

Mission:

To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.



Rick Scott
Governor

John H. Armstrong, MD, FACS
State Surgeon General & Secretary

Vision: To be the Healthiest State in the Nation

February 27, 2015

Ms. Marjorie Holladay
Chief Attorney
Joint Administrative Procedures Committee
Room 680, Pepper Building
111 West Madison Street
Tallahassee, Florida 32399-1400

RE: Chapter 64-4, F.A.C.

Dear Ms. Holladay:

The Department is in receipt of your letter dated February 26, 2015. To implement the Compassionate Medical Cannabis Act of 2014, the Department has worked relentlessly to create a regulatory structure so that dispensing organizations can begin providing a low-THC cannabidiol product to children with intractable epilepsy and people with advanced cancer as quickly and safely as possible. This task has been challenging, yet the Department believes the proposed rules provide a statutorily authorized vehicle to deliver this product to the patients who need it.

As required by law, the Department has responded to your questions and comments in three categories (attachment). As for the Statement of Estimated Regulatory Costs, it is final. Your suggestion for potential additional costs is too speculative for the Department to include in a SERC. There is even more uncertainty regarding Rule 64-4.003, F.A.C., because the Department's costs to continue this program will be different from the start-up costs. The renewal fee will not even be set until the Department has a better idea of those recurring costs. As a result, the Department will not be moving forward with adoption of 64-4.003, F.A.C., at this time.

The Department has done its due diligence drafting a valid regulatory structure. The Department will continue to implement the Compassionate Medical Cannabis Act of 2014 in order to fulfill the statutory purpose of getting this product to children and families dealing with intractable epilepsy and patients with advanced cancer as swiftly and safely as possible.

Sincerely,

Patricia A. Nelson
Director
Enclosure

CATEGORY	COMMENTS ADDRESSED
<p>TECHNICAL CHANGES -- These comments will be addressed with the Secretary of State upon adoption.</p>	<p>Notice; 64-4.002– Form DH8006-OCU-2/2015; 64-4.002(2)(a)-(h) page 4, items 3.e.ii. and iv and page 10, Part IV; 64-4.002(2)(a)13; 64-4.002(2)(a)15; 64-4.002(2)(b); 64-4.002(5)(a)- Form DH8007-OCU-2/2015, page 1 word “recall”, page 1 number 167, page 2 punctuation; page 3; 64-4.005(2)</p>
<p>RESOLVED THROUGH APPLICATION PARADIGM OF COMPETITION, NOT CRITERIA -- This entire system is based on competition. The point is that the Department has not set minimum criteria, but it has identified items of information that it believes will allow it to evaluate the Applicants for the elements of the law that were highlighted by the Administrative Law Judge in his Final Order in the challenge to the previous version of this regulatory structure (DOAH case number 14-4296RP) (“Final Order”). Our singular statutory duty is to pick the best Applicants such that the product is available and accessible to the people that need it. Our statutory duty is NOT to tell any Applicant how to structure its organization and operation; our statutory duty is to compare the organization and operation to the other Applicants and choose the five Applicants that will best provide for the availability and accessibility of this product. Once you have comprehended the entirety of the regulatory structure, the Department is confident that your many questions about what certain words or phrases mean will become abundantly clear.</p> <p>or</p> <p>PLAIN AND ORDINARY MEANING</p>	<p>64-4.001(1); 64-4.001(2); 64-4.001(3), (4), (5), and <i>passim</i>; 64-4.001(10); 64-4.001(13); 64-4.001(14); 64-4.002(2)(a)-(h); 64-4.002(2); 64-4.002(2)(a); 64-4.002(2)(a)3; 64-4.002(2)(a)4; 64-4.002(2)(a)9.a.; 64-4.002(2)(a)9.d.; 64-4.002(2)(a)10; 64-4.002(2)(a)11; 64-4.002(2)(a)13 – “good handling practices.”; 64-4.002(2)(a)14; 64-4.002(2)(b) – documentation required; 64-4.002(2)(c); 64-4.002(2)(c)1; 64-4.002(2)(c)2; 64-4.002(2)(c)3; 64-4.002(2)(c)4; 64-4.002(2)(c)5.a; 64-4.002(2)(c)6; 64-4.002(2)(c)11; 64-4.002(2)(c)11.b; 64-4.002(2)(c)13; 64-4.002(2)(c)14; 64-4.002(2)(c)16; 64-4.002(2)(d); 64-4.002(2)(d)15; 64-4.002(2)(e); 64-4.002(2)(f); 64-4.002(2)(f)7; 64-4.002(2)(f)11 –lawsuits; 64-4.002(2)(h) – applicant submissions; (2)(h)1. through 17; how items can be compared among applicants; 64-4.002(2)(h) – how items pertain to the medical director’s ability to “supervise the activities of the dispensing organization.”; 64-4.002(2)(h)16; 64-4.002(2)(h)17; 64-4.002(4); 64-4.002(5); 64-4.002(5)(a), Form DH8007-OCU-2/2015; points are assigned and how scores or points are allotted on a percentage basis for each item; 64-4.002(5)(c); 64-4.002(5)(d); 64-4.002(5)(d) – statutory authority; 64-4.003(2); 64-4.003(3); 64-4.003(4) – why fee is non-refundable; 64-4.004; 64-4.004(1)(b); 64-4.004(2); 64-4.004(3); 64-4.005(1); 64-4.009(2), Form DH8009 – OCU-2/2015; 64-4.009(4)</p>
<p>AUTHORIZED OR REQUIRED BY FINAL ORDER -- The Final Order in the prior rule challenge affects most aspects of this regulatory structure because it makes clear the Department must select the best Applicant. The Department has identified the information it needs to make that determination The Department has set out in detail how it will score each item relative to the other items. In the end, the Department will have done its statutory duty without placing unlawful or invalid minimum criteria on the Applicants.</p>	<p>64-4.002, Application Part III; 64-4.002(2)(a); 64-4.002(2)(a)10; 64-4.002(2)(a)21., 24., 26.b.-d; 64-4.002(2)(a)21.,26.b., 26.d.; 64-4.002(2)(a)26.c.; 64-4.002(2)(c)1; 64-4.002(2)(c)12.c.; 64-4.002(2)(d)15; 64-4.002(2)(e)3.a; 64-4.002(2)(f) – statutory authority; 64-4.002(2)(f)11 lawsuits; 64-4.002(2)(h) – statutory authority; 64-4.002(2)(h) –how items pertain to the medical director’s ability to “supervise the activities of the dispensing organization.”; 64-4.002(5)(d) – statutory authority; 64-4.004(1)(b) –qualified patient representative.</p>