patient discovered that smoking marijuana relieved his pain and improved his appetite better than any medication prescribed by physicians. In fact, the patient found that vaporizing marijuana was just as effective and alleviated his concern for damage to his lungs from smoking the raw plant. When the patient cannot smoke or vaporize marijuana, he ingests it in the form of an extract mixed into food or fluids. Tomorrow, he is scheduled for Gamma Knife radiosurgery, an alternative to traditional surgical treatment of his tumors. As he prepares for his overnight hospital stay, he packs marijuana and a vaporizer in his overnight bag. He does not realize that in spite of emerging state laws allowing patients to use marijuana medicinally, healthcare facilities are not yet prepared to incorporate marijuana into inpatient care plans for various regulatory, legal, and policy reasons. In fact, the hospital does not realize how ill prepared they are to address this patient’s request to use medical marijuana during his overnight stay.
Emerging Trend: Patient Use of Medical Marijuana

Hospitals are always affected by the emerging social, technological, regulatory, and legal trends in their surrounding communities. Everything from information technology, laptop, and cell phone usage, to social media and cultural diversity awareness has had a significant impact on hospital operations. To ensure patient satisfaction, hospital staff and administration must be sensitive to the needs of consumers and strive to accommodate patients’ needs. In the case of medical marijuana, new state laws allowing patient use are prompting a response from hospital administrators in consultation with risk management and legal counsel. Clearly, there is a need to develop policy and education programs for hospital staff. Staff education should include explanation of how the laws relate to clinical care of patients in the inpatient setting, the physician’s role and pertinent medical board licensure considerations to avoid staff operating in uncertainty. Stanford Hospital and Clinics Risk Consulting (SRC) has recognized how this patient-driven phenomenon catalyzes many issues in the clinical setting for hospital stakeholders.

This white paper provides a brief overview of medicinal marijuana and how the evolution of clinical study and law in this area results in several considerations in the hospital setting. It is not intended to advocate any particular position or decision on the question of medical marijuana. In 2010, SRC examined these issues in the process of developing hospital policy on patient use of medicinal marijuana. Based in Northern California where California’s Compassionate Use Act has been in effect since 1996, Stanford Hospital and Clinics (Stanford) has already embarked on the journey to reconcile the tensions between expectations of patients, physicians, healthcare regulations, and the overarching state and federal lawmakers by instituting a principle-based policy that acknowledges that patients use marijuana for treatment of symptoms of debilitating disease, but that use in the inpatient setting can generally be precluded by existing hospital policy and regulations.
The 1999 Institute of Medicine Report (IOM), *Marijuana and Medicine: Assessing the Science Base*, supported the need for increased investment in research of the medical components of marijuana. Since that time citizens of various states along with advocates in support of the medicinal value of marijuana and legalization of marijuana overall have prompted an emerging trend in compassionate use state laws on behalf of seriously ill or debilitated patients for which conventional medication has not provided relief. California began the trend in 1996 and Arizona became the 15th state in this trend with the passing of the “Arizona Medical Marijuana Act” in November 2010. Like the laws that came before it, Arizona’s law makes marijuana available to patients who obtain a written recommendation from a physician that states a patient may use marijuana medicinally to alleviate symptoms caused by the patient’s medical condition. Compassionate use state laws such as these cause tension in light of overarching federal laws. Patients and physicians are placed in a precarious position due to the incongruence in the laws.

**Background on Marijuana as Medicine**

“The evidence in this record [9-6-88 ruling] clearly shows that marijuana has been accepted as capable of relieving the distress of great numbers of very ill people, and doing so with safety under medical supervision. It would be unreasonable, arbitrary and capricious for DEA to continue to stand between those sufferers and the benefits of this substance in light of the evidence in this record.” Judge Francis Young, DEA Administrative Law Judge, Sept. 1988 (procon.org)

