Interpretation of California’s Marijuana Regulations after Proposition 64 and Pharmacy Practice Roles in Medical Marijuana Dispensing against Federal Enforcement Risks

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Abstract

California was the first state in the union to pass medical marijuana legislation with Proposition 215, the voter enacted California Compassionate Use Act (CCUA, 1996), though regulatory oversight for the medical marijuana industry was negligible over the next 20 years. In 2015, California legislators passed the Medical Marijuana Regulation and Safety Act (MMRSA), providing a new and comprehensive regulatory framework for medical marijuana, subsequently renaming it the Medical Cannabis Regulation and Safety Act (MCRSA), with a planned implementation of January 1, 2018. In 2016, California’s marijuana landscape dramatically changed with the Adult Use of Marijuana Act (AUMA), also known as Proposition 64 (“Prop 64”), a voter initiative successful in legalizing recreational marijuana, where many prior similar initiatives had failed. In 2017, California lawmakers merged the two Acts (MCRSA and AUMA) into the Medical and Adult Use of Cannabis Regulation and Safety Act, (MAUCRSA), known as Senate Bill 94 (SB 94), which passed overwhelmingly and created a single comprehensive marijuana regulatory scheme for California by integrating the 2015 recreational marijuana law with the state’s longstanding medical marijuana program, also effective in January 2018. Given the current national marijuana landscape and political climate, California’s novel unified model for regulating and taxing marijuana will likely influence how other states proceed to regulate and tax the emerging legal marijuana industry, which has an estimated value of $7 billion. Part One of this article provides an overview of the soon to be effective “harmonized” regulatory scheme for California’s medicinal and recreational marijuana industries, touching on its potential to influence other states. Part Two surveys the changed national marijuana landscape within which three states have already implemented medical marijuana programs, also effective in January 2018. Given the current national marijuana landscape and political climate, California’s novel unified model for regulating and taxing marijuana will likely influence how other states proceed to regulate and tax the emerging legal marijuana industry, which has an estimated value of $7 billion. Part One of this article provides an overview of the soon to be effective “harmonized” regulatory scheme for California’s medicinal and recreational marijuana industries, touching on its potential to influence other states. Part Two surveys the changed national marijuana landscape within which three states have already implemented medical marijuana programs, also effective in January 2018.

1. Evolution of California’s Medical Marijuana Legislation, Reconciliation of California’s Medical and Recreational Marijuana Laws after Proposition 64: Reinstating California’s Leadership

Background

California became known as the nation’s birthplace for legalization of medical marijuana in 1996, when voters passed Proposition 215 (Prop 215), also known as the California Compassionate Use Act (CCUA) in a general election.(1) Prop 215 provided limited protection, in the form of an exemption, from criminal prosecution for the authorized use, possession or cultivation of marijuana for medical purposes on the condition that a California licensed physician, osteopath or surgeon made that recommendation for medical use.(1) However, California’s medical marijuana dispensaries operated for more than 20 years after Prop 215 without significant state regulatory oversight. Like many other states which authorized medical marijuana use during the period since 1996, California’s medical marijuana program remained flawed with regulatory and enforcement gaps. Moreover, while the numerous state laws authorized marijuana’s medicinal use, its classification in Schedule I (C-I) of the Controlled Substances Act was unchanged, and marijuana remained illegal under federal law.(2) After Prop 215, it was eight more years before the California Legislature passed Senate Bill 420 (SB 420), the “Medical Marijuana Program Act” (MMPA) in 2004, which aimed to clarify the scope of Prop 215, further define its terms and provisions, and ensure it was uniformly applied across the state.(3)

Medical Cannabis Regulation and Safety Act (“MMRSA”)

In a major step toward bringing the state’s medical marijuana program closer into compliance with federal law, the 2015 California legislature passed Assembly Bills 243 and 266 and Senate Bill 643, which together comprise the Medical Marijuana Regulation and Safety Act (MMRSA, 2015). (4) MMRSA represented a long-overdue comprehensive regulatory framework for the production, transportation, and sale of medical marijuana, and established certain provisions, programs, and agencies, providing both the authority and funding to regulate medical marijuana in California. (4) MMRSA also created the new Bureau of Medical Marijuana Regulation supported by the Medical Marijuana Regulation and Safety Act Fund, which aimed to ensure that patients in need would have access to medical marijuana within a robust tracking system, and to demonstrate that California was indeed serious about implementing robust control measures for medical marijuana to the Department of Justice (DOJ) and the DEA. (5) Though most components of MMRSA would take effect on January 1, 2018, California’s state agencies began work immediately to develop

Keywords: Proposition 64; medical marijuana; medical cannabis; Controlled Substances Act; pharmacist liability.

“Marijuana in its natural form is one of the safest therapeutically active substances known to man. By any measure of rational analysis marijuana can be safely used within a supervised routine of medical care ... 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.”

-- DEA Chief Administrative Law Judge Francis L. Young,

guidelines for local government, law enforcement, businesses, patients and health providers to prepare for, and adapt to, a newly regulated system for medical marijuana, which was nonexistent in the previous 20 years. Effective January 1, 2017, MMRSA imposed many new rules on California medical marijuana businesses, which included a broad range of regulations for cultivation, manufacturing, testing, distribution, transportation, and dispensing of medical marijuana.(4) 

Medical Cannabis Regulation and Safety Act (MCRSA): From Marijuana to Cannabis?

