

*Information Summary and Recommendations*

# Medical Marijuana Scheduling Options

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## Executive Summary

During the 2015 legislative session, Second Substitute Senate Bill 5052 (2SSB 5052) was passed by the legislature. It was signed by Governor Inslee on April 24, 2015. The Governor vetoed Sections 42 and 43, which would remove from Schedule I of Washington State's Controlled Substances Act any medical marijuana product that the Department of Health (department) identifies in rule as "appropriate for sale to qualifying patients and designated providers in a retail outlet that holds a medical marijuana endorsement."

In his veto message, the Governor noted that rescheduling just medical marijuana "may cause serious problems such as having the unintended effect of limiting the types of marijuana that are considered medicine." Therefore, he directed the department to "thoroughly consider this idea in consultation with medical professionals and stakeholders, and bring an appropriate resolution to me and the Legislature by next year."

The department developed three marijuana scheduling options to propose for stakeholder input. On November 20, 2015, we held a public meeting to present and discuss the three options. We used the department's medical marijuana web page and ListServ as primary means of notification. We also used email to notify all marijuana producer, processor and retailer licensees and applicants of the Washington State Liquor and Cannabis Board (LCB). Law enforcement and healthcare practitioners and organizations were also invited to attend.

Nearly 50 people representing patients, growers, and dispensaries/retail stores attended the public meeting. None of the in-person attendees identified themselves as healthcare practitioners or members of law enforcement. Some healthcare practitioners and members of law enforcement listened to the meeting using web conferencing. We did receive email feedback from a pharmacist and from a prescriber who were not in favor of rescheduling. To date we have not received any feedback from members of law enforcement.

During the public meeting, a fourth option regarding scheduling emerged. We then held a discussion with the Pharmacy Quality Assurance Commission (commission) at its public meeting on December 11, 2015. We believed this was appropriate due to the commission's role in regulating drug distribution and delivery in Washington including under RCW 69.50.201, which grants the commission authority to add substances to or to delete or reschedule substances listed in Washington's Controlled Substances Act. The commission proposed a fifth option.

After thoroughly considering all five options, the department recommends making no changes at this time for the following reasons:

- Medical and recreational users currently have adequate access to marijuana despite its designation as a Schedule I controlled substance.
- Federal designation of marijuana as a Schedule I controlled substance complicates implementation of any meaningful state change and renders many options merely symbolic.
- Re-scheduling or de-scheduling marijuana would require significant revisions to state laws and rules; further complicate and confuse the currently evolving regulatory system; and potentially cause the federal government to intervene.

## **Marijuana Scheduling Options**

The department initially proposed the following three options for consideration and discussion:

### **1) Do nothing at this time.**

*Implications of this option:*

- Maintains the current situation.
- Does not require any changes to Washington state laws or rules.
- Keeps the Washington Controlled Substances Act aligned with federal law.
- The use of marijuana for either medical or recreational reasons continues to be illegal under federal law.
- Marijuana can be authorized (but not prescribed, administered or dispensed) by healthcare practitioners without putting their DEA registration at risk.
- Marijuana is distributed by retail outlets regulated by the LCB. Pharmacies do not jeopardize their DEA registration or banking options by dispensing marijuana.
- Schedule I penalties apply to any use, possession, sales, and distribution of marijuana or THC products outside the legal market established under I-502, SB 5052 and chapter 69.51A RCW.
- The Washington Controlled Substances Act continues to list marijuana as a substance that has no currently accepted medical use, which conflicts with chapter 69.51A RCW.
- Though not in compliance with federal law, Washington State's tightly regulated system focuses on meeting the federal government's enforcement priorities.

### **2) Change marijuana to Schedule II - V or to a legend (prescription) drug.**

*Implications of this option:*

- Requires changes to existing Washington State laws and rules.
- Conflicts with I-502's recognition and legalization of recreational use of marijuana.
- Formally recognizes that marijuana has medicinal benefits.
- Makes marijuana subject to all the same requirements of any other prescription drug. The requirements for prescribing, manufacturing, wholesaling, distributing, selling, dispensing, and administration of prescription drugs would apply.
- Treated like other prescription drugs, growing for personal medical use would not be allowed.

