Advancing Roles for Cannabis Pharmacists

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Objectives:

1. Identify states and countries that require a pharmacist in their medical Cannabis program
2. Demonstrate different roles of the pharmacist in medical versus recreational state programs
3. Review potential formulations that are available in medical Cannabis programs
4. Compare the role of different governing bodies in state and federal Cannabis programs

While more countries and states in the U.S. adopt medical and recreational Cannabis programs, the majority of the international community continues to classify Cannabis as an illegal narcotic. The United Nations Single Convention on Narcotic Drugs of 1961 is an international treaty which established controls and required criminalization of the international and domestic traffic in narcotics, coca leaf, cocaine, and Cannabis. The

Convention on Psychotropic Substances of 1971 was designed to establish similar control over stimulants, depressants, and hallucinogens that were not initially included in the 1961 treaty. 1971 was also the year that Richard Nixon coined the term ”War on Drugs” and classified drugs as ‘Public Enemy Number One”. The Commision on Narcotic Drugs meets annually to determine the classification of psychotropic substances under international control based on the recommendations of the World Health Organization (WHO). The main role of the WHO as a participant on these committees is to assess the medicinal properties of a substance from a public health perspective which includes evaluating Cannabis, its derivatives and analogues, both naturally occurring and synthetically manufactured.

Historically, the United States Pharmacopeia (USP) officially recognized Cannabis as a drug in 1850 when they published ‘Extractum Cannabis’ monograph. There have been several updates to the monographs such as Cannabis Americana in 1916 and USP XI in 1936, including Extractum Cannabis and Fluidextracta Cannabis until its exclusion in response to the Federal Bureau of Narcotics, the predecessor of the DEA, Drug Enforcement Agency, in 1942.

Non-medical or adult-use of Cannabis is legal in Canada, Mexico, South Africa, Uruguay, and Georgia. Medical Cannabis is legal or decriminalized to varying degrees in much of South America, Africa, Europe, and Australia. Israel has a very robust medical Cannabis program that emphasizes the importance of research. Thailand was the first Asian country to approve medical Cannabis followed by South Korea. The vast majority of Asian and Middle Eastern countries do not support the medical use of Cannabis in any capacity.

The legality of Cannabis consumption varies by country in terms of possession, distribution, cultivation, medical use, and mode of consumption. Decriminalization does not mean a substance can be used with impunity, but instead refers generally to the reduction of penalties, or the reclassification of a criminal offense as a civil offense. Typically these regulations specify the type and amount of Cannabis product that is

allowed before it is considered illegal. Decriminalization does not retroactively pardon those already incarcerated or otherwise affected by previous prohibition laws, although certain states like California are looking to change this. Medical use refers to the therapeutic use of Cannabis for a specific medical condition or symptom typically under the supervision of a healthcare professional.

There are several federal agencies in the United States that guide medical and recreational Cannabis programs. The DEA is responsible for overseeing the Controlled Substance Act (CSA) which passed in 1970 and categorizes Cannabis as a schedule 1. This classification means that a substance, including Cannabis extracts and analogues are considered to have no medical use and a high potential for abuse. All researchers interested in studying the effects of Cannabis or marijuana must register with the DEA to reduce the risk of diversion. Schedule 1 researchers must obtain their study Cannabis grown by the National Institute on Drug Abuse (NIDA) through their Drug Supply Program. NIDA is part of the National Institute of Health (NIH) and is specifically tasked with researching the effects of drug abuse, addiction, and other health effects of both legal and illegal drugs in support of public health.

The Food and Drug Administration (FDA) is responsible for the regulation of foods including dietary supplements, drugs (prescription and non-prescription), biologics, cosmetics, medical devices, and tobacco products. The FDA helps to ensure public health and consumer protections for products that are sold across state lines. The FDA has approved Epidiolex ® as a prescription-strength cannabidiol (CBD) product for specific types of pediatric seizure disorders. Although the federal government allows hemp products with less than 0.3% THC, the FDA has not approved any other CBD formulations as an over-the-counter drug or dietary supplement. The FDA has been actively scrutinizing and warning companies that mistakenly include drug claims on their CBD/hemp labels. Making false claims of therapeutic success such as pain relief, cancer treatment, or for use in pets, can result in warnings, fines, or product seizures by the FDA as these companies are violating the Food, Drugs and Cosmetic (FD&C) act. Drug claims include any substance that is promoted to diagnose, cure, mitigate, treat, or

prevent diseases. Many drug manufacturers get around this by saying their product promotes wellness or wellbeing. However, if they list specific symptoms or diseases that could benefit from their product, they are guilty of misbranding in violation of the FD&C act.

