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THE FLORIDA LEGISLATURE  
**JOINT ADMINISTRATIVE  
PROCEDURES COMMITTEE**

February 26, 2015

Ms. Patricia A. Nelson, Director  
Office of Compassionate Use  
Department of Health  
4052 Bald Cypress Way, Bin A-02  
Tallahassee, Florida 32399-1703

**Re: Department of Health  
Rules 64-4.001, .002, .003, .004, .005, and .009, F.A.C.**

Dear Ms. Nelson:

I have conducted a preliminary review of the above-referenced proposed rules, which were advertised in the Florida Administrative Register on February 6, 2015. I have the following comments.

**Notice:**

The titles of rules 64-4.004 and 64-4.005 are inconsistent in the notice and the rule text. The notice indicates the title of rule 64-4.004 is "Denial or Revocation for Dispensing Organization Approval," whereas the title of the rule in the text is "Revocation of Dispensing Organization Approval." The notice indicates that the title of rule 64-4.005 is "Inspection Procedures," whereas the title of the rule in the text is "Inspection and Authorization Procedures." Please publish a notice of correction with the correct titles of these rules.

**Summary of Statement of Estimated Regulatory Costs and Legislative Ratification:**

Please explain why the SERC provided to the committee indicates that it is a draft. If it is a draft, please provide the finalized copy of the SERC to committee staff.

Please publish a notice of correction in the next available FAR summarizing the SERC based on the factors set forth in section 120.541(2), as required by section 120.54(3)(a)1., in order to

provide the requisite notice to the public. It appears that the department's determination that legislative ratification is not required for rule 64-4.002 should be based upon the SERC prepared by the agency.

Also, it appears that a SERC may be required for rule 64-4.003. That rule provides that the applicants seeking biennial renewal must pay an unknown biennial renewal fee. It appears that rule 64-4.003 may directly or indirectly increase regulatory costs in excess of \$200,000 in the aggregate within one year after implementation, necessitating the preparation of a SERC pursuant to sections 120.54(3)(b) and 120.541(1)(b). If the department determines that a SERC is not required for rule 64-4.003, please explain how the department reached that conclusion.

**Legislative Ratification:**

Page three of the SERC states that, based on the consensus reached by the negotiated rulemaking committee, the growers on the committee decided that approximately 15 nurseries that meet the requirements of section 381.986(5)(b)1. would apply for department approval. Please explain whether the department's identification of approximately 15 nurseries takes into consideration that these 15 nurseries may apply in multiple regions. It appears that if any of these 15 nurseries apply in more than one region, then the regulatory costs associated with this rule may exceed \$1,000,000, and ratification may be required. *See* § 120.541(2)(a) and (3), Fla. Stat.

Proposed rule 64-4.003 requires dispensing organizations applying for biennial renewal to pay an unknown fee. Depending on the amount of this fee, the statutory threshold for legislative ratification could be triggered, especially because there will be three renewal fees to be paid by the five dispensing organizations seeking renewal within five years after implementation of the rule. *See* § 120.541(2)(a) and (3), Fla. Stat.

Moreover, it appears that the economic impact of proposed rules 64-4.002 and 64-4.003 should be considered together. A dispensing organization seeking renewal pursuant to rule 64-4.003 necessarily obtained approval and authorization pursuant to rule 64-4.002, and presumably dispensing organizations that have been approved and authorized pursuant to rule 64-4.002 will seek renewal pursuant to rule 64-4.003. Thus, it appears that the costs associated with obtaining approval and authorization pursuant to rules 64-4.002 and 64-4.003 should be considered together for ratification purposes.

Please explain whether ratification of proposed rules 64-4.002 and/or 64-4.003 is required pursuant to section 120.541(3). If the department does not believe ratification of these rules is required, please explain how the department reached this conclusion.

**64-4.001(1):**

It appears that the word "operator" should be defined. *See* § 120.545(1)(i), Fla. Stat.

**64-4.001(2):**

Please explain why the definition of approval states that the applicant "is prepared to be inspected." It does not appear that the rules require any inspections.

