



Montana Cannabis Information Association

MTCIA

March 14, 2018

Interim Committee on Revenue and Transportation

Re: Medical Marijuana Program

Contact: Kate Cholewa, Government Relations

The regulatory model that is being implemented by DPHHS is not the regulatory model discussed over four months and passed by the people of Montana via the initiative in 2016 and the legislation passed by the 2017 legislature.

Situation simplified: the goals of the legislation and the goals of the department are not the same. The process for rolling out the law created by the initiative and legislation is a different process than how the department is choosing to roll it out.

Goals of the legislation: a program that is transparent, contained, functional, and safe. The process was methodical implementation and phase-in regulatory mechanisms. The initiative gave the department 8 months to put the regulatory mechanisms of the initiative in place, licensing and inspection. The legislation gave the department a year to institute tracking and testing. Licensing and inspections created the foundation for tracking and licensing.

Goals of the department: get something up and going by the April implementation date, which isn't to say they don't want it to be transparent, safe, etc. But wanting it to be and building it to be are two different things. Because the program and new law were neglected for a year, the effort since January is to do over a year's worth of work in 14 weeks. There's no methodical phase-in, which was for their sake as much as anyone in the program. **The primary regulatory mechanisms are not being implemented in a way that will make them serve the purpose they are supposed to serve.**

So, different goals and different ways of getting there. That means you're implementing something other than the model in the legislation and the medical marijuana program market in Montana is being structured by the bureaucracy in DPHHS.

I appreciate that the department is wanting to meet those implementation dates despite the neglect. But it's too late for timely. That clock got burned by a guy who's gone. The good news is structuring this program to meet the goals of the legislation can still be accomplished at an impressive timeline.

We appreciate the department's rush. The worker tasked with saving the day has been on for two and a half months. I believe this person can get this program up and going in an impressive timeline. But not in 14 weeks. You can't go from zero to a regulatory system for a novel industry and market in which every state has a different model in three months. I don't think that is a critical thing to say. I say, enable this competent person to succeed and thereby let the program succeed and the work of the legislature succeed.

Three Major Problems with the Implementation

Licensing by Square Footage/Canopy Tiers

The department has set production parameters at 10x more than what is needed to serve those in the program. This leads to overproduction, diversion, and price-fixing.

The legislation forwarded a square footage, or "canopy," licensing model to manage and measure production. The goal was to license by the amount of sq. footage cultivated, or by tiers of square footage.

Here's is how the department is implementing the canopy. They are allowing for 50 square feet per patient. Here's what that means. The allowance of 50 sq. ft per patient equates to a single provider with 1000 patients in Montana's medical market (of about 22,000 patients total) having twice the allowable cultivation space as a recreational cannabis grower in Washington in the highest licensed tier (meaning greatest amount of allowable square footage) serving a market of over a million customers. The highest tier in Washington allows for 30,000 square feet. A provider with 1000 patients in Montana is allowed 50,000 square feet. A provider in Montana with 200 patients with half her allowable sq. footage in flower producing at a below

average per sq. ft. is producing enough cannabis to serve 2,640 cardholders per month (see attachment).

So, a mechanism intended to contain production and prevent diversion and price manipulation is being implemented to facilitate those very things. This is our #1 concern.

Licensing Roll Out

Second, licensing is being rolled out in such a way that makes some providers accountable for following regulations up to 8 months before others, depending upon when one's current provider registration expires. This translates to tens of thousands of dollars one provider will have to expend while another has that money to invest in their business or "buy patients." It's costing one guy \$40,000 more than another and that other can use the \$40,000 he is saving to buy out the guy who must pay it and must go out of business as a result. So, someone loses their business not because they can't afford the mechanisms of regulation, but because they can't afford them when they get the down the street doesn't have to pay them, too.