Since the widespread adoption of medical Cannabis programs in 37 states, USP has researched and developed Reference Standards (RS) for medical Cannabis product validation to ensure consistency for safety and quality. Reference Standards are used for qualitative applications including identification, system suitability, and chromatographic peak markers. USP has existing monographs for all FDA approved Cannabis products including Dronabinol and is actively working to develop a monograph for synthetic cannabinoids including Nabilone (Cesamet ®) and Epidiolex ®. Current research published by USP has been utilized by ASTM International (formerly known as American Society for Testing and Materials) in their development of quality standards. ASTM is a volunteer-based organization that creates technical documents of consensus standards for materials, products, systems, and services. ASTM formed Committee D37 in 2017 to develop standards for Cannabis products and processes. Their latest endeavor is looking to standardize labeling standards that can be used and recognized internationally.

The 2018 Farm Bill legalized the cultivation and sale of hemp in the United States at the federal level. The Bill defines hemp as Cannabis or any part of the plant with a THC concentration of not more than 0.3 percent. At the federal level in the US, Cannabis remains classified as a Schedule I drug under the Controlled Substances Act (CSA). The 2018 Farm Bill specifically removed hemp from the definition of “marijuana” or Cannabis in the CSA. The states that have legalized Cannabis are technically still in violation of federal law, but the federal government has taken a hands-off approach to enforcement in states where Cannabis is legal as long as they do not engage in sales across state lines. This hands-off approach is widely recognized under the ‘Cole Memo’ after Attorney General James Cole provided guidance on how federal funding should be prioritized when enforcing prohibition of Cannabis under the CSA in 2014.

Many states with medical programs assign their program oversight to the Department of Health or Board of Medicine. Recreational programs are typically regulated by the states' Department of Agriculture or under the supervision of the Alcohol and Tobacco board.

Within the United States, recreational adult use of Cannabis is legal in 18 states, 2 territories, and the District of Columbia. Adult Use regulations have been approved in Alaska, Arizona, California, Colorado, Connecticut, Illinois, Maine, Massachussets, Michigan, Montana, Nevada, New Jersey, New Mexico, New York, Oregon, South Dakota, Vermont, Virginia, Washington, Washington D.C., Puerto Rico, and Guam. Many of these states also have medical programs in which patients pay no or less taxes on their medicine. Medical Cannabis is legal in 37 states with only 4 states remaining that lack any formalized process for obtaining Cannabis for medical or recreational purposes. The states that lack any formal programs for medical or recreational use include Idaho, South Carolina, Tennessee, and Wyoming. States have to individually decide who is eligible for their medical programs in terms of qualifying conditions and the process of registration, as well as the companies that are able to supply medical Cannabis, and the involvement of healthcare professionals in certification, consultation, and/or dispensing oversight. A registered pharmacist is required by law to be present to some degree at medical Cannabis dispensaries in 11 states. These states include Connecticut, Arkansas, Minnesota, New York, Ohio, Louisiana, Maryland, West Virginia, Virginia, Utah, and Pennsylvania.

To make it easier to follow, we categorized states into tiers based on different restriction levels. This is not a government issued list as state regulations are viewed more as a spectrum approach however, its purpose is to provide a basic understanding as well as a visual model to analyze and compare the different types of state legislations.

Tier 1 - Fully Recreational/Adult Use

Going in order from least regulated to most regulated, the states in the “tier 1” category are permitted to use Cannabis products for both medicinal and recreational purposes. These include states like California and Colorado. As previously mentioned, there are currently 18 states in the U.S where recreational use of Cannabis is legalized as well as 4 of the 5 inhabited U.S territories (i.e., District of Columbia). Though the states in this first tier are less strict as far as the purpose of use (medical vs recreational), there are still regulations that need to be met to be in compliance with state laws. For example, The Department of Cannabis Control (DCC) for California, is responsible for the licenses and regulations for retailer, distribution, microbusiness, and laboratory testing of Cannabis. Furthermore, those 21 and over may possess up to 28.5 grams of Cannabis, or up to 8 grams of concentrated Cannabis, while only an infraction for those under 21. Forms can include capsules, vape cartridges, and extracts if the THC content is less than 1000 milligrams per package for the adult-use market and 2000 milligrams per package for the medicinal market. Edible Cannabis products (such as cookies and gummies) have a THC limit of 10 milligrams per serving and 100 mg per packet for both medicinal and adult use. Anything over 100 mg most likely does not come from an approved dispensary and can be very dangerous for your health and safety.

