MONTANA DPHHS Healthy People. Healthy Communities. Department of Public Health & Human Services

Department of Public Health and Human Services

Director's Office ♦ PO Box 4210 ♦ Helena, MT 59620 ♦ (406) 444-5622 ♦ Fax: (406) 444-1970♦ www.dphhs.mt.gov

Steve Bullock, Governor

Sheila Hogan, Director

March 23, 2018

Senator Mary Caferro, Chair
Children, Families, Health and Human Services Interim Committee

RE: Response to RTIC Letter to Committee Regarding the Montana Medical Marijuana Program Implementation

Dear Chairwoman Caferro and Members of the Children, Families, Health and Human Services Interim Committee (CFHHS):

It is my understanding that you have received a recommendation from the Revenue and Transportation Interim Committee (RTIC) to object to the Department's adopted rules regarding the implementation of the Montana Medical Marijuana Program. The letter, dated March 16, 2018, contemplates objection under 2-4-406 MCA, which has certain requirements and constraints specific to:

- Notice and hearing requirements
- Emergency or temporary rules
- Requisites for validity -- authority, and statement of reasons

The Department contends that the rules adopted under MAR Notice 37-820 meet the requirements in the statue cited by RTIC, making objection under this statute inapplicable.

However, the Department recognizes that the RTIC letter states four specific concerns with the rules as adopted. Additionally, there was public testimony provided during the RTIC meeting that may raise additional questions. Finally, I've read Sue O'Connell's recent update to this committee regarding implementation, and note her analysis indicates there may be items still unaddressed by the Department. I'd like to take this opportunity to respond to these concerns, and provide an update on the actions taken by the Department to address them.

Grow Canopy Allowable Limits

SB333 "delinked" the number of registered patients from the number of mature plants, seedlings and amount of usable marijuana that providers could possess. Testimony provided to RTIC, and feedback received by the Department, further suggests that this delinking created an opportunity to design a tiered licensing structure that would set licensing fees, and establish maximum square footage of canopy, by the size of the grow canopy "tier". To increase canopy space, a provider would need to apply for an additional licensing tier. However, SB333 established a per patient licensing fee structure that conflicts with a true tier approach, leading the Department to establish rules that set canopy limits on a per patient basis.

In a provider site visit conducted on March 9, 2018, by regulatory officials, it became clear that the canopy space allowed by rule was more than what would be required to meet the needs of an individual patient. The provider visited was well below the established amount, and demonstrated clearly how a reduced canopy limit would still meet the needs of individual patients. The Department immediately began compiling alternatives to the 50-square foot maximum established in rule. Input on calculating the appropriate canopy limits provided by MTCIA, providers, and an independent, neutral cannabis consortium has been considered in the amended calculation analysis.

The Department has analyzed the ability to invoke the emergency rule process pursuant to 2-4-303 MCA. Given the high standards of immediate peril required by this statute, the Department will be filing rules on April 3, 2018, pursuant to our rulemaking authority in 50-46-344 MCA to reduce the amount of canopy per registered patient. The proposed rule will also amend the measurement of square footage to include "the total amount of square footage dedicated to live plant production at a registered premise consisting of the area of the floor, platform, or means of support or suspension of the plant". These rules will follow standard rulemaking processes, but will include language to make the change retroactive to April 10, 2018.

With the significantly reduced canopy space, amendment to the measurement of square footage, and the requirement to report recommended dosage per patient in the inventory tracking system, the Department is confident any over-production concerns have been addressed.

Scientific Standards for Testing Laboratories

The Department has adopted rules requiring labs to become ISO/IEC 17025 certified. This provides the requirements for the competence of testing and calibration laboratories, and is the main ISO standard used by testing and calibration laboratories. In most major countries, ISO/IEC 17025 is the standard for which most labs must hold accreditation to be deemed technically competent.

The ISO/IEC 17025 standard itself comprises five elements: Scope, Normative References, Terms and Definitions, Management Requirements and Technical Requirements. The two main sections in ISO/IEC 17025 are Management Requirements and Technical Requirements. Management requirements are primarily related to the operation and effectiveness of the quality management system within the laboratory. Technical requirements include factors which determine the correctness and reliability of the tests and calibrations performed in a laboratory.

Laboratories use ISO/IEC 17025 to implement a quality system aimed at improving their ability to consistently produce valid results. It is also the basis for accreditation from an accreditation body. Since the standard is about competence, accreditation is a formal recognition of a demonstration of that competence.

Two of the four labs currently holding temporary lab licenses in Montana have indicated they are ready to achieve ISO certification and will be able to comply with the rules as established. A copy of the ISO 17025 standards necessary to achieve accreditation are attached to this letter *[Attachment A]*. The Department is confident that these standards establish the level of quality and reliability necessary to ensure that labs 1) demonstrate and maintain proficiency, and 2) identify appropriate equipment and instrumentation to perform the testing offered by each individual lab.

The guidelines for achieving accreditation issued by Perry Johnson Laboratory Accreditation, Inc., and available publicly on the internet, are also attached. This attachment is intended only to offer additional information regarding the process of accreditation to these standards. The Department does not endorse or recommend any accreditation service or body. *[Attachment B]*.

Testing Standards / Protocols

In addition to the ISO certification requirements required in rule, the Department has received input from labs regarding the establishment of protocols. The inventory tracking system includes documented procedures regarding protocols. Any gaps in the system documentation/requirements will be enhanced with Department-issued operating procedures to be included in a lab manual. The Department is sharing those draft documents with all four temporarily licensed labs in Montana to obtain feedback. Once finalized, the Department expects to adopt the manual in rule through reference, similar the Public Health & Safety Laboratory Rules (ARM 37.12). This incorporation will be included in the April 3, 2018, addressing canopy.

