VICENTE SEDERBERG LLP

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Medical Cannabis in Texas

Policy recommendations for improving patient access, treatment outcomes and the economic health of the Compassionate Use Program

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Executive Summary

Texas is one of 48 states that have enacted some form of medical cannabis law. The Texas Compassionate Use Program (TCUP) is undoubtedly helping some patients, but it is relatively limited with regard to who can access medical cannabis, what types of products are available, and where those products can be accessed. Despite an expansion of the program in 2019, there are likely more than one million Texas residents with debilitating medical conditions who could benefit from medical cannabis but are still not allowed to participate.

In 2021, the Texas Legislature can improve the viability of the program and ensure it better meets the needs of state residents by adopting the following policy recommendations, which are characteristic of other healthy state medical cannabis programs around the country:

- Empower physicians and give them the same degree of deference they receive when prescribing other medications.
    - Expand qualifying conditions for medical cannabis in a manner that ensures patients with debilitating medical conditions can access it if their physician believes it would be a safe and effective treatment.
    - Allow a wider variety of medical cannabis products and let physicians determine the most appropriate product form and dosage for each patient.
- Improve treatment options and reduce potential for abuse by removing the current THC limit of 0.5% per product and replacing it with a THC limit based on purchase volume.
- Embrace market competition by licensing additional medical cannabis operators and expanding the types of licenses that are available.

In addition to improving access and potential treatment outcomes, a larger and more robust medical cannabis market could sustain hundreds of new businesses and create tens of thousands of new jobs. It could also result in additional benefits, including criminal justice savings, reduced state public health spending, and a drop in opioid abuse and mortality.

The Texas Compassionate Use Program

In 2015, the Texas Legislature approved and Gov. Greg Abbott signed the Texas Compassionate Use Act (Senate Bill 339), establishing a limited commercial medical cannabis program. It allowed patients with intractable epilepsy, who have received prescriptions from two physicians board-certified in the specialty, to access and consume non-smokable cannabis products with no more than 0.5% THC and at least 10% CBD. It also authorized at least three vertically integrated licensed dispensing organizations to cultivate, process, and sell cannabis products to registered patients.

In 2019, the state enacted House Bill 3703, expanding qualifying conditions for medical cannabis to include a broader range of epilepsy and seizure disorders, as well as multiple sclerosis, spasticity, amyotrophic lateral sclerosis, autism, terminal cancer, and incurable neurodegenerative diseases. HB 3703 removed the two-physician prescription requirement, but maintained the requirement that patients receive a prescription from a board-certified specialist in the applicable specialty. It also amended the definition of low-THC cannabis to remove the 10% CBD potency requirement (but retained the limit of 0.5% THC). To date, the Texas Department of Public Safety (DPS) has issued licenses to only three vertically integrated dispensing organizations.

Expanded, but Still Falling Short

Despite its expansion in 2019, the Texas Compassionate Use Program (TCUP) is still not meeting the needs of most state residents who could benefit from medical cannabis. As of September 2020, the program had just 2,892 registered patients, a patient-to-population ratio (PPR) of 0.01%.[1] By comparison, the medical cannabis program in Arkansas, a neighboring state with about one-tenth the population, had 90,528 registered patients as of October 27, 2020, a PPR of 2.89%. Adjusting for population, Texas' medical cannabis program is growing at a rate about 300 times slower than Arkansas' program and about 500 times slower than Oklahoma's.[2, 3]

There are likely more than one million Texas residents with debilitating medical conditions who would be able to benefit from medical cannabis if they lived in one of the comparison states but are not currently allowed to participate in the TCUP.

The state's exceptionally small patient population and limited growth also raise concerns about the viability of the three existing medical cannabis dispensaries. Even if these vertically integrated operations are well-capitalized and professionally managed, such businesses can only survive a limited time when operational costs exceed total medical cannabis sales.

To sufficiently improve patient access and ensure the viability of the TCUP, policymakers must make additional improvements in the following areas:

***Who* is allowed to access medical cannabis:** Texas expanded its list of qualifying conditions for medical cannabis in 2019, but it does not provide access to individuals with a variety of medical conditions who could potentially benefit from medical cannabis and would qualify for medical cannabis programs in other states.