- Conflicts with federal law, so healthcare practitioners wouldn't be able to legally prescribe, dispense or administer marijuana. If they did, they could face federal criminal and administrative penalties and their DEA registration could be revoked.
- Marijuana would have to be dispensed through a pharmacy, which conflicts with the systems created under I-502, SB 5052 and chapter 69.51A RCW.
- Dispensing marijuana may place a pharmacy's DEA registration in jeopardy and may result in loss of banking options.
- Healthcare practitioners and facilities that prescribe or dispense marijuana could be excluded from participating in Medicare/Medicaid.

**3) Amend Washington State's Controlled Substances Act to be consistent with I-502, SB 5052 and chapter 69.51A. All other use would still be illegal.**

*Implications of this option:*

- Requires changes to existing Washington State laws and rules.
- Marijuana would no longer be a Schedule I drug for people following all the rules for growing, processing, selling, possession and use under I-502, SB 5052 and chapter 69.51A RCW.
- Schedule I penalties would still apply to any use, possession, sales, and distribution of marijuana outside the legal market established under I-502, SB 5052 and chapter 69.51A RCW.
- The use of marijuana for either medical or recreational reasons would continue to be illegal under federal law.
- Marijuana could continue to be authorized (but not prescribed, administered or dispensed) by healthcare practitioners without putting their DEA registrations at risk.
- The Washington Controlled Substances Act would align with I-502, SB 5052 and chapter 69.51A RCW.
- Though not in compliance with federal law, Washington State's tightly regulated system focuses on meeting the federal government's enforcement priorities.

**Stakeholders' Proposed Option**

The majority of responses by stakeholders to the three options proposed by the department were that none of those options are preferred. Overwhelmingly, the stakeholders who actively participated in the discussion were in favor of the following:

**4) Remove marijuana completely from the Washington Controlled Substances Act, make it unregulated, and treat it like any other plant.**

*Implications of this option:*

- Requires extensive changes to existing Washington State laws and rules.
- Removing marijuana from Schedule I without maintaining the existing regulation would allow any person to possess, use and grow any amount, and to distribute and sell any amount at any time to anyone in the same manner as any other plant.
- Eliminates the current regulated recreational market implemented under I-502 and codified in the Controlled Substances Act. This includes eliminating quality assurance standards, testing and labeling requirements, protections for minors, and taxation which funds marijuana treatment and education.
- Eliminates the need for specific regulation for medical marijuana under chapter 69.51A RCW, including the quality assurance standards in SB 5052.
- Is not compliant with federal law or the Cole memo. An unregulated system does not meet the federal government's enforcement priorities, particularly preventing the distribution of marijuana to minors.

**Pharmacy Quality Assurance Commission Meeting**

On December 11, 2015, the department presented the four options to the commission and also shared a summary of the stakeholders' comments from the November 20 meeting. The commission deliberated on the original three options and without strong support for any of the options presented, decided to develop their own option:

**5) Maintain I-502 for recreational marijuana; work with stakeholders to restructure SB 5052 and chapter 69.51A RCW to put medical marijuana under the commission's jurisdiction and treat it as a prescription drug.**

*Implications of this option:*

- Requires extensive changes to Washington State laws and rules.
- Recreational users would still use the retail market established under I-502 but patients would have their medical marijuana prescribed by healthcare practitioners and dispensed by pharmacies.
- The LCB would transition authority to regulate production, processing, lab testing and sales of medical products to the commission.
- The commission would assume responsibility for ensuring patients have access to safe, quality medication.
- Formally recognizes that marijuana has medicinal benefits.
- There is no scientific basis for determining what marijuana is medical or recreational. Identical products are used for both medical and recreational purposes.

- Treated like other prescription drugs, growing for personal medical use would not be allowed.
- Under federal law, the DEA could take action against practitioners who prescribe marijuana and pharmacies that dispense marijuana.
- Healthcare practitioners and facilities that prescribe or dispense marijuana could be excluded from participating in Medicare/Medicaid.
- Patients could face inadequate access if pharmacies chose to not stock marijuana due to concerns over federal law.
- Though not in compliance with federal law, a tightly regulated system would still focus on meeting the federal government's enforcement priorities.

## **Recommendation**

The department sincerely appreciates the collaborative and amicable efforts of everyone who participated in discussions regarding this issue. Clearly, there is no easy answer. Every option presents both positive and negative implications depending on individual perspective and preference. Of paramount significance is marijuana's ongoing federal status as a Schedule I controlled substance.

