Missouri Section for Medical Marijuana Facility License & Compliance Section Guidance Document 7 Facility Operational Deadline

Dear Medical Marijuana Licensee,

As we approach the end of the first year of licensure in Missouri, we would like to offer some notes on what may or may not be considered favorably in any requests for extension of a facility's operational deadline. For reference, the applicable requirement can be found in 19 CSR 30-95.040(1)(F)4, which says, "If a facility is granted a license or certification but has not passed a commencement inspection within one (1) year of the department issuing the license or certification, the license or certification may be revoked." Extension requests would need to be made as a request for variance, pursuant to 19 CSR 30-95.025(2), and should include an explanation for exactly what variance the facility is requesting. Specifically, a request to vary from the original operational deadline would need to include a new proposed operational deadline. And of course, the variance request should also include a detailed argument for why the facility cannot meet its original deadline. The below is guidance related to this second point.

First, as we have discussed publicly many times, the primary expectation is that every licensee will make a good faith effort to meet its operational deadline. A licensee should be able to show the work it has done to make progress and concrete evidence of any cause of delays and also any work that was done to overcome delays. Examples of circumstances that would not be considered favorably include:

- 1) Lack of responsiveness or failure to provide requested documentation in a timely manner during the minimum standards review process or during the Commencement Inspection process;
- 2) Refusing to take action on an existing license until resolution of appeals in other, affiliated applications for licensure;
- 3) Last minute requests for changes of location or for other material deviations; and
- 4) Claims of difficulties related to COVID-19 without actual evidence of COVID-19 affecting that particular licensee's ability to commence.

While most regulations are not specifically associated with a particular consequence, failure to pass a Commencement Inspection within a year is specifically associated with revocation. As such, revocation is the most likely resolution for a licensee that cannot comply with this obligation, and the Department does not view application to transfer a license under 19 CSR 30-95.040(4)(C)1.B. as an equally appropriate resolution. To be clear, the licensee should not expect to receive approval for sale of a license until after it becomes operational.

Finally, it is important to note the requirement is that the facility <u>pass</u> a Commencement Inspection within a year and not that the facility <u>request</u> a Commencement Inspection within a year. At this time, when a facility is prepared and responsive during the Commencement Inspection process, the Department is able to guide the facility through the process in as little as two weeks. However, if a majority of licensees wait until shortly before their deadline to request a Commencement Inspection, it will not be possible to proceed this quickly. Waiting until the last minute to request a Commencement

Inspection is likely to result in a facility missing its operational deadline. The same is true for requesting a variance from the operational deadline.

Just as important, the facility must be ready to complete the Commencement Inspection process when making the request to the Department. A facility that demonstrates it has made a request for a Commencement Inspection without actually being prepared to proceed will be removed from the Commencement Inspection list and asked to request a Commencement Inspection when the facility is fully prepared. This ensures Department resources are available for and focused on facilities that are ready to begin operations. Once again, making a <u>request</u> for a Commencement Inspection will not serve to meet the requirement that a facility <u>pass</u> a Commencement Inspection within a year, and a premature request will also not be considered evidence of a good faith effort to become operational. The full list of documents and information required for the Commencement Inspection is located at <u>https://health.mo.gov/safety/medical-marijuana/resources.php</u> under the Compliance heading.

As always, our hope is that each of our licensees is successful, and if there is anything we can do to help you meet your deadline or to provide additional clarification on these expectations, please reach out to us.