**64-4.001(3), (4), (5), and *passim*:**

Please explain the criteria the department will use to authorize a dispensing organization to begin cultivating low-THC cannabis, to begin processing low-THC cannabis to derivative product, and to begin dispensing derivative product. *See* § 120.52(8)(d), Fla. Stat.

**64-4.001(10):**

Please explain why the definition of “dispensing organization” is not inconsistent with the statutory definition of “dispensing organization” in section 381.986(1)(a). *See* § 120.52(8)(c), Fla. Stat.

Please provide statutory authority for a nursery’s contractual agents to be considered a part of the “dispensing organization.” *See* § 120.52(8)(c), Fla. Stat.

**64-4.001(13):**

*See* comment to 64-4.001(1) above.

It appears that the word “supervise” or “supervisor” should be defined. *See* § 120.545(1)(i), Fla. Stat.

Please explain the differences between “operators,” “managers,” and “supervisors.” These words, or variations of them, are used in this definition. *See* § 120.52(8)(d), Fla. Stat.

**64-4.001(14):**

Please explain why “permanent resident” is defined. It does not appear that this term is used in this rule chapter.

It appears this term may be defined in order to set forth how permanent residency is established for a patient who may receive low-THC cannabis from a dispensing organization. It appears, however, that the doctor ordering the low-THC cannabis, not the dispensing organization or facility, enters the patient’s name into the registry. *See* § 381.986(1)(d) and (2)(a), Fla. Stat.

Notwithstanding the foregoing comments, this definition of “permanent resident” does not appear to contemplate the permanent residence of minors who reside part of the year with a parent who lives in another state. It also does not appear to contemplate military personnel or the children and dependents of military personnel who are stationed, but not domiciled, in Florida. Please clarify this definition or explain why it is not necessary. *See* § 120.52(8)(d), Fla. Stat.

**64-4.002:**

The introductory paragraph of this rule incorporates by reference Form DH8006-OCU-2/2015, entitled “Application for Low-THC Cannabis Dispensing Organization Approval.”

Form DH8006-OCU-2/2015:

This form is incorporated by reference in rules 64-4.002 and 64-4.003. The form should display both rule numbers. *See* § 120.55(1)(a)4., Fla. Stat.

See comments to 64-4.002(2)(a)-(h) below.

Pages 2-3: The application requests the e-mail addresses of the nursery, the nurseryman, and the medical director. It appears that providing these e-mail addresses to the department causes those addresses to become a public record, and they may not be exempt from public records disclosure.

See § 119.011(12), Fla. Stat. Please revise the form to advise that providing this information is optional. It may be helpful to include in the form that providing this information is a public record. Cf. § 668.6076, Fla. Stat. (requiring agencies to post on their websites a disclaimer that under Florida law, e-mail addresses are public records).

Page 3: Part II of the form states in part, “A failure to submit the information required in Part II will result in the application being denied prior to any scoring as contemplated in rule 64-4.002(5), F.A.C.” Please explain how this sentence is consistent with the requirements of section 120.60(1).

Please explain how many points are assigned for each item included in part III of the application. Also, please explain how scores or points are allotted on a percentage basis for each item in part III. See § 120.52(8)(d), Fla. Stat.

It does not appear that part III of the application contains any ascertainable minimum thresholds or standards to demonstrate each item. See § 120.52(8)(d), Fla. Stat.

Page 4: Items 3.e.ii. and iv. request a description of the “cultivation environment, e.g., greenhouse, clean room, aseptic, et cetera.” It appears that this item should only be considered once.

Page 10: In part IV, the applicant is advised that the application must include a nonrefundable fee in the amount of \$60,036. Rule 64-4.002(1) requires an initial application fee of \$60,063. It appears that either the rule text or the application form should be changed to reflect the correct amount of the application fee.

Please explain why the application states that this fee is non-refundable. Absent statutory authority to the contrary, it appears that if an applicant requests a refund of this fee prior to any action being taken concerning the applicant’s qualifications, the fee should be refundable. See Op. Att’y Gen. Fla. 75-293 (1975).

As this form is also used for the biennial renewal as provided for in rule 64-4.003, it appears that the form should include the amount of the biennial renewal fee.

**64-4.002(2):**

Please explain whether any apparent errors, omissions, or the failure to include any information that must be addressed in subsection (2) will result in the application being considered incomplete. See § 120.60(1), Fla. Stat.

