AmericansFor SafeAccess
Advancing Legal Medical Marijuana Therapeutics and Research

February 23, 2015

Introduction:

Americans for Safe Access (ASA) would like to thank the Office of Regulation and Policy Coordination at the Department of Health and Mental Hygiene (Department) and the Natalie M. LaPrade Medical Marijuana Commission (Commission) for the opportunity to comment on the proposed regulations for the state's medical marijuana program. These regulations appear to be a sincere effort on the part of the Commission to implement the state's medical marijuana program in a thoughtful way; however, there are a number of areas for concern that will either harm patient access or create needless inefficiencies within the program. It is ASA's understanding that the Department can only make non-significant changes to the regulations, and that if significant changes are required, that will force to Commission to revisit the entirety of the regulations, which could delay the start of the program by months or even years. ASA hopes that the Department will avoid having to send the regulations back to the Commission to be redrawn. If significant changes are necessary, ASA urges the Department and the Commission to consider whether these changes are necessary immediately, or if they can be revised in a new round of regulations. For example, regulations concerning the ability to license laboratories could be figured out over the next several weeks or months while the Commission begins its work on patient and physician registration. With that in mind, ASA submits the following comments on the proposed medical marijuana regulations in Maryland.

1. Physician education requirement is not required by statute and will limit patient's ability to gain access to medical marijuana therapy. 10.62.03.01.

Issue: ASA supports physician education; however, imposing a requirement on physicians to have a certain number of CME hours in order to simply be eligible to apply will prevent physicians for utilizing the program. The statutory requirement of physician registration is already a heavy burden, and if physicians are required to take additional classes before they can even apply, this will certainly dissuade a number of Maryland physicians. Doctors are not required to take specific education on any other type of medication in order to write a prescription. Moreover, the CME requirement is elective and not required by statute.

Suggestion: Strike all references to required CMEs. The Commission should encourage the Commission develop and promote CME courses for physicians, but they should not be required.

2. Requiring patients to select a single dispensary limits patient treatment options and may artificially inflate prices. 10.62.22.01.

Issue: The proposed regulation to require patients to designate a single dispensary from which they may purchase medical marijuana products from is harmful for several reasons. First, it limits patient options to whatever their single dispensary currently has in stock. If that dispensary runs out of a certain product, patients would have no alternative means to obtain the medical marijuana product that work for them. Second, by eliminating competition, dispensaries will not have to compete with one another, thereby exposing patients to artificially high prices for their medicine. Third, it will be burdensome and expensive for patients to switch dispensaries if they are forced to re-register with the program. Patients in the neighboring District of Columbia have been subjected to this unnecessary inefficiency, which is part of the reason why the price of medicine has reached upwards of $25/gram.

Suggestion: Delete this provision and allow patients to shop at any dispensary in the state.

3. Written certification rules are unclear and likely burdensome to patients and physicians 10.62.03 and 10.62.05.

Issue: The length of validity for a written certification and the provisions associated with it are novel at best, and unclear and inefficient at best. Rather than follow the best practices of other medical marijuana programs, Maryland appears to be issuing cards that are valid for a year, but the written certification is only valid for a short period of time. They should be valid the same length of time. In order to avoid unnecessary confusion, Maryland should make these the same length of time.

Suggestion: Make written certifications and patient registrations cards valid for 2 years by default, and allow physicians to make them valid for a shorter period of time if the physician feels the patient would not need medical marijuana therapy for the full 24 months. Several states such as Michigan, New Jersey, and Rhode Island use this patient friendly approach.

4. Clinical director requirement may attract DEA interference. 10.62.17.

Issue: Requiring a party with a DEA license to prescribe or dispense controlled substances may attract DEA inference. This happened in 2014 in Massachusetts, where the DEA forced clinical directors to turn over the DEA license if they wished to continue working at the dispensary.

Suggestion: Strike all references to clinical directors. Alternatively, amend the provision to allow anyone with medical marijuana expertise to be a clinical director. The Commission could require some sort of vetting and approval process to ensure the expertise of the prospective clinical director.

5. Regulations on chronic and severe pain are more restrictive than the statute. 10.62.03.01(B)(2)(d).

Issue: The Maryland statute encourages the Commission to approve physician applications for the treatment of “severe or chronic pain,” but the proposed

National Office
1806 Vernon St. NW, Suite 100, Washington DC 20009
PHONE: 202.857.4272 **FAX**: 202.857.4273

California Office
770 L Street, Suite 950, Sacramento, CA 95814
PHONE: 916.449.3975

General Information
WEB: www.AmericansForSafeAccess.org
TOLLFREE: 888-929-4367

regulations only call for “severe pain.” The Commission should not impose further restrictions than the statute on qualifying conditions.

Suggestion: Change to “severe or chronic pain.”

6. No access to edible forms of medical marijuana products. <u>10.62.01.02(B)(22)(b)</u>.

Issue: ASA appreciates the thought and effort that went into the Maryland proposed regulations on concentrates and extracts; however, edibles have been completely ignored, and in fact are forbidden in the draft rules.

Suggestion: Use the American Herbal Products Association guidelines for edibles.[1]

7. Ability to uses restricted pesticides could be harmful. <u>10.62.09.04(H).</u>

Issue: ASA strongly advise against granting permission for the use of restricted pesticides. Currently the EPA has not approved a single pesticide for use in the cultivation of cannabis. Most states tend to stick with those pesticides that are part of the National Tolerance Exempt List. Some have added additional pesticides, such as those that are certified organic (OMRI).

Suggestion: Limit pesticides to those on the National Tolerance Exempt List or OMRI.

8. Lack of clarity for patients if they need to switch physicians. <u>10.62.22.01</u>

Issue: The requirement that patients may only have a single certifying physician may present problems for patients who are using medical marijuana to treat multiple conditions or for patients who need to switch their physician. The proposed rules do clearly state the process by which patients can obtain a written certification in the event that their current certifying physician retires, leaves the state, or is otherwise to continue treatment. This is of particular concern if the patients are frequently forced to have their written certifications reauthorized on less than annual basis by their certifying physician, as is currently being proposed elsewhere in the regulations.

Suggestion: Allow patients to have more than one certifying physician.

---

[1] Available at:
https://d3n8a8pro7vhmx.cloudfront.net/americansforsafeaccess/pages/7453/attachments/original/1406050488/14_0722_AHPA_Recommendation_for_Regulators_MPLH-For_Distribution.pdf?1406050488.

National Office
1806 Vernon St. NW, Suite 100, Washington DC 20009
PHONE: 202.857.4272 **FAX:** 202.857.4273

California Office
770 L Street, Suite 950, Sacramento, CA 95814
PHONE: 916.449.3975

General Information
WEB: www.AmericansForSafeAccess.org
TOLLFREE: 888-929-4367