

Municipal Dispensary License Allocation: Florida¹

Economic and Social Considerations

Synopsis: This report describes the benefits and costs that should be considered by Florida’s city and county planners as they prepare their cannabis dispensary licensing rules. As cannabis policy and planning experts, the Marijuana Policy Group makes the following recommendations:

- *Phased Approach:* Based upon past experience, municipalities should use an incremental approach to issuing dispensary licenses. This mitigates the cost of early-stage errors in license criteria and processing. In general, it is easier for authorities to issue additional licenses over time, than to revoke licenses from previously issued licensees.
- *Optimal Number of Dispensaries:* The optimal number of dispensaries depends upon the number of patients likely to register, the local area population, and the required scale of operation for dispensaries to remain profitable. The average resident ratio among similar states (with laws similar to Amendment 2) is one dispensary per 67,222 residents (1:67,222). This ratio is found to be “optimal” by the MPG for cities and counties in Florida.
- *Risks of Unprofitable Dispensaries:* Unlike conventional business, cannabis business failure creates risks because the product is still prohibited by federal law. Small and struggling cannabis entities are more likely to sell (or “divert”) into illegal markets (e.g., minors and out-of-state smuggling). For example, struggling entities can utilize their license to legally cultivate or purchase cannabis, and then re-sell to illegal markets, if they cannot survive in Florida’s legal market.
- *The Minimum Effective Scale Ratio:* As a second rational approach to setting standards for dispensary numbers, it is helpful to note that the minimum effective scale for a dispensary is approximately 600 patients. Under Amendment 2, the minimum population-to-patient ratio in Florida should be *no more* than one dispensary for each fifty-thousand residents (1:50,000) with the optimal ratio at 1:67,222.
- *The Failure Rate:* The percentage of companies expected to become unprofitable in the regulated market is 61% if the allocation ratio is 1:30,000. Expected failures decline to 32% if the ratio is 1:50,000, and to only 13% if the ratio is 1:67,222.

¹ The Marijuana Policy Group (MPG) is a Denver-based economics and policy consulting firm dedicated to cannabis economics and policy. This memo provides a quantitative assessment of the benefits and challenges related to cannabis dispensary permitting and licensing. The MPG is nationally recognized for its role in shaping the Colorado regulated cannabis market. Since 2014, the MPG has served as the lead cannabis economist for the State of Colorado, providing detailed market and economic analysis that informs state legislators and policymakers. MPG experts have also advised private sector clients for location, investment, and operations – this experience helps the MPG to bring private-sector understanding into the public-policy forum in an articulate manner. The MPG now operates in 13 states and two foreign countries.

- *Upper-Bound Sales:* The MPG finds no evidence to indicate an upper-boundary on the ability of dispensaries to service or supply customers. Single storefronts in Washington State, for example, were serving as many as 6,000 patrons in July 2016. It is therefore unlikely that a dispensary would experience “too many” patients to service.
- *Cole Memo Compliance:* Florida regulators should respect the priorities stated in the United States Department of Justice’s 2013 Cole Memorandum. This memorandum outlines the position of the federal government, and the conditions under which federal authorities will allow state-level rule on cannabis possession. Two of the eight priorities in the Cole Memorandum are to mitigate diversion to minors, and mitigate diversion out of the state. Proper allocation of licenses should be designed to ensure that licensees will remain compliant with state laws, and with federal guidelines.
- *Inexperienced Operators:* Due to increased risks associated with dispensary failures, regulators should prioritize license applicants who have demonstrated the ability to operate a successful cannabis business in the past.

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Background

Florida’s medical cannabis program is changing rapidly. The passage of Amendment 2 in November 2016 will increase substantially the size and scope of the program. This ballot measure represents the latest of three measures which altered the state’s approach to medical cannabis.

