AmericansFor SafeAccess
Advancing Legal Medical Marijuana Therapeutics and Research

INTRODUCTION

Americans for Safe Access (ASA) would like to thank the New York Department of Health (Department) for the opportunity to comment on the draft regulations for the state's medical marijuana program. These regulations represent a good faith effort on the part of the Department to bring safe and legal access to medical marijuana products for New York's patient population. ASA is pleased to see certain patient-focused regulations, such as the inclusion of good agricultural practices and the non-resident registration options.

However, there significant areas concern within the proposed regulations that will impede the goal of safe and legal access for New York patients. While many of these areas will require legislative changes, we hope the Department and the Commissioner will work with the State Legislature to improve the program.

In addition to the comments found here, ASA strongly suggests basing regulations on the guidance provided by the American Herbal Products Association (AHPA) on medical marijuana operations.[1] These model regulations were developed by AHPA utilizing the best practices of the medical marijuana industry.

ASA also hopes that that the Department will review our recently published report *Medical Marijuana Access in the U.S.: A Patient-Focused Analysis of the Patchwork of State Laws*. This report evaluates the state medical marijuana programs in four sets of criteria and provides guidance on how states can improve their laws and regulations: (1) patient rights and civil protection from discrimination; (2) access to medicine (marijuana and/or marijuana products); (3) ease of navigation; and (4) functionality (effectiveness of current program). ASA recognizes that the Department can only take action in areas in which the statute has authorized them to act upon, but feels that this guidance can still help the Commission create the best program possible for Maryland patients. While New York currently has a relatively low grade, and many areas can only be improved through legislative action (such as access to medicine in it dried-flower form and putting physicians in control of qualifying conditions), the Department can help improve Maryland's current grade by implementing the cultivation and dispensary licenses in a timely and sensible manner.

PRIMARY AREAS OF CONCERN

ASA agrees with the concerns raised by Compassionate Care New York regarding low-income access; the limited number of dispensaries; the lack of clarity regarding qualifying conditions; the lack of access to whole plant forms of marijuana (such as

[1] *See* Recommendations for Regulators – Cannabis Operations, Cannabis Committee American Herbal Products Association available at http://www.ahpa.org/Portals/0/pdfs/13_0709_Cannabis_Lab_Recommendations.pdf

dried flowers); restricting the forms and variety of available medicine through rules on “brands;” restrictions on where patients may medicate; only allowing physicians to recommend; pharmacist requirements; lack of expedited access; advertising restrictions that go far beyond statutory requirements, on site consumption; and hurdles to entry for the industry. Certain areas here will require statutory change, but not all. We would like to see patient-focused changes to the draft regulations in the following areas:

1. Qualifying condition expansion and clarification: The list of qualifying conditions allowed by the legislature is one of the restrictive in the country; yet the statute allows the Commissioner to add conditions without restriction. The measure of a successful medical marijuana program should not be its level of strictness, but rather increasing the quality of life for the greatest number of patients, in the best way possible. It is extremely disappointing that the Commissioner has failed to add any new conditions in the draft regulations, as well the lack of a clearly defined and regularly occurring process by which the Commissioner considers adding new conditions. Better yet, we urge the Department to include the following change:

> *Strike*: §80-1.2(9)(vi), “such other conditions, symptoms or complications as added by the commissioner.”
>
> *Replace* with: “or any condition for which treatment with medical marihuana would be beneficial, as determined by the patient’s physician.”

2. Access to whole plant marijuana: While the statute passed by the legislature forbids the smoking of marijuana, it does not expressly deny access to marijuana in its dried flower form. Patients should be able to legally vaporize whole plant marijuana. Dried flowers are the common form of usable marijuana, and therefore patients have the most familiarity with using this form to treat their condition. New York should be examining ways of how increase the available number of medical marijuana treatment options available to patients, not limit them. Limiting patient choice means patients are restricting from being able to use medical marijuana in the manner that best treats them individually.

3. Eliminate rules on branding: Similarly, the rules on branding will also restrict patient options for wellness. No other state using this branding model, making it as novel as it is unnecessary. Medical marijuana patient access programs have functioned successfully without this needless burden. Moreover, if a registered operator produces marijuana that does not meet the strict branding standards, it will adversely impact the amount of available medicine. Given the market price controls established by statute, this could potentially harm producers who may have to destroy an entire crop that does not meet the standards for branding. A better model in place today for regulating medical marijuana is the batch model system recently implemented in Nevada. This system is based on best practices and does not create needless oversight that will harm patient access to medicine.