(Speaking of licensing, provider licensing was required by the initiative (Nov 2016) and just getting initiated next month. Lab licenses were in the legislation that passed in April 2017. Labs had temporary licenses by July 1. Also, there was no RFP for the tracking system. We hear the department is currently putting out an RFP for a testing consultant.)

Testing

Attached you will find the MTCIA's response to the proposed rules in terms of needed regulation of the labs in order that the testing provision is meaningful. It's too expensive to be allowed to be snake oil or throw a monkey wrench into the entire program. A state license implies state sanction. It's a commitment to the people of Montana that the testing is giving people meaningful information.

But the rules came out without any performance standards for labs other than they be ISO certified within a year. But no standardization. There are no required turnaround times. No proficiency testing, which is available through a company called Emerald Scientific and one of Montana labs has done it on their own.

Testing is mandated for all as of April 10, although not everyone will be accountable for it due to the licensing implementation plan. But, as of April 10 an expensive slew of tests for every five lbs. or less produced by a harvest is mandated. Here's what we have to service that: 4 temporarily licensed labs of which only 2 are up and going.

The information we have provided since December 2016 stresses the importance of assuring this component works. We can learn from giant, well-publicized disasters in other states who have had their systems backed up for 3 months due to issues with testing labs. Being backed up in a recreational market is bad enough. It's not acceptable in a medical one.

(Interesting data: In February, it was reported at a conference in Denver that in California where recreational marijuana became available in January and whose regulatory systems are not yet all in place, the Department of Agriculture is conducting about 3700 pesticide tests a day on agricultural products (non-cannabis). The cannabis testing labs are doing 2000 tests per day. So, that's 2000 cannabis pesticide tests per day and 3700 pesticide tests on every other agricultural crop combined.)

The consequences of what I've mentioned here is bad policy for the state. Regulatory junk. A production model meant to limit and manage production is being implemented in such a way to create and enable overproduction, price fixing, and diversion. It provides no way to calculate production in the program. It has, literally, the opposite of its intended effect. The testing system is not validated. There are no performance standards. The regulatory mechanisms as being implemented don't achieve the purpose of the mechanism. That's regulatory junk. Rules divorced from a purpose.

My hope is that if the department hears from you that a methodical implementation that reflects the goals of the legislation is preferable to a trainwreck that meets a deadline, it will encourage a more deliberative implementation. The prediction of a trainwreck is not pessimistic. It's mechanistic. The canopy and testing issues alone make that clear.

The department has put so many pieces on the table on such a short timeline and we commend them for that. But, if it's not assembled correctly, the hurry becomes a waste of time. We believe a proper canopy model for licensing can be worked out in the space of a day or less. If the department takes two or three months to get people licensed and inspected, they may find they aren't going to be dealing with 600 providers when it comes to tracking and testing, which will make integrating those components all the smoother.

Licensing and inspecting is the groundwork of this program. Who are these providers? Who is invested in them? Are they growing medical marijuana under safe conditions? What's real out there and what isn't? People were licensed to make extractions who didn't even own extraction equipment. Labs that don't exist in the material world have licenses.

Organize the system. Who, what, where? Now, track the cannabis and test it. Given the regulatory elements of the initiative are late by almost a year, 2 – 3 months to avoid a trainwreck doesn't seem like a big ask. We're happy to help in any way we can.

Bottomline for avoiding the next catastrophe is fix the square footage licensing, create performance standards for the lab system, and don't hit the go button on a testing mandate when it's obvious the infrastructure isn't ready to support it.

Allowing for 50 Square Feet of Cultivation Space Per Patient

Under the department's rule of 50 sq. ft per patient, a provider with 200 cardholders/patients is permitted 10,000 sq. ft to cultivate. 10,000 is the highest tier in your table but by no means the highest number of sq. ft allowable in Montana. There are providers with more than 200 patients.

Let's say the provider with 200 patients has half of his/her space in flower: 5000 sq. ft. The studies say the average production is 42 grams per sq. ft. Let's say this grower is not that good and is only producing 30 grams per sq. ft. That's 150,000 grams per sq. ft (5000 x 30). If the provider is harvesting every 8 weeks, that's 75,000 (150,000/2) grams per month.