It is helpful to understand the history and present-day status of marijuana as medicine. Marijuana refers to the plant officially named cannabis sativa, famous for its main psychoactive element, delta-9-tetrahydrocannabinol (THC) and controversial due to preclinical, clinical, and anecdotal reports supporting its medicinal value. The plant is made up of more than 60 different cannabinoids and may also treat symptoms associated with many debilitating
diseases. In addition to the 60-plus cannabinoids, the raw plant also contains more than 400 different identifiable chemical compounds such as steroids and Vitamin A. Marijuana was once considered a medicine and was even included in the United States Pharmacopoeia. It was removed from the Pharmacopoeia in 1942 due to federal legislation that deemed marijuana an illegal drug. In 1970, the federal government categorized marijuana as a Schedule I drug under The Controlled Substances Act for lack of medicinal value and high potential for abuse. The Schedule 1 categorization of marijuana precludes robust research and evidence-based study of potential medicinal benefits and risks in cannabinoid compounds found in marijuana. Currently, the only recognized legal form of medicinal marijuana that is well studied and approved by FDA is a synthetic form of THC (Marinol®) that is ingested as an oral pill.

The American College of Physicians (ACP) released a position paper in 2008 supporting the need for research into the therapeutic value of marijuana citing several compelling potential therapeutic properties, highlighting the need for a better delivery system than smoking, and the need for clarification of the risks associated with use. The therapeutic effects of THC taken orally or smoked have been clinically established, however further research is needed to understand the other cannabinoids in marijuana. Researchers have also discovered and long studied cannabinoid receptors in the brain. CB1 is a cannabinoid receptor that mediates the central nervous system. CB2 is a receptor outside of the central nervous system (expressed in peripheral tissues) that may have anti-inflammatory and immunosuppressive activity. Further research of the individual medicinal compounds of the raw plant and their interaction with these receptors is needed.

The ACP encourages the development of safer delivery systems for THC—those other than smoking. Today, the main delivery system for THC is smoking the raw plant, ingesting the plant in food or drink, or using the THC extract. Most patients say that ingesting it is not ideal. It is slower acting and the psychoactive effects are much stronger and longer lasting because the THC is transformed in the liver to the more powerful psychoactive agent delta-11 THC before entering the bloodstream. In patients with
difficulty swallowing or nausea and vomiting, the oral delivery method is difficult. Given these issues, smoking remains the preferred delivery system for marijuana due to its immediate effects. However, the chronic effects of smoking marijuana include lung damage, increased risk of cancer, pneumonia, and poor pregnancy outcomes. Most physicians would hesitate to recommend smoking the raw plant as it deviates from the standard practice of prescribing pure medications in standardized dosages. Currently, a non-FDA approved vaporizing device is becoming increasingly popular due to its ability to heat the marijuana plant enough to release THC as vapor while decreasing risks associated with smoke and tar. Studies are ongoing to evaluate the mitigating effects, if any, of vaporizing THC.

Sativex—A Cannabinoid Medicine

Clinical studies of cannabinoids such as Cannabidiol (CBD) are ongoing in the United Kingdom and Canada, and the studies are slowly making their way to the United States. CBD makes up the second largest compound in marijuana and does not have the psychoactive effects of THC. The British government approved the establishment of GW Pharmaceuticals in 1998 to develop cannabis-based medicine resulting in the development of Sativex®. Sativex is a mouth spray derived of whole plant medicinal cannabis extract and indicated for the relief of multiple sclerosis (MS) symptoms and the treatment of severe neuropathic-related cancer pain. In 2005, the Canadian government approved Sativex for treatment of neuropathic pain associated with MS. Then in 2007, Canada extended regulatory approval to use as an adjunctive analgesic in the treatment of adult patients with advanced cancer pain. Also in 2007, the FDA approved Phase I of Sativex trials in the U.S. for patients with advanced cancer and whose pain could not be relieved by opioids. Recent reports from GW Pharmaceuticals, developers of Sativex, announced Phase 3 which includes approximately 350 patients. So far, the clinical trials support the finding that Sativex is safe and effective in treatment of neuropathic pain, spasticity, and sleep disturbances.
Recategorizing Marijuana? The Debate Continues

Clearly, from a scientific perspective there is significant work still to be done in the area of medicinal marijuana research. For this reason, several professional organizations in addition to the ACP advocate for recategorizing marijuana from a Schedule 1 Controlled Substance to Schedule 2, a category of drugs that are deemed potentially addictive with some medicinal use. However, it should be pointed out that due to strong opposition at recent hearings from the Drug Enforcement Administration (DEA), it is highly unlikely that marijuana will be rescheduled. Even though one DEA administrative law judge stood in favor of recategorizing marijuana to a Schedule 2 Substance,\textsuperscript{11} the DEA overruled the administrative judge’s order and, in 1992, issued a final rejection of all requests for recategorization of marijuana.