Options two and five both involve making medical marijuana a prescription drug. While this comports well with chapter 69.51A RCW's acknowledgement of marijuana as having medical value, it fails to take into account the many collateral impacts of such an act. Prescription drugs must be prescribed or administered by a healthcare practitioner and dispensed either by the prescriber or a pharmacy. Prescribing, administering and dispensing marijuana remain illegal under federal law. Healthcare practitioners who chose to engage in these actions could be criminally charged. They could also face administrative sanctions such as loss of their DEA registration and exclusion as a Medicare/Medicaid provider. Healthcare facilities such as pharmacies and hospitals that participated or allowed these actions could also face administrative sanctions as well as potential loss of banking opportunities.

It is likely that most pharmacies and hospitals would decline to allow prescribing or dispensing of marijuana by healthcare practitioners for these reasons. If so, patients could face significant difficulties in accessing marijuana for medical use.

In the alternative, Washington could take a purely symbolic action similar to Oregon, i.e. move marijuana to Schedule II but take no affirmative steps to treat it as such. This creates a legal fiction which diminishes the authority of law, further confuses the issue of legalization, and fails to actually address the underlying issues.

Option four removes all regulatory control of marijuana. Many stakeholders strongly believe marijuana is simply a plant and should be treated no differently than other plants (tomato plants are a common comparison). While it is true that marijuana is, in fact, a plant, this reasoning

ignores marijuana's psychoactive effects. It also diminishes the argument that marijuana should be acknowledged and treated as medicine.

Simply removing marijuana from Schedule I without creating an alternative regulatory structure would mean any person could grow, purchase, use, sell or trade marijuana without limitation. The existing recreational and medical markets, which are both based on some level of regulation, would become obsolete. A patient would no longer need an authorization to buy or grow as much marijuana as desired. Licensing for producers, processors, and retail stores would no longer be necessary because there would be no penalty for growing or selling outside the formerly regulated market. There would be no controls on product safety or restrictions on youth access. Importantly, it is unlikely that the federal government would allow such a situation to exist in light of the enforcement priorities listed in the Cole memo.

If change were truly required, option three would be the least disruptive choice. It would maintain the existing medical and recreational markets. Marijuana would be removed from Schedule I if used in compliance with I-502, SB 5052 and chapter 69.51A RCW. Schedule I penalties would continue to apply to violations of the regulatory system. In the alternative, it could be removed entirely from Schedule I and new penalties could be devised for violations. In this way, marijuana would be treated similarly to alcohol and tobacco in that it would be legal but subject to strict regulation, with penalties for people operating outside that regulation. However, the end result would be remarkably similar to the current situation – marijuana would be legal for recreational or medical use within the regulated system and illegal outside the regulated system. The only real change would be the symbolic act of removing marijuana from the state's Controlled Substances Act.

In the absence of a solution that would not result in jeopardy for healthcare practitioners and pharmacies, create an entirely unregulated situation, or be a merely symbolic act, the department recommends option one – do nothing at this time.

The current situation is not perfect. Washington is experiencing a monumental shift in law and policy as marijuana becomes normalized. Changes from the 2015 legislative session are still being implemented. Many cities and counties who have enacted bans or moratoria prohibiting recreational marijuana, medical marijuana or both are now reconsidering their positions. Licensed producers, processors and retailers bear the burdens and reap the benefits of strict regulation. Most of all, patients are wary of the evolving regulation of medical marijuana because they will no longer be able to grow, buy, sell and trade marijuana in the nearly unfettered way of the past.

Despite this, the vast majority of both recreational and medical users currently have adequate, if not ideal, access to marijuana. Changing the status of marijuana as a controlled substance in Washington will not result in a significant positive change. Eliminating all regulation is not responsible legal or social policy. Rescheduling marijuana or making it a prescription drug would grant marijuana recognition as a legitimate medicine but it would also require it to be prescribed and dispensed within the traditional medical system. Rather than benefitting patients, this would likely reduce access due to concern about federal penalties and impacts. Rescheduling without transitioning marijuana into the traditional medical system would be purely symbolic, as would be removing it from Schedule I but maintaining essentially the same penalties for violations.