On June 27, 2016, the California legislature passed Senate Bill No. 837 (SB 837) amending portions of MMRSA.(5) SB 837 renamed the former Medical Marijuana Regulation and Safety Act and agencies established under MMRSA (Bureau of Medical Marijuana Regulation, Medical Marijuana Regulation and Safety Act Fund), as the “Medical Cannabis Regulation and Safety Act” (MCRSA), Bureau of Medical Cannabis Regulation (BMCR), and the Medical Cannabis Regulation and Safety Act Fund.(5) With these changes in terminology, SB 837 acknowledged a known industry-wide preference for use of “cannabis” over the term “marijuana,” and all previous references to “medical marijuana” or “marijuana” were also modified under MCRSA to “medical cannabis” or “cannabis” respectively.(6) While the terms amended by SB 837 may to some appear minor, upon due consideration, the change speaks volumes.

Other organizational changes under SB 837 dealt with reallocation of roles assigned to state regulatory agencies, including: a) BMCR replacing the Department of Public Health (DPH) as the agency responsible for licensure of testing laboratories; b) Department of Food and Agriculture (DFA) replacing BMCR in “establishing apppellations of origin” for cannabis grown in the state; and c) expansion of DPH’s role in regulating manufacturing to include labeling and developing labeling standards for medical cannabis products manufactured, as well as edibles; and identifying and reporting any such products misbranded or adulterated.(6) Figure 1 lists these California regulatory agencies with their primary assigned responsibilities.

In summary, SB 837 (MCRSA) subjects California medicinal marijuana businesses to a multitude of regulations ranging from packaging and labeling, quality assurance testing, advertising, seed to sale tracking, environmental impact restrictions, plant canopy and potency limitations, to financing and ownership restrictions.(6) The license application process for California commercial medical cannabis businesses is scheduled to begin January 1, 2018.(6) A prerequisite for the issuance of a California state license is possession of a license, permit, or other authorization from the local jurisdiction where the proposed commercial cannabis activity will take place.(6)

Control, Regulate, and Tax Adult Use of Cannabis Act (“AUMA”) (Prop 64)

The 2016 California ballot initiative for Proposition 64 (“Prop 64”) was sponsored by a marijuana policy coalition that had historically played an active and vital role in passing most previous marijuana legislation.(6) On November 8, 2016, California voters again made history when 57% of voters passed Prop 64, known by its official name as the Control, Regulate, and Tax Adult Use of Cannabis Act (the “Adult Use of Marijuana Act” or “AUMA”), to legalize recreational marijuana, with the anticipation that its level of regulation and government oversight would be the same as medical marijuana.(7) Thus, while it protects and expands access to medical marijuana in California, Prop 64 also legalizes and controls non-medical adult cultivation, use and sales, and incorporates with some minor modifications the existing medical marijuana and industrial hemp laws.(8) More significantly, Prop 64 satisfies another overarching goal because once implemented, it will bring California into further compliance with the federal policy calling for more stringent regulatory control and enforcement over the marijuana supply chain.

Prop 64 represents a genuine attempt to address the legitimate concerns of a public that has for the most part lived for over one hundred years under a social prohibition of marijuana, while also balancing legal access to recreational marijuana with an age of consent.(8) Prop 64’s basic provisions authorize: a) possession by adults 21 years and older of up to one ounce of marijuana and cultivation of up to six plants for personal use (adults, 21 years of age or older, can legally possess, transport, purchase, consume, or share up to one ounce (< 28.5g) of marijuana, and up to 8 grams of marijuana concentrates); b) regulation and taxation of the production, manufacture, and sale of marijuana for adult use; and c) revision of criminal penalties to reduce the most common marijuana felonies to misdemeanors, and allow prior offenders to petition for reduced charges.(9)

Marijuana advocacy groups believe that California marijuana reform will not end with Prop 64. While Prop 64’s regulatory provisions were largely patterned on the 2015 framework established by MMRSA,(5) and it continued to maintain licensing for medical versus adult use marijuana distinct and separate, Prop 64 had always contemplated these two industries would eventually be managed by a single agency in the Department of Consumer Affairs, and anticipated that the California legislature and agencies would consolidate the regulatory framework into one.(10) Figure 2 describes non-medical marijuana activities allowed and not allowed, as well as the limitations imposed under Prop 64.

<table>
<thead>
<tr>
<th>Regulatory Agency</th>
<th>Primary Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bureau of Medical Cannabis Regulation (BMCR)</td>
<td>License medical marijuana distributors, transporters, testing facilities, and retailers</td>
</tr>
<tr>
<td>Department of Food and Agriculture (DFA)</td>
<td>License and regulate medical marijuana growers</td>
</tr>
<tr>
<td>Department of Public Health (DPH)</td>
<td>License and regulate producers of edible marijuana products</td>
</tr>
<tr>
<td>State Water Resources Control Board (SWRCB)</td>
<td>Regulate the environmental impacts of marijuana growing on water quality</td>
</tr>
<tr>
<td>Department of Fish and Wildlife (DFW)</td>
<td>Regulate the environmental impacts of marijuana growing</td>
</tr>
<tr>
<td>Department of Pesticide Regulation (DPR)</td>
<td>Regulate pesticide use for growing marijuana</td>
</tr>
</tbody>
</table>

(1a) Adapted from the California General Election November 8, 2016, Official Voter Information Guide; Analysis by Legislative Analyst, © California Secretary of State. http://voterguide.sos.ca.gov/en/propositions/64/analysis.htm
Reconciliation of California's Medical and Recreational Marijuana Laws (after Prop 64)