Patients supported by individual and organizational advocates have strongly disagreed with the federal position on marijuana as medicine. They feel that the federal ruling has stood between sufferers and the heavily debated medicinal benefits of marijuana. That said, compassionate use laws that provide patients with access to medicinal marijuana have increased in recent years.

The next section of this paper discusses the interaction of state and federal marijuana laws.

Emerging State Compassionate Use Laws and the Federal Controlled Substances Act

There is a gray area between state and federal law where states can decriminalize patient use of medicinal marijuana without federal preemption while the DEA continues to prosecute growers, distributors, and users of marijuana. Per the Supremacy Clause of the U.S. Constitution, federal law will supersede a state law that is in conflict.\textsuperscript{12} The Supreme Court has ruled that in order to find preemption, the court looks to the intent of the federal law and express intent of Congress to supersede state police powers provided under the Tenth Amendment.\textsuperscript{13} Neither of these threshold elements are met with respect to marijuana because the intent of the federal and state laws differ—in addition, the Controlled Substance Act (CSA) does not overtly state congressional intent
to supersede state police powers. Therefore, there is room within the federal framework for states to regulate use, possession, and growing of marijuana.

The intent of the CSA differs from the intent of the state laws with regard to marijuana. The intent of the CSA is to combat *recreational use* of marijuana by making it unlawful to manufacture, distribute, dispense, or possess any controlled substance. The intent of state law is to decriminalize use for a specific subset of the population, patients with state identified medical conditions. By limiting safe access to a clear subset of the population and connecting any use and possession of marijuana to a medical purpose, the laws avoid positive conflict with the CSA’s ban on recreational use. The state laws are intended to promote patient autonomy in treatment options by decriminalizing use, possession, and growing of marijuana by patients. The protection extends to a caregiver’s ability to assist a patient in his or her use and ability to obtain or grow marijuana as well. While no state can authorize violation of federal law, states can reserve the right not to exercise police power to punish a certain federal marijuana offense if the individual is in compliance with state regulation.

The states with medical marijuana laws have repealed the ‘strict ban’ on marijuana by decriminalizing the use of marijuana as medicine by certain qualified patients. Assuming an individual met the criteria of the state law, state law enforcement would not prosecute them, however, federal law enforcement could choose to prosecute, but most likely would not due to changes in DEA practice.

The U.S. Deputy Attorney General issued a memo in 2009 that provided clarification and guidance to federal prosecutors on where to invest resources for investigation and prosecuting marijuana offenses in states that have enacted laws authorizing the medical use of marijuana. The Deputy Attorney General stated that federal resources are best used on those individuals falling outside of the protection of any governing state compassionate use law. Therefore, the federal government would not be interested in prosecuting patients, physicians and care providers who are in compliance with their state medical marijuana law.

**DID YOU KNOW**

*15 States & DC have Medical Marijuana Decriminalization Laws*

- California (1996)
- Alaska (1998)
- Oregon (1998)
- Maine (1999)
- Nevada (2000)
- Hawaii (2000)
- Colorado (2000)
- Vermont (2004)
- Rhode Island (2006)
- New Mexico (2007)
- Michigan (2008)
- Arizona (2010)
- New Jersey (2010)
- Washington, DC (2010)
State compassionate use laws are a legislative response designed to provide patients with access to medicinal marijuana use, despite the federal categorization of marijuana as a Schedule 1 drug with no medicinal value and minimal federal funding for further research. Clearly, the mounting evidence that marijuana alleviates symptoms of some of the most debilitating medical conditions has persuaded states to consider these laws.

