Missouri Section for Medical Marijuana Facility License & Compliance Section Guidance Document 10 Further Commencement Inspection and Operational Variance Guidance

Dear Medical Marijuana Licensee,

While the rollout of the medical marijuana industry in Missouri is rapidly expanding each week, or perhaps because of how rapidly it is expanding, we have noticed a series of misunderstandings or mismatched expectations between facilities and the Department that we would like to address. It is our hope that resetting expectations, particularly related to the commencement inspection process and variances, will help more facilities reach the Approval to Operate smoothly.

Commencement Inspection Rule: 19 CSR 30-95.040(5)(B)

First, there seems to be some misunderstanding about 19 CSR 30-95.040(5)(B), which says, "Once a licensed or certified facility believes it will, within a month, be ready to begin operations and meet all state and local requirements for its facility, it shall request that the department conduct a commencement inspection to confirm the facility is in compliance with all requirements of this chapter." This rule does not create an obligation on the part of the Department to inspect a facility within 30 days of receiving a request. Rather, it creates the expectation that a licensee will submit a request "within a month" of when it believes it will be ready so that the Department and licensee can work through the commencement inspection process together. While some facilities will proceed through the process more quickly than 30 days, such as those that have prepared well for the process prior to submitting a request and those that are fully equipped to immediately fulfill all aspects of their application proposals, others will take longer than 30 days. This is especially true during this period of time when a large portion of the industry is seeking commencement all at once. It would be reasonable to expect the process to take 30-60 days at this point. However, please do not submit a request early in hopes that you will secure a place in line and to achieve a particular operational date; requesting a commencement inspection before you are prepared will more likely result in being set aside so that our compliance officers can devote their time to other licensees who are actually ready to proceed toward becoming operational.

Variances and Operational Deadlines beyond September 30, 2021

Second, we are aware that some licensees are considering requests for operational deadline extensions beyond September 30, 2021. Here is what we recently communicated to industry representatives when asked about this:

We have emphasized with licensees for a while now that extensions beyond September 30 are very unlikely to be approved. We continue to discuss with staff to be make sure our messaging is consistent on this – that such a request is unlikely to be approved rather than certain to be denied.

As always, if a licensee feels it must submit a variance request, we will consider the arguments presented before ruling on that request. However, we will continue to hold our licensees to as accelerated a timeline as possible and would remind anyone considering a new request that approval of additional time was never a guarantee. Certainly we would expect to see evidence of significant progress in construction at this point, but at some point, even that would not be

persuasive, particularly if the evidence is that progress has stalled. The requirement was to be operational within a year. Everything after that is a concession not lightly given, and we are mindful of the fact that granting an additional year to a licensee will always be problematic since we could have revoked that licensee at the one-year mark and replaced them with someone who could meet that obligation.

Facilities that were licensed later than the first batch are showing us every day that they are capable of becoming operational within a year or even significantly less. We are concerned with the level of pressure our staff are receiving from licensees that seem to feel variance approval is inevitable, particularly in cases where licensees are still changing their plans significantly instead of committing to becoming operational on their approved timelines. Certainly there are licensees who have experienced unforeseeable setbacks, but there are far too many licensees that are still considering changes that would make it impossible to meet a reasonably extended deadline. DHSS will continue to work with each licensee according to their particular circumstances, but this is not the time to be counting on significant extensions."

This issue of variance requests for operational deadlines extending well into 2021, or even beyond, is one we take very seriously. We encourage everyone to go forward with the plan they presented in an approved variance request and strongly discourage adjustments to the plan that would put them in the position of needing more time, such as change requests that require additional time for the Department to review and for Licensees to then implement. If we see variance requests for such extended timeframes, we absolutely expect proof of significant progress, including actual construction, perhaps contracts committing all involved to remaining timeframes, and we would also expect to see a history of working with the assigned compliance officers to monitor milestones along the way. Please remember: if you wish to discuss settlement of appeals in relation to extending operational deadlines, as always, those discussions should be directed to DHSS' Office of General Counsel and not to program staff.

Notices of Pending Revocation

Finally, we have had questions about the Notices of Pending Revocation that have been sent to some licensees in recent months. There are several circumstance that could lead to such a notice, but all have been regarding failure to pass a Commencement Inspection. For instance, these notices might be received when a licensee has not provided sufficient justification for a variance request for extension of the operational deadline. In such a case, we would deny the variance request and issue a Notice of Pending Revocation because the licensee has not passed a Commencement Inspection by its one-year deadline and also has not been granted a variance from that rule. A notice might also be sent when a facility has missed a Commencement Inspection deadline, whether the deadline is for full implementation of the Licensee's proposals or for a phase of implementation approved via a variance approval, and has not submitted a new variance request. In each case, the licensee is given 10 days to respond. One situation for which we have not issued a Notice of Pending Revocation is where a licensee has requested a Commencement Inspection within a month of its deadline, is appropriately and responsively working through the process with us, but has seen its deadline pass by while in that process. We are not requiring a new variance request in such circumstances and are not issuing a Notice of Pending Revocation.

Thank you for taking the time to read and study this guidance. If you have any questions about what we intend to convey here, please reach out so we can be sure we are understanding each other in this critical phase of implementation.