

Core Attributes of a Patient-Centric, Medical Cannabis Regulatory Program

As more states legislatively address the topic of regulating medical cannabis access and distribution, NORML has seen a shift away from patient-focused programs and toward more politically expedient policies. These latter programs are neither evidence-based nor do they adequately address patients' needs.

NORML contends that an effective, patient-centric, evidence-based medical cannabis program must include the following core tenets:

- Access to whole-plant cannabis;
- Limited taxes and fees;
- Wide latitude for doctors to decide treatment regimens;
- Personal cultivation rights;
- Employment protections;
- And other reasonable civil statutory protections.

Patients must be legally able to obtain and possess herbal formulations of whole-plant cannabis that may be administered via inhalation/vaporization; their therapeutic choices must not be limited solely to orally administered cannabis-derived extracts, oils, or pills

Some states impose arbitrary legal restrictions on the types of cannabis products available and/or their intended route of administration. Specifically, a small number of states have prohibited patients from possessing or inhaling herbal forms of cannabis — instead requiring program participants to orally consume cannabis-derived oils or pills containing extracts from the whole plant. NORML opposes these arbitrary limitations on patients' choices.

Limiting patients' options to extracted oral formulations is not in their best interests. Herbal cannabis contains more than 100 distinct cannabinoids (unique physiologically active components in the plant), many of which act synergistically with one another. Moreover, the plant's oils contain numerous terpenes that also possess a variety of therapeutic effects.

Many scientists now believe that the combined administration of all of these parts of the plant produce a synergistic effect that is necessary in order for patients to achieve maximum therapeutic benefit. As **acknowledged** by famed neurosurgeon Dr. Sanjay Gupta: "[A]ll these components of the cannabis plant likely exert some therapeutic effect, more than any single compound alone. ... Unlike other drugs that may work well as single compounds, synthesized in a lab, cannabis may offer its most profound benefit as a whole plant, if we let the entourage effect flower." Restricting patients' access to herbal cannabis limits their exposure to these therapeutic properties, as many of these constituents are no longer present in formulations produced following the extraction of individual cannabinoids.

Furthermore, orally administered non-herbal forms of cannabis possess delayed onset and their effects are far less predictable than those of herbal cannabis. Once inhaled, cannabinoids like THC or CBD rapidly pass from the lungs to the blood stream — resulting in the rapid onset of drug effect. By contrast, pills must be metabolized by the liver over a period of up to several hours before the patient experiences any therapeutic benefits. This delayed onset and high degree of variability of drug effect makes it extremely difficult for patient

to accurately self-regulate their dosing. As a result, many patients seeking rapid relief of symptoms such as pain, nausea, or spasticity will not particularly benefit from cannabis-infused pills, tinctures, or edibles.

While concerns with regard to the potential risks associated with cannabis smoke exposure are understandable, they are largely not evidence-based. Cannabis smoke exposure, even over the long-term, is **not associated** with the same sort of detrimental health effects as is tobacco exposure. Specifically, longitudinal trials **do not** show a causal link between cannabis smoke exposure and lung cancer, COPD, or detrimental effects on pulmonary function. Also, patients' exposure to unwanted combusive gasses may be readily mitigated by the use of a vaporizer, a device which heats herbal cannabis to a point where cannabinoid vapors form, but below the point of combustion — thereby reducing the intake of combusive smoke or other pollutants, such as carbon monoxide and tar. In clinical trials, researchers have acknowledged that such devices are a **"safe and effective"** method for delivering cannabis to patients.

Finally, the bulk of **clinical trials** establishing cannabis' safety and efficacy have been conducted using inhaled, whole-plant herbal cannabis. By contrast, alternative formulations of cannabis and administrative routes remain largely untested and unproven.

Patients must not be forced to pay unreasonable taxes and fees

The commercial production and retail sale of recreational cannabis in legal jurisdictions is presently subject to both excise taxes and sales taxes, similar to other commercial goods. However, such taxation generally does not apply to activities involving the production and retail sale of medical cannabis to state-qualified patients. Patients, many of whom are on disability or fixed income, should not be seen by lawmakers as a viable source of new tax revenue. Therefore, any proposed taxes and regulatory fees placed upon medical cannabis production and sales must be nominal. This will ensure that legal cannabis products do not remain out of reach from those patient populations who need them most. Further, it will ensure that market prices remain low enough so as to not incentivize patients to obtain cannabis from the black or grey market.