Please explain whether prospective employees can address each item in this subsection. *See* § 381.986(5)(b)2., Fla. Stat.

The rule text states that, “In any explanation, the Applicant must address each item listed for each criterion below.” The application states on page one that, “Each individual item listed in the Rule and the Application is not mandatory but is designed to elicit information from the

Applicant that will assist the OCU in making its selection.” It appears that the statement contained in the rule text is contradicted in the application. Please explain.

**64-4.002(2)(a):**

This rule paragraph asks the applicant to address the “technical and technological ability to cultivate, process, and dispense low-THC cannabis.” Section 381.986(5)(b)1. requires the applicant to demonstrate the “technical and technological ability to cultivate and produce low-THC cannabis.” Please explain why this rule paragraph does not impermissibly enlarge, modify, or contravene section 381.986(5)(b)1. *See* § 120.52(8)(c), Fla. Stat.

Please explain the level or degree of experience and knowledge that must be addressed by the applicant for each of the items listed in this rule paragraph. Please explain how an applicant knows of any minimum thresholds and standards required to demonstrate each item enumerated in this paragraph. *See* § 120.52(8)(d), Fla. Stat.

Please explain how each of these items, as written, can be compared among the applicants. *See* § 120.52(8)(d), Fla. Stat.

**64-4.002(2)(a)3.:**

Please explain in the rule text what the department means by “experience introducing new varieties of plants.” *See* § 120.52(8)(d), Fla. Stat.

**64-4.002(2)(a)4.:**

Please explain in the rule text what the department means by “regional cultivation” and to what region the department is referring. *See* § 120.52(8)(d), Fla. Stat.

**64-4.002(2)(a)9.a.:**

Please explain in the rule text what the department means by “proper cultivation conditions and techniques.” *See* § 120.52(8)(d), Fla. Stat.

**64-4.002(2)(a)9.d.:**

Please explain in the rule text what the department means by “high quality product” and “short time.” *See* § 120.52(8)(d), Fla. Stat.

**64-4.002(2)(a)10.:**

Please explain why the department is asking for “experience with tracking each plant in a harvest.” It does not appear that a dispensing organization is required to track the plants in a

harvest. *See* § 120.52(8)(e), Fla. Stat. Also, “harvest” is not defined. *See* § 120.545(1)(i), Fla. Stat.

**64-4.002(2)(a)11.:**

Please explain in the rule text what the department means by “good agricultural practices.” *See* §§ 120.52(8)(d), .54(2)(b)2., Fla. Stat.

**64-4.002(2)(a)13. [sic]:**

It appears that this subparagraph should be renumbered as (2)(a)12., and the subsequent subparagraphs should also be renumbered.

Please explain in the rule text what the department means by “good handling practices.” *See* §§ 120.52(8)(d), .54(2)(b)2., Fla. Stat.

**64-4.002(2)(a)14. [sic]:**

Please explain in the rule text what the department means by “good manufacturing practices.” *See* §§ 120.52(8)(d), .54(2)(b)2., Fla. Stat.

**64-4.002(2)(a)15. [sic]:**

It appears there may be a word missing following “analytical.”

**64-4.002(2)(a)21., 24., 26.b.-d. [sic]:**

Please provide statutory authority for requesting these items. It does not appear that these subparagraphs and sub-subparagraphs are logically related to demonstrating the technical and technological ability to cultivate and produce low-THC cannabis pursuant to section 381.986(5)(b)1. *See* § 120.52(8)(e), Fla. Stat.

**64-4.002(2)(a)21., 26.b., 26.d.[sic]:**

Please explain why the department is considering an applicant’s experience interacting with patients, its training program for employees addressing patient education, and its training program for employees addressing patient counseling. *See* § 120.52(8)(e), Fla. Stat. Nurseries are not pharmacies, and it does not appear that dispensing organizations, and the owners, managers and employees thereof are subject to licensure or regulation under chapter 465. *See* § 381.986(7)(c), Fla. Stat. Please provide statutory authority for requesting this information. *See* § 120.52(8)(c), Fla. Stat.