Program Evolution: 2014-2016

Under the *Compassionate Medical Cannabis Act*, passed in 2014, the Legislature permitted low-THC/high CBD, non-smokable cannabis to be dispensed and utilized for the treatment of a handful of medical conditions. However, due to the legal restrictions, limiting access and prescriptions, and by forbidding smokable products, few patients have chosen to obtain medical cannabis through legal channels.

On March 25, 2016, Florida Governor Rick Scott signed House Bill 307 into law. This law expanded access to medical cannabis, including high-THC products as an efficacious treatment for patients with terminal illnesses. The state has licensed six medical cannabis dispensing organizations, which are vertically integrated and authorized to cultivate, manufacture, and sell medical cannabis. However, the program remains nascent; as of August, 2016, the Florida Department of Health has just 87 registered cannabis patients.

The passage of Amendment 2 is likely to expand significantly the number of registered patients and potential dispensaries seeking to serve such patients. State and local authorities must prepare themselves for an onslaught of medical cannabis dispensary applications. Under current law (section 381.986(8)(b), Florida Statutes), each county and municipality is authorized to implement rules and regulations for permitting of retail cannabis dispensaries. The statute specifies that such regulations should be reasonable and tailored to protect the public health, safety, and welfare. Most city or county managers have not faced such a decision, and are uncertain how many dispensaries to permit in a certain locality. This document is designed to help these authorities to understand what has been done elsewhere, and what to expect if too many or too few dispensaries are permitted in specific localities.

State-Level Licensing and Restrictiveness

The MPG collected state-level medical cannabis program data for 22 states where some form of medical cannabis is allowed. Each state chose a regulatory system that is influenced by local sentimentality toward cannabis. Despite the disparity among different state and county rules, most impose restrictions on medical cannabis programs through 1) Limitations on the scope of medical conditions treatable using medical cannabis and the medical prescription (“recommendation”) process; and 2) Rules to limiting dispensary numbers.

Restrictions on Condition Types – and the Capture Rate

Certain states restrict use by limiting the types of conditions that are allowed to be treated using cannabis. Illinois, for example, has such restrictive conditions that there are only 7,000 approved medical cannabis patients, in a state with 12.8 million residents. The corresponding patient to population ratio – called the “Capture Rate” – is therefore just 5 people per 10,000, or 0.05%.

Most states have fewer restrictions on allowed medical conditions, and higher Capture Rates, than Illinois. Colorado, Maine, and Oregon allow most types of conditions, including “chronic pain,” to be recommended for treatment using cannabis. As a result, these states have much higher capture rates. The rate in Colorado is 1.94%, in Oregon, it is 1.83%, and in Maine it is 3.42%, the highest in the dataset. Table 1 provides a listing for selected states (22 different states where information was available), of the current patient count, compared to the resident population, to provide a *capture rate* for each state program.

Table 1: Medical Cannabis State Populations and Eligible Patient Populations, based upon allowed medical conditions for medical cannabis.

State	State population (2015)	Patient numbers	Current through	Capture Ratio
Maine	1,329,328	45,520	6/16/2016	3.42%
Michigan	9,922,576	203,889	6/18/2016	2.05%
Colorado	5,456,574	106,066	5/31/2016	1.94%
California	39,144,818	715,133	6/16/2016	1.83%
Oregon	4,028,977	73,605	6/6/2016	1.83%
Arizona	6,828,065	97,938	5/27/16	1.43%
Rhode Island	1,056,298	14,459	6/15/2016	1.37%
Montana	1,032,949	13,288	5/31/2016	1.29%
New Mexico	2,085,109	24,902	6/3/2016	1.19%
Hawaii	1,431,603	14,074	6/1/2016	0.98%
Nevada	2,890,845	18,599	5/31/2016	0.64%
D.C.	672,228	3,707	6/3/2016	0.55%
Vermont	626,042	2,936	6/27/2016	0.47%
Massachusetts	6,794,422	25,980	5/31/2016	0.38%
Connecticut	3,590,886	10,861	6/12/2016	0.30%
Delaware	945,934	1,490	6/15/2016	0.16%
Alaska	738,432	1,071	5/31/2016	0.15%
New Jersey	8,958,013	7,956	6/15/2016	0.09%
New Hampshire	1,330,608	780	7/1/2016	0.06%
Illinois	12,859,995	7,000	6/1/2016	0.05%
Minnesota	5,489,594	1,486	6/10/2016	0.03%
New York	19,795,791	4,688	6/9/2016	0.02%
Average:				0.92%

Source: MPG Calculations based upon publically-available state patient and population data. Patient data was sourced from the Marijuana Policy Project.

