

Overview

We appreciate the proposed updates to South Dakota's medical marijuana regulations from the SD Department of Health. We support, with one exception, the changes the Department is suggesting as compliant with recent statutory changes and consistent with best practices in the industry.

Following we suggest changes to rule that we believe will bring medical marijuana rules in compliance with statutory authority, recognize current supply chain issues that threaten to delay timely commencement of operations, and address inconsistencies with best practices.

We are requesting the following specific changes to rule (in order of rule number):

- Extend the one year operational requirement to account for lack of available equipment and supplies due to nation-wide supply chain delays.
- Reduce security video storage requirement from 90 to 45 days.
- Replace the odorization of hazardous substances requirement with a requirement that flammable gas be stored and handled in accordance with applicable fire and life safety codes. This change will be consistent with the regulatory requirement for extractions that mandates 99 percent purity.
- Grant licensees 45 rather than 15 days to become compliant with the electronic inventory tracking system prescribed by the Department upon Department notification to all licensees that the electronic inventory tracking system is live. X
- Removal of the requirements that proposed qualifying medical conditions only be approved if "Treatments currently available for the proposed condition are either ineffective or produce harmful side effects" and that medical use of cannabis will (rather than "is likely to") provide therapeutic or palliative benefits that outweigh the risks of cannabis use.

The full reasoning supporting these requests follow.

Finally, we note proposals for continued rules development we support that we identified in our first informal contacts with the Department in this rules process:

- Improve ability for out of state patients to access SD medical marijuana
- Prohibit establishments that are not cultivators from growing plants to maturity.
- Provide protections for whistleblowers who report illegal activity.
- Provide immunity for state agencies, officers & employees in performance of duties.
- Prevent sales to anyone visibly intoxicated.
- Produce badges including an alphanumeric number to match with METRC inputs.
- Set meeting dates/date parameters for the oversight committee created in 34-20G-93

One year operational requirement

44:90:03:16. Department awarding of certification -- Tiebreaking procedures -- Notice to unsuccessful applicants. The department shall award certification as follows:

...

Any establishment granted a certificate pursuant to this section must become operational within one year of date of award or the certificate is deemed void and will be awarded to the next applicant on the waiting list.

...

Comment Several CIASD members are experiencing delays in securing equipment necessary to become operational. It is in their best interest to become operational as soon as possible but, for reasons out of their control, they may not be able to meet the one year deadline.

Recommendation Amend 03:16 as follows: "Any establishment granted a certificate pursuant to this section must become operational by the later of ~~within~~ one year ~~of~~ from date of award or December 31, 2023 or the certificate is deemed ..."

Security video storage

44:90:04:09. Storage of camera footage. An establishment shall maintain surveillance recordings for a minimum of 90 days, either:

...

Comment Industry experience suggests that a 90 day data storage requirement considerably exceeds the amount of time in which problems typically are revealed. A 45 day storage requirement will provide adequate time to expose the need to review, use, and hold security camera data while reducing regulatory expense on private businesses by half. Other state's requirements include: Alaska, 40 days; Arizona, 30 days; Arkansas, 90 days; California 90 days; Colorado, 40 days; Florida, 45 days; Iowa, 60 days; Massachusetts, 90 days; Nevada, 30 days; New York, 90 days; Rhode Island, 60 days; Vermont, 30 days; Washington, 45 days. Several states (Alaska, Arizona, Florida) require footage of thefts or other incidents to be held longer term.

Recommendation Amend 04:09 as follows: "An establishment shall maintain surveillance recordings for a minimum of ~~90~~ 45 days"

Odorization requirement

44:90:07:08. Extraction using inherently hazardous substances.

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Any extraction method using inherently hazardous substances must be listed in the operating procedures on file with the department and use a substance of 99 percent or greater purity. The resulting extract must not exceed residual limits for the substance established by the department as part of testing requirements.

...

The use of any inherently hazardous substance other than butane, propane, acetone, heptane, or pentane requires written approval of the department, upon documentation of the safety and efficacy of the selected method. All flammable gas must be odorized.

Comment CIASD concurs with Emmett Reistroffer's testimony at the 6/21/22 public hearing regarding the conflict in 44:90:07:08 between the requirement that manufacturers use a substance of 99 percent or greater purity and the requirement that all flammable gas must be odorized. An odorized gas cannot be 99 percent or greater purity as it contains an odorizing agent, often sulfate, which also imposes serious health risks when producing products for human consumption.

Recommendation Amend 44:90:07:08 as follows: "~~All flammable gas must be odorized.~~ All flammable gas must be stored and handled in accordance with applicable fire and life safety codes."

Inventory tracking – compliance once system goes live

44:90:11:01. Inventory tracking system ~~Required use~~ Requirements and procedures.

...