Patients, Caregivers, Medical Conditions and Risks

State laws vary in the designation of qualified medical conditions, amounts for personal use, and implementation of registry systems for qualified users and physicians, but the intent — to provide safe access to debilitated patients for whom conventional medication has not provided sufficient relief — is the same. The most prevalent medical conditions designated for medical marijuana use by state laws are listed on the left table. Thirteen of the 15 states that have decriminalized medical marijuana also provide protection for treating other conditions. These include any chronic or persistent medical condition that limits major life activities and, if not treated, may cause harm to the patient’s physical or mental health. Some states include a provision that broadens access to patients with conditions approved by specifically authorized state agencies as meeting criteria for safe access to medical marijuana under the law.¹⁸

Another issue is the role of the patients and their primary home caregivers in the management of medicinal marijuana. In many respects, caregivers are functioning as ‘physicians’ on behalf of patients by establishing their dosage by choice of plant and route of delivery, titrating dosage, and by determining timing of medication regime. This goes against standard practice in medication management, and exasperates the controversy around patient use of medical marijuana and voter-driven decriminalization laws. However, there are no reported deaths or serious disabilities caused by THC overdose,¹⁹ which cannot be said for many FDA-approved drugs or other alternative herbal medications. The lethal dose of a drug is the LD₅₀, the dose at which 50 percent of subjects die. In animal models, oral doses of THC ranging up to 9,000mg/kg in monkeys did not result in death.²⁰ Even heavy users of marijuana are highly unlikely to exceed 500 mg per day even smoking heavily or ingesting THC throughout the day.²¹
The most concerning health risks are associated with chronic smoking of marijuana. The IOM concluded and the ACP supports that “except for harm associated with smoking, adverse effects of marijuana use are within the range of effects tolerated for other medications.” Therefore, it is conceivable that physicians who have researched the literature available in the U.S. and countries that take a different stance on marijuana may feel comfortable making a recommendation to a patient to enable safe access under the state law.

**Physician Considerations and Perspectives**

Physicians have a First Amendment right to discuss treatment options with patients. Freedom of speech between physicians and patients has been challenged historically when the state government attempted to script the physician-patient discussion as it related to the controversial topic of abortion. In *Planned Parenthood v. Casey*, the Supreme Court concluded that mandated, ideological speech couldn’t be inserted in the physician-patient relationship because it would jeopardize the trust necessary to the treating relationship. In 2003, the Supreme Court let stand a Ninth Circuit Court of Appeals ruling that gave physicians the freedom to recommend to patients the use of medicinal marijuana based on their clinical judgment. Based on this ruling, the federal government’s right to regulate controlled substances does not include or give rise to a right to quash speech about the use of marijuana by patients for medicinal purposes. On the other hand, those physicians who do not support the use of marijuana as medicine are not legally obligated to discuss such with their patients because inherent in the freedom of speech is the freedom to remain silent on a given topic. Physicians are not required to recommend marijuana, especially given that it is not a first-line medicine and generally arises only after conventional medicine fails to treat the symptoms associated with debilitating disease.

Physicians have a duty to meet the standard of care in their treatment of patients and to stay within the regulatory framework mandated by their licensure boards. In discussion with patients about marijuana, physicians must be honest about the available clinical data regarding marijuana. The benefits are anecdotal
and preclinical reports of the benefits and risks are unsupported by evidence-based study in humans and vary according to delivery system and medical condition being treated. Currently, there is no widely accepted standard practice for the prescription or use of medicinal marijuana nor is marijuana listed in the *Physician Desk Reference*, an FDA-approved source for information on medications. Ethically, some physicians faced with a debilitated and likely terminal patient for whom all conventional medication has failed to adequately alleviate symptoms will still provide the recommendation for use of medical marijuana.

Physicians in states with medical marijuana laws who stay within the construct of the law can assert that they have complied with and therefore are exempt from state and federal prosecution; however, this white paper cannot predict what steps might be taken by a specific state or federal jurisdiction. Currently, the allegations of medical malpractice related to prescribing medications arise from a physician’s duty to comply with applicable state and federal laws as well as the standards of care. This would include providing an appropriate informed consent in part based upon competent data from reputable studies including drug manufacturer data. In the case of medicinal marijuana, physicians do not have evidence-based studies to rely on, and securing approval to start clinical trials aimed at establishing protocols is not easy. Further, it is unclear whether a physician who incurs a claim asserting damages due to the physician’s recommendation for medical marijuana will be covered by their malpractice insurance. For this reason, it is important that physicians consult with hospital legal counsel and/or their insurance provider about such recommendations.

