Joint Informational Hearing

Assembly Committee on Business and Professions- Chair, Susan A. Bonilla
Assembly Committee on Health- Chair, Rob Bonta
Assembly Committee on Agriculture- Chair, Bill Dodd

Medical Marijuana Regulation: The Plan for Statewide Implementation

Tuesday, January 19, 2016
1:30-4:00p.m.
State Capitol, Room 4202

Background Paper

In October 2015, nearly 20 years after the passage of Proposition 215, which authorized the use of medical marijuana (MM), Governor Jerry Brown signed into law a trio of bills [AB 243 (Wood), Chapter 688, Statutes of 2015, AB 266 (Bonta, Cooley, Jones-Sawyer, Lackey, and Wood), Chapter 689, Statutes of 2015, and SB 643 (McGuire), Chapter 719, Statutes of 2015] collectively known as the Medical Marijuana Regulation and Safety Act (Act). The Act established the state's first regulatory framework for MM. This background paper is intended to provide a brief overview of the history leading up to the Act, the content of the Act, the landscape of the MM industry, and a prospective look at additional issues relating to the implementation of the Act.

BACKGROUND

Medical Marijuana. The marijuana, or cannabis, plant produces a resin containing compounds called cannabinoids, which are the active ingredients that directly affect the central nervous and immune systems in the human body. Some cannabinoids are psychoactive, which act on the brain and have the potential to alter mood or consciousness. Two of the primary active cannabinoids within the marijuana plant are tetrahydrocannabinol (THC) and cannabidiol (CBD). Results from the limited research on the medicinal properties and adverse effects of marijuana suggest that cannabinoids are associated with improved symptoms of patients with a variety of clinical indications, though not all studies have yielded statistically significant results. For example, some studies provide limited evidence that cannabinoids may be beneficial for conditions such as spasticity resulting from multiple sclerosis, and pain due to chronic neuropathy and cancer (see the National Institutes of Health website for medical marijuana for more information: https://nccih.nih.gov/health/marijuana). However, clinical trials on the medical efficacy of marijuana are extremely limited because the federal government considers the marijuana plant a Schedule I drug, and therefore it is considered a dangerous controlled substance with no accepted medical benefits, and a high potential for abuse.

The Compassionate Use Act (CUA) and Medical Marijuana Program (MMP). In 1996, California voters approved Proposition 215, otherwise known as the CUA, which protects qualified patients and primary caregivers from prosecution related to the possession and cultivation of marijuana for medical purposes, if recommended by a physician. The CUA also

prohibits physicians from being punished or denied any right or privilege for making a MM recommendation to a patient. The CUA also makes findings and declarations, including encouragement of the federal and state government to implement a plan to provide for the safe and affordable distribution of marijuana to all in-need patients.

In an effort to increase access to MM by qualified patients and primary caregivers, and to provide protections to qualified patients and primary caregivers from prosecution for the possession and cultivation of MM, California enacted SB 420 (Vasconcellos), Chapter 85, Statutes of 2003, which established the MMP. The MMP created a MM card program for patients to use on a voluntary basis, which can be used to verify that a patient or caregiver has authorization to possess, grow, transport, or use MM in California. Under the MMP, a person is required to obtain a recommendation for MM from an attending physician; written documentation of this recommendation is required to be submitted to the county of residence of the applicant in order to receive a MM card. The MM identification cards are intended to help law enforcement officers identify and verify that cardholders are able to cultivate, possess, and/or transport limited amounts of marijuana without being subject to arrest. Lastly, the MMP created protections for qualified patients and primary caregivers from prosecution for the formation of collectives and cooperatives for MM cultivation.

Since the passage of the CUA and the MMP, the state had not adopted a framework to provide for appropriate licensure and regulation of MM until late last year. As a result, in the nearly 20 years since the passage of the CUA, there has been a proliferation of MM collectives and cooperatives that are largely left to the enforcement of local governments. Consequently, a patchwork of local regulations was created with little statewide involvement.