Finally, all state action regarding legalization or decriminalization of marijuana is contrary to federal law. The current administration has elected to tolerate these actions based on the existence of, and compliance with, a strict state regulatory structure. It could just as easily decide to withdraw that tolerance and engage in robust enforcement action. The primary reason to change the status of marijuana is its designation in the Controlled Substances Act as having no medical value even though other state laws recognize it as having medical value. However, this is mostly a philosophical argument. In reality, patients do currently have adequate access to marijuana for medical use, just as recreational users have adequate access to meet their needs. For this reason, the department recommends maintaining the status quo rather than inviting uncertain outcomes and risk.

## **History and Background**

The department considered the following when assessing potential implications of each option.

### **Federal Law, 1970**

Although criminalization efforts began decades earlier, Congress first categorized marijuana as a Schedule I controlled substance, the most restrictive classification available, in 1970. Under this categorization, marijuana is considered to have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use of the drug or other substance under medical supervision.<sup>1</sup> Healthcare practitioners cannot legally prescribe or dispense Schedule I controlled substances.

### **Washington Law, 1971**

Following the federal government's lead, Washington State enacted its own Controlled Substances Act in 1971. Marijuana was, and continues to be, listed as a Schedule I controlled substance. In addition to the legislative authority to amend the act, the state Board of Pharmacy (later renamed Pharmacy Quality Assurance Commission) was granted rulemaking authority to add substances or delete or re-schedule controlled substances. Petitions to the commission to re-schedule marijuana in rule have been unsuccessful.

### **Initiative 692, Medical Use of Marijuana in Washington State, 1998**

The medical use of marijuana in Washington State was first authorized by voter Initiative 692 in 1998. It granted an affirmative defense to criminal prosecution to qualifying patients and their primary caregivers.<sup>2</sup> The patient was required to have a recommendation from a healthcare practitioner and could possess no more than a 60-day supply of marijuana.

The initiative, codified as chapter 69.51A RCW, was amended many times over the years. For example, the list of terminal or debilitating conditions has been expanded, as has the list of healthcare practitioners who may recommend or authorize the medical use of marijuana. Notably, a 2011 amendment allowed up to 10 qualifying patients and/or designated providers to form a collective garden for the purposes of combining resources.

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<sup>1</sup> 21 U.S.C. § 812(b)(1).

<sup>2</sup> "Primary caregiver" was changed to "designated provider" in ESSB 6032 (2007).

### **Initiative 502, Legalized Purchase and Possession of Marijuana in Washington State, 2012**

In November of 2012, Washington voters passed Initiative 502. I-502 legalized the purchase and possession of small amounts of marijuana for all adults. It also created a taxed and highly regulated system for the production, processing and retail sale of marijuana. This resulted in the existence of two distinct markets – the unregulated medical market and the regulated recreational market.

### **2SSB 5052, Cannabis Patient Protection Act in Washington State, 2015**

The legislature reconciled the two markets with the passage of Second Substitute Senate Bill 5052 and Second Engrossed Second Substitute House Bill 2136 earlier this year. It is important to note, however, that the medical use of marijuana is not yet legal at either the state<sup>3</sup> or federal level. Beginning July 1, 2016, 2SSB 5052 will legalize the medical use of marijuana for patients and designated providers who are entered into a patient authorization database. Patients and designated providers who choose not to be entered in the database will continue to have an affirmative defense to criminal prosecution. The medical use of marijuana remains illegal at the federal level despite a certain level of tolerance conditioned upon full compliance with applicable state laws.<sup>4</sup>

### **Marijuana Remains Illegal under Federal Law**

In 2011, former Governor Chris Gregoire, together with the governor of Rhode Island, petitioned the Drug Enforcement Administration (DEA) to reclassify marijuana as a Schedule II controlled substance. Such rescheduling would make marijuana a drug with accepted medical uses but would also impose strict regulation due to a potential for addiction. Schedule II controlled substances can only be prescribed and dispensed by healthcare practitioners authorized to do so by law. This would seriously impact patients' ability to grow their own marijuana. It would also conflict with Washington's existing regulatory system for both medical and recreational marijuana.