***How* access to medical cannabis is granted:** The 2019 legislation defined "prescription" as an entry in the compassionate use registry rather than a conventional medical prescription, but continued use of the term "prescription" deviates from other state medical cannabis programs (which use "recommendation"), creating confusion and concerns for doctors since "prescription" drugs are controlled federally by the U.S. Food and Drug Administration and the Drug Enforcement Administration.

***What* forms of medical cannabis and types of products are available:** The removal of the 10% CBD potency requirement allowed for products with a wider variety of CBD-THC ratios, but Texas patients are still limited to fewer types of medical cannabis products and fewer forms of consumption than patients participating in most other states' medical cannabis programs.

***Where* medical cannabis can be accessed:** The extremely limited number of dispensaries in Texas makes it difficult for patients to access medical cannabis in many parts of the state and diminishes competition, resulting in limited product variety and higher prices. While DPS allows licensed dispensaries to service patients by delivery or from partner-clinic locations, only one of the three licensees is fully operational and offering both of these services (largely due to the state's exceptionally small patient population).

Policy Recommendations to Improve the Health of the TCUP — and Patients

Policymakers must further expand the TCUP to better serve current and potential patients. In doing so, it can ensure the economic survival of the current dispensing organizations that have already invested in helping the state's patients, as well as create new economic opportunities. This can be accomplished through the following policy changes.

Empower Physicians to Recommend Cannabis Based on their Expertise

Physicians serve an essential regulatory role in state medical cannabis programs. They monitor patient use, evaluate effectiveness, assess appropriate product types and dosage, and provide guidance and oversight aimed at preventing abuse. In every state with a medical cannabis or low-THC program, patient participation begins with a medical examination, at which time his or her physician determines whether cannabis treatment is medically appropriate, with primary attention to safety and potential for efficacy. Texas law currently requires physicians to determine whether any risks associated with medical cannabis use are reasonable in light of potential benefits to the patient. In some states, including Texas, physicians must also determine whether the patient has one of the specific conditions or symptoms for which medical cannabis is authorized.

Texas currently lists epilepsy and seizure disorders, multiple sclerosis, spasticity, ALS, autism, terminal cancer, and incurable neurodegenerative diseases as qualifying conditions, but there are many others that can also be safely and effectively treated with medical cannabis. For example, in 2017 the National Academies of Sciences, Engineering, and Medicine reported, "There is substantial evidence that cannabis is an effective treatment for chronic pain in adults..." and "the use of cannabis for the treatment of pain is supported by well-controlled clinical trials."[4] After thoroughly reviewing the medical evidence, states across the country have chosen to include chronic or intractable pain, as well as other conditions that affect significant segments of the population, such as severe nausea and post-traumatic stress disorder. While some states have enumerated these conditions in their lists of qualifying conditions, others have more generally authorized access to medical cannabis for any condition for which it is recommended by a qualified physician.

Recommendations: To ensure the TCUP meets the needs of Texas residents, the Legislature should empower physicians to recommend medical cannabis and give them the same degree of deference they receive when prescribing other medications. Specifically, the Legislature should expand qualifying conditions for medical cannabis in a manner that ensures patients with debilitating medical conditions can access it if their physician believes it would be a safe and effective treatment. This would ensure Texas residents have access to the same medical treatment options as residents of other states, and that they will not be forced to relocate to obtain relief. It would also ensure Texas physicians are able to provide their patients with the best possible care in accordance with their medical training and expertise.

> *"There is substantial evidence that cannabis is an effective treatment for chronic pain in adults… [The] use of cannabis for the treatment of pain is supported by well-controlled clinical trials."*
>
> — National Academies of Sciences, Engineering, and Medicine, 2017

Texas should also replace its current "prescription" language with wording that reflects the fact that patients must receive "recommendations" (and not "prescriptions") from their physicians. This would reduce confusion and bring Texas' law in line with all of the other effective state medical cannabis laws around the country. Most importantly, it would alleviate concerns among physicians who may currently be unwilling to authorize their patients' use of medical cannabis because they fear issuing a "prescription" would run afoul of federal law.

Allow Physicians to Determine Appropriate Product Forms and Dosages for Their Patients

Physicians have vast discretion when it comes to prescribing medications and determining dosages. While they are subject to regulatory oversight, they are generally able to direct their patients to use the products they believe will be safest and most effective, without interference from the government. But this is not the case with Texas' current medical cannabis program, which dramatically restricts the types of products that are available to patients and limits doctors' ability to prescribe or recommend what they believe to be the most effective forms or doses.