***California Attorney General's Compassionate Use Guidelines*.** Among other things, the MMP required the California Attorney General to "…develop and adopt appropriate guidelines to ensure the security and non-diversion of marijuana grown for medical use by patients qualified under the Compassionate Use Act of 1996." In 2008, then Attorney General Brown released guidelines that affirmed the legality of MM collectives and cooperatives, but made clear that such entities could not operate for profit nor purchase marijuana from unlawful sources, and must have a defined organizational structure that includes detailed records proving that users are legitimate patients. In addition, the guidelines sought to: (1) ensure that marijuana grown for medical purposes remains secure and does not find its way to non-patients or illicit markets; (2) help law enforcement agencies perform their duties effectively and in accordance with California law; and, (3) help patients and primary caregivers understand how they may cultivate, transport, possess, and use MM under California law. In 2011, after a series of meetings with stakeholders to assess whether to clarify the 2008 guidelines to stop the exploitation of California's MM laws by gangs, criminal enterprises, and others, Attorney General Harris wrote a letter to the Legislature with her decision to postpone the issuance of new guidelines because of pending litigation. Instead, she urged the Legislature to amend the law to establish clear rules governing access to MM.

***California Supreme Court Affirms Local Control Over Medical Marijuana*.** By exempting qualified patients and caregivers from prosecution for possessing, or from collectively or cooperatively cultivating MM, the CUA and the MMP essentially authorized the widespread cultivation and distribution of MM. These laws triggered the growth of MM dispensaries in

many localities, and in response, local governments have sought to exercise their police powers to regulate or ban activities relating to MM. After numerous court cases and years of uncertainty relating to the ability of local governments to control MM activities, particularly relating to the zoning, operation, and existence of MM dispensaries, the California Supreme Court, in *City of Riverside v. Inland Empire Patients* (2013) 56 Cal. 4th 729, held that California's MM statutes do not preempt a local ban on facilities that distribute MM. The Supreme Court held that nothing in the CUA or the MMP expressly or implicitly limited the inherent authority of a local jurisdiction, by its own ordinances, to regulate the use of its land, including the authority to provide that facilities for the distribution of MM be prohibited from operating within its borders.

Federal Controlled Substances Act. Despite the CUA and the MMP, marijuana is still illegal under state and federal law. Under California law, marijuana is listed as a hallucinogenic substance in Schedule I of the California Uniform Controlled Substances Act. Yet, the CUA prohibits prosecution for obtaining, distributing, or using marijuana for medical purposes. However, federal law preempts state law, and under the federal Controlled Substances Act, it is unlawful for any person to manufacture, distribute, dispense or possess a controlled substance, including marijuana, whether or not it is for a medical purpose. As a result, patients, caregivers, and dispensary operators, who engage in activities relating to MM, could still be vulnerable to federal arrest and prosecution. According to the California Attorney General's guidelines, the difference between state and federal law gives rise to confusion. However, California has tried to avoid this conflict by deciding not to use the state's powers to punish certain marijuana offenses under state law when a physician has recommended its use to treat a serious medical condition.

U.S. Department of Justice (USDOJ) Guidance Regarding Marijuana Enforcement. On August 29, 2013, the USDOJ issued a memorandum (also known as the 2013 "Cole" memo) that updated its guidance to all U.S. Attorneys in light of state ballot initiatives to legalize the possession of small amounts of marijuana, and provide for the regulation of marijuana production, processing, and sale. While the memorandum notes that illegal distribution and sale of marijuana is a serious crime that provides a significant source of revenue to large-scale criminal enterprises, gangs, and cartels, it also states that the USDOJ is committed to using its limited investigative and prosecutorial resources to address the most significant threats, which include the prevention of: (1) distribution to minors; (2) revenue from marijuana from going to criminal enterprises; (3) diversion to other states where marijuana is not legal under state law; (4) state-authorized marijuana from being a cover for trafficking in other illegal drugs or illegal activity; (5) violence in cultivating and distributing marijuana; (6) drugged driving and other public health problems from marijuana use; and, (7) growing, possessing, or using marijuana on public lands or on federal property.

According to the USDOJ, "In jurisdictions that have enacted laws legalizing marijuana in some form and that have also implemented strong and effective regulatory and enforcement systems to control the cultivation, distribution, sale, and possession of marijuana, conduct in compliance with those laws and regulations is less likely to threaten the federal priorities set forth above. In those circumstances, consistent with the traditional allocation of federal-state efforts in this area, enforcement of state law by state and local law enforcement and regulatory bodies should remain the primary means of addressing marijuana-related activity." As a result, the memorandum

suggests that the existence of a strong and effective state regulatory system, and a marijuana operation's compliance with such a system, may allay the threat that an operation's size poses to federal enforcement interests, and encourages federal prosecutors to review marijuana cases on a case-by-case basis, and consider whether or not the operation is in compliance with a strong and effective state regulatory system prior to prosecution.