Recently, on June 15, 2017, California lawmakers successfully passed Senate Bill 94 (SB 94), aiming to “fix” gaps identified across the regulatory schemes between MCRSA (June 2016) and Prop 64 (AUMA, November 2016).\(^{(9)}\) SB 94 was signed into law by the governor on June 27, 2017, after a collaborative legislative effort at integrating these two Acts (MCRSA and AUMA) into a single unified framework for California marijuana regulation.\(^{(9)}\) SB 94 merges requirements from each of the two Acts to permit single agency enforcement and oversight.\(^{(8)}\) SB 94 also renamed the combined scheme as the “Medicinal and Adult-Use Cannabis Regulation and Safety Act” (MAUCRSA), and substituted the term “cannabis” where previously “marijuana” was used.\(^{(9)}\) The purpose and intent of SB 94 was to establish a comprehensive statewide regulatory and enforcement system with oversight and control of cultivation, distribution, transport, storage, manufacturing, processing, and sale of both (1) medicinal cannabis and medicinal cannabis products for patients with valid physician’s recommendations; and (2) adult-use cannabis and adult-use cannabis products for adults 21 years of age and over.\(^{(9)}\) The newly proposed and unified scheme of regulations under SB 94 will take effect January 1, 2018.\(^{(9)}\) In addition, SB 94 revised all references to “marijuana” or “medical cannabis” in existing law to instead refer to “cannabis” or “medicinal cannabis” respectively, uses a definition of “cannabis” similar to that in the earlier law, MCRSA, and renamed the Bureau of Cannabis Control as oversight agency.\(^{(6)}\) SB 94 allows for state licensed commercial cannabis activity in twenty (20) different license classifications including the cultivation, possession, manufacture, distribution, processing, storing, laboratory testing, packaging, labeling, transportation, delivery or sale of cannabis and cannabis products.\(^{(6)}\)

Reinstating California’s Leadership in Marijuana Regulation (and Industry)

Expert marijuana market analytics report that 2016 was a year of substantial gains across the marijuana industry, and as the industry accelerated at a remarkable pace, North American consumers spent $6.7 billion on legal marijuana products, up 34% from 2015, with that increase reportedly driven largely by adult recreational sales of marijuana.\(^{(17)}\) According to a state-sponsored economic study conducted by the University of California Agricultural Issues Center, California alone is “on the verge of creating a legal market for marijuana worth more than $5 billion.”\(^{(12)}\)

As Californians anticipate implementation of a unified state regulatory and enforcement scheme for medical and recreational marijuana on January 1, 2018, it is valuable to reflect on California’s history and trajectory in the context of medical marijuana legislation. California was the first state in the country to pass medical marijuana legislation with Prop 215 in 1996.\(^{(1)}\) On November 8, 2016, voters passed Prop 64 by 55.8% (for) and 44% (against), and California joined an expanding number of states legalizing recreational marijuana use for adults.\(^{(15)}\) Prop 64 moved the state a step closer to federal compliance and established a uniform marijuana industry, once again positioning the state to set an example for other states watching these recent developments. Assuming successful implementation of SB 94, California’s leadership in establishing a uniform marijuana industry could foreseeably set the national standard for marijuana regulation and enforcement.

Conclusion: Is History Repeating Itself?

California has had a general tendency to pioneer on issues with significant social impact. Stemming back as far as the 1849 gold rush – which gave rise to California’s official nickname as the “golden state” – California has been viewed by many as the place to find “golden” opportunity. For those in the multi-billion dollar cannabis industry, this new era may be another such “golden” opportunity.

<table>
<thead>
<tr>
<th>Activity</th>
<th>Activities Allowed Under the Measure</th>
<th>Activities Not Allowed Under the Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Possessing marijuana for personal use</td>
<td>Smoking marijuana in a private home or at a business licensed for on-site marijuana consumption.</td>
<td>Smoking marijuana (1) while driving a car, (2) in any public place (other than at a business licensed for on-site consumption), or (3) anywhere that smoking tobacco is prohibited.</td>
</tr>
<tr>
<td>Smoking marijuana</td>
<td>Possession of up to 28.5 grams (about one ounce) of marijuana and up to 8 grams of concentrated marijuana (such as hash).</td>
<td>Possession of marijuana on the grounds of a school, day care center, or youth center while children are present.</td>
</tr>
<tr>
<td>Growing marijuana</td>
<td>Growing up to six marijuana plants and keeping the marijuana produced by the plants within a private home.</td>
<td>Growing in an area that is unlocked or visible from a public place.</td>
</tr>
<tr>
<td>Giving away marijuana</td>
<td>Giving away to other adults up to 28.5 grams of marijuana and up to 8 grams of concentrated marijuana.</td>
<td>Providing marijuana to minors under the age of 21 for nonmedical use.</td>
</tr>
</tbody>
</table>

\(^{(2a)}\) Adapted from the California General Election November 8, 2016, Official Voter Information Guide; Analysis by Legislative Analyst, © California Secretary of State. http://voterguide.sos.ca.gov/en/propositions/64/analysis.htm
California voters opened its doors in 1996 to medical marijuana with Prop 215 (CCUA), prompting the start of an evolution of changing attitudes toward medical marijuana over the last 20 years in the state and across the nation, and again, in 2016 with Prop 64 (AUMA), to adult recreational marijuana. California is clearly ushering in a new era with the promise of significant growth across the marijuana industry, and which is certain to bring with it both challenges and opportunities for many in the state, including among them local governments, regulators, entrepreneurs, and landowners.

