STATE OF DELAWARE
STATE COUNCIL FOR PERSONS WITH DISABILITIES
Margaret M. O'Neill Bldg., Suite 1
Dover, Delaware 19901
302-739-3621

The Honorable John Carney
Governor

John A. McNeal
Director

MEMORANDUM

DATE: February 27, 2019

TO: Ms. Alanna Mozeik, Division of Public Health

FROM: Mr. J. Todd Webb - Chairperson
State Council for Persons with Disabilities

RE: 22 DE Reg. 652 [(Division of Public Health/Office of Medical Marijuana Proposed Medical Marijuana Code Regulations (February 1, 2019)]

The State Council for Persons with Disabilities (SCPD) has reviewed the Department of Health & Social Services/Division of Public Health's Office of Medical Marijuana (DHSS/DPH/ OMM) proposed regulations governing the Medical Marijuana Code. This proposed regulation was published as 22 DE Reg. 652 in the February 1, 2019 issue of the Register of Regulations. Most of proposed changes involve the addition of regulations for "Safety Compliance Facilities" to provide quality control testing of medical marijuana and the addition of regulations to permit the production and sale of edible marijuana products at "Marijuana Infused Food Establishments." Some additional changes are made throughout the Medical Marijuana Code and are discussed in the analysis section. Of particular note, the new regulations change the rules for children in a manner that is mostly consistent with the statute, but those restrictions do not appear to have adequate medical bases. Most of the proposed regulations appear reasonable, but SCPD has the following observations and recommendations.

I. Permissible diagnoses and physicians

a. Adults

For adults, the new regulations add diagnoses of terminal illness, seizure disorder, glaucoma, and debilitating migraines to the list of permitted diagnoses. This was done to make the language consistent with the statutory language at 16 Del. C. § 4902A(3)(a).

b. Children

The current and proposed regulations significantly limit the diagnoses that will allow children access to medical marijuana by creating a separate list of "pediatric qualifying conditions."[1] It is unclear on what basis OMM imposes the additional restrictions on children. The underlying statute has identical language but does not contain any medical or policy reasoning for such separate restriction. The new regulation reads:

> Pediatric qualifying conditions are limited to any of the following related to a terminal illness; pain; anxiety; depression; seizure disorder; severe debilitating autism; or a chronic or debilitating disease or medical condition where they have failed treatment involving one or more of the following symptoms: cachexia or wasting syndrome; intractable nausea; severe, painful and persistent muscle spasms.

It is unclear why diagnoses such as amyotrophic lateral sclerosis ("ALS") have been excluded for children but included for adults in both the statute and regulation.

As an initial matter, the term "qualifying conditions" is meaningless. This regulation is within the definition of "Debilitating medical condition," the language found in the statute. The regulation also fails to define "pediatric." While it may be intended to mean "under the age of 18,"[2] the field of pediatrics extends through age 21 and can be further extended in unusual cases.[3] More importantly, the eligible diagnoses are unclear. As written, it is unclear if "pain; anxiety; depression; seizure disorder; severe debilitating autism" [4] are only eligible if they are "related to a terminal illness." Sections 3.3.3.1-3.3.3.3 of the new regulation, as well as the statutory language in 16 Del. C. § 4090A(b), clarify the situation but introduce another problem because those sections include "intractable epilepsy" as a separate eligible diagnosis. While "intractable epilepsy" is probably covered under "seizure disorders," these regulations need to be consistent and clear. As written, they are neither.

SCPD requests that the "pediatric qualifying condition" definition and Sections 3.3.3.1-3.3.3.3 be rewritten to be consistent with one another and with the statutory language. Additionally, the SCPD recommends that the availability of medical marijuana for minors should be as broad as possible under the statute or at least available for the same diagnoses as adults. It is unclear what the medical or policy basis is for additional restrictions on children and, equally important, children whose doctors believe that medical marijuana is the best treatment for them should be able to access that treatment to the fullest extent allowable by law. Because 16 Del. C. § 4906A permits additional diagnoses to be added to the acceptable list of diagnoses, this situation could be corrected without a need for a statutory amendment.

---

1 Under the current regulations there is no separate definition of pediatric qualifying conditions, but section 3.3.3 provides additional limits for patients under the age of 18 that do not exist for adults.

[2] *See* 16 Del. Admin. C. § 4470-2.0 (Definition of physician).

[3] Hardin, et. al., *Age Limit of Pediatrics*, American Academy of Pediatrics, http://pediatrics.aappublications.org/content/140/3/e20172151.

4 Autism Spectrum Disorder is a recognized diagnosis, "severe debilitating autism" is not. The term is not defined elsewhere in the regulations or code.