Producing 75,000 grams/mos., one is producing 165 lbs. (75,000/454) of cannabis per month.

Studies and anecdotal knowledge report average patient use at one ounce/mos. There are 16 oz in a pound. So, at an ounce per month, every pound serves 16 patients/mos.

Producing 165 lbs. per month, with each pound serving 16 cardholder/patients means 165 lbs. of production per month can serve (165 x 16) 2,640 cardholder/patients per month.

Summary: A grower with 10,000 sq. ft based on 200 patients at 50 sq. ft per patient is producing enough cannabis in half their space to serve 2,640 patients per month.

Math review:

30 gr/sq. ft at 5000 sq. ft = 150,000 grams every 8 weeks (2 months)

If it is 150,000 every 2 mos., it is 75,000/mos. (150,000/2=75,000)

There is 454 grams per lb.

75,000/454= 165 lbs.

Every month, the provider is producing 165 lbs. from 5000 sq. ft.

1 lb. serves 16 patients

165 x 16= 2,640

165 lbs. per month serves 2,640 patients per month.

When the proposed rule of 50 sq. ft per patient was put out for comment, the MTCIA provided the following:

Canopy

As canopy was discussed over the course of the legislature, it was in terms of providers being licensed by how much square footage one was cultivating. It also involved separating production from patient numbers. Licensing by square footage would have allowed the state to know the cap on how much cannabis was being cultivated by the program or by an individual provider.

The formula for determining canopy that comes from the two studies was provided throughout the legislative process and to the department on several occasions. In fact, the materials provided to legislators was provided to the department in December 2016 as a “heads up” as to what we were pursuing for the medical marijuana program. I have included the provided studies and formulas as an appendix, if you are interested in revisiting the material.

The summary of the studies is that average use whether medical or recreational is .07 gram per day per person, though this is often rounded to an ounce a month. A square foot of canopy produces about 40 grams per harvest. Every square foot has 4-6 harvests per year. This is the basic formula for determining statewide canopy needs and individual provider needs. The formula allows an accurate measure of cannabis production in the program, as well as managing that production to avoid overproduction which leads to diversion.

The department uses the word “canopy” in their rules, but rather than licensing by square footage using the provided formula, they chose to allow 50 sq. ft per patient.

This fails to address the goals of transparency and containment.

Problems with this version of implementing a canopy model include:

- Proposed canopy provision still has cultivation tied to patient numbers.
- The proposed canopy allowance provides for four times the cultivation area suggested by the two studies that exist for estimating square footage needs per customer demand.
- The allowance of 50 sq. ft per patient equates to a single provider with 1000 patients in Montana’s medical market (of about 22,000 patients total) having **twice the allowable cultivation space as a recreational cannabis grower in Washington in the highest licensed tier (meaning greatest amount of allowable square footage) serving a market of over a million customers.** The highest tier in Washington allows for 30,000 square feet. A provider with 1000 patients (MT has one) is allowed 50,000 square feet.

- Further, if the state doesn't know what percentage of the allowable square footage a given provider is cultivating, there is no way of calculating production within the program and the point of the canopy is lost.
- The 50 sq. ft per patient version of canopy results in overproduction, diversion, and collapsed prices.
- Shifting to a licensing by square footage model was forwarded to meet particular program goals, none of which are met by the version in the rules.