***Medical Marijuana Industry in California and the Need for Statewide Regulation*.** Although the CUA was passed in 1996, statewide regulation of MM was not passed until 2015. The impetus for the passage of the Act was recognition that the MM industry was virtually unregulated across the state, and to a large degree operated in the shadows for fear of local, state, and federal enforcement action. As a result, many practitioners in this industry are part of an underground economy that is unregulated, unlicensed, and untaxed, despite the fact that some local governments have established comprehensive licensing and regulatory schemes, while others have banned the cultivation and sale of MM altogether.

There are currently tens of thousands of estimated cultivation sites and thousands of MM dispensaries, with or without local authorization, operating within the state. Without an effective statewide system for regulating and controlling MM, cities, counties, and local law enforcement officials have been uncertain about the legality of some MM activities. Cities and counties that have MM ordinances have taken the first step in protecting consumers and the public, but are not all fully consistent or compliant with the 2013 Cole Memo, and lack a strong statewide regulatory body to oversee all aspects of the product chain. Consumers still have very little ability to obtain information regarding the risks of MM unless they have personal knowledge of the product.

Because marijuana remains a Schedule I drug, no legitimate pharmacy may dispense marijuana, and federal and state food and drug laws do not apply. For patients, there is a critical need for meaningful regulatory standards to address testing, purity, potency, labeling, identification and elimination of contaminants, and secure protocols for processing and transport of the product. Without such regulation, harm to consumers is possible given that no health and safety standards exist for marijuana. The same is true in regard to requirements for packaging, labeling, and tracking of the product for the entirety of its life cycle. Hazard to the public is magnified in the case of marijuana-infused and extracted products such as edibles, tinctures, and waxes due to the potentially high concentration of marijuana per serving, and attendant psychotropic or hallucinogenic properties that vary with strain.

In addition to health and safety concerns, there has been public demand for marijuana cultivation standards that mirror established agricultural standards in order to alleviate the environmental degradation to watersheds, forests, and rivers across the state caused by marijuana cultivation. Despite the efforts of regional and state water boards and the California Department of Fish and Wildlife, streams and rivers have been running dry, and high quantities of sediments and toxic wastes have been illegally dumped into the watersheds. The lack of regulation has complicated the water supply for millions of legal residential and commercial water users throughout the state. Additionally, lack of regulation is compounded by limited enforcement efforts against the illicit mowing down of entire tracts of forests by rogue growers who then plant marijuana without permits, oversight, or regard for the environment.

Furthermore, the lack of clear guidelines as to who can operate these MM businesses and how to address public safety issues arising from MM activities highlights the need for statewide regulation and minimum standards. There simply has not been a cohesive strategy for protecting consumers in the industry, and as a quasi-legal industry, the industry has found difficulty in trying to self-police. Clear guidance from the state, or guidance from a local jurisdiction that is backed by the state, is the only way to ensure protection of consumers and the public. Consequently, the Act seeks to address these issues and protect consumers through regulation of MM activities by: (1) establishing oversight and accountability of operations; (2) providing enforcement funding and mechanisms; (3) instituting health, safety, and environmental standards and ensuring they are met; (4) preventing diversion; and, (5) maintaining local control. Lastly, adopting an effective statewide regulatory system is aligned with the guidelines issued in the 2013 Cole memo.

***Medical Marijuana Frameworks in Other States and Increasing Support for Marijuana Use*.** As of last year, 23 states, the District of Columbia, and Guam allow MM programs. Even though California was the first to authorize the medical use of marijuana, it was the only state that allowed marijuana-use without a robust state regulatory framework until passage of the Act. States with MM laws generally have a form of patient registry, which may provide some protection against arrest for possession up to a certain amount of marijuana for personal medicinal use. A limited number of states restrict MM usage to products with low to zero THC and high CBD concentrations, in an effort to more strictly limit the use of THC due to its known psychoactive effects. To date, only Alaska, Colorado, Oregon, Washington, and the District of Columbia have legalized recreational marijuana.

According to the Brookings Institute, U.S. public opinion has trended in favor of marijuana legalization since the early 1990s; support has risen sharply since 2010, by 11 percentage points. A majority of Americans support legalization by a margin of seven points—52% to 45%, according to findings from a Pew Research Center survey in March 2013.

This increase in support for marijuana legalization exists in California as well, with recent polls showing that a majority of Californians support marijuana legalization. Currently, there are multiple recreational marijuana initiatives attempting to qualify for the 2016 ballot. In order for any marijuana scheme to be effective, it should address all parts of the industry, including the establishment of a robust licensing, regulatory, and taxation scheme, provision of health and safety standards, and assurance that the public is protected. However, if the measure is too prescriptive, it may hamper the ability for the state to address any unintended consequences or fill in any policy gaps without having to go back to the ballot. While the proposed initiatives vary with regard to their comprehensiveness, some rely heavily on the framework established under the Act, and apply some of its provisions to recreational marijuana in addition to MM.

