

Nebraska's Medical Cannabis Emergency Regulations Ignoring the Will of Voters and Gutting Medical Cannabis Access

On November 5, 2024, Nebraska voters overwhelmingly decided to allow patients to use and safely access medical cannabis. In landslide votes of 71% and 67% in favor, they approved the Nebraska Medical Cannabis Patient Protection Act (Initiative 437) and the Nebraska Medical Marijuana Regulation Act (Initiative 438).

Initiative 438 created a new Nebraska Medical Cannabis Commission and charged it with implementing the medical cannabis business part of the law. Outrageously, the commission's emergency regulations kneecap the program in numerous ways, including banning raw cannabis and edibles, which the initiatives allow. The regulations also cap the total number of plants statewide at 5,000, even if that is insufficient to meet demand, and impose numerous burdens that will deter medical practitioner participation.

These are *emergency* regulations, and permanent rules must be adopted. Make your voice heard <u>at</u> <u>the commission</u> to ask them to respect the will of voters, and reverse these burdensome regulations that set up the program to fail.

Here are ways we believe permanent regulations need to change from the emergency regulations:

I. Remove the ban on raw, botanical cannabis, edibles, concentrates, and vaporized cannabis.

Nebraska's voter-enacted medical cannabis laws allow medical cannabis in its raw, botanical form. The initiatives authorized vaporization, edibles, concentrates, and accessories for inhalation. In stark contrast to the language of the voter-enacted law, medical cannabis businesses are prohibited from selling all of these products in the emergency rules.

Emergency rule 013.09(B) prohibits dispensaries from selling "raw plant material," "any product administered by smoking, combustion, or vaping," and "food or drink that has cannabis baked, mixed, or otherwise infused into it." Instead, it only allows a handful of extracted preparations — "oral tablets;" gels, lotions, and other topical applications; suppositories; transdermal patches; and oils for nebulizers or inhalers.

These unacceptable changes would deprive patients of preparations that work best for them. The rule is also directly at odds with the will of voters.

The Nebraska Medical Cannabis Patient Protection Act allows patients to possess up to "five ounces of cannabis." Both initiatives authorize cannabis accessories which they define as including "products ... intended for use ... vaporizing ... cannabis ... or inhaling ... cannabis." Both define cannabis as including marijuana, hashish, and "all parts of the plant of the genus cannabis whether growing or not."

Botanical cannabis includes more than 100 cannabinoids, which work synergistically to provide relief through the "entourage effect." Limiting patients to extracts will deprive many patients of the treatment option that works best for them. Raw cannabis can be consumed in smoothies or other preparations, in addition to being inhaled.

Numerous studies have found the efficacy of smoked and vaporized cannabis, including in alleviating migraines, neuropathic pain, induced pain, nausea, and spasticity from multiple sclerosis. While smoking tobacco — which is legal for adults in Nebraska — kills over 480,000 Americans per year, cannabis smoke does not carry the same risks. Cannabis smoking has not been shown to cause lung cancer or COPD.

Meanwhile, smoked and vaporized cannabis allows for almost immediate relief. Rapid relief is crucial for releasing spasms, preventing an oncoming seizure, quelling nausea, and relieving attacks of debilitating pain. Peak THC levels are reached in only 6-10 minutes after inhalation. In contrast, oral administration takes 30-60 minutes to take effect, with peak levels at between 1.5 hours and three hours post-administration. People who are nauseated, paralyzed on the floor with a spasm, or writhing in pain should not be forced to suffer.

Because it is so fast-acting, inhalation also allows for precise dose titration. For obvious reasons, modes of administration that take up to two hours do not allow for precise dosing based on the needs of the patient.

While rules provide for nebulization, which is also fast-acting, nebulized cannabis has not been subject to the studies that smoked and vaporized cannabis have been. Many patients may be more comfortable with modes of administration that have been studied for decades.

Raw cannabis is also typically far less expensive than extracts, which is vital since insurance does not cover medical cannabis and people with serious illnesses typically have very limited incomes.

Initiative 437 allows cannabis to be added to food and drink. Its definition of cannabis includes "preparation[s]" of cannabis plant and it provides that the five ounces of cannabis allowed "does not include the weight of any other ingredient combined with cannabis as part of topical or oral administrations, food, drink, or other preparations." Both initiatives define cannabis products as "products that are comprised of cannabis, cannabis concentrate, or cannabis extract, and other ingredients, and that are intended for use or consumption, such as, but not limited to, edible products, ointments, and tinctures." The emergency rules ban the sale of what both initiatives clearly allow.