Florida State Estimated Capture Rates

Under HB 307/SB 460

Although HB 307/SB 460 has added access medical cannabis for the terminally ill, it is estimated that the patient-count will remain low given the restrictions that remain. Based upon the new regulations, the MPG estimates that the state’s patient Capture Rate will grow from current levels to approximately 12,000 patients.

The most binding constraints to access include the low-THC requirement for several of the qualifying conditions, difficulty for doctors to legally recommend the drug, and a cumbersome / costly path to become a registered cannabis patient. In total, the MPG estimates the Capture Rate under existing legislation to be approximately six-tenths of one percent (0.06%).

Under Amendment 2

Upon passage of Amendment 2, the number of eligible conditions will expand to include more prevalent indications, and the use of high-THC, smokable products would be allowed, making the Florida law similar to laws in approximately 7 other states.

Using these states for guidance, the MPG constructed an estimated capture rate for Florida. The estimated capture rate for the state under Amendment 2 is 1.21%. The results are shown below, in Table 2.

Table 2: Florida-Specific Patient Population - Based upon MPG Estimated Capture Rates

Florida Estimated Patient Population	
Sample Average	0.92%
Average (Programs similar to Florida):	1.21%
Florida Population (2015)	20,271,272
<i>Estimated Florida Patient Count:</i>	
Using Sample Average (0.92%)	186,575
Using Similar Program Ave (1.21%)	244,472
Using Upper Bound (2.2%)	445,968

Source: MPG Calculations

While the overall sample average capture rate was 0.92%, the average for states who have deployed a program that is *similar* to Florida’s, is 1.21%. This higher rate reflects the exclusion of certain highly-restrictive states (e.g., New Jersey, New York, and Illinois).

Dispensary License Allocations

The passage of Amendment 2 will lead to an onslaught of cannabis dispensary applications, and city and county planners must be prepared to handle such applications. Cannabis dispensaries and storefronts are perceived by many planners to carry increased risks compared to typical merchandise stores. These stores sell products that are prohibited under federal law, and they tend to hold large quantities of cash and high-value products. Accordingly, these stores can become burdensome on law enforcement resources. Additionally, community leaders in other states have expressed concern that numerous

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cannabis dispensaries increase the risk of blight and may reduce property values for neighboring communities.

In order to mitigate these risks and the burden on law enforcement, state and municipal authorities have placed limitations upon the number of dispensary operations in a given area. The first and most common limitation is population-based, where a fixed number dispensary licenses are allowed within a specific population center.

Experience from Other Industries

Rationing and allocation of licenses to certain types of private businesses is not new. Certain states with a more pious outlook continue to limit liquor store licensees. Utah, for example, limits storefronts to 1:44,000 residents.² Other regional limits are often requested by private business due to high startup costs. Hospital developers require a setback that limits competition for a period of time – in order to ensure they can survive and provide medical services. Pure public goods, such as fire stations and parks, are allocated to meet community needs, while balancing the costs and benefits of additional service outlets.

Cannabis dispensaries are privately-funded entities that provide services to a specific population segment. Therefore, the benefits of increased access to these entities is balanced against the potential costs of having too many outlets and subsequent failing businesses (along with considerations for the health, safety, and wellbeing of the public including increased risk of crime and burdens on law enforcement). While zoning rules can help to navigate the location of these entities, the number of entities can be directly controlled through license allocations.

