



Governor's Advisory Council for Exceptional Citizens (GACEC) 516 West Loockerman St., Dover, DE 19904
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February 26, 2019

Alanna Mozeik
Division of Public Health
417 Federal Street
Dover, DE 19901

DHSS/DPH Proposed Changes to Delaware Medical Marijuana Code Regulation [22 DE Reg. 652 (February 1, 2019)]

Dear Ms. Mozeik:

The Governor's Advisory Council for Exceptional Citizens (GACEC) has reviewed the Delaware Health and Social Services/Division of Public Health Office of Medical Marijuana proposal to make changes to the Delaware Medical Marijuana Code. Council would like to share the following observations.

One, Section 2.0 Definitions

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." It is unclear on what basis the Office of Medical Marijuana imposes the additional restrictions on children. The underlying statute does not contain any 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. The regulation is unclear.

Two, the regulation fails to define "pediatric" in Definitions subsection (c). While it may be intended to mean "under the age of 18," the field of pediatrics extends through age 21 and can be further extended in unusual cases.

Three, 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 the Office of Medical Marijuana has the authority to add these specialties at all. Council asks that the definition of “physician” and Section 3.3.3 be rewritten to be consistent with one another and with the statutory language.

Four, the definition of Employee or Agent includes the phrase “...an individual performing work under contractual agreement...”. This phrase makes the definition too broad and would lead to too many background checks to be done.

Five, in section 3.3.3.1, it is unclear if “pain; anxiety; depression; seizure disorder; severe debilitating autism” are only eligible if they are “related to a terminal illness.”

Six, Section 3.3.3.3.2 includes “intractable epilepsy” as a separate eligible diagnosis. Council contends that “intractable epilepsy” is probably covered under “seizure disorders,” and it would be helpful if these regulations are consistent and clear. As written, they are neither.

Seven, Council recommends 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. Council also recommends that the availability of medical marijuana for minors should be as broad as possible under the statute. It is unclear whether the additional restrictions on access for minors are even permissible under the statute 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.

Eight, current and new regulations both use the phrase “primary caregiver” in multiple places. The term “primary caregiver” is not defined in Section 2.0. It appears from context that “primary caregiver” is being used in place of “designated caregiver,” a term that is defined in Section 2.0. Council suggests the regulations be rewritten to use the defined term “designated caregiver” and eliminate the undefined term “primary caregiver.”

Nine, Council would like additional information on who is responsible for conducting the criminal background check in section 4.2.1.1.

Ten, in section 5.3.4, a \$20 fee is mentioned. Is there a fee schedule that lists this fee, along with other dollar amounts listed throughout the regulation? How was the amount of the \$20 fee determined?

Eleven, sections 5.3.1.3 and 5.3.4 discuss changes that would negate the registry identification cards and require the patient to be issued a new card at a cost of \$20. Council questions the fairness of requiring the patient to have to pay an additional fee if the certifying physician loses his/her eligibility.

Twelve, in section 5.3.7, is there a process for appealing the decision of the certifying physician or the opportunity to get a second opinion from another physician who may say the marijuana is still necessary?

Thirteen, section 5.4.2.4 states an application may be denied if “the applicant or the designated caregiver provides false or falsified information.” Council queries how either party would know that the other party has provided false information.

Fourteen, in section 7.1.5.5.3, it appears the compassion center is able to compost medical marijuana once it is made unusable. Who is in charge of ensuring the composting is in compliance with applicable County statutes and regulations?

Fifteen, section 7.2.2.3.2 authorizes closing the physical building impacted by the failure of the security system. Council does not understand how closing the building that no longer has an operating security system would make the premises secure until the security system has been restored to full operation. We suggest physical deterrents, such as onsite security personnel rather than simply closing the building. Council would also suggest utilizing alternate security for periods lasting for less than the eight-hour timeframe listed in section 7.2.2.3.

Sixteen, in section 7.2.3 on Video Surveillance, Council would suggest the regulation be more specific in stating whether this is continuous monitoring or merely continuous recording. Also, does this infer that DHSS is also monitoring or recording the surveillance footage?

Seventeen, sections 7.2.4.2.5 and 8.2.1.4.2.1.3 discuss the scope and sustainability of the alarm system. Scope and sustainability are determined by the requirements mandated by the Department of Health and Social Services. As written, there is not enough information on security provided on windows or doors and information is lacking on sustainability of the system. Are these requirements listed or based on “adequate security” standards in another regulation?

Eighteen, Council would suggest the verbiage in 7.4.4 include the same parameters as the verbiage in section 8.4.1.3.

Nineteen, in section 7.5.1.2, there is no mention of background checks on investors of over \$5000.

Twenty, in section 7.10.2.3, explanations or examples would be helpful in defining the term, “...serious concerns...” in order to ensure conformity.

Twenty-one, section 8.2.1.2.3.2 discusses alternative security measures. As mentioned earlier, Council notes that closing the building if the security system fails does not secure the building.

Twenty-two, section 8.2.1.3 does not explain if video surveillance is actual monitoring or simply a recording.

Twenty-three, in section 8.11.1.3, Council would suggest a definition of the term “serious”.

Twenty-four, Section 8 outlines the general requirements for operation of a facility. There does not appear to be any information in the section or other sections of the regulation outlining procedures and requirements for the disposal of marijuana if licenses are terminated or suspended.

Twenty-five, Section 9.1.1 permits on-site interviews of patients or caregivers to determine eligibility for medical marijuana. 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. Council suggests that this section be rewritten in such a way that it will meet the Department’s needs without placing undue burden and stress on persons with disabilities. Council also questions the legality of such a search.

Twenty-six, section 9.2.5 through 9.5.10 in 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. In such a situation, the patient may request a “record review,” 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. 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, and the decision on the hearing must be issued with 30 days after the hearing. 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. Council suggests 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 be able to have a hearing AND receive a decision before they are forced to go without their medication.

Twenty-seven, in section 9.2.1, what is meant by the term “civil police contact” and how does it differ from police contact?

Twenty-eight, Section 9.2.5.1.5.1 – Council would suggest the items listed here in relation to a written request for a record review be moved to section 9.2.5.1.1 which introduces the record review request.

Twenty-nine, Section 9.4 seems redundant since it is almost identical to the information found in section 9.2.5.1.1

Thirty, Section 11.3.7 appears to be stating that no other testing is required after the initial testing is done on a private well. This seems to assume that there will never be ground water contamination of a private well.

Thirty-one, Section 15.0 on Facility Requirements discusses cleaning requirements. Council would suggest more specific information be included and defined in this section on the proper cleaning and maintenance procedures and materials to ensure cleanliness. Wiping a dusty surface with a wet paper towel will remove the dust but does not clean the surface.

Thirty-two, section 15.3 of 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. Services animals are not pets, but they are animals. As such, this arguably excludes services 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 (ADA) requires places of public accommodation to permit service animals in most places. It may be appropriate to exclude a service animal from certain areas of the establishment where and when food is being prepared, but a blanket ban on 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 in conflict with the ADA. Council asks that this portion of the regulation be rewritten more narrowly to ensure that it complies with the ADA.

Thirty-three, in section 17.2.1.3, Council notes that there are no parameters or timeframes listed for the corrective action plans noted in this section.

Please feel free to contact me or Wendy Strauss at the GACEC office if you have questions on our comments. Thank you for the opportunity to share our recommendations with you.

Sincerely,

Ann C Fisher

Ann C. Fisher
Chairperson

ACF: kpc