Rule 015.01 also caps products at 60% THC. Some patients with extreme pain, cancer, and other ailments find relief from very-high THC products. Moreover, this cap may force additives to be inhaled in nebulizers. Inhaling additives, specifically vitamin E acetate, was the culprit in the EVALI lung crisis.

To respect the will of voters and comport with the statutes, the bans on the sale of raw cannabis, edibles, concentrates, and products that can be vaporized, combusted, or smoked needs to be removed. Under Initiative 437, patients can possess cannabis regardless of the source. These undemocratic bans will drive many patients across state lines to get the product they are legally entitled to and that helps them, wasting their time and gas money.

II. Remove limitations, burdens, and restrictions on medical practitioners.

A. Remove "written orders," including removing the requirement that practitioners specify products, dosage, and the dispensary.

In keeping with other states' medical cannabis laws, Initiative 437 allows a qualifying patient to use and possess a specific amount of cannabis (up to five ounces) with a physician, nurse practitioner, or physician assistant's recommendation, which is First Amendment-protected speech. Emergency rules 2.40 and 13.05 depart dramatically from this approach by requiring dispensaries to only dispense cannabis if their medical professional completed a "written order" including the recommended product, potency, number of doses, directions for use, and the dispensary to obtain it from. These requirements are impractical, inconsistent with the initiatives, and likely to seriously deter practitioners' participation due to federal law.

Due to federal restrictions, there is limited research on the wide array of cannabinoids, terpenes, and medical cannabis products. Physicians will not have knowledge of every available product and how it will work for an individual patient. Patients use trial-and-error to find the product or products that work best for them. Some patients use a variety of products and strains depending on which symptoms are present and whether it is daytime or nighttime. What dosage is needed will depend on how severe the symptoms are, which is not something a physician can anticipate.

In addition to being impractical and contrary to the best interests of patients, these rules put practitioners at risk and will thus depress their participation. A federal circuit court ruled that recommending cannabis is protected First Amendment speech, and that doctors' authority to prescribe controlled substances could not be revoked based on such a recommendation. However, it noted doing so with the specific intent that the recommendation be used to acquire cannabis would not be protected. Specifying what products and how much a patient could obtain would show a specific intent that the recommendation be used to purchase cannabis, and thus put the physician at legal risk. Many physicians would be unwilling to participate if their livelihood could be put in jeopardy for doing so.

Under Initiative 437, patients may possess cannabis with a recommendation — with no added requirement of a "written order" with the form of cannabis or dosage being included. As is the case with many of the other burdens in the emergency regulations, this will drive patients to Missouri, Colorado, and the illicit market, where they can make their own decisions about products.

B. If "written orders" are not removed, allow refills.

Emergency rule 013.08 reads, "NO REFILLS. A dispensary may not sell or transfer medical cannabis to the same qualified patient for the same written order more than once." This requires a doctor to write a new order every 30 days for time that is not covered by insurance. This is absurdly burdensome, cost-prohibitive, and will drive patients across state lines to get cannabis.

C. If "written orders" are not removed, remove that they specify the dispensary.

Emergency rule 2.40 (L) requires "written orders" to include the specific dispensary where they can be filled. If the dispensary runs out of stock, or the patient cannot afford its prices, the

patient would have to wait another 30 days to get their medicine. This requirement needs to be removed.

D. Remove the registration and CME requirement.

Initiative 437 does not have a continuing medical education requirement or registry requirement for recommending to certify patients. Yet rules 019.01 and 019.02 require recommending practitioners to enroll in a Recommending Health Care Practitioner Directory and complete 10 hours of CMEs within a year, plus two per year thereafter. This would apply even if the practitioner only certified a few patients, meaning they would have to spend vastly more time on the CMEs than with medical cannabis patients. There is no state-mandated CME requirement for the vast majority of other specific medications.

These excessive burdens need to be removed.

E. Remove the requirement that doctors primarily practice in Nebraska.

Rule 019.01 requires recommending practitioners "primarily practice medicine in Nebraska." Initiative 437 allows practitioners from other states to recommend cannabis. This should track the language of the initiative. At a minimum, any practitioner licensed in Nebraska should be allowed to certify patients.

III. Allow enough cannabis cultivation to meet patients' needs.

Emergency rule 014.06 creates a hard cap of 1,250 plants per cultivation center. Meanwhile, rule 005.11 caps cultivators at four, or five if four is not enough to meet demand. The rules provide for no possibility of increasing beyond the cap if 6,250 total plants in the state are insufficient to meet demand.