Experience from Other States

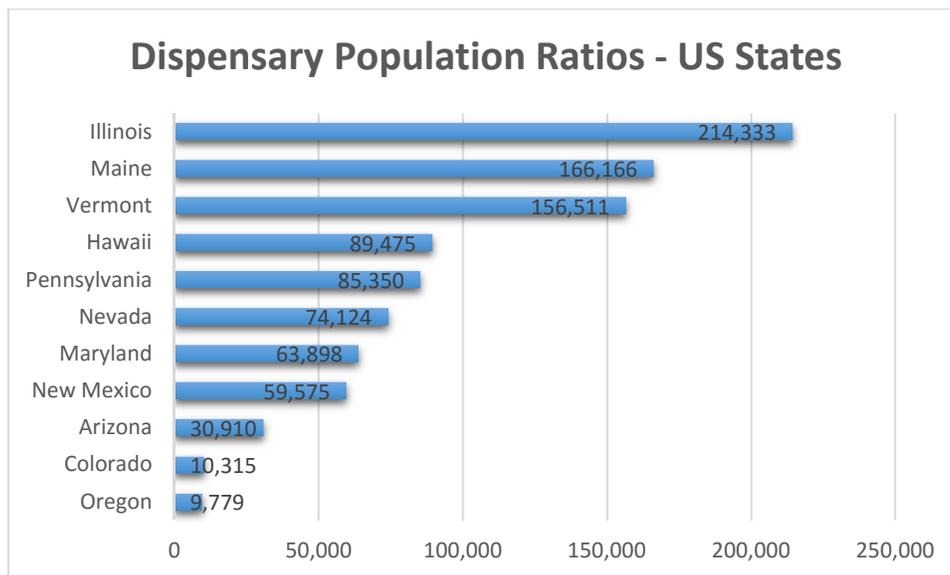
Of the 22 states from which MPG collected data, three states place no explicit limit upon the number of dispensing licenses: Colorado, New Mexico, and Oregon. Colorado and Oregon provide licenses to any applicant who can meet the qualifications to be an operator, while New Mexico takes into consideration the need for additional dispensaries on an annual basis. Since two of these states have legalized cannabis for anyone over 21 years of age, their policies should be viewed differently from states with medical programs only.

Among medical-only states, there is a gap between two types of dispensary allowances. Many states have systems that allow 1 dispensary for every 60,000 to 80,000 residents. The MPG compared these states with the program in Florida outlined in Amendment 2 – the most similar states are Arizona, New Mexico, Maryland, Nevada, Pennsylvania, and Hawaii. Those states had an average of 67,222 residents per dispensary. See Figure 0-1 below, for a graphical depiction of dispensary ratios.

² Most state have liquor store ratios that average 1 for every 3,000 residents.

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Figure 0-1: Ratio of State Resident Population to Cannabis Dispensaries for Selected US States (2015/2016)



Source: MPG Calculations based upon publically-available state patient and population data.

Two states stand out for the extremely “low” population to dispensary ratios: Colorado and Oregon. However these ratios can be misleading because most of these licensees are allowed to sell recreational (adult-use) cannabis from the same location.³ The ability to sell adult-use as well as medical cannabis means that these locations are not relying solely upon patients to sustain their business, as dispensaries in medical-only states do.

Case of Oregon Dispensaries

The history of Oregon’s medical program offers some insights as a medical-only state that converted into an adult-use state. In Oregon, no *a-priori* limit was placed on dispensary licensing. As a result, the industry faced a “boom/bust” scenario.

In 2014 and 2015, some Oregon towns incurred periods of under-supply, and then over-supply, eventually leading to dispensary failures.⁴ In 2015, pre-existing dispensaries benefitted by an interim law passed by the Oregon legislature, allowing medical dispensaries to sell cannabis to any adult over 21 years of age. At the same time, no recreational retail licenses were issued, giving pre-existing dispensaries exclusive rights to sell recreational cannabis to adults. Starting in January 2017, medical dispensaries must choose whether to sell exclusively to recreational or medical markets.