**64-4.002(2)(a)26.c. [sic]:**

Please explain why the department is considering an applicant’s training program for employees addressing compliance. Please explain what sort of compliance must be addressed. *See* § 120.52(8)(d), Fla. Stat.

**64-4.002(2)(b):**

It appears that the word “must” in this paragraph should be deleted.

Please explain what documentation is required to demonstrate each of the requirements of this paragraph. For example, would the department accept a photocopy of the nursery's certificate of registration? Also, please explain what must be provided to the department to demonstrate that the applicant is operated by a nurseryman as defined in section 581.011, and that the applicant has been operated as a registered nursery in Florida for at least 30 continuous years. *See* § 120.52(8)(d), Fla. Stat.

**64-4.002(2)(c):**

As each applicant will be evaluated based on its ability to meet the criteria listed in subparagraphs (2)(c)1. through 16. and the sub-subparagraphs thereof, please explain what each applicant must submit in order to address each of these items. Please explain how each application is evaluated if there are no minimum thresholds or standards required for demonstrating each item enumerated in this paragraph. *See* § 120.52(8)(d), Fla. Stat.

Please explain how each of these items, as written, can be compared among the applicants. *See* § 120.52(8)(d), Fla. Stat.

**64-4.002(2)(c)1.:**

Please provide statutory authority for requesting the lease terms for the properties enumerated in this subparagraph. *See* § 120.52(8)(c), Fla. Stat. Section 381.986(5)(b)2. requires the applicant to demonstrate its ability to secure premises, but does not appear to authorize the department to require disclosure of such lease terms.

**64-4.002(2)(c)2.:**

It does not appear that this item lends itself to a sketch or illustration as required by paragraph 64-4.002(2)(c). *See* § 120.52(8)(e), Fla. Stat.

**64-4.002(2)(c)3.:**

See comment to 64-4.002(2)(c)2. above.

Please explain how an applicant can demonstrate the ability to obtain zoning approval before it is authorized to become a dispensing organization. *See* § 120.52(8)(e), Fla. Stat.

**64-4.002(2)(c)4.:**

Please explain why the department is requesting a sketch or illustration of the land topography and vegetation of the proposed property. This does not appear to be logically related to paragraph (2)(c). *See* § 120.52(8)(e), Fla. Stat.

**64-4.002(2)(c)5.a.:**

Please explain what the department means by "capacity," and please explain how much capacity is expected of the dispensing organization. *See* § 120.52(8)(d), Fla. Stat.

**64-4.002(2)(c)6.:**

Please explain why the department is requesting a “description of the ability or plan to expand any of the areas proposed for low-THC cannabis” when the rule text does not contain any minimum thresholds for production. *See* § 120.52(8)(d) and (e), Fla. Stat.

**64-4.002(2)(c)11.:**

It appears that sub-subparagraphs (2)(c)11. a. and b. should refer to “proposed dispensing facilities,” instead of “dispensing facilities.”

**64-4.002(2)(c)11.b.:**

The applicant is required to address the “proximity of dispensing facilities to patient populations.” Please explain how an applicant addresses this item when the rule text does not state where the patients are located or where the department anticipates the patients will be located. *See* § 120.52(8)(d), Fla. Stat.

**64-4.002(2)(c)12.c.:**

Please provide statutory authority for requesting professional licensure disciplinary action in all jurisdictions for all current and proposed staff. If an employee of a proposed dispensing facility has had disciplinary action taken against a license in an unrelated profession, it does not appear that there is a rational relationship between that disciplinary action and his or her duties in a dispensing organization. *See* § 120.52(8)(c) and (e), Fla. Stat.

**64-4.002(2)(c)13.:**

As the department is requesting an organizational chart illustrating the supervisory structure of the proposed dispensing organization, it may be helpful to define “supervisor” or “supervisory.” *See* § 120.545(1)(i), Fla. Stat.

**64-4.002(2)(c)14.:**

It appears that “key personnel” should be defined. *See* § 120.52(8)(d), Fla. Stat.

**64-4.002(2)(c)16.:**

Please explain why the department is requesting the applicant to address “relationship(s) with an independent laboratory(ies) with cannabis testing protocols and methods.” It does not appear that these proposed rules require testing, other than authorizing the department to identify samples for laboratory analysis in rule 64-4.005(1). *See* § 120.52(8)(e), Fla. Stat.