In adult-use programs, direct healthcare professional involvement is lacking within the dispensary, however, there are still opportunities for involvement by providing independent consulting services. Education in these programs remains extremely important for ensuring safety and efficacy. In these states community outreach, speaking engagements, development of product formulations, and private consultations are all areas where the pharmacist can make a meaningful impact.

Tier 2 - Medical Conditions Only

The states in this tier are classified as medicinal use only and have much more regulations involved. Every state except for Nebraska and Idaho has passed some legislation allowing the use of medical Cannabis, though some are more restrictive. For example, places like Alabama, Texas, and the Carolinas have legal medicinal use, however low-THC (less than 5%) CBD oil is the only legal form of medical Cannabis

approved. Not all states are this strict, moreso mimicing regulations to that of Ohio and Pennsylvania. Initially, medical Cannabis could only be taken through pills, oils, ointments, patches, tinctures, or liquids under the supervision of a physician; however, in 2018 vaporized herbal Cannabis was approved for medical use. Under Ohio law like every other state, there are qualifying conditions that allow for physicians to recommend medicinal Cannabis. Some of these conditions include AIDS, cancer, epilepsy, multiple sclerosis, PTSD, and sickle cell. The rest of the conditions can be found on Ohio's regulation website. There are limits to both the day's supply of Cannabis as well as THC content. The 2021 Ohio Medical Marijuana Laws states that within a 90-day limit:

- Tier 1: No more than 8 oz. of plant material (2.83 grams per day)

- Tier 2: No more than 5 and 3/10 oz. of plant material
- No more than 26.55 grams of THC content in patches, lotions, creams, or ointments (295 mg per day)
- No more than 9 and 9/10 grams of THC content in oil. Tincture, capsules, or edible form (110 mg per day)
- No more than 53 and 11/10 grams of THC content in oil for vaporization (590 mg per day)

These regulations are slightly different with terminal illness. Lastly, the law prohibits any form that is attractive to children. However, a certified physician may recommend treatment with medical marijuana only after obtaining the consent of a parent or another person responsible for providing consent to treatment. Minors are also required to have an adult caregiver. Pharmacists can be useful in both the regulation aspect as far as how much Cannabis is being dispensed, and similarly to the section above, the counseling aspect of safe use and expectations.

Dispensary and retail pharmacy based practice settings allow for collaboration with other healthcare professionals. Documentation of encounters, suggested changes to regimens, and interprofessional approaches are possible within both settings. The

encounters can be in person, on the phone, or via zoom. Outreach and word of mouth from patients can foster relationships with other providers, thereby encouraging a collaborative experience for the patient and a potential billing opportunity for both pharmacist and physician when working together.

A special exception for pharmacy practice in a dispensary is Louisiana. Louisiana is the only state to have Marijuana Pharmacies. Louisiana Association of Therapeutic Alternatives (LATA) helped to develop the medicinal Cannabis program in Louisiana. Products dispensed in the program include oils, extracts, sprays, solutions, suspensions, gelatin-based chewables, lotions, transdermal patches, suppositories, metered dose inhalers, and as of June 2021, whole plant flower for smoking. The Louisiana Board of Pharmacy has special requirements in order to apply for a license with special evaluation criteria that must be met in order to grant approval. One marijuana dispensary permit is allowed per state region. Some evaluation criteria can include the posed benefit to the population in the area, as well as location of the dispensary to establishments such as schools and places of worship so that dispensary activities are not disrupted to the community. Support from locals and having established methods to reduce diversion are other requirements which may result in application denial. These pharmacies, much like dispensaries, offer discounts on products, despite being operated within a pharmacy. In order to make purchases patients need to be at least 18 years of age and have a physician who believes they will benefit from medicinal Cannabis certify them within the program.

In other countries, Cannabis flower can be directly dispensed with a prescription from a physician. Tilray and Bedrocan are two examples of manufacturers of this pharmaceutical grade flower. Bedrocan products are produced from certified sites in the Netherlands and come in standardized concentrations of THC and CBD depending on the product dispensed. Tilray is a Canadian company which produces oil and capsules that meet GMP standards. Other product types manufactured by Tilray include whole flower, vape pen, pre-rolls, topicals, and edibles.

