ASSOCIATION OF CANNABIS SPECIALISTS
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A Federal Framework of Regulation for Medical Cannabis Use

Overview

While a patchwork of state cannabis laws exists, the lack of a unified, federal framework regulating medical cannabis places patients at risk, and undermines the relationships that doctors must maintain to ensure an effective and safe treatment paradigm. Such a framework is both overdue and sorely needed for safe, optimized care of patients across the country.

Summary Background

In 1970, the Controlled Substances Act (CSA) modernized and consolidated earlier federal drug laws. It placed cannabis in Schedule I, the most restrictive category, citing no evidence of the accepted medical use of herbal cannabis. Tetrahydrocannabinol (THC), the principal active ingredient in cannabis, is listed in Schedule III in its synthetic form.

While cannabis remains illegal at the federal level, the enactment of state medical cannabis laws signaled a major shift in cannabis policy. Since California legalized cannabis for medical use in 1996, a total of 46 states including the District of Columbia have legalized some form of medical cannabis. Yet current state-based systems are not adequate to provide for the often complicated and nuanced needs of patients. These systems do not ensure that patients get either professional medical guidance or a physician-advised medical regimen, which are necessary to promote good health outcomes.

Preserving the Sanctity of Physician-Prescription Relationship

Current State Law Paradigm
Wide variation exists in state medical cannabis laws and policies governing both supply and use. The most restrictive laws limit the access of cannabis to individuals who suffer from specific illnesses or conditions. Others establish strict limits on the production and distribution of cannabis to at-home cultivation by patients and caregivers. In states that regulate the operation of storefronts known as dispensaries, patients can be sold potentially unlimited and unregulated types of cannabis products. Staff at the dispensaries, while not legally allowed to give medical advice, nonetheless often feel empowered to do so to make a sale.

Patients vs. Social Consumers
The needs of medical patients are significantly different from those of recreational cannabis users. Patients do not derive benefit from, and in fact may often be harmed by, the current state-based systems

that are loose and non-specific. Dispensaries, and their personnel, inherently lack the medical expertise to guide patient medication purchases, and are driven by sales motives and quotas. This ultimately endanger patient health and safety.

The reliability and specificity of a true medical regimen could be achieved through a process similar to, if not the same as, prescriptions for any other medication. Conventional prescriptions allow a physician or other clinician—who has deep training, knowledge, and qualification—to specify the kind of medication, dose, frequency, and the amount to be sold.

Patients are recognized as a vulnerable population and are accorded special rights and protections under the law. Current state-based regulations allow dispensary agents to circumvent these protections and to take advantage of patients. A prescription-based system is designed to prevent this kind of misconduct because it puts the onus for the medical decisions on the knowledgeable clinician. Preventing unqualified sales representatives from making medical determinations protects patients, and ultimately the industry.

The Role of Dispensaries
It is important to create uniform nationwide regulations with regard to preventing cannabis salespeople from making medical recommendations to people presenting medical questions at point of sale. Dispensaries should neither intervene in, nor replace, the relationship between patient and physician, wherein the physician uses her or his best judgement, expertise, and experience to prescribe medications appropriately for patient care.

Need for Federal Framework
While the federal government frequently relies on state and local authorities to enforce criminal prohibitions on cannabis retail and use, federal law remains an important factor in responsible medical cannabis regulations. In keeping with the large number of states already permitting medical cannabis recommendation and sale, it is proposed that the federal government specifically add a national framework of regulation as an overlay to existing states' regulations.

The Association of Cannabis Specialists argues that any federal law must include at a minimum the following parameters:

- Exact prescriptions: A prescribing paradigm that provides a system to ensure patients need both prescriptions and products that support very specific and reliable regimens. Regulations that limit the amount that a dispensary can sell to patients, as per the prescription, and based on the regimen needed by that patient, rather than limiting the amount of medicine that a patient is permitted to have in its possession.

- Medical claims: Prohibition of sales representatives from upselling or making medical determinations on behalf of the patient. Regulation addressing claims made by manufacturers, as well as statements that are allowed by lay people, such as bud tenders, who are selling these products.

- State-to-state interoperability: Patients must be allowed to travel with their medication, including by air, within all U.S. states, use their medication in all states, and purchase their medication in all states subject to their prescription. These conditions are crucial to proper and effective medical treatment.

- Common safety standards: A regulatory regime governing the growing, harvesting, manufacturing, testing, and packaging of cannabis medicine in such a manner consistent with other medications.

- Clinical Discretion: Regulations limiting the lists of qualifying medical conditions because physicians are more qualified than state lawmakers to assess what medications are appropriate for patients' care.

- Purchase feedback: Regulations that mandate nation-wide tracking of cannabis medicine sales in a HIPAA-compliant, protected, and de-identified (when appropriate) fashion so that system compliance can be monitored, scientific data can be extracted, and individual patient purchase information can be fed back to and monitored by their clinicians. Such a system would be similar to the PMP systems used for opioid, and other controlled substance, monitoring.

- Recreational system overlap: Regulations limiting dispensary sales teams from making medical recommendations to people presenting in the recreational market with medical questions.

  (For example, if a 50 year old man presents to a retail cannabis establishment and asks the question, "what have you got for my back pain?" the sales agent's appropriate and legally constrained response should be, "I'm sorry I cannot address these questions. I would be happy to put you in touch with a physician who can.")

- Research agenda: Regulations governing cannabis medication with regard to efficacy and specific illnesses, as they do any other medications, through the promotion of ongoing research efforts. This should be overseen by the FDA and have a clearly defined pathway for both pharmaceutical and botanical forms of cannabis medicine.

Irrespective of the direction that federal law and policy takes to protect state programs and laboratories of democracy, it is critical that there be a unified national policy for the prescribing of cannabis for patients, just as there is for any other medication. Cannabis prescriptions should be held to the same standard of legal regulation and enforcement as any other prescription.

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