



STATE OF DELAWARE
STATE COUNCIL FOR PERSONS WITH DISABILITIES
MARGARET M. O'NEILL BUILDING
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November 24, 2015

Mr. Jamie Mack
Division of Public Health
Jesse Cooper Building
417 Federal Street
Dover, DE 19901

RE: 19 DE Reg. 409 [DPH Final Medical Marijuana Regulation]

Dear Mr. Mack:

The State Council for Persons with Disabilities (SCPD) has reviewed the Division of Public Health's (DPH's) final regulation to adopt some discrete amendments to the State of Delaware Medical Marijuana Code. The final regulation was published as 19 DE Reg. 409 in the November 1, 2015 issue of the Register of Regulations.

SCPD commented on the proposed version of this regulation in August, 2015. A copy of the August 26 SCPD letter is attached for facilitated reference. The Division of Public Health has now adopted a final regulation incorporating some amendments prompted by the commentary.

First, the Councils supported access to marijuana oil for covered adults and questioned whether the existing language precluded such access. The Division clarified that adult access to marijuana oil is available and no amendments are necessary.

Second, the Councils questioned whether the 3 oz. cap on usable marijuana should apply to both dried plant product and oil. The Division clarified that the calculation for oil is expressed in milligrams (mg.). Since there are 15 mg of active ingredient per milliliter of oil, a 3 ml syringe would contain 45 mg of active ingredient. Since there are 28,350 mg. in an ounce, there are 85,350 mg in 3 ounces. Therefore, a covered user could obtain 1,897 3 ml syringes per 14-day period. The 3 oz. cap should obviously not be a problem when applied to oil.

Third, the Councils recommended an amendment to correct grammar. The Division adopted the recommended amendment verbatim.

Fourth, the Councils recommended an amendment to clarify that a prescribing pediatric physician would only be necessary for patients under the age of 18. The Division adopted a conforming amendment.

Fifth, the Councils noted that the term "seizures" had been omitted as a symptom in §3.3.3.2. The Division inserted the term.

Sixth, the Councils recommended an amendment to correct grammar. The Division adopted a conforming amendment.

Seventh, the Councils recommended an amendment to correct grammar. The Division adopted the recommended amendment verbatim.

Eighth, the Councils endorsed adoption of more flexible standards on compassion center inventory. The Division acknowledged the endorsement.

Ninth, the Councils suggested consideration of removing limits on amounts of medical marijuana. The Division responded that the limits are statutory.

SCPD certainly appreciates the Division's consideration in adopting many of the recommendations Council submitted.

Sincerely,



Daniese McMullin-Powell, Chairperson
State Council for Persons with Disabilities

cc: Ms. Karyl Rattay, DHSS-DPH
Ms. Debbie Gottschalk, DHSS
Mr. Brian Hartman, Esq.
Developmental Disabilities Council
Governor's Advisory Council for Exceptional Citizens

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August 26, 2015

Ms. Jamie Mack
Division of Public Health
Jesse Cooper Building
417 Federal Street
Dover, DE 19901

RE: 19 DE Reg. 91 [DPH Emergency Medical Marijuana Regulation] and 18 DE 116 [DPH Proposed Medical Marijuana Regulation]

Dear Ms. Mack:

The State Council for Persons with Disabilities (SCPD) has reviewed the Division of Public Health's (DPH's) proposal to adopt some discrete amendments to the State of Delaware Medical Marijuana Code. The new standards appear in the August 1, 2105 Register of Regulations as both an emergency regulation at 19 DE Reg. 91 and proposed regulation at 19 DE Reg. 116. The primary impetus for the revisions is the recent enactment of S.B. 90. Background on that legislation is contained in the attached May 14, 2015 News Journal article and summary published in the Delaware Senate Republican Caucus newsletter. As these sources indicate, the primary focus of the legislation was to amend the medical marijuana law to allow children under age 18 to use medical marijuana-based oils to treat seizures.

SCPD has the following observations.