The DEA has not acted on the petition to reschedule marijuana. Thus, it remains illegal under federal law for healthcare practitioners to prescribe or dispense marijuana.<sup>5</sup>

Following the passage in 2012 of initiatives in Washington and Colorado to legalize the recreational use of marijuana, Deputy U.S. Attorney General James Cole provided a memo for all U.S. attorneys entitled "Guidance Regarding Marijuana Enforcement." This document (known as the Cole memo) listed nine enforcement priorities of particular import to the federal government. U.S. Attorneys were instructed to focus their enforcement resources and efforts on persons or organizations whose conduct interferes with those priorities regardless of state law. The guidance "rests on the expectation that states and local governments that have enacted laws

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<sup>3</sup> *State v. Rejs*, No. 90281-0 (Washington Supreme Court, May 7, 2015)

<sup>4</sup> A 2015 federal spending bill contained the following language, "None of the funds made available in this Act to the Department of Justice may be used, with respect to the States of Alabama, Alaska, Arizona, California... Washington, and Wisconsin, to prevent such States from implementing their own State laws that authorize the use, distribution, possession, or cultivation of medical marijuana."

<sup>5</sup> The National Institute of Drug Abuse (NIDA) does contract with the University of Mississippi to grow marijuana for use in approved research studies. It also provides marijuana to a very small number of patients under the Compassionate Investigational New Drug Program which was established in the late 1970s and is currently closed to new participants. Neither of these actions by NIDA alters the federally illegal status of marijuana.

authorizing marijuana-related conduct will implement strong and effective regulatory and enforcement systems” both on paper and in practice.<sup>6</sup>

### **Oregon’s Attempt to Reschedule Marijuana**

In 2009, the Oregon legislature passed Senate Bill 728 which required the state Board of Pharmacy<sup>7</sup> to “classify marijuana as a controlled substance in Schedule II, III, IV or V.” On June 16, 2010, the board adopted permanent rules rescheduling marijuana from Schedule I to Schedule II, the most restrictive option permitted under the bill. Thirteen days later, the board issued a news release stating it complied with the bill “to correct a technical conflict in the law and in no way intended to infer or imply that [marijuana] is or should be available by prescription. In fact, marijuana is not available by prescription... **marijuana or products containing any amount of marijuana will not be available by prescription in Oregon unless they have been approved by the [Food and Drug Administration].** The Board of Pharmacy’s action to reschedule marijuana on the state list does not supersede federal law or create a direct conflict with federal law. It simply does not address federal law.” (emphasis original)

### **Conant v. Walters**<sup>8</sup>

California became the first state to recognize the medical use of marijuana with the passage of Proposition 215 in 1996. Shortly thereafter, the federal government promulgated a policy declaring a physician’s action of recommending or prescribing a Schedule I controlled substance would lead to revocation of the physician’s DEA registration to prescribe controlled substances. Two months later, the Department of Justice and Department of Health and Human Services sent letters to national, state, and local practitioner associations outlining the policy and warning that physicians who intentionally provide their patients with oral or written statements in order to enable them to obtain controlled substances in violation of federal law risked revocation of their DEA prescriptive authority.

Patients suffering from serious illnesses, physicians licensed in California, a patient organization, and a physician’s organization filed an action in 1997 to enjoin enforcement of the government’s policy insofar as it threatened to punish physicians for communicating with their patients about the medical use of marijuana. The District Court granted a permanent injunction against the government which was later upheld by the Ninth Circuit Court of Appeals.<sup>9</sup> The United States Supreme Court declined to hear the case. Thus, it remains binding case law to this day.

The Court in Conant held that physician speech, including speech about the potential benefits of medical marijuana, is entitled to First Amendment protection because of the significance of the doctor-patient relationship. The possibility that the physician’s recommendation may lead to federally illegal conduct by the patient, i.e. possession of marijuana, is not sufficient to overcome the physician’s First Amendment rights. However, the Court recognized the slippery slope between orally recommending the medical use of marijuana and taking affirmative steps toward facilitating a federal crime. The injunction specifically did not bar federal prosecution of a

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<sup>6</sup> Cole Memorandum, August 29, 2013, <http://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf>, accessed December 28, 2015.

<sup>7</sup> In Oregon, all controlled substances are classified in board rules, not statute.

<sup>8</sup> Conant v. Walters, 309 F.3d 629, United States Court of Appeals, 9<sup>th</sup> Circuit, 2002

<sup>9</sup> The Ninth Circuit includes California, Arizona, Nevada, Hawaii, Montana, Idaho, Alaska, Oregon and Washington.

physician when government officials in good faith believe they have probable cause to charge under aiding and abetting or conspiracy charges.

