



Governor's Advisory Council for Exceptional Citizens (GACEC) 516 West Loockerman St., Dover, DE 19904
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December 20, 2019

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

RE: 23 DE Reg. 433 [DHSS/DPH Proposed Delaware Medical Marijuana Code Revisions Regulation (December 1, 2019)]

Dear Ms. Mozeik:

The Governor's Advisory Council for Exceptional Citizens (GACEC) has reviewed the Delaware Office of Medical Marijuana, Division of Public Health (DPH) and Department of Health and Social Services (DHSS) proposal to amend the State of Delaware Medical Marijuana Code. Council would like to share the following observations on the proposed amendments.

First, DHSS proposes to amend the definition of "debilitating medical condition." to include terminal illness, seizure disorder, glaucoma, chronic debilitating migraines, and new daily persistent headache. According to the National Center for Complementary and Integrative Health, cannabis and cannabinoids are also helpful in treating anxiety, inflammatory bowel disease, irritable bowel syndrome, movement disorders due to Tourette Syndrome, and sleep problems. (<https://nccih.nih.gov/health/marijuana-cannabinoids#hed11>). Council would like to encourage DHSS to consider adding these additional health conditions to its definition of "debilitating medical condition."

Second, DHSS is also proposing to add an additional subsection under the "debilitating medical condition" definition that describes the qualifying conditions for individuals under the age of 18. It reads as follows:

2.0(c) Pediatric qualifying conditions are limited to any of the following related to a terminal illness: pain, anxiety, or 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; and chronic debilitating migraines and new daily persistent headache that are refractory to conventional treatment and interventions;

For clarity, Council would like to recommend that DHSS consider using subsection headings to divide each qualifying condition. The section would then read as follows:

2.0(c) Pediatric qualifying conditions are limited to

- (1) any of the following related to a terminal illness: pain, anxiety, or depression;
- (2) seizure disorder; severe debilitating autism; ~~or, chronic debilitating migraines and new daily persistent headache that are refractory to conventional treatment and interventions;~~ or
- (3) 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; ~~or, and chronic debilitating migraines and new daily persistent headache that are refractory to conventional treatment and interventions;~~

Alternatively, DHSS could use the same format and division as used in the proposed amended 3.3.3:

2.0(c) Pediatric qualifying conditions are limited to

- (1) any of the following related to a terminal illness: pain, anxiety or depression; or
- (2) intractable epilepsy or seizure disorder;
- (3) a chronic or debilitating disease or medical condition where the patient has failed treatment involving one or more of the following symptoms: cachexia or wasting syndrome; intractable nausea; seizures; severe, painful and persistent muscle spasms; spasms; or chronic debilitating migraines and new daily persistent headache that are refractory to conventional treatment and interventions; or
- (4) severe debilitating autism.

Third, DHSS proposes a definitional change involving the addition of the term “terminal illness” which includes language similar to the federal definition used for Medicare and Medicaid services. The biggest difference between the two definitions is that the proposed definition gives a life expectancy of 12 months whereas the federal definition gives a life expectancy of six months. Council supports the proposed amendment as it gives more time and allows more individuals access to medical marijuana.

Fourth, Section 3.4 adds information on the “compassionate use card”. The requirements for the compassionate use card are more expansive and cumbersome than those used for the regular registry card because the compassionate use card allows a physician to certify a patient for the card for a medical condition that is not currently covered by the Act. Section 3.4.2 includes the requirement for physicians to re-evaluate the treatment for different medical conditions at different rates including every 15 days for the first 90 days and then every 30 days for substance use disorder; every 30 days for mental health disorders; every 30 days for the first 90 days and then every 90 days for autoimmune disease; and every 30 days for any other conditions. Council would suggest standardizing the timeframes to make the process less confusing. Council would also recommend longer intervals of re-evaluation given how cumbersome these timeframes may be.

Fifth, DHSS proposes to make the denial of an application or renewal for a compassionate use card not subject to judicial review. (5.4.4.1). Presently, the denial of an application or renewal for registry identification cards is subject to judicial review in the Superior Court. Council recommends DHSS

remove section 5.4.4.1 which would allow denials of applications or renewals for compassionate use cards be subject to judicial review.

Sixth, although not presently being amended, Council would like to request that DHSS consider amending section 6.0, which details the procedure for the addition of debilitating medical conditions, or otherwise addresses the lack of published information on denied conditions. Currently, there is only a database for the medical conditions that have been approved to be added as debilitating medical conditions. There is no database containing the medical conditions that have been denied. DHSS considers a petition to add a new debilitating medical condition to have “merit” if, among other requirements, the particular medical condition has not been the subject of a petition in the preceding two years. If DHSS also includes information on those petitions that were denied, the date, and the reasoning in the same location as those that have been approved, it would provide consumers and Delawareans with additional information and could prevent the spending of additional staff hours on petitions.

Seventh, section 15.3.1 of the proposed addition of the regulations and procedures for Marijuana Infused Food Establishment states the following: “No animals/pets shall be permitted in the kitchen area of a Marijuana Infused Food Establishment during the preparation, packaging, or handling of any marijuana infused products. Under the Americans with Disabilities Act, individuals who utilize service dogs are afforded certain protections under law. Guidance by the Food and Drug Administration explains that in the context of food service:

Decisions regarding a food employee or applicant with a disability who needs to use a service animal should be made on a case-by-case basis. An employer must comply with health and safety requirements, but is obligated to consider whether there is a reasonable accommodation that can be made.

(pg. 537; <https://www.fda.gov/media/87140/download>). There may be situations where an employee could have their service dog at work, with precautions in place to prevent handling of the animal during food prep duties. Council supports the amendment but would like to request that DHSS change 15.3.1 to include similar language as the FDA guidance, such as:

Decisions regarding a Marijuana Infused Food Establishment employee’s use of a service animal should be determined by the employer on a case-by-case basis, considering both health and safety requirements and whether there is a reasonable accommodation that can be made.

Thank you for this opportunity to share our observations with you. Please contact me or Wendy Strauss at the GACEC office if you have any questions.

Sincerely,

Ann C Fisher

Ann C. Fisher
Chairperson

ACF: kpc