**64-4.002(2)(d):**

As each applicant will be evaluated based on its ability to meet the criteria listed in subparagraphs (2)(d)1. through 16. and the sub-subparagraphs thereof, please explain what each applicant must submit in order to address each of these items. Please explain how each application is evaluated if there are no minimum thresholds or standards required for demonstrating each item enumerated in this paragraph. *See* § 120.52(8)(d), Fla. Stat.

Please explain how each of these items, as written, can be compared among the applicants. *See* § 120.52(8)(d), Fla. Stat.

**64-4.002(2)(d)15.:**

Please explain why the department is requesting “plans for the recall of any Derivative Products that have a reasonable probability of causing adverse health consequences based on a testing result, bad patient reaction, or other reason.” It does not appear that the rules require laboratory testing of batches or harvests, other than authorizing the department to identify samples for laboratory analysis in rule 64-4.005(1). *See* § 120.52(8)(e), Fla. Stat.

Also, without requiring testing of batches or harvests, please explain how defective derivative products can be identified and recalled.

**64-4.002(2)(e):**

This rule paragraph requires the applicant to address, “an infrastructure reasonably located to dispense low-THC cannabis to registered patients statewide or regionally as determined by the department.” Please state in the rule text whether the department is authorizing statewide or regional dispensing. *See* § 120.52(8)(d), Fla. Stat.

As each applicant will be evaluated based on its ability to meet the criteria listed in subparagraphs (2)(e)1. through 8. and the sub-subparagraphs thereof, please explain what each applicant must submit in order to address each of these items. Please explain how each application is evaluated if there are no minimum thresholds or standards required for demonstrating each item enumerated in this paragraph. *See* § 120.52(8)(d), Fla. Stat.

Please explain how each of these items, as written, can be compared among the applicants. *See* § 120.52(8)(d), Fla. Stat.

**64-4.002(2)(e)3.a.:**

Please explain why the department is considering an applicant’s proposed areas designed to protect patient privacy. *See* comment to 64-4.002(2)(a)21., 26.b., and 26.d. [sic] above.

**64-4.002(2)(f):**

As each applicant will be evaluated based on its ability to meet the criteria listed in subparagraphs (2)(f)1. through 14., please explain what each applicant must submit in order to address each of these items. Please explain how each application is evaluated if there are no minimum thresholds or standards required for demonstrating each item enumerated in this paragraph. *See* § 120.52(8)(d), Fla. Stat.

Please explain how each of these items, as written, can be compared among the applicants. *See* § 120.52(8)(d), Fla. Stat.

Please provide statutory authority for requesting the information in subparagraphs (2)(f)4. through 12. *See* § 120.52(8)(c), Fla. Stat.

**64-4.002(2)(f)7.:**

Please clarify in the rule text what the department means by “any other individuals or entities.” *See* § 120.52(8)(d), Fla. Stat.

**64-4.002(2)(f)11.:**

Please explain the relevance of requesting information regarding any lawsuits (as opposed to judgments entered) within the past seven years to which the applicant was a party. *See* §§ 120.52(8)(e), .545(1)(i), Fla. Stat.

Also, it is unclear what information about these lawsuits the department is requesting. *See* § 120.545(1)(i), Fla. Stat.

**64-4.002(2)(h):**

As each applicant will be evaluated based on its ability to meet the criteria listed in subparagraphs (2)(h)1. through 17., please explain what each applicant must submit in order to address each of these items. Please explain how each application is evaluated if there are no minimum thresholds or standards required for demonstrating each item enumerated in this paragraph. *See* § 120.52(8)(d), Fla. Stat.

Please explain how each of these items, as written, can be compared among the applicants. *See* § 120.52(8)(d), Fla. Stat.

Please provide statutory authority for requesting the information in subparagraphs (h)1. through 17. *See* § 120.52(8)(c), Fla. Stat.

As the medical director will not be ordering low-THC cannabis for use by patients, please explain how the items in subparagraphs (h)1., 2., 3., and 4., pertain to the medical director's ability to "supervise the activities of the dispensing organization." *See* § 381.986(5)(b)7., Fla. Stat.