The approved list of qualifying conditions must be expansive and must allow physicians the option to recommend cannabis therapy for the treatment of chronic pain

Cannabinoids have been shown to **safely and effectively treat** a wide range of symptoms and, in some cases, these compounds likely hold the potential to modulate the course of serious diseases. A recent literature **review** identifies over 140 controlled clinical trials evaluating cannabinoid therapy for a multitude of serious, chronic conditions — including multiple sclerosis, Tourette Syndrome, epilepsy, Crohn's disease, epilepsy, IBS, spinal cord injury, and others. Consequently, physicians ought to be provided wide latitude and discretion with regard to which patients they believe in their expert opinion will benefit from cannabis treatment. Legislators and regulators should not unduly interfere with the sanctity of the doctor-patient relationship or in any way impede physicians from providing what they believe to be the best course of treatment for their patients.

To date, the largest number of controlled clinical trials are specific to the use of cannabis to effectively mitigate chronic pain conditions, especially treatment-resistant neuropathy. A recent review of these scientific trials by the National Academy of Sciences, Medicine, and Engineering **acknowledged** that conclusive evidence exists to support the use of cannabis and cannabinoids "for the treatment of chronic pain in adults." **Multiple studies** further show that patients with legal cannabis access often use it as a substitute for the use of more dangerous opioids. In fact, jurisdictions that regulate medical cannabis experience far lower rates of **opioid-**

related mortality and overall prescription drug spending than those states that do not. As a result, no evidence-based medical cannabis program ought to place limitations with regard to the use of cannabis as an analgesic.

Registered patients ought to have the legal option to cultivate personal use quantities of cannabis in their own private residence

Patients are legally permitted to cultivate personal use quantities of medical cannabis in half of the jurisdictions that regulate its use and distribution. In almost all cases, these provisions have led to few incidences of abuse or diversion. In no instance has a legislature moved to eliminate patients' home grow rights in a jurisdiction that has previously permitted such activity.

Nonetheless, lawmakers in several states in recent years have elected to move forward with medical cannabis programs that explicitly prohibit patients from engaging in home cultivation. NORML opposes this position. NORML maintains that disallowing patients to engage in the personal cultivation of cannabis is an arbitrary prohibition that has absolutely no basis in public safety.

NORML supports the right of individuals to grow their own cannabis as an alternative to purchasing it from licensed commercial producers. NORML maintains that the inclusion of legislative provisions protecting the non-commercial home cultivation of cannabis serves as leverage to assure that the product available at retail outlets is high quality, safe, and affordable. Further, many patients respond best to specific strains of the cannabis plant. Permitting select patients the option to produce these specific strains at home assures that they will have an uninterrupted and cost-effective supply of the medicine that is best suited to their own particular therapeutic needs.

Finally, it must be acknowledged that the timeline between the passage of a medical cannabis program and the operation of state-licensed cannabis dispensaries is often several years. Patients who would otherwise benefit from legal, medical cannabis access should not be forced to go without their medicine during this period. Allowing state-qualified patients the ability to home cultivate medical cannabis provides patients with the immediate access they need and deserve.

Patients should not face either workplace discrimination or sanctions solely based upon their medical cannabis status

Registered patients should not be forced to choose between their medicine and gainful employment.

Just as employers would not be permitted to fire or to refuse to hire an employee due to their physician-authorized use of opioids or other conventional medications, those who legally engage in cannabis therapy should not face arbitrarily discrimination for activity that is unrelated to their work performance — such as testing positive for carboxy-THC (an inert metabolite of THC that may be detectable for several months post-abstinence) on a drug screen. In recent months, courts in two medical cannabis states — Connecticut and Massachusetts — have upheld statewide legislative protections shielding employers from taking punitive actions against medical cannabis patients, and many states now impose similar provisions as part of their medical cannabis regulations.

Patients should not be withheld medical treatment in hospitals — such as being denied organ transplants — solely based upon their status as a medical cannabis patient



There are numerous examples of patients being arbitrarily denied medical treatment from hospitals because of their status as medical cannabis patients. In many cases, patients requiring organ transplants are **refused** services.

Scientific **reviews** find **no negative association** between a cannabis use history and organ transplant survival rates. As a result, various states — such as California and Maine — have in recent years enacted statutory language explicitly prohibiting hospitals from arbitrarily withholding services from patients solely because of their medical cannabis status.

Below are examples of other key provisions NORML supports:

- Patients should not face a loss of child custody solely based upon their status as a medical cannabis patient;
- Patients should not be subject to housing discrimination based solely upon their status as a medical cannabis patients;
- Cannabis and/or cannabis-derived products provided at state licensed dispensaries must be subject to adequate testing for quality, potency, pesticides, and adulterants;
- Cannabis product packaging must prominently display accurate information with regard to cannabinoid content and potency;
- In order to assure that market demand is adequately met and that registered patients have convenient access to medical cannabis products, regulators should not impose arbitrary caps on the number of licenses available for qualified commercial producers, manufacturers, or dispensing facilities.