Texas and other states that have enacted similarly restrictive programs have encountered problems as a result. Most notably, they have failed to meet the needs of most individuals who could benefit from medical cannabis. For example, inhalable forms of medical cannabis, such as flower or extracts consumed via vaporization, are fast-acting and usually provide the quickest form of relief, which is extremely important for certain patients, such as those with seizure disorders. They also allow for easier titration. For example, a patient can inhale a small amount of vapor and know within one or two minutes whether they need to consume more to achieve the desired effect, whereas an oral tincture may take 30 minutes or longer to begin experiencing the effects. Strong restrictions on product types have also resulted in financially unstable programs due to extremely limited patient numbers. In Florida, a slow and measured expansion of product selection has improved patient access and helped ensure a financially stable medical cannabis market. Most of the other successful state medical cannabis programs also allow for more types of products.

Recommendations: To ensure patients can access the most effective treatment options, the Legislature should allow a wider variety of medical cannabis products and let physicians determine the most appropriate product form and dosage for each patient. Allowable product forms should include all types of orally and topically active products, as well as fast-acting inhalable formulations. All products should be subject to regulations, and physicians should be allowed to determine which product is most appropriate for each patient. Providing Texans with more options for treating their qualifying conditions will also

incentivize patients to participate in the state's program and obtain their medical cannabis from regulated dispensaries instead of the illicit market or other states' medical cannabis markets.

Limit THC Dispensation by Purchase Volume Rather Than Individual Product

Providing the most effective medical care requires that physicians be able to recommend a full range of medical cannabis products. Texas' current policy of limiting THC quantity per individual product does little to prevent abuse or reduce diversion, and it limits the array of medical products physicians can recommend to their patients. Especially those with qualifying conditions who may benefit most, or only, from specific ratios of cannabinoids. Further, the dispensation of medicine to patients is generally regulated by volume, not ingredient potency, which is typically determined by physicians, along with dosage.

Many states with successful medical cannabis programs apply THC restrictions based on purchase volume, and some have transitioned to this approach after failed experiments with limiting THC on individual products. In Iowa, for example, the Department of Public Health's Medical Cannabidiol Board determined its low-THC program was not adequately meeting patients' needs because its 3% THC limit on individual products "does not allow for effective tincture or vaporizable forms, both of which enable more precise dosing by the patient." Its review of the current medical literature provided "convincing evidence of benefit from medical cannabis for various conditions with THC doses up to 30 milligrams (mg) per day (which is 2.7 grams (g) of THC per 90-day period)."[5] The Board recommended and the Legislature agreed to remove the 3% THC limit on individual products and instead restrict patient purchases to no more than 4.5 grams of THC per 90 days.

> *"[Iowa's] current 3% THC limit does not allow for effective tincture or vaporizable forms, both of which enable more precise dosing by the patient."*
>
> — Iowa Medical Cannabidiol Board Annual Report to the General Assembly, 2019

Recommendations: The Legislature should enact a policy change similar to the one embraced by policymakers and regulators in Iowa. Specifically, it should remove the current THC limit of 0.5% per product and establish a new THC limit based on total purchase volume (stated in grams instead of percentage of THC). This will improve physicians' ability to effectively address the specific needs of their patients, especially those who medically require higher concentrations of THC and/or benefit from lower frequency of administration. It will also increase controls over the volume of potentially intoxicating products patients could purchase.

Embrace Market Competition by Licensing Additional Operators and Expanding License Types

Texas continues to lag other states in providing its residents with compassionate access to medical cannabis. Low-THC products are expensive, selection is limited, and they can only be accessed by an extremely limited number of patients from a small number of providers. A review of medical cannabis programs around the nation finds that states are best able to meet the needs of patients when they have at least one dispensary for every 100,000 residents, geographically dispersed based on population.[6] Texas currently has only three licensed dispensaries, or one for every 9.7 million residents, and the existing operators may struggle to remain viable due to the small size of the current patient base (currently just 0.01% of state residents). The lack of competition is likely contributing to higher prices for patients and reducing the incentive for businesses to develop wider selections of products or new and potentially more effective and/or efficient products. The three existing dispensaries are also vertically integrated, limiting them to providing only

products they produce themselves. Diversifying licensing opportunities — e.g., offering licenses specifically for product manufacturing and/or testing — allows companies to specialize in one aspect of the supply chain, which fosters new product development and a wider variety of products available to patients.