Most recently, California passed SB 94 (MAUCRSA), a further landmark legislation introducing the novel concept to harmonize medical and recreational marijuana laws and to create a single uniform regulatory and enforcement scheme for both marijuana industries, which might foreseeably lead to the possibility that California very soon could be, or even more well-known, for its imminent 2018 “green rush” than for its historic 1849 “gold rush.”

Part Two: Marijuana and the State of the Union ... A Changed Landscape ... How Do Pharmacists Fit In?

1. November 8, 2016: Welcome to a New America

Background

In November 2016, a record number of ballot measures across nine states (Arizona, Arkansas, California, Florida, Maine, Massachusetts, Montana, Nevada, North Dakota) were expected to relax the rules on marijuana, either by legalizing or decriminalizing it, with California having the largest population, at 39 million residents. Seventy-five million people live in the eight states where voters passed marijuana legislation on Election Day in 2016. As far as marijuana is concerned, the 2016 election results seemed to be a turning point for the country. Eight of the nine states successfully passed ballot measures legalizing cannabis in some form. Of those nine states that considered ballot measures on cannabis legislation in 2016, five considered adult–use (recreational) and four considered medical cannabis. To date, a total of 29 legislation in 2016, five considered adult–use (recreational) and nine states that considered ballot measures on cannabis are expected to relax the rules on marijuana, either by legalizing or decriminalizing it, with California having the largest population, at 39 million residents. Seventy-five million people live in the eight states where voters passed marijuana legislation on Election Day in 2016. As far as marijuana is concerned, the 2016 election results seemed to be a turning point for the country. Eight of the nine states successfully passed ballot measures legalizing cannabis in some form. Of those nine states that considered ballot measures on cannabis legislation in 2016, five considered adult–use (recreational) and four considered medical cannabis. To date, a total of 29 states, plus the District of Columbia (DC), have legalized and/or decriminalized marijuana, where notably, comprehensive medical cannabis programs allow qualified patients with state-approved medical conditions access to cannabis products in various dosage forms.

An interactive US map that illustrates those jurisdictions can be found on the Marijuana Policy Project website. Over 20% of Americans live in a state where marijuana is legal for adults 21 years of age and older. While this current marijuana landscape has developed over decades, it has dramatically transformed the nation in recent years.

That said, just months before the November 2016 elections, the DEA had announced that on the issue of enforcement, “no changes” would be made to marijuana’s classification and it would continue as an illegal substance under the federal law, in Schedule I. As then President Obama acknowledged, the DEA and FBI would likely continue to be stymied in federal enforcement in the marijuana context.

Reading the “Marijuana Leaves”: What’s Next in the US?

What is the forecast for the future? First, the wave of marijuana legislation passed by voters in 2016 is likely to continue in 2017, and beyond. With the pattern and scope of marijuana legislation passed in 2016 (and over the past few years), as well as the new initiatives continuing to gain momentum across the country, it should be obvious that voter-led social change is “happening” before our eyes. With numerous developments in states, including Michigan, Missouri, Delaware, and Rhode Island, marijuana advocacy groups are further optimistic about the next twelve to 24 months. In states where significant activity has already been identified, Table 1 presents those states likely to encounter similar marijuana legislation in 2017-2018, differentiating between adult-use and medical cannabis use.

Yet further changes are needed both in state and federal law to avoid the possibility that federal law enforcement might be directed against 20% of the country. Other changes would be helpful in related additional contexts frustrated by the current conflict in marijuana laws, for example, facilitating affordable medical access to marijuana, employment and housing rights protection, banking, and interstate commerce for marijuana related industries.

2. Turning the Page on Prohibition: A New Chapter for Medical Marijuana

“One of the things they don’t tell you about life is that if you hang around long enough, you will see [the improbable], or even the impossible” happen.

The public debate on medical marijuana has for decades been heavily influenced by the overriding, and somewhat paternalistic, opinions of science and medicine. Specifically, based upon their superior training and clinical experience, physicians were long viewed to have superior knowledge concerning marijuana’s medical values and risks, and accordingly, the public reasonably believed them to be subject matter experts on the topic. As a result of this widely accepted public perception of the medical community’s superiority, the public simply deferred to physician opinions and recommendations. In recent years, a fundamental shift and transformation in public opinion on medical marijuana

Table 1. States listed are likely to encounter cannabis legislation in 2017-2018 (differentiating between adult-use and medical cannabis use)

<table>
<thead>
<tr>
<th>State</th>
<th>Adult-Use Cannabis</th>
<th>Adult-Use Cannabis</th>
<th>Medical Cannabis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vermont</td>
<td>Michigan</td>
<td>Michigan</td>
<td></td>
</tr>
<tr>
<td>Rhode Island</td>
<td>Missouri</td>
<td>Texas</td>
<td></td>
</tr>
<tr>
<td>Delaware</td>
<td>Maryland</td>
<td>North Carolina</td>
<td></td>
</tr>
<tr>
<td>California</td>
<td>39 million</td>
<td>39 million</td>
<td></td>
</tr>
<tr>
<td>Massachusetts</td>
<td>7 million</td>
<td>7 million</td>
<td></td>
</tr>
<tr>
<td>Nevada</td>
<td>3 million</td>
<td>3 million</td>
<td></td>
</tr>
<tr>
<td>Maine</td>
<td>1 million</td>
<td>1 million</td>
<td></td>
</tr>
<tr>
<td>North Dakota</td>
<td>750,000</td>
<td>750,000</td>
<td></td>
</tr>
</tbody>
</table>

a Voter initiatives by states (ranked from highest to lowest population) which approved regulated legalization (adult use) of cannabis included California (39 million), Massachusetts (7 million), Nevada (3 million), and Maine (1 million); and those which legalized medical cannabis (ranked from highest to lowest population) Florida (20 million), Arkansas (3 million), Montana (1 million) and North Dakota (750,000).