According to an article by the *Guardian*, Southeast Portland had approximately 12,000 medical card holders, and 136 medical dispensaries during calendar year 2015. This meant there were just 88 patients per dispensary, on average – leading to closures, license transfers, and product diversion. After October 2015, many dispensaries were revived, as their client base was expanded to any adult over 21 years of

³ Stores and dispensaries are allowed to sell both products, so long as the area can be easily distinguished between medical and recreational retail. Most stores have a large orange line down the floor to indicate each section.

⁴ See for example: <https://www.theguardian.com/us-news/2015/nov/21/oregon-cannabis-legalization-medical-marijuana-dying-market>.

age. In general, the Oregon program is perceived as one that was fraught with uncertainty, leading to general discontent among industry members.

Dispensary Economics – Minimum Effective Scale

The Marijuana Policy Group has unique access to operating information for small and large vendors, both for medical and adult-use markets. The MPG can utilize their unique experience and insights to calculate – in a clear way – the so-called “minimum effective scale” required to sustain a medical cannabis operation. Clearly, cities and the state wish to have a well-organized and functional dispensary system, one that does not create negative incentives for failing operators.

Approach: We use the State of Florida capture rate that was estimated above (1.21%) to illustrate some basic economics related to the dispensary licensees – and to compute the share of “failing” dispensaries under different scenarios. We find that in Florida under Amendment 2, the minimum effective scale is one dispensary for every 50,000 residents. However, given the risk associated with failing dispensaries, the “optimal” ratios is one dispensary for every 67,222 residents.

If the estimated capture rate is used, then on average, each dispensary would serve either 813 patients using the 1:67,222 ratio, or 605 patients using the 1:50,000 ratio.

Demand by Patients: Previous demand studies conducted by the MPG show that medical patients typically use cannabis on a near daily basis. Those consumers are estimated to demand 1.6 grams of flower (or its equivalent in non-flower products) per day of use.⁵ The average use rate is 29 days per month. Thus, total demand by weight for these customers is expected to be 1.6 g per day * 29 days per month = 44.6 grams of cannabis per month – or 1.66 ounces of cannabis per month.

The average price of medical cannabis flower in Colorado is \$5.05 per gram. Typically, medical cannabis is purchased in portions of 1 ounce at a time.⁶ If the dispensary ratios are 1:67,222, then a typical dispensary will serve 813 patients, and these dispensaries can be expected to have average revenues of approximately \$190,600 per month, under these assumptions.

On average, the cost of wholesale cannabis inputs account for 50% of total sales value (i.e., there is a 100% markup on product).⁷ Thus, net revenues on average would be approximately \$95,300 per month. While rent and payroll expenses can vary widely, we can make some basic assumptions in order to provide context and draw a line of profitability.

⁵ See “Market Size and Demand for Colorado” (2014), produced by MPG and commissioned by the Colorado Marijuana Enforcement Division. This study supplied a deep assessment of market demand (by weight) for cannabis flower. The study found that heavy users consume almost 3 times as much cannabis per day than irregular users.
<https://www.colorado.gov/pacific/sites/default/files/Market%20Size%20and%20Demand%20Study%2C%20July%2009%2C%202014%5B1%5D.pdf>

⁶ The price of illicit cannabis, according to “ThePriceofWeed.com” – a crowdsource site for product pricing, equals \$7.92 per gram for medium quality cannabis in Florida. This price is expected to decline, as it did in Colorado, under a regulated market.

⁷ The same logic applies to vertically-integrated firms, who grow and sell the product. These firms implicitly pay wholesale prices for their own cannabis, because they could have sold their product at the wholesale price. This is a well-known economic concept regarding implicit versus explicit pricing.