Typically, medical programs that include dry flower as an approved formulation have the stipulation that it must be vaporized. Healthcare professionals should recommend vaporizers with variable voltage and the ability to set specific temperatures. Cannabinoids and terpenes have different temperatures at which they vaporize, and having the ability to control temperature gives the user a greater ability to control the effects. At the very least, choosing to vaporize at lower temperature helps prevent burning or combustion of the plant matter to avoid carbon monoxide production and potential throat and lung irritation. Other medical users have reported benefit with juicing or otherwise eating/consuming dry flower for its raw cannabinoids.

Tier 3 - No Cannabis Programs

These states, like Nebraska and Idaho, have no current legislation that allows for Cannabis use however, the push for medical purposes is on the 2022 ballot for both tier 3 states. In these states, hemp-derived CBD products are still available from retailers including craft CBD shops, “vape shops” which specialize in vaporized nicotine products, gas stations, and even grocery stores. While Nebraska has provided legal provisions to decriminilaze a certain amount of Cannabis possession, Idaho continues to fully criminialize any amount of Cannabis possession.

Hemp-based CBD products are commonly found formulated as an oral liquid like tinctures or oral solutions, capsules, tablets, and gummies. Hemp CBD can also be formulated into a topical preparation including lotions, creams, and body butters with varying inactive ingredients and therefore thickness. A quick online search will also find more exotic formulations like CBD infused toothpicks, bath bombs, and even toothpaste. The medicinal value of these alternative formulations have never been studied or validated and are either sold as a cosmetic product or for comedic, novelty purposes.

Hemp CBD products are typically classified as isolates, broad spectrum, or full spectrum. Isolates are chemically synthesized and winterized to ensure the final product has a purity of 99% CBD or higher. CBD isolates are tasteless, odor less, and is

guaranteed to not contain any other cannabinoids. Broad spectrum products contain additional cannabinoids and/or terpenes but are filtered to ensure no THC whereas full spectrum products do have the potential to contain THC. It's important to recognize both broad spectrum and full spectrum products may result in a positive drug screen for THC and the legal considerations that follow.

In a medical Cannabis dispensary there are many potential roles that may need to be filled including but not limited to working reception, ringing out sales, inventory management, counting money (typically cash), resolution of product related issues, staff conflict resolution, monitoring payroll, scheduling, providing medical consultations, educating staff, hiring, and firing of employees. Each state will vary in their allotted roles and responsibilities. A pharmacist consult in a dispensary will have a similar structure to that of a traditional medication review in the ambulatory care setting, however, there are some important differences to think about, namely due to patient autonomy. Setting expectations during a medical Cannabis consult is key because many patients come to Cannabis as a last resort. Intention for use matters in plant-based medicine because of the variability in symptoms and medication sensitivity. Cannabis consultants need to know a patient's individual treatment goals, typically based on their presenting or qualifying symptoms, to ensure the patient's needs are being met. As a clinician, we seek to avoid doing any harm, so assessing tolerance is key. If the patient hasn't consumed in the last 30 days, it is safest to start low, and go slow, and encourage a titration based treatment plan. Even patients experienced using Cannabis may not have the same results when transitioning from "street" to medical grade Cannabis and should be aware of potential increased toxicity. There are no clear methods established to determine a patients' tolerance, which is further complicated by differences in endocannabinoid tones. A strategy if the patient has consumed in the last month is to ask about what their preferred method of consumption is and the amount they use over a specific period of time. For example, if flower is preferred, ask how long does it take for them to consume 3.5 grams or an 'eighth'? If someone is able to consume that amount of flower in a couple days, it is safe to assume they have a high tolerance. This can be used to help guide decision making until more evidence based methods are

established. However, keep in mind, edibles result in the formation of metabolites that are more potent than the original cannabinoid. It can be strategic to be more conservative when switching from inhaled to oral forms of consumption, however, genetics will ultimately determine how true this is for an individual. Are they open to oral, inhaled, or topical dosage forms? The availability of these product types will vary from state to state, which can create frustration for a patient who may like traditional chocolate edibles that may not be an option in the patients' state of residence. Once expectations are set, treatment goals are established, tolerance is assessed, and we know what forms of consumption the patient is open to, it is time to educate. Beneficial cannabinoids, terpenes, and differences between forms of consumption are necessary to discuss. If at any point earlier in the conversation with the patient you notice that what the patient prefers may not necessarily be the best route, now is the time to gently bring that into the discussion. During this part of the consultation it is imperative to explain how to navigate the medicinal Cannabis landscape to the patient, as they will need to be their own advocates. For example, they may want a 'pineapple express' cultivar to treat their anxiety, but not realize that cultivar chemical content will vary from state to state, geographically within the same state, or even between various growers in the same state. Therefore, if chemical content labeling is available in your state's program, use that to help guide the patient. Regardless of what the final recommendation may be, make sure it is patient centered and remember they have autonomy. Towards the end of the encounter provide instructions, educational materials, and use the teach back method to confirm the patient's understanding.

