

Information Summary and Recommendations

Medical Marijuana Specialty Clinics

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Executive Summary

During the 2015 legislative session, Second Substitute Senate Bill 5052 (SB 5052) was passed by the legislature. It was signed by Governor Inslee on April 24, 2015. Section 41 requires the Department of Health (department) to “develop recommendations on establishing medical marijuana specialty clinics that would allow for the authorization and dispensing of marijuana to patients of health care professionals who work on-site of the clinic and who are certified by the department in the medical use of marijuana.”

The medical use of marijuana was first authorized by Washington State Voter Initiative 692 in 1998. Legalization of recreational marijuana followed in 2012 by Initiative 502, which allowed the purchase and possession of small amounts of marijuana for adults, and 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. The legislature reconciled the two markets with the passage of SB 5052 and Second Engrossed Second Substitute House Bill 2136 earlier this year. However, 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.

Recommendation

The department does not support establishing medical marijuana specialty clinics in Washington at this time.

Rationale:

- Healthcare practitioners cannot legally prescribe or dispense schedule I controlled substances and would potentially risk criminal prosecution, as well as civil and financial liability.
- Injured patients may be left without an adequate remedy if malpractice does occur.
- Further research using accepted scientific protocols is needed.
- Significant changes to existing licensing laws for commercial marijuana would be needed. Without such changes, practitioners at specialty clinics would not be able to access the marijuana they would later dispense to patients, which could present issues with supply.

Instead, the department recommends that individual practitioners become, to the extent possible given limited scientific research, educated and knowledgeable about the risks and benefits of the medical use of marijuana so they can provide their patients with accurate information and safe, competent care.

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Background

Requirements of Second Substitute Senate Bill 5052

During the 2015 legislative session, SB 5052 was passed by the legislature. It was signed by Governor Inslee on April 24, 2015. Section 41 requires the department to “develop recommendations on establishing medical marijuana specialty clinics that would allow for the authorization and dispensing of marijuana to patients of health care professionals who work on-site of the clinic and who are certified by the department in the medical use of marijuana.” Recommendations must be reported to the chairs of the healthcare committees of both the Senate and House of Representatives by December 1, 2015.

Brief History of Medical Marijuana in Washington

The medical use of marijuana was first authorized by Washington State Voter Initiative 692 in 1998. It granted an affirmative defense to criminal prosecution to qualifying patients and their primary caregivers.¹ 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 professionals who may recommend or authorize the medical use of marijuana. Notably, a 2011 amendment allowed up to 10 qualifying patients and designated providers to form a collective garden for the purposes of combining resources.

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.

The legislature reconciled the two markets with the passage of SB 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 state² or federal level. Beginning July 1, 2016, SB 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.³

¹ “Primary caregiver” was changed to “designated provider” in ESSB 6032 (2007).

² *State v. Rejs*, No. 90281-0 (Washington Supreme Court, May 7, 2015)

³ 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.” The U.S. Department of Justice also indicated tolerance of recreational marijuana if states enact strong regulatory and enforcement systems that promote eight priorities that are particularly important to the federal government. <http://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf>, accessed November 5, 2015.

Summary of Information

Marijuana Remains Illegal Under Federal Law

Under federal law, marijuana is a schedule I controlled substance. This means it is classified as having a high potential for abuse, no accepted medical use, and a lack of accepted safety.⁴ Healthcare practitioners cannot legally prescribe or dispense schedule I controlled substances.

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 strict regulation due to a potential for addiction. 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 because schedule II controlled substances can only be dispensed by healthcare practitioners authorized to do so by law.

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

Conant v. Walters⁶

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 a letter 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 prescription authority.

Patients suffering from serious illnesses, physicians licensed in California, a patient organization, and a physicians' organization (collectively "Conant") 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 Conant a permanent injunction against the government which was later upheld by the Ninth Circuit Court of Appeals.⁷ The United States Supreme Court declined to hear further appeal of 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

⁴ 21 U.S.C. § 812(b)(1)

⁵ 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.

⁶ Conant v. Walters, 309 F.3d 629, United States Court of Appeals, 9th Circuit, 2002

⁷ The Ninth Circuit includes California, Arizona, Nevada, Hawaii, Montana, Idaho, Alaska, Oregon and Washington.

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 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.”⁸

Under this holding, healthcare practitioners who dispense marijuana to their patients would be at significant risk of federal administrative and criminal prosecution.⁹

Liability Issues

Under current Washington law, authorizing 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 THC¹⁰ 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 is not dispensing or administering 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 also dispensed the marijuana. For example, a practitioner could be held liable for providing marijuana containing mold, unapproved pesticides, or other contaminants.

⁸ Conant at 636.

⁹ 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.

¹⁰ Cannabidiol (CBD) is a cannabinoid that does not result in a “high” whereas tetrahydrocannabinol (THC) is the primary psychoactive component of marijuana.

In early October of 2015, a lawsuit was filed in Colorado by a pair of marijuana users, one of them a medical patient with 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 rather than purchased at a retail store, the practitioner could also potentially be held liable for distributing a tainted product.

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 “[p]rovide 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 Issues

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 common although not authorized by law, are an off-shoot of the collective garden model. Patients age 21 and older can also purchase marijuana products from more than 200 stores licensed by the Washington State Liquor and Cannabis Board (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 plants¹¹ and participate in small, noncommercial cooperative grows. All legal commercial marijuana, whether intended for medical or recreational use, will be grown, processed, and sold through the LCB’s licensed system.