> ***Recommendations:*** To ensure an operable program and best meet the needs of patients, the Legislature should embrace the competitive economic factors it applies to other industries. In addition to removing unnecessary bureaucratic red tape, it should require DPS to license additional medical cannabis operators and expand the types of licenses available. Specifically, it should establish new license classes that allow entrepreneurs to specialize in cultivation, manufacturing, testing, or sales. Rather than setting a statewide cap on the number of licenses available, the state should base licensing availability on patient needs and other market factors. This will ensure adequate access across geographic areas, and it will discourage monopolistic practices that drive up prices.

Potential Size of the Texas Medical Cannabis Market

The regulated medical cannabis market in Texas is significantly smaller than in many other states with medical cannabis programs. As previously discussed, (1) its limited qualifying conditions significantly restrict patient access; (2) it has just three medical cannabis dispensaries; and (3) patients who do have access to the program are significantly limited in the products they can purchase. As a result, just 2,892 of the states' approximately 29 million residents have registered as patients, resulting in a patient-to-population ratio that is more than 100 times smaller than most other states with medical cannabis programs.

Fewer than 3,000 of Texas' approximately 29 million residents are currently registered for the TCUP — a patient-to-population ratio more than 100 times smaller than most other states with medical cannabis programs.

If Texas lawmakers adopt the policy recommendations offered in this paper, participation in the Texas medical cannabis program would increase significantly, resulting in substantial growth of the state's regulated medical cannabis market. To determine the potential growth, we conducted a comparative analysis between Texas and other states with medical cannabis laws that reflect our recommendations.

We used five criteria to determine which states to use for this comparison:

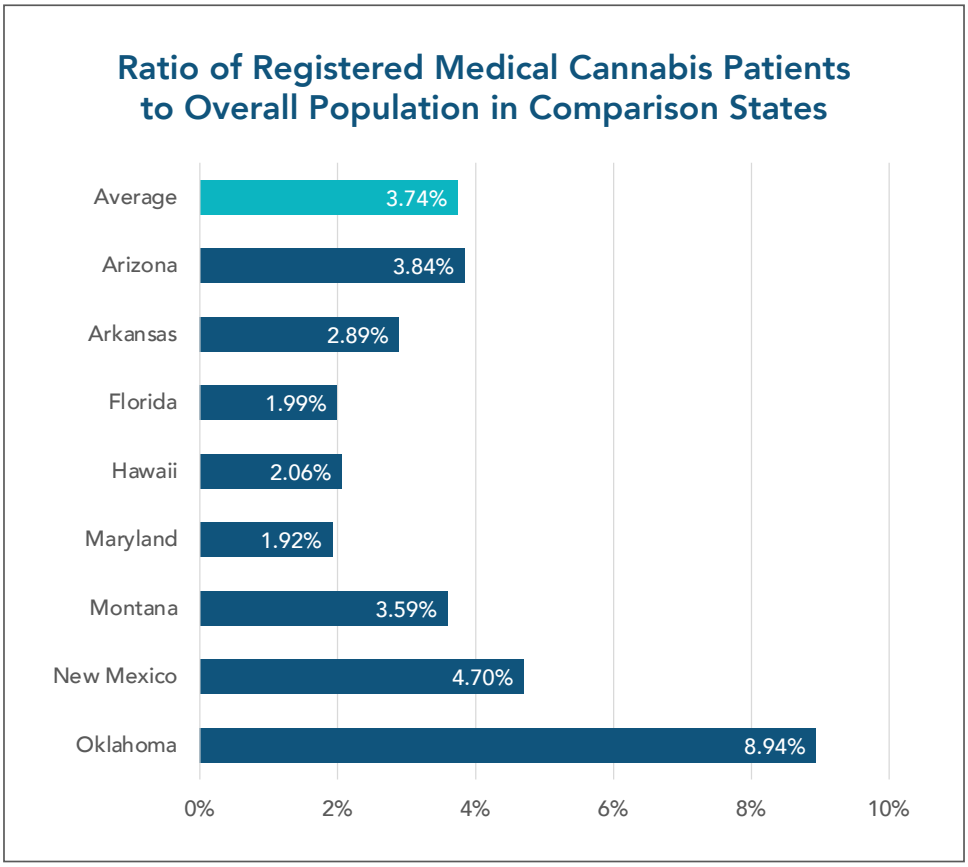
1. The state permits cannabis only for medical use (i.e., it has not also legalized for broader adult use at the time of this analysis).
2. Physicians may recommend medical cannabis for a broad range of debilitating conditions and symptoms for which cannabis is known to be a safe and effective treatment.
3. Regulations do not place arbitrary limitations on THC levels in individual products.
4. Patients have been able to register for at least two years.
5. The state has at least one dispensary for every 100,000 residents.

