

TO: Delaware Department of Health and Human Services

FROM: Americans for Safe Access

DATE: October 31, 2013

RE: Comments on the proposed regulations for the Delaware Medical Marijuana Act

Summary

Americans for Safe Access (ASA) would like to thank the Delaware Department of Health and Human Services (DHHS) for the opportunity to comment on the proposed regulations for the *Delaware Medical Marijuana Act* (Act). Generally speaking, many of the proposed regulations are will provide for a solid basis upon which DHHS can establish a workable medical marijuana distribution system. However, there are several areas throughout the proposed regulations that may have the unintended consequence of inhibiting Delaware patients from being able to receive the desired benefit of their physician-recommended medical marijuana therapy. The following comments and recommendations are offered to help DHHS issue final regulations that will best serve the needs of Delaware patients.

Comments

2.0 Definitions

“Compassion center agent” and “Excluded felony offense”

Problem: The definition for “compassion center agent” states that a person may not become a compassion center agent if they have been “convicted of an excluded felony offense,” or “convicted of a drug misdemeanor within five years.” Later, subpart (b)(2) of the definition for “excluded felony offense” allows for an exception if:

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“an offense that consisted of conduct for which 16 Del.C. Ch. 49A would likely have prevented a conviction, but the conduct either occurred prior to July 1, 2011, or was prosecuted by an authority other than the State of Delaware.”

Solution: Delete the misdemeanor conviction disqualification. It seems impractical to exclude individuals with misdemeanor drug offenses whose conduct would not likely have resulted in a conviction under the Act. However, if such a requirement is deemed necessary, misdemeanor conduct should qualify for the same exemption as found in subpart (b)(2) of the definition for “excluded felony offense.”

“Post-Traumatic Stress Disorder”

Problem: By defining Post-Traumatic Stress Disorder (PTSD), it has become significantly more restrictive than any of the other debilitating medical conditions permitted by the Act. The basis for this additional level of scrutiny seems to be needlessly burdensome for both patients and physicians, as no other condition faces this definition. In fact, based upon the construction of the proposed language, a patient must suffer from all of the included symptoms in order to have a legally sufficient PTSD diagnosis (“including symptoms of intense physical reactions such as tachycardia, shortness of breath, rapid breathing, muscle-tension, *and* sweating,” emphasis added). This seems like a particularly steep hurdle. In order for there to be a clinical diagnosis of PTSD, a physician would be utilizing the DSM-5, which already contains criteria to be met with four symptom clusters and three additional criteria related duration of symptoms, functionality, and symptoms not being attributed to a substance or co-occurring medical condition.¹

Solution: Delete the definition and do not include heightened requirements for PTSD as a qualifying condition. If DHHS finds it necessary to define the term, ASA suggests revising the definition to the following:

“Post-Traumatic Stress Disorder means that a patient meets the diagnostic criteria for Post-Traumatic Stress Disorder (PTSD), per DSM-5 or subsequent current edition.

4.0 Designated Caregiver Registry Identification Card Application Requirements

1 DSM-5 Criteria for PTSD, US Dept. of Veterans Affairs, available at http://www.ptsd.va.gov/professional/pages/dsm5_criteria_ptsd.asp, (last accessed October 30, 2013).

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Problem: There is currently explicit language informing parents and legal guardians of children younger than 18 years of age on how they may become the designated caregiver for a minor qualifying patient under their legal supervision. The statute forbids DHHS from *issuing* a registry identification card to a qualifying patient who is under the age of 18; however, there is no language that prevents a person who is younger than 18 years of age from becoming a qualifying patient. In fact, that provision that prohibits issuance of registry identification card to minors, 16 Del.C. § 4909A(b), specifically refers to “a *qualifying patient* who is younger than 18 years of age,” (emphasis added). If the legislature intended for those younger than 18 years of age to be completely prohibited from becoming qualifying patients, the statute would expressly state that. Instead, the legislature recognized that minors can in fact be qualifying patients, but left it up to the regulatory stage to determine how this should take place. Parents and legal guardians should have clear guidance on how to become the designated caregiver for a minor patient under their supervision.

Solution: **Insert language that expressly allows and provides guidance for parents** and legal guardians to become the designated caregiver for their child if the child is younger than 18 years of age. Such a definition should include written consent from the parent or legal guardian, as well as a signed statement agreeing that they will be in charge of acquisition, possession, and dosage of the physician-recommended medicine. The District of Columbia provision on parental consent is similar to many other state approaches and is one that DHHS should consider adopting (see below).

“A qualifying patient who is a minor may possess and administer medical marijuana only if the parent or legal guardian of the minor has signed a written statement affirming that the parent or legal guardian:

- “(1) Understands the qualifying medical condition or qualifying medical treatment of the minor;*
- “(2) Understands the potential benefits and potential adverse effects of the use of medical marijuana, generally, and, specifically, in the case of the minor;*
- “(3) Consents to the use of medical marijuana for the treatment of the minor’s qualifying medical condition or treatment of the side effects of the minor’s qualifying medical treatment; and*
- “(4) Consents to, or designates another adult to, serve as the caregiver for the qualifying patient and the caregiver controls the acquisition, possession, dosage, and frequency of use of medical marijuana by the qualifying patient.”²*

7.1.1.4 Use of pesticides is prohibited

2D.C. Code § 7-1671.02(e).