**64-4.002(2)(h)16.:**

Please explain in the rule text the duties of the medical director and how the applicant's answer will be evaluated. *See* § 120.52(8)(d), Fla. Stat.

**64-4.002(2)(h)17.:**

Please explain what the department means by "how the Dispensing Organization will ensure it has a medical director at all times." It appears this could mean having a medical director employed, on the premises, or available. Please clarify this item. *See* § 120.52(8)(d), Fla. Stat.

Also, please explain whether the department would accept the employment of more than one medical director. *See* § 120.52(8)(d), .545(1)(i), Fla. Stat.

**64-4.002(4):**

Please explain how this subsection complies with the requirements of section 120.60(1).

**64-4.002(5):**

As the department is requiring a completed application within 21 calendar days after the effective date of this rule, please explain how the department will comply with the time requirements of section 120.60(1), or explain why those time periods do not apply.

**64-4.002(5)(a):**

This rule paragraph incorporates by reference Form DH8007-OCU-2/2015, entitled “Scorecard for Low-THC Cannabis Dispensing Organization Selection.”

Form DH8007-OCU-2/2015:

In order to substantively evaluate the applications and exhibits, it appears that there must be stated standards in the rule text, this scorecard, or in the application. It does not appear that the rule text, the scorecard, or the application contain any minimum thresholds or standards that are required to demonstrate each item. *See* § 120.52(8)(d), Fla. Stat.

See comments to 64-4.002(2)(a)-(h) above.

Please explain how many points are assigned for each item included in the scorecard. Also, please explain how scores or points are allotted on a percentage basis for each item. *See* § 120.52(8)(d), Fla. Stat.

Page 1: It appears that the word “recall” in number 12. should be “recalls.”

It appears that number 167. should be number 17.

Page 2: It appears that the punctuation following numbers 19. and 26. should be corrected.

It appears that the criteria to be considered under Processing – Accountability are inconsistent in the application and in the scorecard. Specifically, the application includes “vehicle tracking systems” and “vehicle security systems” on page 7 in section B.4. Those items do not appear to be included in this section of the scorecard.

Page 3: It appears that the criteria included in Dispensing – Technical Ability are inconsistent in the application and the scorecard. The application includes “knowledge of cannabis routes of administration” on page 7 in section C.1. That item does not appear to be included in this section of the scorecard.

It appears necessary punctuation is missing from item 9. on this page.

It appears that item 16.b. may be missing language contained on page 8 of the application for this criterion. The application begins this item with “For any property owned by the Applicant but subject to a mortgage or a lien, include ....”

It appears that the unnumbered criterion requesting “A list of current and proposed staffing, including ....” should be numbered 22., and the subsequent criteria should be renumbered.

“Vehicle tracking systems” and “vehicle security systems” are included under Dispensing – Accountability in numbers 32. and 33.[sic] of page 3 of the scorecard, but are not included in that section on page 9 of the application.

**64-4.002(5)(c):**

Please explain whether in the event of a tie, any standards and criteria used by each reviewer can change from the initial review of the application. *See* § 120.52(8)(d), Fla. Stat.

**64-4.002(5)(d):**

Please explain whether an applicant can be approved and authorized as a dispensing organization in more than one region. *See* § 120.52(8)(c), Fla. Stat.

Please explain whether the cultivation and processing of the low-THC cannabis must take place in the region where the dispensing organization is approved and authorized. *See* § 120.52(8)(c), Fla. Stat.

Please provide statutory authority for the last sentence of this paragraph. *See* § 120.52(8)(c), Fla. Stat.

**64-4.003(1):**

This subsection incorporates by reference Form DH8006-OCU-2/2015, entitled “Application for Low-THC Cannabis Dispensing Organization Approval.”

Form DH8006-OCU-2/2015:

*See* comments to Form DH8006-OCU-2/2015 in rule 64-4.002.

**64-4.003(2):**

Please provide statutory authority for requesting the information in paragraphs (2)(b) and (c). *See* § 120.52(8)(c), Fla. Stat.

It appears that reasonable quantities of low-THC cannabis that the dispensing organization may dispose of lawfully should be defined by rule. *See* § 381.986(7)(b) and (c), Fla. Stat.