THE ACT

Prior to adoption of the Act, there had been many legislative attempts in recent legislative sessions to address issues relating to MM, such as attempts to establish comprehensive regulatory frameworks, including multiple bills championed by then-Assemblymember Ammiano. As recently as the 2013-14 Legislative Session, there have been two bills seeking to establish a statewide regulatory scheme (AB 1894 (Ammiano) and SB 1262 (Correa)) however, both bills failed during the legislative process. Still, recognition of the need for statewide

regulation persisted and grew stronger, especially in light of the increased environmental, health, and public safety concerns associated with MM. In addition, the likelihood of a statewide ballot initiative on recreational marijuana also highlighted the need for state action. Specifically, stakeholders have expressed the need for the state to have infrastructure and regulations in place to serve as a model for a recreational scheme. All these factors, along with the historic collaboration among members of the Legislature and stakeholders, led to the passage of the Act, which includes AB 243 (Wood), AB 266 (Bonta, Cooley, Jones-Sawyer, Lackey, and Wood), and SB 643 (McGuire).

The Act established, for the first time, a comprehensive statewide licensing and regulatory framework for the cultivation, manufacture, transportation, testing, distribution, and sale of MM to be administered by the newly established Bureau of Medical Marijuana Regulation (Bureau) within the Department of Consumer Affairs (DCA); the Department of Food and Agriculture (DFA); and, the Department of Public Health (DPH), thereby relying on each agency's area of expertise.

The Act vests in the:

- DCA and the Bureau the authority to issue licenses and regulate dispensaries, distributors, and transporters, and to provide oversight for the state's regulatory framework;
- DPH the responsibility to license and regulate laboratories and manufacturers; and,
- DFA the responsibility to license and regulate cultivators.

To assist with the regulatory responsibilities, the Act allows the Bureau to convene an advisory committee to make recommendations to the Bureau and licensing authorities on the development of standards and regulations, including best practices and guidelines, in order to ensure qualified patients have adequate access to MM and MM products. The Act phases out the collective model and its associated immunity, and replaces it with clear licensing requirements for licensees who engage in commercial marijuana activity and are licensed under the Act; those who operate unlawfully according to the Act are subject to prosecution. An important cornerstone of the legislation is the preservation of local control through the requirement of dual authorization from both the state and local government in order to legally operate within the state.

Local governments may establish their own ordinances to regulate MM activity, or choose to ban it altogether. For state licenses, entities may apply for a cultivation, manufacturing, dispensing, testing, distribution, or transport license and are prohibited from holding specific combinations of licenses. For example, testing licensees may not apply for any other license types, and distributors may only obtain an additional license to transport. However the Act does provide limited ability for operators to cultivate, manufacture, and dispense MM, also known as vertical integration, but limits cross licensure to two of three of those categories outside of this exception. In addition, applicants for a state license must meet strict criteria, including: (1) submit fingerprints to the California Department of Justice; (2) provide documentation from a local jurisdiction certifying the applicant is in compliance with all local ordinances and regulations; (3) provide evidence of the legal right to occupy the proposed location; (4) for applicants with 20 or more employees, provide a statement that the applicant will enter into, or already has entered into, a labor peace agreement; and, (5) provide a seller's permit number and other specified

information. Applicants seeking state licensure to cultivate, distribute, or manufacture MM are also required to provide a detailed description of their operating procedures to the licensing authority.

To assure patient health and safety, the Act requires DPH to develop standards for the production and labeling of all MM products manufactured for human consumption. In addition, licensed cultivators and manufacturers are required to package all MM products in tamper-evident packaging, use a unique identifier to distinguish and track the product, and follow specific labeling requirements; prior to sale at a licensed dispensary, these licensees are required to ensure all MM and MM products are taken to a licensed distributor for quality assurance and inspection who will ensure that batch testing is completed by a licensed testing laboratory.

