

September 22, 2014

## Introduction:

Americans for Safe Access (ASA) would like to thank the Natalie M. LaPrade Medical Marijuana Commission for the opportunity to comment on this most recent round of draft regulations for the state's medical marijuana program. The September 9, 2014 draft of the proposed regulations has many sensible improvements from previous drafts, but it is still apparent that more attention needs to be paid in certain areas of the proposed rules. ASA is pleased to see that regulations for dispensary and cultivation operations and transferability of licenses generally appear to be developing in a pragmatic fashion. For example, the inclusion of greenhouses is good policy because by utilizing sunlight to cultivate medical marijuana, they are more efficient in terms of environmental impact and their improved cost-savings ease the out of pocket expense for patients.

However, there are many other areas where the proposed rules will create needless burdens to physicians and patients that may inhibit the ability of patients to gain therapeutic benefit through the program. One area of particular concern is the possibility of removing Post Traumatic Stress Disorder (PTSD) as a qualifying medical condition. ASA strongly recommends maintaining PTSD as a qualifying condition, as it the condition does obviously provide into any of the 5 products of medical conditions that the Commission is directed to approve with respect to a physician's treatment proposal application. It is well-known that marijuana is one of the most powerful and beneficial therapeutic substances to treat PTSD, and the condition affects combat veterans, first responders, and victims of violent crime, such as domestic assault. Several states have included PTSD in recent years, from just 3 states in 2011, to the present number of 9 states and the District of Columbia. Excluding PTSD for any reason would simply deny medical benefit to a great number of Marylanders who have no other viable therapeutic option to treat their condition and goes against the growing body of medical evidence.

## Comments:

### *Timeline*

Issue: According to the HB 881, "the Commission shall adopt regulations to implement" the program "on or before September 15, 2014." Clearly the Commission will not meet this statutory deadline, as the date has passed without adopted regulations. Maryland's patient deserve to know what is the realistic timeframe for implementation.

Suggestion: While ASA understands that the Commission needs more time to complete a workable set of regulations, we also think it the responsibility of the

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Commission to clearly set forth a timeline to have final regulations approved, along with target dates for dispensary and cultivation applications.

*10.62.03.01 A(2)(c) (page 6)*

*(c) That the physician has completed a Commission-approved training course;*

Issue: Imposing an education requirement will make it more challenging for physicians to meet the necessary credentials in order to legally recommend medical marijuana under the rules of the program. Physicians do not need special training in any other type of medication, including powerful prescription medication that - unlike marijuana - can cause fatal toxicity.

Suggestion: If the Commission must impose an education requirement burden, it should approve an already established online medical marijuana CME course, such as TheAnswerPage.com, which was created in for the Massachusetts Medical Society by a Harvard Medical School associate professor.

Additionally, ASA suggests striking the physician CME requirement in *10.62.03.06 C(4)*, but if the Commission insists on including such a requirement, we strongly encourages the Commission to allow for an online, on-demand CME course.

*10.62.03.01 C. (page 6)*

*The Commission shall notify the applicant that the application has been approved.*

Issue: There is no timeframe for how quickly the Commission must notify a physician. The policy should be in place to ensure that physicians are approved *and* notified in a timely manner.

Suggestion: Require the Commission to notify physicians within 24 hours of approval.

*10.62.03.01 E. (page 7)*

*E. A certifying physician may apply to amend the approval at any time.*

Issue: ASA thinks this is good policy, but the manner in which a physician can amend their approval is not provided.

Suggestion: Develop an approval modification form.

*10.62.03.02 B(5) (page 7)*

*(5) If the qualifying patient has been screened for dependence on substances of abuse, including chemical testing, if appropriate, and has been determined by the physician to be of low risk for addiction, dependence, and diversion;*

Issue: This rule goes beyond what the statute requires in terms of drug screening to the point that it will harm Maryland patients who are in serious need of medical marijuana therapy. The term “low risk” is vague, but the requirement means that

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certain patients with histories of addiction or abuse could be denied access to a medicinal option that is less harmful than certain types of prescription options.

Suggestion: Strike “including chemical testing, if appropriate, and has been determined by the physician to be of low risk for addiction, dependence, and diversion.”

For similar reasons ASA also suggests striking 10.62.03.02 G (page 8).

10.62.03.02 D(5) (page 8)

(5) A notification to the Commission in the manner it determines if the certifying physician determines that the qualifying patient need for medical marijuana is greater than 120 grams, but in no case more than \_\_\_\_\_.

Issue: Although the amount of medicine determined to be a 30 day is well below what ASA recommends in our model legislation, the ability for physicians to grant a waiver for amounts above 120 grams is a prudent inclusion. However, requiring a physician to place a limit on the amount of marijuana a patient may need during a 30-day period would require some high-level expertise in the application of medical marijuana therapy, and may also run afoul of *Conant v. Walters* limitations.

Suggestion: Strike, “but in no case more than \_\_\_\_\_.”

10.62.05.01

*Not included - youth registration exemption:*

Issue: It does not seem practical, nor necessary to require that patients under the age of 18 to have patient ID cards. The parent-caregivers of these patients will be the acquiring and controlling the medication, and therefore it only is necessary to have the parent-caregivers register.

Suggestion: Allow the youth patient’s written certification and possession of another form of proof that that parent is indeed the caregiver of the youth patient, such as a school ID.

10.62.05.02 D (page 15)

*The Commission shall provide access to the Commission's register to a Maryland law enforcement agency on a real-time basis for just cause.*

Issue: The term “just cause” is vague and does not provide patients with a clear level of privacy protection. Additionally places a burden on the Commission to determine what is “just cause” each time law enforcement seeks access to the registry.

Suggestion: Strike “to just cause” and replace with “to verify the validity of an identification card in possession of a qualifying patient or caregiver during a police encounter, or upon the presentation a warrant during a criminal investigation.”

10.62.06.05 (19) and 10.62.14.06 (pages 19 and 46)

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## *Pre-Approval of Application*

Issue: The purpose of pre-approved applications is unclear, as it is unclear what being pre-approved allows an applicant to do.

Suggestion: Clearly define what abilities a pre-approved applicant will possess.

### *10.62.07.02 (page 23)*

*D. A prospective grower agent shall be disqualified from association with the licensee if the prospective grower agent:*

*(2) Is currently serving a sentence of parole or probation unless the offense was for conduct involving the possession of less than 10 grams of marijuana.*

Issue: The exemption in subsection (2) of the provision is prudent to not penalize conduct that is not longer criminalized in Maryland; however, a grower agent could have a conviction from another state that would not have happened in Maryland under the medical marijuana affirmative defense.

Suggestion: Add a third subsection that also exempts conduct that would not have been subject to a criminal conviction under Maryland's medical marijuana affirmative defense.

The comment also applies to *10.62.07.06 B(2)* (page 25), *10.62.15.02 F(2)* (page 50) and *10.62.15.05 B(2)* (page 51).

### *10.62.07.04 D (page 24) and 10.62.15.03 D (page 50)*

*D. Unless medically justified, a prospective grower agent who has a positive response to any tested substance on a drug screen that meets the requirements of COMAR 17.04.09.07 may not be registered with the Commission as a grower agent.*

Issue: Providing a medical justification exemption to the grower agent substance abuse screening is good policy; however, the term "medical justified" is vague and could adversely impact patients seeking employment from in the Maryland medical marijuana industry.

Suggestion: Clearly define "medically justified" to include qualifying patient status in the Maryland medical marijuana program.

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