MTCIA Response to Proposed Rules Regarding Testing

We request the establishment of performance standards for marijuana testing labs and the lab system for the program which include:

- Licensed labs must turn around sample results within 7 work days. A licensed lab may not accept or retrieve samples they are unable to turnaround within the timeframe unless the testing is being done for private purposes and not for certification for sale.
- Lab licensees must submit to standardization monitoring by the department. Standardization will be monitored by the DPHHS Laboratory Division. The division will provide samples from the same test lot to each licensed marijuana testing lab and the hemp program within Department of Agriculture. If THC and/or CBD scores for samples from the same lot deviate by > than 10%, among 40% of the licensed medical marijuana testing labs and the Department of Agriculture, an audit must be conducted and testing mandate suspended until rectified.
- Marijuana testing labs needs to be certified by the state of Montana in addition to ISO certification.
- If the lab system is unable to meet turn around standards in a manner that assures the flow of product to patient cardholders, the state may offer cannabinoid profiling services through the Department of Agriculture's hemp program, and/or the testing mandate must be suspended if the lab system is unable to meet performance targets and in such a case all product must be labelled as untested.
- Licensed private testing labs shall undergo two unannounced audits per year.
- Upon completion of a beta test that the lab system can meet performance standards, the testing mandate shall become effective.
- All bulk discounts must be publicly advertised and cannot exceed 30%. A lab may not offer unadvertised discounts.

Appendix: Canopy Studies

The information below was provided throughout the legislative session and is part of the legislative record. The department also received this information.

Two studies have looked at how much canopy space is necessary to meet the needs of a population. Usage studies from 2013 in the Netherlands and 2016 in the U.S. found that medical marijuana users consumed 0.7 grams/day on average. The research in the Netherlands was conducted by Bedrocan. Bedrocan holds the government contract there to produce medical marijuana. BOTEK was contracted with by the Washington State Liquor and Cannabis Board (WSLCB) to conduct a study to find out how much cannabis needed to be produced in the state to meet demand. The BOTEK study also showed that indoor production allows for 4 – 6 harvests per year and the harvests produce approximately 40 grams per square foot. However, like other agricultural products, yields can vary due to controlled variables (cultivator choices), partial or complete crop failure, and random variation.

BOTEK's recommendation was to allow for double the canopy needed to meet demand. Given that ancillary space (facility space used for walkways and activities other than growing) may run half the size of the canopy space, 2/3 of a facility may be devoted to canopy. Two studies have looked at how much canopy space is necessary to meet the needs of a population. Usage studies from 2013 in the Netherlands and 2016 in the U.S. found that medical marijuana users consumed 0.7 grams/day on average. The research in the Netherlands was conducted by Bedrocan. Bedrocan holds the government contract there to produce medical marijuana. BOTEK was contracted with by the Washington State Liquor and Cannabis Board (WSLCB) to conduct a study to find out how much cannabis needed to be produced in the state to meet demand. The BOTEK study also showed that indoor production allows for 4 – 6 harvests per year and the harvests produce approximately 40 grams per square foot. However, like other agricultural products, yields can vary due to controlled variables (cultivator choices), partial or complete crop failure, and random variation.

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Under the canopy model, the DPHHS would license providers based on how much of the state canopy a provider applies to utilize. In Washington, there are three tiers representing different ranges (square footage) of utilization. If a provider applies to utilize a given measure of canopy, and that provider's application justifies the tier applied for and is approved, the provider must cultivate that amount of space.

This rule prevents the licensing of space that is unused, which can generate intentional shortages that drive up prices for patients and block other providers from canopy access. The canopy model combined with a tracking system also eliminates the need for the problematic limits on product on hand per patient. It does this in two ways. 1) The amount of cannabis in the system is managed instead by the canopy limit. 2) Tracking makes overproduction monitored, rather than diverted.

In sum, a tracking system combined with a rational statewide canopy limit dis-incentivizes over-production and creates obstacles to criminal activity.

The materials on canopy provided throughout the legislative session to legislators, the department, and bill drafters included:

A canopy-based volume management model would alter the current licensing fee structure. Rather than licensing based on patient numbers, licensing would be based on which “tier” a provider seeks a license for, each tier represents different ranges of square footage. As with the model in the initiative, the cost of licensing should support the administration of the program.

For more information, contact Kate Cholewa, MTCIA Government Relations, 406.459.4092