To ensure accountability and prevent diversion of MM and MM products, the DFA is required, in consultation with the Bureau, to establish a track and trace program for reporting the movement of MM items throughout the distribution chain. The track and trace program requires the use of a unique identifier and secure packaging that provides specified information, including the licensee receiving the product, the transaction date, and the cultivator from which the product originates. In order to track MM and MM products, the DFA is required to create a database containing electronic shipping manifests which are to include: (1) the quantity or weight, and variety of products shipped and received; (2) estimated and actual times of departure and arrival; and, (3) license number and unique identifiers issued by the licensing authority for all licensees involved in the shipping process. The Act also directs the State Board of Equalization to adopt a system, in consultation with the DFA, to report the movement of commercial MM and MM products throughout the distribution chain and requires the Bureau to establish security requirements for the commercial transportation and delivery of MM and MM products.

To ensure adequate resources for this regulatory scheme, the Act provides for a General Fund (GF) or special fund loan, of up to $10 million from the GF, to the Bureau to support the initial regulatory activities authorized by the Act. The licensing fees established by the regulatory authorities are required to repay the loan, and then cover the cost of administering and enforcing the framework. To assist with enforcement efforts, the Act requires the Bureau to establish a grant program to fund activities by state and local law enforcement to remedy the environmental effects of marijuana cultivation.

PURPOSE OF THE HEARING

The Act became effective on January 1, 2016, although the operative date of many of the Act's provisions are postponed until necessary regulations are adopted and the state begins to issue licenses. Entities operating in accordance with other state and local laws are expected to continue to do so until such time as their licenses are approved or denied under the new licensing scheme. On October 9, 2015, the Governor signed the trio of bills into law and stated,

> "Assembly Bill 243, Assembly Bill 266, and Senate Bill 643, establish a long-overdue comprehensive regulatory framework for the production, transportation, and sale of medical marijuana. While many of these new standards take effect in January 1, 2018, state agencies will begin working immediately with experts and stakeholders on crafting clear guidelines, so local government, law enforcement, businesses, patients and health providers can prepare and adapt to the new

regulated system.

This new structure will make sure patients have access to medical marijuana, while ensuring a robust tracking system. This sends a clear and certain signal to our federal counterparts that California is implementing robust controls not only on paper, but in practice."

The Act established a new comprehensive licensing and regulatory scheme for MM. While the legislation itself was comprehensive and established many requirements to comply with the law, even more is left to the implementing agencies, including the newly-established Bureau under DCA, DFA, and DPH, which are tasked with administering the Act. In addition to the challenges of creating a brand new regulatory body, other hurdles exist such as adopting a bevy of regulations to address complex issues that cover everything from minimum potency for MM to the types of requirements that licensees must meet in order to obtain licensure. Licensing authorities and other state and local boards and agencies will also be responsible for enforcing the Act in order to ensure that participants are compliant and, in turn, that consumers, the public, and the environment are protected.

The Governor's proposed Budget for 2016-17 includes a total of $5.4 million Medical Marijuana Regulation and Safety Act Fund in 2015-16 to fund initial regulatory activities. In addition, the Budget includes $12.8 million GF, $10.6 million Medical Marijuana Regulation and Safety Act Fund, $1.2 million other special funds, and 126 total positions to implement the Act in California. Specifically, the Budget proposes the following:

- DCA: $1.6 million in 2015-16 and $3.8 million from the Medical Marijuana Regulation and Safety Act Fund and 25 positions in 2016-17 to create the Bureau within DCA;
- DPH: $457,000 in 2015-16 and $3.4 million and funding for 14 positions in 2016-17;
- DFA: $3.3 million in 2015-16 and $3.4 million from the Medical Marijuana Regulation and Safety Act Fund and 18 positions in 2016-17;
- Department of Pesticide Regulation: $700,000 Pesticide Regulation Fund and three positions in 2016-17 to the Department of Pesticide Regulation to develop guidelines for the use of pesticides in the cultivation of medical marijuana;
- Department of Fish and Wildlife: $7.6 million GF and 31 positions in 2016-17 for the Department of Fish and Wildlife to expand and make permanent the statewide multi-agency task force established in 2014 to address environmental impacts of medical marijuana cultivation and work with the State Water Resources Control Board (Water Board) and Department of Food and Agriculture to regulate water diversions; and,
- State Water Resources Control Board: $5.7 million ($5.2 million GF and $472,000 Waste Discharge Permit Fund) and 35 positions in 2016-17 for the Water Boards to develop and implement a regulatory program to address the environmental impacts of medical cannabis cultivation. This program will protect instream flows for fish from water diversions related to marijuana cultivation.

This hearing is intended to evaluate next steps the licensing authorities must take to implement the Act, explore potential concerns and issues from local governments and stakeholders, and consider recommendations to assist the licensing authorities in their implementation of the Act.