While the Court held that merely recommending the medical use of marijuana does not rise to the level of aiding and abetting or conspiracy, it stated:

“A doctor would aid and abet by acting with the specific intent to provide a patient with the means to acquire marijuana. Similarly, a conspiracy would require that a doctor have knowledge that a patient intends to acquire marijuana, agree to help the patient acquire marijuana, and intend to help the patient acquire marijuana.”<sup>10</sup>

Under this holding, healthcare practitioners who dispense marijuana to their patients would be at significant risk of administrative action and criminal prosecution under federal law.<sup>11</sup>

### **Liability Issues**

Under current Washington law, healthcare practitioners do not prescribe or dispense marijuana. Instead, they may authorize or recommend its medical use. This is consistent across the other 22 states and Washington D.C. that have some sort of medical marijuana laws, as well as the 17 states that currently allow high CBD/low THC<sup>12</sup> products for medical use. Most often, the patients themselves ask for the authorization. Once the authorization is provided, patients typically obtain the marijuana from a third party or grow it themselves. The authorizing practitioner may or may not discuss specific types of products available or routes of administration.

To date, the department has not identified any medical malpractice cases relating to the medical use of marijuana. This is not surprising given that patients typically expect to receive no more than an authorization from the healthcare practitioner, and the practitioner does not dispense or administer the marijuana. However, as the medical use of marijuana becomes more widely accepted, it is likely that the expectations for practitioners will increase. Lawsuits alleging improper authorization, inadequate examination, adverse drug interactions, or failure to warn of risks such as driving under the influence, cognitive effects, or the potential for addiction are likely. This risk would increase if the practitioner or a pharmacy also dispensed the marijuana. For example, a practitioner could be held liable for providing marijuana containing mold, prohibited pesticides, heavy metals or other contaminants.

In early October of 2015, a lawsuit was filed in Colorado by a pair of marijuana users, one of them a medical patient suffering from a brain tumor. They sued a large state-licensed marijuana grower for allegedly using a potentially dangerous pesticide on products later introduced into the retail market. Had this marijuana been provided by a healthcare practitioner or pharmacy rather than purchased at a retail store, the practitioner or pharmacy could also potentially be held liable for distributing a tainted product.

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<sup>10</sup> Conant at 636.

<sup>11</sup> A subsequent U.S. Supreme Court case held the U.S. Attorney General cannot, by interpretive rule, prohibit practitioners from prescribing Schedule II controlled substances in compliance with Oregon’s Death with Dignity Act. Gonzales v. Oregon, 546 U.S. 243 (2006). However, that case involved prescribing and dispensing legal Schedule II drugs for a purportedly improper reason (i.e. to hasten death) rather than prescribing and dispensing marijuana, a Schedule I drug.

<sup>12</sup> Cannabidiol (CBD) is a cannabinoid that does not result in a “high” whereas tetrahydrocannabinol (THC) is the primary psychoactive component of marijuana.

Most healthcare liability insurers do not have specific exclusions for practitioners who authorize the medical use of marijuana, but many do have exclusions for any claim alleging a criminal violation of a state or federal law or rule. In the case of a medical malpractice claim based on authorizing or dispensing marijuana, coverage could be denied based on these exclusions until such time as the federal law is amended to allow prescribing and dispensing marijuana. This would leave the practitioner without liability insurance and vulnerable to significant financial loss. It could also lead to an injured patient having limited ability to collect on a claim against an insolvent practitioner.

### **Medicaid/Medicare Provider Eligibility**

To provide services to Medicaid recipients in Washington, a healthcare practitioner must “provide all services according to federal and state laws and rules...” WAC 182-502-0016(1)(b). A practitioner’s status as a Medicaid provider may be terminated for failure to abide by this requirement. WAC 182-502-0030(1)(ix). A practitioner who has been suspended or excluded from Medicaid may also be excluded from participation as a Medicare provider. 42 U.S.C. § 1320a-7(b)(5).

Healthcare practitioners in Washington who prescribed and dispensed marijuana in violation of federal law could be excluded from participation in both Medicaid and Medicare. In addition, they could be subject to financial penalties for services rendered to those patients.