**64-4.003(3):**

It appears that this subsection should specifically state when the department will notify the dispensing organization seeking renewal that it intends to renew the approval. *See* § 120.60, Fla. Stat.

**64-4.003(4):**

Please explain why the rule text does not expressly state the dollar amount of the fee that a dispensing organization must pay for biennial renewal. Section 381.986(5)(b) requires the department to impose a biennial renewal fee that is sufficient to cover the costs of administering that statute. Thus, it appears that the fee should be expressly stated in the rule text so that applicants know the amount of the fee. *See* § 120.52(8)(d), Fla. Stat.

Please explain why the rule states that this fee is non-refundable. Absent statutory authority to the contrary, it appears that if an applicant requests a refund of this fee prior to any action being taken concerning the applicant’s qualifications, the fee should be refundable. *See* Op. Att’y Gen. Fla. 75-293 (1975).

**64-4.004:**

Please explain the department's statutory authority to revoke a dispensing organization's approval for anything other than failure to comply with section 381.986(6).

**64-4.004(1)(b):**

Please explain how the dispensing organization can identify the qualified patient representative. *See* § 120.52(8)(d), Fla. Stat.

Please explain what sort of documentation of a qualified patient or a qualified patient representative is required by the dispensing organization. *See* § 120.52(8)(d), Fla. Stat.

This rule paragraph provides that a dispensing organization can have its approval revoked for knowingly dispensing derivative product to an individual other than a qualified patient or a qualified patient's legal representative without noticing the department and taking appropriate corrective action. It appears that the rule text should expressly state how a dispensing organization can properly notice the department. It appears that the rule text should also explain what appropriate corrective action is anticipated by the department. *See* § 120.52(8)(d), Fla. Stat.

**64-4.004(2):**

This subsection provides that the department may revoke its approval of the dispensing organization if the failures enumerated in paragraphs (2)(a) and (b) impact the accessibility, availability, or safety of the derivative product and are not corrected within 30 calendar days after notification to the dispensing organization. The use of the word "may" necessarily implies that the department may or may not choose to revoke its approval based upon whim or caprice, and may vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

**64-4.004(3):**

This subsection provides that the department may revoke its approval of the dispensing organization for failure to meet the deadlines set forth in paragraphs (3)(a) and (b) and if the failure is not corrected within ten calendar days. *See* comment to 64-4.004(2) above.

Please explain whether the department will notify the dispensing organization of its failure to comply with paragraphs (3)(a) or (b). If so, please explain whether the 10 calendar days in which the failure to meet these deadlines runs from the date of notification or from the dates listed in paragraphs (3)(a) and (b).

**64-4.005(1):**

This subsection authorizes the department to inspect any dispensing organization facility and to identify samples of any low-THC cannabis or derivative product for laboratory analysis. Absent mandatory laboratory testing, please explain how the department ensures that the low-THC cannabis and derivative products comply with section 381.986(1)(b).

Please explain what the department will be inspecting in the dispensing organization facility pursuant to this rule. *See* § 120.52(8)(d), Fla. Stat.

Ms. Patricia A. Nelson, Director

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**64-4.005(2):**

It appears that the comma following the word “material” should be deleted.

**64-4.009(2):**

This subsection incorporates by reference form DH8009-OCU-2/2015, entitled “Request for Access to the Compassionate Use Registry.”

Form DH8009-OCU-2/2015:

This form requests the e-mail address of the individual to be given access. It appears that providing the e-mail address to the department causes the e-mail address to become a public record, and it may not be exempt from public records disclosure. *See* § 119.011(12), Fla. Stat. Please revise the form to advise that providing this information is optional. It may be helpful to include in the form that providing this information is a public record. *Cf.* § 668.6076, Fla. Stat. (requiring agencies to post on their websites a disclaimer that under Florida law, e-mail addresses are public records).

**64-4.009(4):**

See comment to 64-4.004(1)(b) above regarding the documentation of the qualified registered patient and patient’s legal representative.

As always, please let me know if you have any questions. Otherwise, I look forward to your response.

Sincerely,



Marjorie C. Holladay  
Chief Attorney