Where Does Medical Marijuana Fit in the Clinical Care Setting?

Hospitals are microcosms of their surrounding communities so emerging trends such as medicinal marijuana are bound to impact clinical practice and patient expectations. In consideration of where medical marijuana use might fit into clinical practice, hospital administrators managing facilities in states with medical marijuana laws should consult with risk management and legal counsel.
This counsel will help them gain a better understanding of their state compassionate use law, review existing hospital policies, and participate in education programs geared for physicians and ancillary clinical staff. Due to existing hospital policies, the idea of patients possessing and using marijuana in the inpatient setting gives rise to a host of issues.

In 2009, Stanford began establishing a principle-based policy that acknowledges the legal framework for patient use of medical marijuana and delineates the boundaries that exist due to existing hospital policy, licensure board limitations, and physician concern over evidence-based practice. The following is intended to guide a facility or medical center toward relevant considerations in the development of hospital policy for addressing patient use of medicinal marijuana.

**Drug and Alcohol Policy**

A relevant consideration is the perception by the general public of marijuana being an illicit substance. Even in a clinical setting, for most staff, the presence of marijuana will trigger the hospital policy against possession of illicit substances on the premises. A patient arriving via the emergency room would raise concern that “pot” has been discovered on a “drug user.” This would undoubtedly result in a call to hospital security for removal and destruction of the substance. Hospitals operating in states with medical marijuana laws might consider guidance for staff on how to ask the right questions and document them in the patient medical record, for example:

- Did you obtain this marijuana via a physician recommendation?
- What is the physician’s name?
- Do you have a medical marijuana safe access card?
- What is the medical condition you are treating?

In the event that the marijuana does not appear to be medicinal as described by law, then staff would follow usual protocol for removal of the substance. However, if it is found to be medicinal, then they will need guidance on what to do in that instance as well. A hospital could consider a process that would manage the discovery of medicinal marijuana on an inpatient with a clear
physician recommendation and identification card versus a patient that could not show such status.

**Impact of No Smoking Policy on Medical Marijuana Use**

Hospitals across the nation have instituted ‘no smoking policies’ based on the The Joint Commission’s (TJC) strong urging to minimize health risks to individuals who smoke and those who breathe second hand smoke, and to reduce the risk of fire. These policies preclude smoking in the facility as well as in the surrounding premises to protect patients, visitors, and employees in those areas. Stanford interprets this to mean no smoking of any type including marijuana. It should be noted that California law on medical marijuana use does not mandate that accommodations be made by hospitals to allow smoking of medical marijuana on hospital premises.

**Alternative Medical Marijuana Delivery Systems**

Understanding that there are several other ways to use marijuana, Stanford investigated their impact on the clinical setting. Vaporizing marijuana is becoming increasingly popular because the device heats the raw marijuana plant enough to release THC vapor while reducing the inhalation of other carcinogens associated with smoking the plant. The safety issues raised by use in the clinical setting are two-fold. First, the device is not FDA approved and as such most hospital clinical engineering policies would preclude use in the facility without a trial protocol. Second, and most importantly, the main component of the device is a plate that heats up to temperatures between 230 to 360 degrees Fahrenheit, a clear environmental safety hazard in the presence of pure oxygen. Patients may also ingest medical marijuana in food, and while this poses no environmental safety risk, it does raise issues that most hospital Pharmaceutical and Therapeutics Committees would find concerning. (see photo) Most hospitals have an existing policy that guides patient requests to use alternative medication. It is important that a hospital consider its existing policy or create one that supports the stance the hospital ultimately chooses on allowing a patient to ingest medical marijuana as an alternative medication during admission.
Pharmaceutical Licensure

Pharmacists have greater liability concerns given their role in medication management and licensure limitations that put medical marijuana out of their scope of practice. As medication experts, pharmacists are expected to provide guidance on chemical compounds in medications, proper dosing, drug to-drug interactions, side effects, and benefits. However, as discussed, the raw marijuana plant is not FDA-approved and is categorized as a Schedule 1 Controlled Substance indicating no medical use. Pharmacists by their training will only recognize Marinol® as medical marijuana that they would actually possess or provide. Additionally, pharmacists fill physician prescriptions as received on DEA-regulated prescription sheets and medical marijuana cannot be prescribed nor can it be recommended on a DEA script. So, what role could a pharmacist conceivably play in medication management involving a patient requesting to ingest medical marijuana?