This is a grave disservice to patients and licensed businesses. In the very likely event that 6,250 plants are insufficient to meet demand, prices will skyrocket and patients will suffer without their medicine. Only those patients who can afford the highest prices will have access to their medicine. And some manufacturers may have no supply.

IV. Eliminate the inadequate cap on how much cannabis is allowed.

Rule 013.07 caps the total amount any patient can receive at 5 grams of THC in 90 days. This will be inadequate for some patients, and will thus cause needless suffering.

In Ohio, the Board of Pharmacy considered expert testimony and literature and came up with the following as a maximum 90-day supply, given the different absorption rates of different products:

- Oils, tinctures, edibles: 9.9 grams of THC.
- Oils for vaporization: 53.1 grams of THC.
- Topicals (lotions, patches, creams): 26.55 grams of THC._

If there will be a limit, it should be no lower than Ohio's.

V. Ensure the laboratory requirement is not a catch-22.

MPP supports public health regulations, including laboratory testing. However, we are concerned that

the requirements related to laboratory testing would create a catch-22 if no laboratories are licensed or authorized under state law. All requirements related to laboratory testing should be contingent on there being a licensed, operational laboratory. Whether there are operational laboratories is outside of licensees' control. (For example, rules 015.07(A), 015.07(E), and all rules under 016.)

VI. Remove or revise the bar for those with any controlled substances conviction.

We urge the removal of the bar on applicants, officers, directors, and operators with any controlled substances-related conviction in the past 10 years. (004.07, 006.07, 007.07, 008.07) This applies even to simple possession of cannabis, including when it was for medical use. Other parts of the regulations sensibly prioritize applicants with experience in cannabis. Of course, even simple possession of cannabis remains federally illegal. People should not be barred from having experience with the plant they are applying to produce or sell.

VII. Remove or revise the bar for anyone with any cannabis-related fine.

The regulations bar a license from being issued or renewed to anyone who "had any citation, fine, sanction, injunction or court judgment levied against the person, or a business owned by the person, involving cannabis or cannabinoid related operations or sales." (S008.07) This turns every minor penalty, including a fine, into a permanent ban.

This is excessive and would be extremely disruptive to access given the small number of licensees. For example, failing to renew a license of a grower would shut down one-quarter or one-fifth of the entire state supply, depriving product manufacturers of the supplies they needs and depriving patients of the medicine they need.

VIII. Allow telemedicine for medical cannabis.

Americans are increasingly relying on telemedicine, which is legal in Nebraska. However, the emergency regulation 002.40 (J) only allows a practitioner to issue a "written order" for cannabis if it includes "A statement that the recommending health care practitioner met with the qualified patient in-person at least once in the last twelve (12) months." There is no such restriction in the voterenacted laws.

Many healthcare providers are not knowledgeable about medical cannabis. Some patients cannot drive or are homebound. This adds a new burden for medical cannabis that was not in the initiatives and is not consistent with other medicines, which are often far more dangerous.

IX. Remove ban on pregnant patients.

Emergency regulation 002.40 only allows a practitioner to issue a "written order" for medical cannabis if it includes a "statement attesting the qualified patient is not pregnant."

The Nebraska Medical Cannabis Patient Protection Act (Initiative 437) has no exception for pregnant patients. Physicians should not be prohibited from weighing the risks or benefits of cannabis, while taking into account pregnancy, as they do with other medicines.

X. Home delivery should be allowed.

Emergency regulation 013.04 prohibits the delivery of cannabis and requires all transfers to occur on

the licensed property. Other medications are delivered to the homes of patients throughout Nebraska. The same should be true of medical cannabis. Some patients are unable to drive due to their ailments. Some live in nursing homes or assisted living facilities. Prohibiting home delivery deprives patients of access to the medicine voters approved.

XI. The cultivator cap is too low.

Rule 005.11 allows only four cultivators in the state, which are limited to 1,250 plants each. If that proves inadequate, only a single additional cultivator is allowed. This is far lower than most medical cannabis programs. At a minimum, the cap needs to be allowed to increase as much as is needed to meet demand.

XII. The product manufacturer cap is too low.

Rule 006.11 allows only four product manufacturers. If that proves inadequate, only a single additional product manufacturer is allowed. This is far lower than most medical cannabis programs. The Commission should approve as many additional licensees are needed to meet demand, and approve applicants who would provide products that are not available at the time.