Eight states meet these criteria — Arizona, Arkansas, Florida, Hawaii, Maryland, Montana, New Mexico, and Oklahoma — and an analysis of these comparison states offers an approximate snapshot of what the Texas medical cannabis market could look like if the state enacts the policy changes proposed in this paper.

Patients

Patient-to-population ratios in the eight comparison states range from 1.92% in Maryland to 8.94% in Oklahoma, with an average patient-to-population ratio of 3.74%, compared to just 0.01% in Texas. If the Texas Legislature adopts the policy recommendations discussed in this paper, the TCUP would grow from 2,892 participating patients to an estimated 1,084,906 participating patients.

In other words, there are likely more than one million Texas residents with debilitating medical conditions who would be able to benefit from medical cannabis if they lived in one of the comparison states but are not currently allowed to participate in the TCUP.

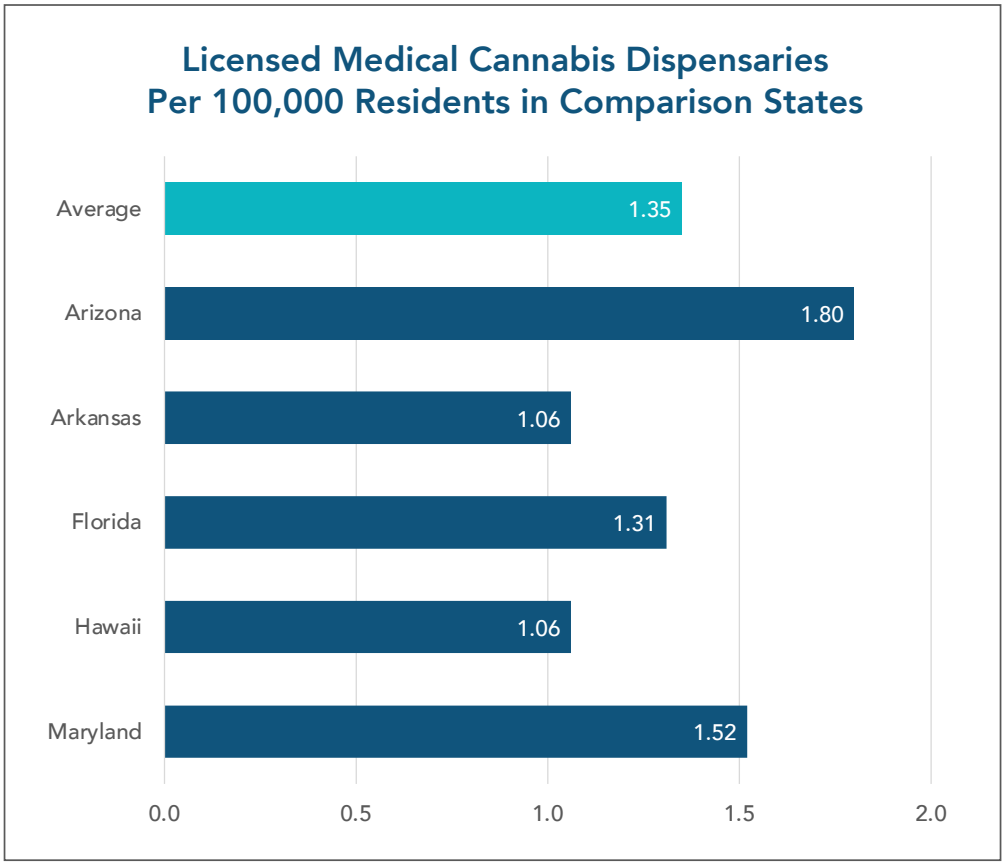


Licensees

Texas currently has only three licensed medical cannabis dispensaries. If it follows the policy recommendations discussed earlier in this paper, the state will need to issue additional licenses to meet the needs of the expanded patient population. To calculate the number of dispensaries needed to serve that estimated population (approximately 1.08 million patients), this analysis considers the number of dispensaries per 100,000 residents in the eight comparison states. While each of these states meets the previously discussed criteria for comparison, they vary with respect to their numbers of licensed medical