Two labs have been testing product in advance of the full rule implementation to identify and solve unanticipated issues, and determine readiness for receiving, sampling, and reporting test results under the final rules. Communications regarding these activities are attached.

Attachments:

- Draft sampling protocols *[Attachment C]*
- Draft quality assurance testing protocols *[Attachment D]*
- Stillwater Laboratories written response to public comment to RTIC on 3/14/18 *[Attachment E]*
- Stillwater Laboratories email and attached Certificate of Analysis *[Attachment F]*
- Fidelity Diagnostics Certificate of Analysis *[Attachment G]*
- Fidelity Labs Blind Proficiency Test Results *[Attachment H]*

Provider Licensing Timelines

The Department has chosen to transfer providers into the new licensing/inventory tracking solution (Complia/METRC) incrementally. This approach is designed to smooth out the workload associated with license renewals, required annual inspections, etc. To require all providers to immediately re-apply for licensure would create an unmanageable and unacceptable backlog, not only at initial implementation, but each year going forward.

Providers will need to be compliant with the new rules beginning April 10, 2018. Providers are not required to register in the Complia/METRC system until their annual renewal date (or by December 31, 2018), but they are expected to be compliant with all laws and administrative rules even if they are not yet in the new inventory tracking system. This includes, but is not limited to testing, labeling, packaging, signage and waste management. Providers are welcome and encouraged to register in the new system sooner than later, which would relieve any administrative burden of having to create manual processes that would be replaced by the automated functions in METRC.

Of the 610 current licensed providers, 221 will be subject to testing requirements beginning April 10. The two established, operating labs in Montana will require services to be ordered independently of

METRC, so registration in the system is not required to comply with testing requirements. Below is the renewal data for the current licensed providers subject to testing on April 10:

Renewal Month	Number of Providers with 11 or more registered patients
April 2018	16
May 2018	8
June 2018	6
July 2018	12
August 2018	9
September 2018	10
October 2018	58
November 2018	22
December 2018 or later	80

In terms of compliance with other portions of the statute and administrative rule, METRC has been custom configured to comply with all components of Montana's medical marijuana program. This includes the vertical integration model intended by the 2017 Legislature.

Incomplete / Missing Rules

The report by Sue O'Connell, Legislative Analyst, to this Committee includes several statutory requirements reportedly not included in rule:

Proof of Montana Residency
ARM 37.107.105 allows for a Montana driver's license or a Montana identification card as proof of residency. If an applicant does not have one of those two stated forms of documentation, the rule lists other forms of acceptable proof. The rule allows for the Department to request additional documentation to prove residency. New provider applicants that were not named by a registered cardholder prior to June 30, 2017, will be asked to submit tax return documentation and/or other documentation to establish proof of compliance with residency requirements.

Laboratory Equipment and Instrumentation for Testing Laboratories
ISO17025 addresses equipment and instrumentation requirements necessary to achieve certification. Requiring through rule that laboratories achieve ISO certification establishes this statutory requirement.

Insurance and Bonding Requirements
These limits will be established in rule with the proposed rules that will be filed on April 3, 2018. The two established labs in Montana are currently carrying errors and omissions insurance; however, specific limits will be proposed in rule.

Lab Proficiency
ISO17025 establishes proficiency requirements. The Department will accept ISO 17025 certification as required by rule as proof of proficiency.

Insect Level
The amount of filth and foreign material – which includes but is not limited to hair, insects, feces, packaging contaminants, and manufacturing waste and by-products – is included in the draft Quality Assurance Testing Protocol *[Attachment D]*. This protocol will be included in the Lab Manual, and incorporated through reference in rule.

Usable Limits for Cardholders Sharing Residency
ARM 37.107.128 establishes possession limits for registered cardholders who have not named a provider at up to 1 ounce, regardless of the cardholder's living arrangements.

Complaint Reporting / Compliance

Members of the RTIC expressed concern over the data metrics regarding the number of prescribing physicians, and complaints regarding those practices. The board of medical examiners is required to report annually to the legislature on the number and types of complaints the board has received involving physician practices. The Department receives a number of complaints across a broad range of issues associated with the medical marijuana program, including physician complaints. A complaint log has been established to track issue reports and resolution. The tracking log form is attached *[Attachment I]*. Additionally, a reporting form is being created so that complaints concerning physician activities can be formally submitted to the board of medical examiners for their review and consideration.

Another concern that is rising the attention of the Department is that of provider advertising, which is explicitly prohibited in 50-46-341 MCA. Our legal staff is currently drafting an official communication letter to send to non-compliant providers.

Regulatory compliance – specifically, demonstrated compliance through inspection – is a priority of the department. Attached are the *draft* inspection checklists that will be used by inspectors *[Attachment J]*. We expect these documents to be finalized in advance of the April 10, 2018, effective date of the rules.

In closing, we take seriously the concerns voiced by the RTIC, this Committee and various stakeholders across the system. Those concerns have been thoroughly reviewed, considered in-depth, and acted upon. I urge you to allow program implementation to continue as planned, and refrain from filing what we view as an unnecessary objection to the already adopted rules.

Thank you for your consideration,

Sheila Hogan
Director, DPHHS

Attachments as listed in this letter

cc: Rep. Jacobson, Chair RTIC