Despite these differences between a typical consultation in a retail pharmacy setting, there are still many similarities. At the beginning of any consultation we want to know the past medical history, allergies, and current medications the patient may be taking to screen for any safety concerns with the active cannabinoids and terpenes or any inactive ingredients that may be in a product, like peppermint. Both consultations will provide some form of a comprehensive medication review and screen for drug therapy problems in indication, frequency, safety, efficacy, and compliance. Assessment of appropriate medication administration techniques will be common to see in both retail

and Cannabis based consults. In the context of a medical Cannabis product, a pharmacist may explain how to appropriately use a tincture or a vaporization device. For example with a tincture, the patient should be counseled to hold the product under their tongue for 1-2 minutes if it is alcohol or glycerin based before swallowing. Or, if the patient experiences uncomfortable burning or irritation due to the alcohol, they should be instructed to place the product on their tongue to allow the ethanol to evaporate before moving the product under the tongue or swallowing directly. At the end of the day both consultation types are different forms of motivational interviewing that should ways be patient centered, whether it is done in person, via telemedicine, or on the phone.

Other differences between traditional practice settings include general workflow and licenses. Dispensaries operate under a dispensary license whereas pharmacies operate under a pharmacy license. Both of which are managed by the individual states' department of health. Dispensaries may run sales on various products and provide different product availability for those who are adult-use versus those who are medical patients. Analogous to drug wholesalers, dispensaries purchase products from grower processors. These facilities produce the products for sale within state lines, however, these products have variability. Due to the nature of plant based medicine being heterogeneous, the products will vary batch to batch and the cultivar chemical content will also vary based on geographic location. The same cultivar produced in a given state at different growers or in different regions will all vary in cannabinoid and terpene content. Whereas traditional western based medications are generally consistent in nature between manufacturers, with some exceptions.

Although medical dispensaries are not technically liable to HIPAA regulations, dispensaries and staff should emphasize the importance of patient privacy. This includes the certification or diagnosis that qualified the patient for medical Cannabis use, any other medications the patient may be using, and personal health information like birthday and address. Dispensaries should have a private area to provide constulations and esnure other patients in the waiting room are not privy to the conversation. The use of barriers and white noise machines should be utilized to protect

patient privacy. The use of Cananbis is still highly stigmatized and patients may already have their reservations about trying medical Cannabis so providing a professional and supportive environment may help to ease any anxieties and discomfort.

Other direct involvement for pharmacists in the Cannabis industry is at the corporate level. Many of these job duties revolve around sales and efficiency. Pharmacists in this setting use operations and marketing data to drive decision making. Other responsibilities include hiring, clinical service development, creating standard operating procedures, conflict resolution, store visits, product development, and bridging gaps between business and clinical operations.

A pharmacist does not need to work directly with medicinal Cannabis to make a difference in patients being treated with it. In community pharmacy practice it is important to check for potential drug interactions, screen for potential medical conditions that may be problematic with Cannabis such as psychotic disorder, educate on labeling, and provide regulatory information on both CBD and delta 8 THC products. Although individual Cannabis products are not found in commonly used drug interaction tools, pharmaceutical based preparations like Dronabinol and Epidiolex ® can be used to search for THC and CBD, respectively. Institutional pharmacy practice involvement is determined by existing hospital policies on administration of Cannabis products to patients, storing Cannabis products, and policies to prevent diversion. Consulting pharmacists or those working in LTCs or group homes can check for drug interactions between THC/CBD products and ensure appropriate policies are in place to prevent diversion, and policies that outline storage and administration of Cannabis. In this setting many sites will need a policy to outline who will pick up the medicine whether that be the responsibility of the resident, a family member, or a charge nurse. Unfortunately, some states require caregivers to be registered with the department of health, which may incur a cost that may be a barrier to access. In academia opportunities for involvement in Cannabis lie in research or teaching in didactic, small group facilitation, and experiential settings.

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