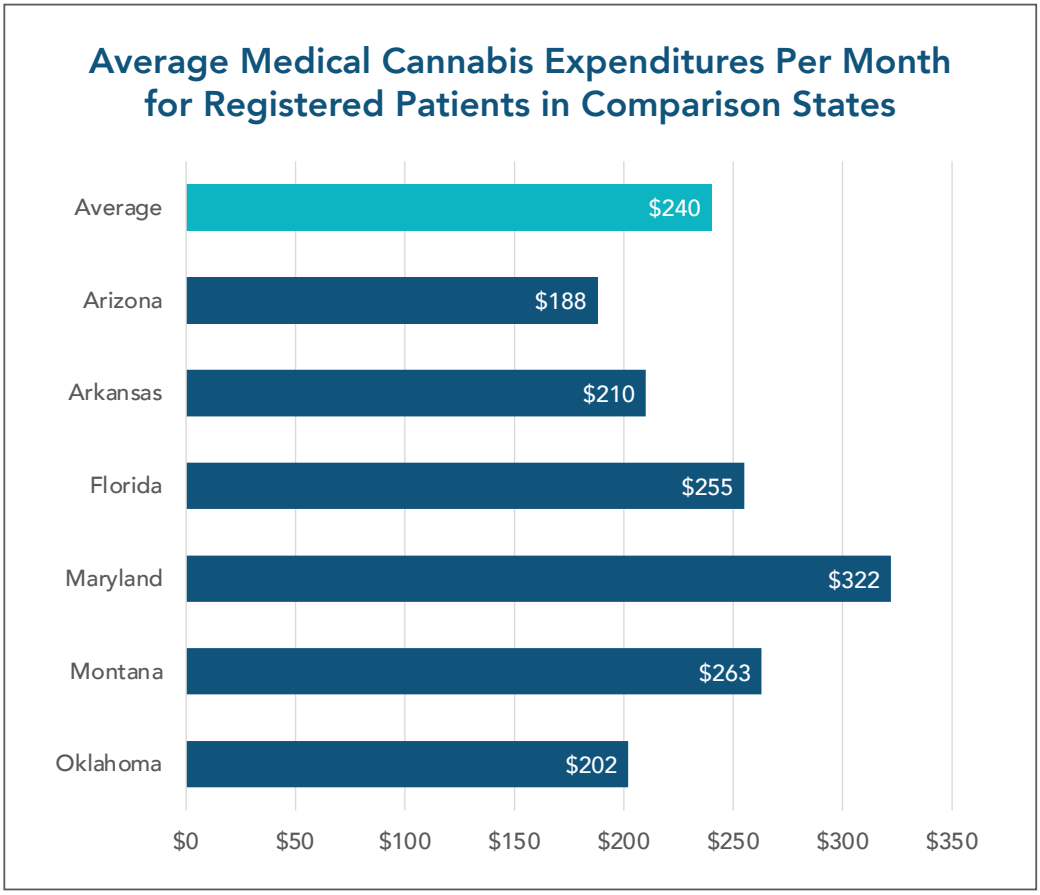
cannabis dispensaries and the degree of competition between licensees. As such, this analysis seeks to determine the *minimum* number of medical cannabis access points required to meet patient demand.

In five of the eight comparison states — Arizona, Arkansas, Florida, Hawaii, and Maryland — the number of dispensaries varied between 1-2 per 100,000 residents. Montana, New Mexico, and Oklahoma have many more dispensaries (33.96, 5.2, and 50.62 per 100,000 residents, respectively), so they were excluded for the purpose of identifying the lower-bound average for the minimum number of dispensaries required to meet demand. For the five remaining comparison states, this lower-bound average is 1.35 dispensaries per 100,000 residents. If Texas follows the policy recommendations discussed earlier in this paper, it should license at least 392 dispensaries to meet the needs of its expanded patient population.



Sales

To estimate total medical cannabis sales in an expanded Texas medical cannabis market, this analysis utilizes current patient registration rates and projected 2020 sales in the comparison states where sufficient sales and pricing data are available. This data is not available in Hawaii and New Mexico. In the remaining six comparison states, average monthly patient expenditures on medical cannabis in 2020 ranged from $188 in Arizona to $322 in Maryland, with an overall average of $240 per patient per month in the six states. If Texas follows the previously discussed policy recommendations and patient registration reaches 3.74% of the population, medical cannabis sales would reach an estimated $3.13 billion per year.