b An additional 18 states have restricted cannabis programs, solely permitting qualified patients access to cannabidiol (CBD), one of hundreds of ingredients in marijuana; though unlike marijuana, CBD is non-psychoactive, yet nonetheless also classified as a C-I controlled substance.
has become evident, in part owing to the general development of a more informed public. However, a dramatic reversal in perspective on medical marijuana arising from the scientific and medical community has accelerated public attitudes and acceptance of medical marijuana toward the recent paradigm shift. An example of such a catalyst is exemplified by the very public reversal on medical marijuana issued by Dr. Sanjay Gupta, the Chief Medical Correspondent for CNN.22 In 2009, Dr. Gupta, broadcasted he was against medical marijuana, arguing that “despite all the talk about the medical benefits of marijuana, smoking the stuff is not going to do your health any good,” only to reverse himself just as publicly in 2013.22 In delivering an unreserved public confession, Dr. Gupta stated that he had realized he “didn’t look hard enough” or “didn’t look far enough,” and further admitted being “too dismissive of the loud chorus of legitimate patients whose symptoms improved on cannabis,” and was even remorseful for believing the DEA had listed marijuana in Schedule I based on “sound scientific proof.” In his 2013 opinion reversing himself to a “pro” medical marijuana position, from a “con” position in 2009, Gupta’s further admitted that “there are very legitimate medical applications” for marijuana and “sometimes marijuana is the only thing that works … we have been terribly and systematically misled for nearly 70 years in the United States, and I apologize for my own role in that.”22 Since the passage of the Controlled Substances Act in 1970, numerous petitions for the rescheduling of marijuana from Schedule I to Schedule II have been filed, each one unsuccessful despite the availability of scientific evidence to support its medical use. With the scientific and medical community removing its earlier objections, the public conscience was finally free to embrace the growing social movement supporting medical marijuana.

3. Medical Marijuana: Dispensing Models, Enforcement Risks, and Challenges

Medical Cannabis: Dispensary or Pharmacy Model?

In states that have legalized medical marijuana, one approach employs non-medical professionals in an “industry” model to grow, process, and dispense medical marijuana to qualified patients.16,24 Though an “industry” model might provide reasonable patient access, if medical marijuana is viewed as a “drug” being dispensed by non-pharmacists, a logical challenge would assert that employing non-medical professionals in an industry model places patients at risk of harm due to the absence of the specialized training and insight about possible interactions, in which pharmacists are trained and routinely screen for.25 Since pharmacists are long-studied experts on the rational evidence-based uses for drugs, their effects, and proper handling, a logical follow-up underscores that pharmacists would serve most appropriately as gatekeepers for medical marijuana, even though the Controlled Substances Act prohibits this as a pharmacy function because marijuana is classified as a C-I and remains illegal for any purpose.25 Illegality aside, for argument’s sake, one could foresee that marijuana may someday be “down-scheduled” to a Schedule II (C-II) and thus, in theory become available by a proper C-II prescription. Support for the proposition that pharmacists should adopt a medical marijuana dispensing role also makes sense because on a day to day basis, pharmacists already handle other controlled substances in C-II, as well as many in C-III, C-IV and C-V. By the same token, pharmacy operations are already equipped with the infrastructure and processes needed for the gatekeeping function, assuming marijuana was moved to C-II. Expertly trained pharmacists functioning in the role of gatekeepers for medical marijuana is also logical because pharmacists are “able” to meet this challenge. Many, if not most, pharmacists likely could not have fathomed this discussion even just five or ten years ago. Most pharmacists would also never have imagined finding a marijuana leaf spread across on the glossy cover of a major pharmacy journal, something seemingly improbable. Well … “the times they are changing”26 and, as health professionals, we certainly need to not only be “able” to meet the challenge, but also ready and willing, assuming of course that the opportunity presents itself.

Medical Cannabis: The Pharmacist’s Role

What is the pharmacist’s role in context of medical cannabis?

Three states have previously passed legislation either authorizing (Minnesota, 2015)27 or requiring (Connecticut, 2014)28 (New York, 2016)29 pharmacists to assume a role in dispensing medical cannabis.18 Pharmacists serve as gatekeepers in a more traditional “dispensary” model in Connecticut, Minnesota, and New York medical marijuana programs.22(27)28(27) Each of these three states have laws that specify medical conditions that qualify patients under each of their respective state medical marijuana programs. Minnesota law lists certain qualifying medical conditions (glaucoma, HIV/AIDS, Tourette’s, ALS, seizures, Crohn’s, severe & persistent muscle spasms; cancer or a life expectancy <1 year; severe/chronic pain, nausea/vomiting, or severe wasting).28 New York law lists ten medical conditions (cancer, HIV/AIDS, ALS, Parkinson’s, MS, intractable spasticity, epilepsy, IBS, neuropathies, Huntington’s; associated/complicating conditions (cachexia, severe/chronic pain, severe nausea, seizures, severe/peristent muscle spasms).18 New York further acknowledges that ongoing review of scientific evidence may support inclusion of additional conditions in the future.29 Connecticut law closely resembles that of New York.18 Pharmacists are the sole gatekeepers for medical marijuana in these three states; however, it remains essential to note their respective state marijuana programs distinctly differ;16(26)(27)(28)(27) Table 2 offers a comparative overview of the various legal requirements and provisions under Connecticut, Minnesota, and New York state marijuana programs.18

Connecticut’s medical marijuana program actually requires pharmacists licensed by the Connecticut Department of Consumer Protection (CDCP) to own and operate its medical marijuana dispensaries.16 Legal protections are afforded pharmacists under the Connecticut program through immunity provided by CDP.28 (Table 2) In addition, the Connecticut legislature has unambashedly reclassified marijuana by state law as a C-II controlled substance.19(28) A curious fact that flies in the face of the federal Controlled Substances Act placing marijuana in C-I.20 (Table 2) In so doing, the Connecticut state legislature must have clearly understood that without reclassification of marijuana as a C-II, pharmacists handling marijuana in Connecticut could be exposed to criminal prosecution, and liability on various levels.