Upon Department notification to all licensees of a live, electronic inventory tracking system prescribed by the Department, licensees shall become compliant within the electronic inventory tracking system requirements and this Section within 15 days.

Comment This new proposed language requires licensees to become compliant with the state's electronic inventory tracking system in just 15 days from the "go live" date. CIASD submits that a 15 day window is not nearly sufficient to allow brand new users to become compliant with a brand new system administered for the first time ever by state regulators. We submit that a 15 day requirement is not a reasonable implementation of the law as it affects persons likely affected by the rule.

Recommendation Amend this new language from "15 days" to "45 days"

Qualifying medical conditions –

44:90:13:02. Department's decision. The department's written decision to approve or deny a petition shall be issued within 180 days of submission and must include the factors supporting the decision, including whether the written petition, public testimony, written comments, peer-reviewed research, and consultation with practitioners support the following conclusions:

- (1) The proposed medical condition is recognized by the medical profession as a serious and chronic medical condition;
- (2) Treatments currently available for the proposed condition are either ineffective or produce harmful side effects; and
- (3) Medical use of cannabis will provide therapeutic or palliative benefits that outweigh the risks of cannabis use.

Comment Nothing in SDCL 34-20G limits qualifying debilitating conditions to only those for which current treatments are either ineffective or produce harmful side effects. Nor does SDCL 34-20G limit qualifying debilitating conditions to those for which medical use of cannabis is certain ("will") to provide therapeutic or palliative benefits. In fact, such standards would have excluded most or all of the eight conditions the Department sought to include as debilitating conditions via rule in 2021.

The scope of qualifying debilitating conditions in SDCL 34-20G is clear:

34-20G-1 Definitions

- (8) "Debilitating medical condition,":
 - (a) A chronic or debilitating disease or medical condition or its treatment that produces one or more of the following: cachexia or wasting syndrome; severe, debilitating pain; severe nausea; seizures; or severe and persistent muscle spasms, including those characteristic of multiple sclerosis; or
 - (b) Any other medical condition or its treatment added by the department, as provided for in § 34-20G-26;

Qualifying conditions in SDCL 34-20G-1 (a) are defined by characteristics such as chronic, debilitating, cachexia, pain, nausea, seizures, and muscle spasms. They are not limited by the efficacy, side effects, or any other characteristic of treatments currently available for those conditions. Likewise, the department's authority to add other medical conditions or their treatments in SDCL 34-20G-1 (b) is not limited by the efficacy, side effects, or any other characteristic of treatments currently available for those conditions.

Nor does SDCL 34-20G limit qualifying debilitating conditions to those for which medical use of cannabis is certain ("will") to provide therapeutic or palliative benefits.

In 2021 the SD Department of Health proposed adding the following conditions by rule as qualifying debilitating medical conditions if the practitioner certifies they are debilitating for the patient.

1. Acquired immune deficiency syndrome and positive status for human immunodeficiency virus;
2. Amyotrophic lateral sclerosis;
3. Multiple sclerosis;
4. Cancer or its treatment, if associated with severe or chronic pain, nausea or severe vomiting, or cachexia or severe wasting;
5. Crohn's disease;
6. Epilepsy and seizures;
7. Glaucoma; and
8. Post-traumatic stress disorder.

Each of these conditions are consistent with 34-20G-1 (a) in that they are a chronic or debilitating disease or medical condition or its treatment that produces one or more of the following: cachexia or wasting syndrome; severe, debilitating pain; severe nausea; seizures; or severe and persistent muscle spasms, including those characteristic of multiple sclerosis. Medical use of cannabis is likely to provide therapeutic or palliative benefits to patients with these conditions.

The Rules Committee reverted that particular rule as the Committee determined debilitating medical conditions could only be added after completion of a formal review process for each.

But, it's worth noting that there are currently treatments for most or all of these conditions which are effective without producing harmful side effects. And, while medical use of cannabis is likely to provide therapeutic or palliative benefits to patients suffering these conditions, such benefits are not certain to be realized by every patient. That's to say, conditions the Department believed were consistent with the terms of SDCL 34-20G would not have passed muster under the requirements of 44:90:13:02 (2) and (3).

As written, 44:90:13:02 (2) and (3) are not a valid exercise of delegated legislative authority and are not consistent with the expressed legislative intent pertaining to 34-20G. They are not reasonable implementations of the law as they affect the convenience of the general public or persons likely affected by the rules.

Recommendation Amend 44:90:13:02 as follows:

- (1) The proposed medical condition is recognized by the medical profession as a serious and chronic medical condition;
- ~~(2) Treatments currently available for the proposed condition are either ineffective or produce harmful side effects; and~~
- (3) Medical use of cannabis ~~will~~ is likely to provide therapeutic or palliative benefits that outweigh the risks of cannabis use.