Neighboring South Dakota, which has less than half of Nebraska's population, has 33 licensed cultivation facilities. [15]

XIII. The dispensary cap is too low.

Rule 004.11 allows only one dispensary per District Court Judicial District, for a total of 12. If the amount is insufficient, a second dispensary may be added per district the year after it finds the single dispensary is insufficient. The Commission should be allowed to license as many dispensaries as are needed to serve demand.

Neighboring South Dakota has more than 60 dispensaries. South Dakota is slightly smaller than Nebraska, and has less than half of Nebraska's population. Nebraska also has a broader medical cannabis law by allowing physicians' discretion to certify patients for medical cannabis.

XIV. The 1,000-foot buffer for many locations should be pared down.

The emergency rules ban dispensaries and other cannabis businesses within 1,000 feet of any "covered location," which includes schools, churches, licensed daycares, hospitals, and mental health and substance use treatment centers. (004.08, 006.08, 002.11) A 1,000-foot buffer from this wide array of locations may be excessive. It may prohibit dispensaries in any commercial area in some towns and cities. At a minimum, cities and towns should be able to reduce the buffer for locations.

In addition, the buffer from a hospital should be reduced to 300 feet or eliminated. Cannabis is now recognized as a medicine under Nebraska law, and pharmacies are located in hospitals.

XV. The ban on vertical integration should be removed.

Rule 004.01 provides, "Vertical licensing is not permitted. An applicant may not possess more than one license type authorized by this chapter." Vertical integration should be allowed, but not required. At a minimum, manufacturers should also be allowed to be cultivators to ensure they have an adequate supply of cannabis to produce products from.

XVI. Cultivators should not be restricted regarding where they obtain seeds.

Cannabis seeds have under 0.3% THC. Under federal law, they are thus "hemp" and can be legally transferred. However, rule 014.09 dramatically reduces the options for where seeds can be obtained, which would prevent cultivators from obtaining them from federally legal sources and dramatically restrict genetics. It provides, "A cultivator may only obtain cannabis seeds, immature cannabis plants, or cannabis genetic material from another Nebraska licensed cultivator or a cultivator authorized to operate in another state of the United States."

It should be revised to: "A cultivator may only obtain immature cannabis plants, or cannabis genetic material other than seeds, from another Nebraska licensed cultivator or a cultivator authorized to operate in another state of the United States. A cultivator may obtain cannabis seeds from any federally legal source, from another Nebraska licensed cultivator, or a cultivator authorized to operate in another state of the United States."

XVII. Prompt deadlines are needed for licensing.

The emergency rules don't include deadlines for accepting applications or issuing licenses. Initiative 438 required the commission to begin granting business registrations by October 1, 2025. The permanent rules should ensure that licenses are issued swiftly, but that each application window is open for at least 30 days. There should also be a firm deadline for it to begin accepting all remaining types of applications, which should be in 2025.

The cultivation licensing process is underway. It is essential to the financial welfare of the applicants that they have manufacturers and dispensaries where their products can be sold in a timely manner. It is also essential to honor the will of the people by providing timely access to medical cannabis.

XVIII. Minors should be allowed to accompany parents in dispensaries.

Emergency rule 12.04 bars minors from all cannabis facilities. Children are allowed at pharmacies, and they should be allowed to accompany their parents to dispensaries. Barring children requires many parents to pay for child care, adding unnecessary costs.

XIX. Remove the reclamation bonds.

Emergency rule 012.09 requires a \$200,000 reclamation bond for all licensees to the state of Nebraska. Nebraska does not own the licensed property. Planting, manufacturing, and selling medical cannabis in accordance with regulations will not cause harm to Nebraska. This is an unwarranted expense that will merely drive up costs for businesses and patients.

XX. Application and licensing fees should be reasonable for small businesses.

The emergency rules don't include application or licensing fees. If and when it has the authority to impose fees, application fees need to be modest enough that those who do not have extremely deep pockets can afford to apply. Licensing fees should also be reasonable for small businesses. Application fees should not exceed \$2,500 and licensing fees should not exceed \$10,000.

Concluding Comments

Nebraska's emergency rules thwart the will of voters, which was to provide Nebraska patients with

safe, in-state access to medical cannabis. They deprive patients of the most commonly used modes of administering cannabis, edibles and flower, despite those options being clearly allowed in the people's initiatives. The rules also add onerous burdens on physicians that increase costs, create legal risks, and deter participation. The rules undermine the law in a myriad of ways and deprive patients of the relief voters intended. If the issues are not fixed in the permanent rules, this burdensome approach will drive many across state lines, wasting time and money, and causing more suffering and pain.

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