Additional Considerations

In addition to improving treatment access and improving the economic stability of the existing program and dispensaries, expanding the TCUP would likely result in additional fiscal and public health benefits, including, but not limited to:

Criminal Justice Savings

Texas prosecutors had 109,487 active misdemeanor cannabis possession cases on their dockets in 2019.[7] Texas law enforcement officers reportedly spend an average of four hours per cannabis arrest, which means they spent approximately 437,948 hours enforcing cannabis possession laws.[8] According to an analysis performed earlier this year, the state could save an estimated $311 million per year in criminal justice costs and allow law enforcement officials to spend significantly more time addressing other priorities if Texas legalized cannabis for adult use.[9] Expanding the medical cannabis program would not reduce arrests and prosecutions at nearly the same rate as such broader reform, but criminal justice savings would accumulate over time if legal protections were extended to more than one million new medical cannabis patients.

Medicare and Medicaid Savings

A growing body of research has demonstrated legalizing medical cannabis generates state public health savings on prescription drug coverage as part of Medicaid and Medicare Part D. In two separate, peer-reviewed articles published in *Health Affairs* in 2016 and 2017, researchers concluded that medical cannabis laws generate savings for states as patients substitute medical cannabis for government-subsidized prescription drugs. Specifically, they reported that both program and enrollee spending in Medicare Part D fell by $104.5 million in 2010 and that cost savings had risen to $165.2 million by 2013.[10] For Medicaid, total savings across states with medical laws ranged from $260.8 million in 2007 to $475.8 million in 2014.[11] If Texas further expands the TCUP to include more qualifying conditions and better patient access and treatment options, it could see substantially greater savings than it may currently be experiencing.

Reduction in Prescription Opioid Use, Abuse and Deaths

In 2017, after reviewing more than 10,000 peer-reviewed scientific abstracts published from 1999-2016, the National Academies of Sciences, Engineering, and Medicine confirmed there is conclusive or substantial evidence that cannabis is an effective treatment for chronic pain in adults.[12] A growing body of research shows medical cannabis is a substitute for more dangerous prescription painkillers, and by allowing patients to use cannabis instead of opioids, states have seen reductions in opioid use and related public health problems.

> *"Our findings suggest that providing broader access to medical marijuana may have the potential benefit of reducing abuse of highly addictive painkillers."*
>
> — National Bureau of Economic Research, 2015

A study published by the Journal of Pain in 2016 concluded cannabis use was associated with a 64% decrease in opioid use, decreased side effects of medications, and an improved quality of life.[13] Later that year, the Clinical Journal of Pain published the findings of a clinical trial involving a group of 176 chronic pain patients, which found a 44% decrease in opioid consumption and improved symptoms after just six months of treatment with cannabis.[14] In April 2017, the Journal of Psychopharmacology published a study that found more than three-quarters of regular opioid users reduced their use after they started using cannabis.[15] A study published in the journal Drug and Alcohol Dependence that same month arrived at similar findings, including 23% and 13% reductions in hospitalizations related to opioid dependence or abuse and opioid pain reliever overdose, respectively.[16] Research published by JAMA Internal Medicine in 2014 found, "States with medical cannabis laws had a 24.8% lower mean annual opioid overdose mortality rate compared with states without medical cannabis laws," and it grows to 33% lower within six years.[17]

In 2015, the National Bureau of Economic Research published a report that highlighted the benefit of not only making medical cannabis legal, but making it accessible via regulated dispensaries. It found relative decreases in both opioid addictions and overdose deaths in states with medical cannabis dispensaries compared to states without them, noting that the findings suggest "providing broader access to medical marijuana may have the potential benefit of reducing abuse of highly addictive painkillers."[18]

If Texas follows the recommendations for expanding qualifying conditions for medical cannabis and improving access by allowing for more points of distribution, it could experience a significant reduction in opioid usage, dependence and mortality rates.

Citations

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About Vicente Sederberg LLP

Vicente Sederberg LLP is a top-ranked national cannabis law and policy firm with offices in Austin, Boston, Denver, Jacksonville, Los Angeles, and New York. It has been at the leading edge of cannabis policy since its founding in 2010, helping public and private sector clients evaluate, shape, implement, and navigate cannabis laws and regulations across the U.S. and around the world.

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