Pharmacists share the same First Amendment freedom of speech rights as physicians. They may communicate the legal status of marijuana in their state and under federal law and discuss known risks and benefits in support of treatment. Pharmacists working in an inpatient facility should consult hospital legal counsel and risk management to understand the expectation of their organization with regard to patient requests for medicinal marijuana.

Veterans Health Administration

In July 2010, the Veterans Health Administration (VHA) clearly stated that patients who use medical marijuana will not be precluded from opioid therapy or participation in chronic pain management programs. Previously, veterans who obtained medicinal marijuana in accordance with their state law were precluded under a policy that barred veterans from these therapies and programs if they tested positive for illegal substances. Veterans complained that this would preclude chronic pain patients from participation based on use of medicinal marijuana, illegal under federal law, but obtained in accordance with state law. The policy was clarified and currently, veterans may participate in these...
programs. The U.S. Department of Veteran Affairs (VA) allows a physician to determine along with the patient whether the treatment plan should be modified in light of the addition of medicinal marijuana. The policy does not change the fact that VA physicians are prohibited from filing out of state medicinal marijuana recommendation forms due to pressure from the DEA.

Conclusion

In a perfect world, and getting back to our hypothetical scenario, Mr. Green’s use of medical marijuana would already be documented in his medical record under alternative medications along with a copy of his recommendation form included for reference. The physician admitting Mr. Green to the hospital for the procedure would include medical marijuana in the informed consent discussion because the usual process is to discuss all medications routinely taken by the patient. Further, in consultation with Mr. Green, the physician would discuss the various reasons why both smoking and marijuana vaporizers would not be allowed during his inpatient stay. Mr. Green likely would express his desire to maintain continuity in his medication regime, possibly expressing it as a “legal right” to do so. The physician, in turn, would acknowledge understanding of Mr. Green’s desire to continue his usual medication routine and consider whether any new medications could be added to Mr. Green’s routine based on his procedure. Additionally, the physician would offer to inquire, if he did not know, whether the hospital had a policy that might allow Mr. Green to ingest medical marijuana in liquid or food. Together, the physician and patient would have a framework for managing Mr. Green’s expectations to maintain as much self-determination in his medication management as possible.

The Future is Still Hazy

While the above scenario would be ideal, the reality is that most healthcare facilities are not prepared to manage patient expectation for use of medical marijuana in the clinical setting. There are still too many unresolved questions regarding medical marijuana due to common misconceptions and a general lack of under-
standing of state laws on the use of medical marijuana. But with the increasing rate at which patients are turning to medical marijuana for treatment of their symptoms, how to manage these expectations is something that healthcare institutions and their stakeholders should carefully consider. In so doing, the organization will be placed in a better position of understanding how far it can go to accommodate the patient and how to educate and guide their staff.

However, with the development of pharmaceuticals such as Sativex, which take the medicinal value of marijuana and eliminate the intoxicating effects and hazards of the impurities in the plant, the entire picture of treatment for patients may change. As researchers discover more about the use of cannabinoids in treatment of various diseases, it is possible that someday there may be a variety of FDA approved options for patients who thus far can only find relief from their symptoms with the raw marijuana plant.
Endnotes


7 Id.

8 Joy & Watson, 24.

9 American College of Physicians, 6.


12 U.S. CONST., art. VI, cl. 2.

13 *Wyeth v. Levine* 55 U.S.___(2009); U.S. CONST., art. VI, cl. 2.

14 Brown, E., 3.

15 Procon.org


17 Id.

18 ProCon.org


20 Id.

21 Id.

22 Joy 4.


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