There is no question the Connecticut state legislature’s move to reclassify marijuana to C-II was an effort to shield pharmacists in the state, or at least to provide some element of protection from federal and/or even state prosecution for handling marijuana, still an illegal substance, under federal law.20(26)
### Table 2. Comparison: States Authorizing Pharmacists in a Medical Cannabis Dispensing Role

<table>
<thead>
<tr>
<th>Prescriber Requirements/ Patient Restrictions</th>
<th>Connecticut (2014)(^{(a)}) (^{(b)})</th>
<th>Minnesota (2015)(^{(c)}) (^{(d)})</th>
<th>New York (2016)(^{(c)}) (^{(d)})</th>
</tr>
</thead>
<tbody>
<tr>
<td>Certify medical condition; Qualifying medical conditions resemble those of New York; Stricter program in US; Patient must designate specific dispensary</td>
<td>Certify medical condition; Nine qualifying medical conditions</td>
<td>Certify medical condition; Ten qualifying medical conditions</td>
<td>Certification guidelines, required registry (physicians &amp; patients) (Medical Marijuana Data Management System); Physicians must consult PMDP in advance</td>
</tr>
</tbody>
</table>

| Pharmacist Provisions, Requirements, Protections | Connecticut licensed pharmacist must own and operate dispensary; Only pharmacist certified by Connecticut Department of Consumer Protection (CDCP) can dispense; CDCP provides pharmacist immunity; Marijuana reclassified by state legislature as C-II; PDMP tracking; Limit: No more than 2.5 ounces in 30-day period; Labels mandated to show CBD/THC ratios, expiration dates; May sell for smoking; Edibles and other forms permitted | Selects dose and formulation; Dispenses only after consultation; Counsels on disease state & therapy goals; Board of Pharmacy not involved in medical marijuana | NY licensed pharmacist required on premises to operate and dispense; Limit: No more than 30-day supply; Only two New York approved medical marijuana products must be offered (equal ratio of THC to CBD); Other additional products (w/ varying ratios of THC to CBD); No sale for smoking; Edibles banned |

| Medical Cannabis System | CDCP regulates system: Only licensed growers, dispensaries can handle; Dispensaries purchase only from CDCP licensed producers; dispensary tracking; Initially only six CDCP certified dispensaries; three more approved later (to better serve Connecticut patients); Estimated population of 20,000 people in state may be eligible to use marijuana | Minnesota Department of Health (DOH) regulates system: Two growers; Three dispensaries currently; Law allows up to eight dispensaries | New York State Department of Health (DOH) Commissioner regulates closed distribution (dispensaries & growers): Maximum of 20 dispensaries; Potential patient population estimated between 100,000 to 400,000 in NY. |


Where pharmacists serve in a “dispensary” model, such state programs uniformly maintain closed distribution systems, and neither contemplate nor sanction dispensing of medical marijuana at neighborhood independent or chain drugstores, where patients might have other traditional medication orders filed. (Table 2) In other words, in the “dispensary” model, medical marijuana distribution is limited to specific certified growers and producers, as well as dispensaries. (Table 2)

The states requiring (Connecticut, New York) or authorizing (Minnesota) a pharmacist to dispense further impose restrictions on an individual pharmacist’s license and state certification, and these states administer their respective medical marijuana programs through either a state health department (Minnesota, New York), or department of consumer protection (Connecticut). (Table 2) None of the three states provides for board of pharmacy oversight of their medical marijuana programs. (Table 2) There is some qualified immunity from state liability on an individual pharmacist’s license from state board of pharmacy prosecution in those three states, assuming all other regulatory requirements are met, simply because legislation has either mandated (Connecticut, New York) or authorized (Minnesota) pharmacist dispensing of medical marijuana. However, in spite of the laws in the three states (Connecticut, Minnesota, and New York) dictating only a pharmacist may dispense medical marijuana, the reality is pharmacists in these states, or other states, are not entirely immune from federal prosecution under the federal Controlled Substances Act.