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Table 3: Example Accounting for Florida Dispensaries - by Population Ratio

Cost and Profits: Typical Dispensary Operation			
Assumptions / Estimates:	Minimum	Below Minimum	Optimal
Dispensary Ratio:	1:50,000	1:30,000	1:67,222
Patient Capture Rate:	1.21%	1.21%	1.21%
Number of Patients per Dispensary	605	363	813
Revenues and Costs:			
Total Estimated Revenues	\$142,008	\$85,205	\$190,921
Costs			
COGS (Cost of Goods Sold)	\$71,004	\$42,602	\$ 95,461
Rent (or imputed rent)	\$15,000	\$15,000	\$15,000
Payrolls (including payroll taxes & insurance)	\$25,000	\$15,000	\$30,000
Utilities, cleaning, internet and other basic services	\$5,000	\$5,000	\$5,000
Accounting, legal, consulting, and professional services	\$6,000	\$6,000	\$6,000
Total Estimated Costs:	\$122,004	\$83,602	\$151,461
EBITA (Earnings before Interest, Taxes, and Amortization)			
	\$ 20,004	\$1,602	\$39,461
Income Taxes (assuming 280E Compliance)	\$19,881	\$11,929	\$26,729
Income Taxes (under regular conditions)	\$5,601	\$449	\$11,049
Net Profit (Monthly)			
Under 280E	\$123	(\$10,326)	\$12,732
Under Regular Conditions	\$14,403	\$1,154	\$28,412

*Source: MPG Calculations based upon state captures rates and spending profiles.

Table 3 shows what a Florida state dispensary license holder can expect financially under various dispensary to population ratios. If there exists one dispensary for every 67,222 residents, then net profits after taxes (assuming the owner somehow maneuvers around certain applicable IRS regulations)⁸ are \$31,896 per month on average, or \$382,752 per year. Under Section 280E of the IRS Code, profits would be \$211,392 for the year.

In contrast, if the ratio were 1:30,000 – then the license holder would *lose* approximately \$120,000 under 280E, or earn just \$13,212 under normal operating conditions. Profits are “normal” compared to the at-risk capital if the ratio is 1:50,000. In this case, annual after-tax profits would be \$1,475 under Section 280E, and would be \$172,835 under regular business conditions.

⁸ Section 280E of the IRS Code prohibits cannabis vendors from claiming any expenses, except for the cost of the cannabis product itself. For more information see: <http://www.thedailybeast.com/articles/2016/02/18/feds-slap-70-tax-on-legal-marijuana-businesses.html>

These profit estimates do not include the initial cost of investment, called “at risk capital”. The initial investment expense to open a dispensary is expected to equal approximately \$200,000, depending upon the location, building, staff, and licensing process.

Dispensary Failure Rates Under Three Scenarios

Under an allocation ratio of 1:50,000 residents, the MPG estimates that approximately 32% of the licensees will struggle or become unprofitable, and would present increased risks for enforcement and regulators. An allocation closer to the average among MPG’s sample (1:67,222) results in slightly fewer dispensaries, as well as a higher success rate, effectively shifting the failure rate down from 32% to 13% (i.e. only 1 in 8 licensees fail). In contrast, if more licenses are permitted, then assuming the same capture rate, a higher share of those licensees must be failures, since the total spending on cannabis is effectively “capped” by the number of patients. For example, if a ratio of 1:30,000 is used, more than half of the licensees would be expected to fail or be in danger of failing. Under this regime, the average dispensary teeters between a gain of \$1,039 per month if they do not comply with 280E, or a loss of \$10,379 per month, if they comply. Only 39% of dispensaries are expected to be sustainable under this scenario, and 61% of dispensaries become “high risk” failing entities.

Table 4 below shows the relative number of dispensaries under different allocation schemes:

Table 4: Number of Dispensaries and Expected Failing Stores under different license allocation schemes.

Dispensary Failure Rate			
Population Ratio	Number of Dispensaries	Failure Rate	Number of Store Failures
1:30,000	676	61%	412
1:50,000	405	32%	130
1:67:222	302	13%	39

*Based upon 2015 Florida population, and MPG fail-rate estimates.