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Problem: Although there is clearly a laudable intent with respect to the safety of patients by including a prohibition on the use of pesticides during the cultivation of medical marijuana, a complete prohibition of pesticides is actually undesirable. A total prohibition upon pesticides would make the crops susceptible to infestation that could harm the cultivation of the medicine. Other states, such as Maine, Colorado, and Washington have adopted language that either specifies which specific pesticides are allowed or prohibited, rather than an outright ban.

Solution: **Allow for certain pesticides and require labeling disclosure of pesticides used.** ASA feels that Delaware could best balance the need for medicine free of harmful pesticides with allowing safe pesticides that enable reliable cultivation of medical marijuana free from infestation by adopting language based upon that found in the Maine regulations.³ Along with the suggested language with Maine, ASA suggests adding labeling disclosure under 7.2.8.1 to provide patients with notice if pesticides have been used during the cultivation of the medicine.

7.1.1.4 A compassion center may not use a pesticide on marijuana unless all of the following apply:

7.1.1.4.1 The pesticide is exempt from the federal registration requirements pursuant to 7 United States Code, Section 136w(b);

7.1.1.4.2 The pesticide is registered with the Department of Agriculture pursuant to 3-601 Del. Admin. Code;

7.1.1.4.3. All compassion center agents handling pesticides are certified with the department of agriculture pursuant to 3-601 Del. Admin. Code, § 4.2;

7.1.1.4.4. All compassion center agents handling pesticides have received the training required by 3-601 Del. Admin. Code, § 4.2; and

7.1.1.4.5 All compassion center employees who have direct contact with treated plants have completed safety training pursuant to 40 Code of Federal Regulations, Part 170.130.”

* * *

7.2.8.1.3 If any pesticides were used during the cultivation of marijuana, the pesticides used show be disclosed on a label affixed to the container that that marijuana is sold in. Compassion centers shall make available information about the potential risks and safety of any pesticides used in marijuana they make available for sale.

322 MRSA 2428, sub- 9, G.

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7.2.6 Maximum amount of compassion center inventory

Problem: By limiting compassion center inventory to a mere 150 plants and 1,500 ounces of usable medicine, DHHS is needlessly creating a situation in shortages of medicine are likely to be the ultimate outcome. According to the public notice accompanying the proposed regulations, Governor Markell has reduced “the number of compassion centers from three (one in each county) to one pilot program compassion center.” This means that every patient in the state must be served by this extremely limited inventory. Because qualifying patients may receive up three ounces of medicine in a 14-day period, the program would face medicine shortages if there are just 500 patients purchasing their full bi-weekly limit.

Worse still, this approach has been attempted by other states with less than desirable results. New Mexico sought to limit the number of plants that could be grown by cultivation facilities to 95 plants at the state’s licensed cultivation facilities. The outcome was numerous shortages of medicine, which was harmful to wellness of New Mexico’s patients.⁴ While the District of Columbia has a similar provision, the only reason why there has not been a shortage of medicine in the District is due to the burdens the District Department of Health has imposed on physicians and patients in order to obtain a physician recommendation and registration identification card. As of October 21, 2013, there were only 59 patients registered in the District’s program, meaning that fewer than 0.4% of the District’s 15,000 HIV positive population are currently in the program. Therefore, DHHS should not look to the cultivation limits of the D.C. program as a basis for how to appropriately serve the needs of Delaware patients.

Moreover, the new U.S. Department of Justice memo on federal marijuana enforcement priorities states that the size of an operation is no longer the sole basis for triggering an investigation. Consequently, DHHS need not impose artificial caps on production and inventory based upon the fear of interference by federal agents.

Solution: **Delete language imposing artificial caps** on the number of plants and ounces of medicine that may be cultivated and possessed by a compassion center.

7.2.8.1 Design and security features of medical marijuana containers

⁴New Mexico experiences pot shortage under tight medical marijuana rules, Associated Press, July 10, 2010, available at <http://www.foxnews.com/us/2010/07/16/new-mexico-experiences-pot-shortage-tight-medical-marijuana-rules/> (last accessed October 30, 2013).

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Problem: The requirement in proposed rule 7.2.8.1.2 that all medicine must be stored inside the tamperproof container that medical marijuana is sold in may make sense upon first glance, but is ultimately a burden upon patients, particular those with debilitating pain. While such a limitation is reasonable when patients are transporting their medicine outside of their own personal residences, patients should have the ability to keep their medicine in containers that do exacerbate their condition so long as the medicine remains where the patient resides.

Solution: **Insert language allowing reasonable store at home.** ASA suggests the following language to replace the current language proposed in 7.2.8.1.2.

“Patients and designated caregivers should receive written instruction that the marijuana shall remain in this container when it is outside the patient’s residence, unless it is being prepared for ingestion or being ingested.”

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