With a total of 29 states plus the District of Columbia that currently have laws legalizing and regulating cannabis for medicinal purposes, it remains uncertain whether, or how, pharmacists will assume a similar role in other states’ medical marijuana dispensing operations. In states other than those that expressly require (Connecticut, New York) or expressly authorize (Minnesota) a pharmacist dispensing role, pharmacists are ill-advised to handle medical marijuana, or risk certain liability and even prosecution under state board of pharmacy regulations, or federal controlled substances law. That is because under the Constitution’s pre-emption doctrine, the federal controlled substances act prevails over state laws that are less strict. Since the federal controlled substances act deems marijuana a C-1 controlled substance, it is illegal for any purpose. Indeed, a 2015 Drug Topics survey of 715 pharmacists reported 28% of survey respondents did not believe pharmacists should be dispensing marijuana until it is reclassified as a federal C-II controlled substance. (30) Although the same survey reported 48% of respondents favored pharmacist oversight of state-approved medical marijuana dispensaries. (30)

Where unprotected by state law authorizing or mandating pharmacists as gatekeepers, individual state boards of pharmacy would not hesitate to sanction pharmacists handling a substance illegal under the federal regulatory scheme. Furthermore, under the federal act, individual states are not authorized to reclassify controlled substances, including marijuana. (30) Congress passed the 1970 Controlled Substances Act, preempting states from passing legislation that attempts to reclassify marijuana as C-I or C-II. (31) Short of a Congressional amendment, or an action by the US Attorney General to do so, in theory this can’t, or shouldn’t, happen. But it did. How can this be reconciled? The answer is simple. Federal developments over recent years have simply allowed this.

Most states long ago adopted their own state version of the federal Controlled Substances Act, consistent with the federal act. Luckily the federal government through the end of the Obama administration assumed a laissez-faire approach. (31) It would not be surprising if readers are bewildered. Pharmacists must be aware that substances classified in C-I including marijuana, by definition, have “no legitimate medical use, are unsafe for use even under medical supervision, and have a high potential for abuse,” and under the federal Controlled Substances Act are illegal for any purpose. (31) The state of Connecticut is the only state to challenge this, and “down-schedule” marijuana to a C-II controlled substance, and trigger an actual conflict between the federal act and state controlled substance law. (16)(30)

The truth is “even in states that have legalized medical marijuana, licensed and registered medical marijuana growers, distributors, and patients are breaking federal laws under the Controlled Substances Act every day.” (30)(33)(34) Other challenges to participating in the marijuana industry extend past legal risk and liabilities, though at the same time, also derive from legal ramifications of violating the federal regulatory scheme, and serve as strong disincentives to engaging in it. (30)(34) Banks remain hesitant to establish commercial bank accounts or extend credit to so-called “legal” medical marijuana businesses, whether small or large. (30) Similarly, the IRS disallows standard business deductions for these “legal” medical marijuana companies, which also find it difficult to market themselves to investors who may be fearful of related IRS audits or tax liabilities. (30)(33)(34) Even in California, under Prop 64, and further under SB 94, which merges the marijuana regulatory and enforcement schemes, conflicts with federal law continue to exist, leaving similar unresolved issues yet to be addressed. Although the California scheme does not incorporate pharmacists, California will have a uniform set of rules governing cultivation, distribution and dispensing, by January 2018 when SB 94 is implemented. Elsewhere across the country, there is an absence of consistent rules, quality assurance standards or regulations across the spectrum of states where medical marijuana is cultivated.

Medical Cannabis: Federal Enforcement Risk and Pharmacists’ Liability

As explained, the CSA supersedes state law on the issue of controlled substances. (30) In general, where there is a federal law on a given topic, states may enact laws that are more strict than federal law, but not less strict than federal law. Where a state enacts a law on a matter covered by federal law, and one or another provision conflicts, the state is required to follow the stricter law. Thus, as in the context of states’ marijuana legislation, medical or recreational, since CSA is the stricter law as to the legal status of marijuana, federal law governs, and is enforceable by the Justice Department under the US Attorney General.

Thus, if states across the country are enacting laws concerning marijuana possession, use, and sale that do indeed contradict federal law, what is the solution? This conflict is real.

Additionally, with social attitudes toward marijuana changing, more and more states have been passing legislation permitting its use, possession and sale for medical purposes. During the Obama administration, the DOJ exercised its discretion and simply refrained from enforcing federal marijuana law against those who possess, use or sell marijuana for a bona fide medical purpose, basically implementing a “hands off” policy for those states that had passed medical marijuana laws. The DOJ and DEA were also aware that regulatory and enforcement schemes in most medical marijuana states were flawed with gaps.

To address these “gaps,” in 2013, the DOJ published a set of its enforcement priorities and guidelines known as the “Cole Memorandum,” which it distributed to state approved / legal
DOJ's marijuana enforcement priorities. The Cole Memorandum addressed areas of most concern to the DOJ, and in exchange for refraining from prosecution against states that have legalized medical marijuana, it required those states to demonstrate regulatory schemes within their respective states, comply with the listed DOJ enforcement priorities, among them for example: preventing diversion, illegal trafficking, distribution to minors, cultivation of marijuana on public lands, drugged driving, public safety and environmental risks, etc. Still, despite the enforcement priorities announced with the Cole Memorandum, medical marijuana activities remain illegal federally. Also, if one state is too lenient in its own enforcement scheme, or violates one or another of the DEA enforcement priorities, the agency may not hesitate to prosecute. Soon after the Cole Memorandum, California was brought closer into compliance with CSA and federal enforcement priorities with the passing of MMRSA in 2015. Admittedly, a different administration could also elect to exercise its discretion differently, and choose to enforce federal law against even those states with medical marijuana laws.

DEA enforcement against medical marijuana businesses was further restrained in 2014 by a bipartisan Congressional ban on DOJ and DEA practices of raiding, harassing, and prosecuting medical marijuana providers, growers, and users in states where it is legal. The Rohrabacher–Farr Amendment (R-F Amendment) prohibited the DOJ from using any federal funds, “to prevent such States from implementing their own State laws that authorize the use, distribution, possession, or cultivation of medical marijuana.” The R-F Amendment, set to expire in September 2017, was renewed by a bipartisan vote on July 27, 2017 which effectively extended the protections to medical marijuana states in a rather firm rebuke to the current US Attorney General Jeff Sessions, who earlier in May 2017 wrote Congress appealing for its leadership to reject it.

