DRAFT

September 19, 2022

Chris Alexander
Executive Director
New York State Office of Cannabis Management
Albany, New York 12237

RE: Part 113 - Medical Cannabis - OCM-10-22-00017-R

Dear Mr. Alexander:

On behalf of the over 20,000 physician and student members of the Medical Society of the State of New York, we thank you for the opportunity to present comments regarding the medical cannabis program. We also welcome the opportunity to maintain an ongoing dialogue with your office to ensure that the program is providing patients and health care practitioners with relevant and up to date medical information regarding the effectiveness of medical cannabis to treat various health care conditions.

General Concerns

New York's physician community recognizes the historical significance of the enactment of the MRTA, which eliminated laws that unfairly targeted communities of color, and that the creation of a legal cannabis market presents a significant new opportunity in communities across New York State to redress these historical wrongs. At the same time, the physician community has expressed concerns with the lack of evidence supporting the effectiveness of medical cannabis use in the treatment for several of the listed conditions set forth in the statute. MSSNY has long supported regulatory or legislative efforts which would enable the conduct of high quality, double-blind, placebo controlled clinical trials that may provide scientific evidence of the efficacy and safety of cannabis in the treatment of medical conditions. This is particularly important given that addiction experts have noted that the psychiatric indications are worrisome given the potential for cannabis to exacerbate these conditions.

For example, we note that "substance use disorder" is listed as one of these eligible conditions for medical cannabis use but the only evidence of helpfulness comes from studies of cannabidiol in opioid disorder which haven't been replicated widely yet. Furthermore, the catch-all for certifying a patient for medical cannabis - "any other condition certified by the practitioner" - would seem to make the preceding indications in the statute and regulation essentially meaningless.

In light of our ongoing concerns that cannabis holds the risk for some unhealthy use and uncertain value, we recommend that there be limits placed on the frequency of use, limits on quantity dispensed, akin to limitations statutorily placed

on controlled substances. Moreover, we recommend that patients be required to be informed that, because this product has not been analyzed by the FDA, there is limited information on the products benefits for treating a particular medical condition.

Ongoing Review
We also have a number of questions regarding the process for ongoing review of patients who have been certified for medical cannabis use, in particular regarding the tracking and reporting of adverse events. These questions include:

- How will a registered organization know about adverse events affecting patients?
- Will dispensing sites be required to inform patients about likely adverse events?
- How can a practitioner report to the OCM serious adverse events in 5 business days if the patient is seen annually?

We believe the final regulation should reflect how best to address these concerns, towards ensuring that patients and practitioners are regularly informed of the efficacy of use of medical cannabis for treating certain conditions.

Advertising
We are concerned that the August proposed rule deleted a requirement that had been included in the earlier proposed regulations to further protect the public from unsubstantiated advertising that would have required that any medical marijuana advertisement making any claims or statements regarding efficacy be submitted to OCM for review at least 60 days prior to dissemination. Specifically the following would have to have been provided to OCM in conjunction with the proposed advertisement:

- A cover letter that provides a brief description of the format and expected distribution of the proposed advertisement;
- an annotated summary of the proposed advertisement showing every claim being made in the advertisement and which references support for each claim;
- verification that a person identified in an advertisement as an actual patient or health care practitioner is an actual patient or health care practitioner;
- verification that an official translation of a foreign language advertisement is accurate;
- annotated references to support disease or epidemiology information, cross-referenced to the advertisement summary; and
- a final copy of the advertisement, including a video where applicable, in a format acceptable to the office.

Pre-dissemination review of medical cannabis advertising is a very important public protection given the possibility that some claims about efficacy can be exaggerated. Indeed, one recent study (The Use of Academic Research in Medical Cannabis Marketing: A Qualitative and Quantitative Review of Company Websites - PubMed (nih.gov) of five medical cannabis websites found over 900 research-related health claims, including claims

that the marketers' products treated cancer, mental health disorders, pain, inflammation, and gastrointestinal disorders. However, none of these companies had produced a single publication with causal evidence from a large-scale random clinical trial.

In the absence of pre-dissemination review and approval of medical cannabis efficacy claims, vulnerable patients could be lulled into believing a medical cannabis product will ease their suffering when in fact there is little data to support that claim. Therefore, we recommend that the regulation be amended to re-include pre-publication review any advertisement for a medical cannabis product purporting to be effective in curing, treating, or preventing disease.

Thank you again for your attention to our comments. We would welcome the opportunity to discuss these comments with you at your earliest convenience.

Sincerely,