Under Washington’s existing licensing laws for commercial marijuana, practitioners at a medical marijuana specialty clinic would not be able to access the marijuana they would later dispense to patients. Significant changes to the law would be required.

¹¹ 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.¹² 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.¹³ A second article found only low-quality evidence that marijuana was associated with improvements in weight gain in patients with HIV infection, and in treating nausea and vomiting due to chemotherapy, sleep disorders, and Tourette’s syndrome. It also found an increased risk of short-term adverse events.¹⁴

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.¹⁵

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.¹⁶

These articles illustrate the compelling need for further research performed according to accepted scientific protocols. 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.

¹² <http://jama.jamanetwork.com/Issue.aspx?journalid=67&issueID=934167&direction=P>

¹³ <http://jama.jamanetwork.com/article.aspx?articleid=2338266>

¹⁴ <http://jama.jamanetwork.com/article.aspx?articleid=2338251>

¹⁵ <http://jama.jamanetwork.com/article.aspx?articleid=2338239>

¹⁶ <http://jama.jamanetwork.com/article.aspx?articleid=2338230>

Requirement to Certify Practitioners in the Medical Use of Marijuana

As described in SB 5052, healthcare practitioners working in medical marijuana specialty clinics would both authorize and dispense marijuana. These practitioners would require certification from the department “in the medical use of marijuana.”

A license to practice a healthcare profession in the state of Washington grants the licensee the full scope of practice for that profession unless good cause exists to restrict the licensee’s ability to practice. The department and our partner boards and commissions do not grant licenses based on practice specialties. For example, the Medical Quality Assurance Commission does not issue a license to practice as a pediatrician or a psychiatrist but instead sets the licensure standards for allopathic physicians generally. Specialty designations are granted by entities such as the American Board of Pediatrics or the American Board of Psychiatry and Neurology.

Multiple states require practitioners to register their intent to recommend or authorize marijuana with state licensing entities. Some states require a certain level of training prior to recommending or authorizing marijuana. In Massachusetts, a physician must have two hours of continuing education related to medical marijuana. In New Jersey, physicians must have completed medical education in addiction medicine and pain management within the past two years. New York law requires physicians to complete a four and one half hour online training course before they can provide guidance to patients regarding marijuana.

Findings

- **Marijuana remains illegal under federal law**

Marijuana’s federal status as an illegal schedule I controlled substance creates numerous obstacles to successful implementation. Healthcare practitioners cannot legally prescribe or dispense schedule I controlled substances.

- **Participating healthcare practitioners would potentially risk criminal prosecution**

Although the court in Conant held that physician speech about the potential benefits of medical marijuana is entitled to First Amendment protection because of the significance of the doctor-patient relationship, it specifically did not bar federal prosecution of a physician when government officials in good faith believe they have probable cause to pursue aiding and abetting or conspiracy charges.

- **Liability issues**

Liability coverage related to authorizing or dispensing marijuana is unlikely. This could leave practitioners vulnerable to significant financial loss, and injured patients without the ability to collect on potential malpractice claims. Practitioners could also be excluded from participation as Medicaid and Medicare providers.

- **Further research is needed**

There is a compelling need for further research on the medical use of marijuana that is performed according to accepted scientific protocols. Without such research, healthcare practitioners have limited information about product efficacy, routes of administration, or standardized dosing.

- **Supply issues**

Under existing licensing laws for commercial marijuana, practitioners at a specialty clinic would not be able to access the marijuana they would later dispense to patients. Significant changes would be required to allow them to either: 1) grow and process the marijuana themselves for the exclusive use of their patients; or 2) purchase large amounts of products at wholesale or retail from LCB licensees. Either option would present inventory issues due to the wide variation of strains and products used to treat Washington's diverse patient population – everything from edibles, infused liquids, tinctures, oils, lotions, capsules, transdermal patches, and suppositories to the hundreds of purported strains of dried marijuana.¹⁷ Both scenarios would have to be carefully evaluated to assess and address concerns regarding security and diversion. If such changes to the law are made, the clinic should be required to be licensed by the LCB and fully participate in the seed-to-sale traceability system.

- **Certification of practitioners**

There may be a more effective alternative to department certification of practitioners in the medical use of marijuana. A certain number of continuing education credits for any authorizing practitioner regardless of the practice setting could be required. The University of Washington's two-hour online continuing medical education course on medical marijuana is an example of an existing, accessible and low-cost option.

Recommendation

The department does not recommend establishment of medical marijuana specialty clinics at this time.

Rationale:

- Healthcare practitioners cannot legally prescribe or dispense schedule I controlled substances and would potentially risk criminal prosecution, as well as civil and financial liability.
- Injured patients may be left without an adequate remedy if malpractice does occur.
- Further research using accepted scientific protocols is needed.
- Significant changes to existing licensing laws for commercial marijuana would be needed. Without such changes, practitioners at specialty clinics would not be able to access the marijuana they would later dispense to patients, which could present issues with supply.

Instead, the department recommends that individual practitioners become, to the extent possible given limited scientific research, educated and knowledgeable about the risks and benefits of the medical use of marijuana so they can provide their patients with accurate information and safe, competent care.

¹⁷ As of October 20, 2015, Leafly.com lists 1,614 strains of marijuana. <https://www.leafly.com/explore/sort-alpha>