There is a similar problem with the definition of "physician." In the definition of physician, a "physician" for a patient under 18 years of age is limited to certain types of pediatric specialties. In the definition section, the new regulation adds "pediatric psychiatrist" and "developmental pediatrician" to the eligible types of physicians, BUT section 3.3.3 of the existing regulations does not include these new types of physicians to the types of physicians that can certify a minor for medical marijuana. Additionally, the relevant statute, 16 Del. C. § 4902A(12), does not include the additions to the types of permissible pediatric specialties. As such, it is unclear whether OMM has the authority to add these specialties at all. SCPD recommends that the definition of "physician" and Section 3.3.3 be rewritten to be consistent with one another and with the statutory language.

II. Primary Caregiver

Current and new regulations both use the phrase "primary caregiver" in multiple places. The term "primary caregiver" is not defined. It appears from context that "primary caregiver" is being used in place of "designated caregiver," a term that is defined. SCPD recommends that the regulations be rewritten to use the defined term "designated caregiver" and eliminate the undefined term "primary caregiver."

III. Hearing Procedures

The new regulations regarding hearing procedures are not written clearly and may result in persons utilizing medical marijuana being denied access to their medication for a significant period of time even if "expedited" procedures are used. The problematic procedures are the ones used when the Department determines that a patient's registration card shall be summarily suspended without notice.[5] In such a situation, the patient may request a "record review,"[6] but the regulations do not require the Department to act within a certain period of time. The patient may also request an appeal, and can request an expedited appeal.[7] Although the regulations do not explicitly so state, it appears that expedited appeals are only available to resolve summary suspensions. In an expedited appeal, the hearing must be scheduled within 15 days[8] and the decision on the hearing must be issued with 30 days after the hearing.[9] This means that a person whose eligibility has been summarily suspended may have to wait 45 days for the matter to be resolved. This will likely result in the patient being unable purchase their medication.

This is too long a period for a person to be deprived of their physician-prescribed medication without a decision. Additionally, it is entirely unclear how the "record review" and the hearing interact and whether they are sequential processes or can move forward concurrently. SCPD recommends that the record review and hearing regulations be clarified and that the expedited hearing procedures be revised so that a patient whose eligibility was summarily suspended will

[5] 16 Del. Admin. C. § 4470-9.2.5.1.
[6] *Id.* at §§ 4470-9.5.5.1.1-9.2.5.5.
[7] *Id.* at § 4470-9.5.4.
[8] *Id.* at § 4470-9.5.4.2.
[9] *Id.* at § 4470-9.5.4.4.

be able to have a hearing AND receive a decision before they are forced to go without their medication.

IV. On Site Visits

The current regulations, in a section that the new regulations do not change, permits on-site interviews of patients or caregivers to determine eligibility for medical marijuana.[10] It is unclear why on-site interviews, as opposed to interviews at a Department office, are warranted. The Department is only required to provide 24-hour notice of an interview. Patients are required to provide "immediate access" to "any material and information necessary for determining eligibility." The requirement to assemble all pertinent information on short notice and have it available for immediate inspection may be a significant hardship for persons with mental illness or developmental or intellectual disabilities. SCPD suggests that this section of the regulations be rewritten in such a way that it will meet the Department's needs without placing undue burden and stress on persons with disabilities.

V. Service Animals

The new regulations for Marijuana Infused Food Establishments prohibits any "animals/pets" in the establishment "during the preparation, packaging, or handling of any marijuana infused food products.[11] Services animals are not pets, but they are animals. As such, this arguably excludes service animals and persons who need them from Marijuana Infused Food Establishments. It should be noted that the exclusion is for the entire establishment, not just the area where the food is being prepared, packaged, or handled. According to the regulation, a service animal could not be present in the establishment in the area where products are sold to customers if the food products were being prepared in an entirely separate area. The Americans with Disabilities Act requires places of public accommodation to permit service animals in most places. A blanket ban on service animals anywhere in the establishment at any time food is being prepared, packaged, or handled in the establishment is overbroad. As a federal law, the ADA will preempt this regulation, but the state should not promulgate a regulation that is facially in conflict with the ADA. As such, SCPD recommends that this portion of the regulation be rewritten more narrowly to ensure that it complies with the ADA.

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

cc: Karyl Rattay, MD. MS, Division of Public Health
Ms. Laura Waterland, Esq.
Governor's Advisory Council for Exceptional Citizens
Developmental Disabilities Council

22reg652 dhss-dph medical marijuana 2-28-19

[10] 16 Del. Admin. C. § 4470-9.1.
[11] 16 Del. Admin. C. § 4470-15.3.