### **Supply**

Recreational marijuana is produced, processed and sold by persons or entities licensed by the LCB. All products are tracked from seed to sale and are subject to quality assurance standards, testing, and labeling.

Healthcare practitioners and pharmacies licensed in Washington do not dispense marijuana for medical use due to its designation as a Schedule I controlled substance at both the state and federal levels. Distributing a Schedule I drug could result in criminal charges as well as loss of DEA registration, Medicaid/Medicare provider status, and banking privileges.

Currently, patients with a valid authorization for the medical use of marijuana have limited options for accessing products. They have an affirmative defense to criminal prosecution for growing up to 15 plants at any given time. They have the same affirmative defense if they participate in a collective garden with up to nine other patients or designated providers.

Dispensaries, which are commonplace although not authorized by law, are an off-shoot of the collective garden model and currently provide retail access to patients. Patients age 21 and older can also purchase marijuana products from more than 200 stores licensed by the LCB.

On July 1, 2016, collective gardens will be abolished. Patients and designated providers entered into the authorization database will be able to legally grow plants<sup>13</sup> and participate in small, noncommercial cooperative grows. All state-legal commercial marijuana, whether intended for medical or recreational use, will be grown, processed, and sold through the LCB’s licensed system.

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<sup>13</sup> The presumptive plant count will be six. A healthcare practitioner may authorize up to 15.

### **Lack of Scientific Evidence Regarding Efficacy and Standardized Dosing**

Existing evidence does not prove that marijuana either is or is not beneficial for medical use. Many people claim marijuana provides more relief than approved prescription drugs, but this is still largely anecdotal. The level of health risks involved with the various routes of administration is also unknown. There is a genuine difference of expert opinion on the subject, with growing amounts of scientific and anecdotal evidence supporting both points of view.

In June of this year, the Journal of the American Medical Association (JAMA) printed a series of articles related to the efficacy of medical marijuana.<sup>14</sup> One article found the use of medical marijuana for chronic pain, neuropathic pain, and spasticity due to multiple sclerosis is “supported by high-quality evidence” and suggested that marijuana may be efficacious for these indications.<sup>15</sup> A second article found only low-quality evidence that marijuana was associated with improvements in nausea and vomiting due to chemotherapy, weight gain in HIV infection, sleep disorders, and Tourette’s syndrome. It also found an increased risk of short-term adverse events.<sup>16</sup>

A third article detailed a study of dose and label accuracy in edible marijuana products. It evaluated 75 products purchased at medical dispensaries in Seattle, San Francisco and Los Angeles. Of the 75 products, 17 percent were accurately labeled, 23 percent were under-labeled, and 60 percent were over-labeled with respect to THC content. Labeling of other cannabinoids was similarly problematic. Because the products were intended for use by patients with serious health conditions, these inaccuracies raise concerns about the quality and consistency of marijuana used for medical purposes.<sup>17</sup>

Finally, JAMA published an editorial pointing out that most of the conditions for which a patient may be authorized for the medical use of marijuana are based on “low-quality scientific evidence, anecdotal reports, individual testimonials, legislative initiatives, and public opinion.” It further notes that unlike approved medications that have a relatively uniform composition, marijuana products vary substantially which makes precise dosing difficult. Marijuana is a complex organism with more than 400 compounds including more than 70 cannabinoids. Each of these cannabinoids has individual, interactive, and entourage effects that are not yet fully understood. Similarly, the interaction of marijuana with prescription drugs has not been sufficiently tested.<sup>18</sup>

These articles illustrate the compelling need for further research performed according to accepted scientific protocols. In 2015, HB 2136 created a research license in order to allow clinical investigations and research regarding the efficacy and safety of administering marijuana as part of medical treatment.

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<sup>14</sup> <http://jama.jamanetwork.com/Issue.aspx?journalid=67&issueID=934167&direction=P>

<sup>15</sup> <http://jama.jamanetwork.com/article.aspx?articleid=2338266>

<sup>16</sup> <http://jama.jamanetwork.com/article.aspx?articleid=2338251>

<sup>17</sup> <http://jama.jamanetwork.com/article.aspx?articleid=2338239>

<sup>18</sup> <http://jama.jamanetwork.com/article.aspx?articleid=2338230>

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