While there have been several other federal-level actions of various forms proposed, none have yet been successful in changing the classification of marijuana under federal law from C-I to C-II. One bipartisan proposal introduced in the Senate on March 10, 2015, is the Compassionate Access, Research Expansion, and Respect States (CARERS) Act of 2015 (S. 683). The CARERS Act (S. 683), is considered the most comprehensive to date on the topic of marijuana rescheduling, and proposes to transfer medical marijuana from its classification as C-I to C-II of the CSA, and would resolve the conflict between federal and state marijuana laws. If passed, the CARERS Act stands to eliminate existing barriers to research, allow banks to service marijuana businesses, and to permit veterans access to medical marijuana within the Veterans Affairs (VA) healthcare system. The CARERS Act would also exclude “cannabidiol” (CBD) from the official definition of “marijuana” and instead define it as a distinct substance “cannabidiol,” which in effect would remove CBD entirely from the CSA. To accomplish its goal, the language of S.683 focuses on extending the principle of federalism to states’ drug policy. The CARERS Act (S.683) currently sits in the Senate Judiciary Committee, and should be closely followed because its novel approach to shift drug policy to the realm of the states carries significant potential to alter marijuana policy in the US.

Furthermore, pending legislation in several state legislatures directly confront the federal government’s role in marijuana policymaking. Bills or resolutions in California, Georgia, Massachusetts and Pennsylvania petition Congress either to reschedule marijuana or to concede to states the authority for marijuana policy. Several other bills pending in Congress, if passed, would address and improve tax policy for states with legalized marijuana businesses; authorize states’ adult-use legalized marijuana; and end the federal marijuana prohibition.

Conclusion: Effects of the Current Political Climate on Federal Enforcement

Irrespective of the evolution of social acceptance, and even government acceptance, of medical marijuana over the past two decades, a debate between political factions continues. Liberals, on one hand, support legalization of medical and recreational marijuana, right wing conservatives remain feverishly opposed, while the moderate position appears to align with the liberal view. The Trump administration in its first few months signaled it was inclined to ignore the bipartisan congressional ban under the 2014 R-F Amendment that prohibits any federal interference with states’ medical marijuana programs. Trump asserted that the limits Congress imposed were not binding on him, as president, and his constitutional powers superseded those of Congress. Trump’s Attorney General Sessions, in his May 1, 2017, letter to congressional leadership, urged them to get rid of the amendment’s medical cannabis protections entirely. From those initial actions, it was clear the Trump administration was to crack down, not only on states where recreational cannabis is legal, but also where medical cannabis laws exist, and even in face of overwhelming bipartisan support by Americans across the country for medical marijuana. Bipartisan Congressional support to maintain medical marijuana protections is consistent with recent voter polls. Earlier, on April 20, 2017, the independent Quinnipiac University poll reported a record level of voter support at 94% (5% against) in favor of “allowing adults to legally use marijuana for medical purposes if their doctor prescribes it.” In reality, Sessions may still pursue the eight states where laws authorize recreational marijuana. However, short of federal funding to pursue the 29 states (and District of Columbia) where medical marijuana laws currently exist, Sessions’ ability to fight them is limited or rather restricted by the federal budget.

About the Author

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1. CCUA acted as defense or exemption to criminal prosecution where cultivation and use of marijuana for medical purposes was: a) based on the recommendation or approval of a California licensed provider; b) the patient was over the age of 18, and c) the marijuana is cultivated and/or possessed for the “personal medical purposes of the patient in the treatment of cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, migraine, or any other illness for which marijuana provides relief.” California Compassionate Use Act of 1996 (CCUA), is also known as Proposition 215 (California Health and Safety Code Section 11362.5(b)).


3. Senate Bill 420 (SB 420), the Medical Marijuana Program Act, regulated the State Department of Health Services to establish and maintain a voluntary program for issuance of identification cards to qualified patients, and to establish procedures under which a qualified patient with an identification card could use marijuana for medical purposes, including development of related protocols and forms, and establishing application and renewal fees for the program. Thus, SB 420 imposed duties upon county health departments relating to issuance of identification cards, and created various crimes related to the identification card program by creating a state-mandated local program. http://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=2003020040SB420.

4. Enacted by the California legislature, AB 243, AB 266, and SB 643 comprise the “Medical Marijuana Regulation and Safety Act” (MMRSA), which created the framework and standards needed for licensing businesses, as well as testing, packaging, labeling, and tracking marijuana products. MMRSA established the Bureau of Medical Marijuana Regulation (“Bureau”) under the Department of Consumer Affairs to oversee the medical marijuana system. Medical marijuana businesses currently operating will be required to obtain local approval to continue operating. The Bureau will phase out the current system of collectives and cooperatives, and marijuana businesses are expected to apply for state licenses beginning in January 2018, when Assembly Bill No. 243, Chapter 688, Wood, Medical Marijuana (2015-2016) take effect. Approved by Governor October 09, 2015; Filed with Secretary of State October 09, 2015, http://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=2015020160AB243; Assembly Bill 266 Chapter 689, Bonta, Medical Marijuana (2015-2016), Approved by Governor October 09, 2015; Filed with Secretary of State October 09, 2015, http://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=2015020160AB266; Senate Bill 643, Chapter 719, McGuire, Medical Marijuana (2015-2016), Approved by Governor October 09, 2015; Filed with Secretary of State October 09, 2015, http://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=2015020160SB643.