First, it would be preferable to permit an adult with a qualifying condition to receive marijuana oil as juxtaposed to traditional dried-plant-based marijuana. The regulation ostensibly disallows adults from acquiring marijuana oil. See §7.2.8.3.1.4. Indeed, it is defined as "Pediatric Medical Marijuana Oil". Consider the following:

- A. Ingesting an oil would not have the adverse lung effects of smoking marijuana.
- B. A minor turning 18 for whom the oil is effective must categorically stop using the oil. See §5.3.8. It is difficult to imagine that the efficacy of the oil would change on someone's birthday.
- C. The May 14, 2015 article suggests that other states allow adults access to the oil-based marijuana:

Fourteen states have approved cannabis oil for the treatment of epilepsy and other serious conditions. The list includes Virginia, where lawmakers earlier this year passed legislation allowing residents, including children, to use marijuana oils to treat seizures.

- D. The synopsis to S.B. 90 posits that age of the user should be immaterial:

These oils don't have enough "active ingredient" to get someone high. Therefore, there is no reason whatsoever not to allow its use for treatment of these conditions, no matter what the age of the person needing its help.

E. The text of S.B. 90 does not limit access to marijuana oils to minors. The definition of "usable marijuana" is amended to include "marijuana oil" and adults are eligible to receive "usable marijuana".

Second, it's unclear how much marijuana oil can be dispensed (to a child or adult). Section 7.2.8.3.1.2 limits dispensing to no more than 3 ounces of usable marijuana during a 14 day period. Three ounces of a liquid oil may be quite different than three ounces of a dried plant product. The Division may wish to assess whether the 3-oz. cap should apply to oils.

Third, the definition of "Responsible Party", second sentence, merits correction for grammar. There is a plural pronoun ("their") with a singular antecedent ("Party"). Consider substituting "Responsible Party's" for "their".

Fourth, an adult with a qualifying condition for whom a guardian has been appointed could participate in the program with the guardian serving as the "Responsible Party". However, §3.3.3 categorically presumes that anyone with a guardian will be a minor. Thus, only pediatric physicians are authorized to certify eligibility. The requirement that a pediatric physician certify the eligibility of an adult with a guardian should be corrected. Note that the reference to pediatric physicians in §3.3.3 may be redundant anyway given the definition of "Physician".

Fifth, §3.3.3.2 should be reviewed. Since there is a plural pronoun ("they") with a singular antecedent ("patient"), consider substituting "the patient has" for "they have". Moreover, the term "seizures" should be inserted after "nausea;". Compare S.B. No. 90, §4902A(3)b. There could be seizures without "painful and persistent muscle spasms".

Sixth, the grammar in §3.3.5 should be corrected. Substitute "Parties" for "Party's".

Seventh, the grammar in §5.3.8, first sentence, should be corrected. Consider the following substitute: "When a registered qualifying pediatric patient passes their 18th birthday attains 18 years of age, they the patient may...."

Eighth, §7.2.6 adopts more flexible standards for the maximum inventory of marijuana that can be maintained by a compassion center. This change is consistent with a recommendation in the attached article, M. Lally, "What's in Store for Delaware's First Medical Cannabis Dispensary" at p. 23:

In addition, Delaware law prohibits a registered compassion center from having more than 150 marijuana plants, irrespective of the stage of grow, or from possessing more than 1,500 ounces of usable marijuana, regardless of formulation. These restrictions may adversely impact the ability of registered dispensaries to produce enough medicine.

Adopting a more flexible standard is ostensibly a prudent amendment.

Ninth, instead of having a limit on the amount of medical marijuana determined by regulation (which is not individualized) it should be treated like other drugs and DPH should consider allowing physicians the ability to prescribe the amount and periodicity of medical marijuana administration.

Thank you for your consideration and please contact SCPD if you have any questions or comments regarding our observations on the proposed regulation.

Sincerely,



Daniese McMullin-Powell, Chairperson
State Council for Persons with Disabilities

cc: The Honorable Ernesto Lopez
Mr. Mark Lally, First State Compassion Center
Ms. Karyl Rattay, DHSS-DPH
Ms. Debbie Gottschalk, DHSS
Mr. Brian Hartman, Esq.
Developmental Disabilities Council
Governor's Advisory Council for Exceptional Citizens
19reg91 dph emergency medical marijuana 8-26-15