SPECIFIC REGULATION COMMENTS

§80-1.1(b) - Commissioner approval of education programs
Issue: The statute requires that physicians go through four hours of education before they can be registered. In order to make sure that this education requirement does not present a burden, ASA recommends that the Department to approve courses that are available online and on-demand.
Suggestion: Approve online courses that cover the necessary curriculum, such as the already available course from Harvard Medical School and the Massachusetts Medical Society, *the Answer Page*.

§80-1.2 - Practitioner issuance of certification concerns
Issue: Several of the subsections contained in the section require physicians to perform tasks that go beyond what federal courts have said physicians may do with respect to state medical marijuana programs. The case of Conant v. US limits the type of information a physician may include with medical marijuana recommendation. Physicians may be unwilling to participate in the program the requirements of this section are imposes. Of particular concern are subsections (a)(12)(i) and (a)(12)(ii).
Suggestion: Strike §80-1.2(a)(12).

§80-1.3 - Administratively shortening the length of time registrations are valid
Issue: A patient registration card issue under §80-1.3 is only valid during the one-year period when a certification is valid. However, patients might not receive a registration ID card for up to 30 days after submitting their materials to the Department. This means that patients will not have safe and legal access to medical marijuana products for the full year of their certification. Considering the fees, lack of health insurance coverage, and other burdens that patients face, they should not be short-changed any time for their period of safe and legal access
Suggestion: Make registration ID cards valid from the date of issuance rather than the date of written certification.

§80-1.6(b)(1) - Consistency of Products
Issue: It may prove difficult for applicants to be able to sufficiently meet the proposed requirements on consistent cannabinoid profile. While the regulations do allow for a for a +/- of 10%, this acceptable range will be difficult to meet, especially for low-THC products. For example, if a product aims to have a THC level of 0.25%, and it happens to have a THC of 0.28%, the batch will not meet the required standard.
Suggestion: Strike the requirement requiring that all products have an established cannabinoid profile. High quality testing and labeling will give patients better options without running the risk of destroying perfectly usable medical marijuana products.

§80-1.7 - Notice for renewal of registered organization
Issue: The section would impose a short window of time during which a registered organization may apply for renewal, but does not include any sort of notice requirement that must be provided by the Department to each registered organization.

Suggestion: Add a subsection that that says “The Department shall issue a notice of renewal of registration to a registered organization no more than 210 days and no less than 200 days prior to expiration of registration.”

§ 80-1.8(b) Non-transferability of registrations could harm access
Issue: It appears is written with the laudable intent of preventing operators from flipping their business for a quick profit, we believe that the unintended outcome of all of the changes proposed to this entire chapter may mean that patients end up with fewer operators providing them with medicine. For example, if a board member of a registered organization passes away, there is no way to reassign that person’s interest in the organization. Another potential problem could come up if a registered organization faces financial challenges and would have to stop operations, patients would be shut out of at least 20% of the available registered organizations within the state. The provision that requires 120 days notice before a registered organization can end its operations may not be practical if an organization experiences sudden and significant financial or legal issues.
Suggestion: Allow transfers only with the approval of the Commissioner, such as the following suggested text.

> A. No interest to a registered organization issued pursuant to this chapter shall be assignable or transferable unless:
> (1) The Department has received notice in a manner determined by the Department of the intent of the owner of the interest, or of the estate of the owner of the interest, to transfer or assign an interest in a license to another party;
> (2) The transferee has had forwarded the criminal history record information and footnoted financial statement to the Commission of the transferee;
> (3) The Department does not object to the transfer or assignment within 180 business days of its receipt of notice; and
> (4) The transferee has paid the required fee specified in XXXX.
> B. The Department may deny transfer of an interest in a license if the criminal history record information or the background investigation demonstrates an absence of good moral character, or the payment of taxes due in any jurisdiction is in arrears, for any proposed transferee.

§ 80-1.9 Failure to operate provision does not address replacement operator
Issue: ASA supports “use it or lose it” provisions, as they provide incentive for operators to not subject patients to needless delays. However, it a registered organization fails to operate, there is no requirement for the Department to find another operator to become a registered organization.
Suggestion: Add a subsection (c) that says “If there are fewer than 5 licenses in good standing, the Department shall open the application process until 5 valid registered organization licenses are issued.”