The expected failure rate is 61% under a 1:30,000 ratio. This rate falls to approximately one-third (32%) if fewer licenses are issued, to bring the dispensary population in-line with the state population (405 stores). Under this scenario, the number of failed stores falls from 412 to 130, for a 68% reduction in failed licensees. Under a ratio of 1:67,222, the failure rate falls to 13%, and the number of failed stores falls from 130 down to 39. The MPG believes that 1:67,222 provides an “optimal” balance between access of store locations and risks of store failures, given the estimated parameters for Florida, under passage of Amendment 2. It is also important to note that, because the six currently licensed organizations in Florida also offer statewide delivery, patients will have additional access to medicine (in addition to retail outlets). This suggests that rural and remote populations can still be served, in some manner, even when store density is not high.

Regulatory Risks from Failing Dispensaries

In general, the free market system is an effective mechanism that allocates resources to their best use. It rewards efficient operators and it eventually pushes inefficient or ineffective operators out of the market through closures or consolidation.

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The free market system works best for the sale and distribution of innocuous goods and services. But there are special risks and considerations when the market is a “Schedule 1” narcotic. Most of these risks are related to product *diversion and crime*. An itemized list of considerations is below:

- Struggling cannabis vendors have an incentive to divert sales to illegal markets if they cannot compete in the regulated market. In order to survive, struggling operators are more likely to allow sales to unauthorized users or to divert some of their products for sale outside of the region, or outside of the state (ex-state diversion).
- The diversion of cannabis to minors or to other states are listed as the Federal Government’s “priorities and concerns” in relation to the state-level sale and distribution of cannabis products. These concerns are prominently described in the 2013 “Cole Memorandum.”
- Struggling vendors are less likely to pay for laboratory testing, for proper packaging, and for proper safety standards in the workplace. Profitable operators have an incentive to maintain their good-standing with state licensing agents, and are more likely to maintain higher levels of safety, quality-control, packaging, and monitoring, compared to poorly-funded organizations.
- Tax compliance and promptness of payment for license fees are generally higher for well-funded and well-organized licensees, compared to struggling and near-bankrupt licensees.⁹ Near-bankrupt operators have “*less to lose*” compared to profitable enterprises, and therefore are therefore less likely to comply with the rules and regulations. This effect has been documented in studies of entrepreneurial behavior and attitudes among small-business owners.
- Until federal laws change, almost all cannabis dispensaries are cash-based operations. This raises the risk of crime and burglaries targeted toward dispensary locations. This, in turn, creates an incremental burden for local law enforcement and potential threats to public safety.

Summary

The passage of Amendment 2 will fundamentally alter Florida’s medical cannabis program. City and county planners throughout the state will be faced with a number of decisions that will ultimately determine the success of medical cannabis operations in their respective communities. This report is intended to assist government administrators as they begin to consider cannabis dispensary licensing rules. MPG’s recommendations, based on other medical cannabis states’ experiences and data-driven economic analysis, provides Florida municipalities with a targeted rulemaking framework that will enable a well-functioning medical cannabis market.

MPG’s calculated “optimal ratio” of one dispensary per 67,222 residents (1:67,222) has been customized to Florida’s specific patient population and regulatory structure. The ratio ensures that the majority of licensed medical cannabis dispensaries in Florida will have a sufficient medical patient customer base, based upon an estimated Capture Rate of 1.21%, to create a profitable business environment for licensed actors. Reducing the number of “at-risk” or failing medical cannabis licensees is imperative for creating a medical cannabis market that mitigates regulatory risk in the form of diversion and crime. The

⁹ See, for example: Kamleitner, et. al. (2012). “Tax Compliance of Small Business Owners: A Literature Review and Conceptual Framework,” *International Journal of Entrepreneurial Behavior & Research* 18(3):330-351.

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actions taken and rules enacted by city and county planners must be cautious, incremental, and should reflect the medical cannabis market unique to Florida, as the ultimate success or failure of the medical cannabis program is highly dependent upon the regulatory structure.