

STATE OF FLORIDA  
DIVISION OF ADMINISTRATIVE HEARINGS

BAYWOOD NURSERIES CO., INC.,

Petitioner,

vs.

Case No. 15-1694RP

DEPARTMENT OF HEALTH,

Respondent.

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FINAL ORDER

Pursuant to notice, a formal administrative hearing was held in this case on April 23 and 24, 2015, in Tallahassee, Florida, before W. David Watkins, Administrative Law Judge of the Division of Administrative Hearings.

APPEARANCES

For Petitioner Baywood Nurseries Co., Inc.:

Charles Moure, Esquire  
Hilary Keeling, Esquire  
Harris Moure, PLLC  
600 Stewart Street, Suite 1200  
Seattle, Washington 98101

For Respondent Department of Health:

W. Robert Vezina, Esquire  
Eduardo S. Lombard, Esquire  
Megan S. Reynolds, Esquire  
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413 East Park Avenue  
Tallahassee, Florida 32301

STATEMENT OF THE ISSUES

This is a rule challenge brought pursuant to section 120.56, Florida Statutes,<sup>1/</sup> to the Proposed Rules of the Department of Health ("Department" or "DOH") 64-4.001, 64-4.002, 64-4.004, and 64-4.005 (the "Proposed Rules"). The main issue in this case is whether the Proposed Rules are an invalid exercise of delegated legislative authority in that the Proposed Rules enlarge, modify, or contravene the specific provisions of law implemented, section 381.986, Florida Statutes; are vague; and/or are arbitrary and capricious. Petitioner also argues that the Proposed Rules impose regulatory costs that could be addressed by the adoption of a less costly alternative. Finally, Petitioner asserts that the Department materially failed to follow the applicable rulemaking procedures and requirements in its promulgation of the Proposed Rules.

PRELIMINARY STATEMENT

On March 24, 2015, Petitioner Baywood Nurseries Co., Inc. (Baywood), and former Petitioner Master Growers, P.A., challenged proposed rules 64-4.001, 64-4.002, 64-4.004, 64-4.005, and 64-4.009. On the Department's motion, Master Growers was dismissed for lack of standing prior to the final hearing.<sup>2/</sup>

As noticed, the final hearing was held on April 23 and 24, 2015, in Tallahassee, Florida. At the hearing, Joint Exhibits 1 through 5 were admitted into evidence. Baywood's Exhibits 1

through 4, 9, 10, 12, 15, 16, 18, 20, 22 through 24, 27, 29, 31, 33, 34, 38, and 41 through 48 were admitted without objection by the Department. Baywood's Exhibits 11, 13, 14, 19, 25, 26, 28, 30, and 49 were received over the Department's objections. The Department's Exhibits 1, 2, and 9 were admitted. Upon the Department's motion, the undersigned took official recognition of Florida Administrative Register Notice 15928969, a "Notice of Withdrawal," withdrawing proposed rule 64-4.003.

Baywood called Raymond W. Hogshead, Baywood's president and corporate representative; Heather Zabinofsky, Master Growers' chief executive officer; and Patricia Nelson, Director of the Department's Office of Compassionate Use. After Baywood rested its case, the Department moved ore tenus for dismissal for lack of jurisdiction, asserting that Baywood lacked standing to challenge the proposed rules. The undersigned reserved ruling on the motion and gave the parties the opportunity to brief the issue. Having reviewed the briefs submitted by the parties on the issue of standing, the Department's motion is denied for the reasons set forth herein.

At the outset of the hearing the Department also renewed prior motions for summary partial final order. The motion as to the Revised Statement of Estimated Regulatory Costs (SERC) was granted based on lack of evidence in the record to support the relief requested. The motion directed at the negotiated

rulemaking process was denied, and ruling was reserved on the motions directed to the certified financials and bond requirements portions of the petition. The Department also moved for dismissal on the grounds that Baywood had not met its initial burden under section 120.56. The undersigned reserved ruling, and again, the issues raised in the motion are addressed and disposed of herein.

Baywood then withdrew its challenge to proposed rule 64-4.009. The Department recalled Ms. Nelson to testify; and also called Jeffrey Barbacci, a certified public accountant who is the director of Thomas Howell Ferguson P.A.'s assurance services department and an expert witness for the Department; and Pedro M. Freyre, Costa Farms, LLC's vice president of the foliage division. The Department offered the testimony of Mr. Hogshead, Baywood's corporate representative, by deposition transcript, which was admitted as Department's Exhibit 2.

A Joint Pre-Hearing Stipulation of the parties was filed prior to the final hearing, stipulating to certain facts which are admitted and issues of law on which there is agreement. To the extent they are relevant those admitted facts and issues of law have been incorporated herein.

The four-volume Transcript of the final hearing was prepared and filed with DOAH on April 27, 2015. Thereafter, the

parties timely submitted Proposed Final Orders, which have been carefully considered in the preparation of this Final Order.

. . .

"Life is always a rich and steady time when you are waiting for something to happen or to hatch."

- E.B. White, *Charlotte's Web*

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#### FINDINGS OF FACT

##### I. The Parties

1. The Department is an agency of the State of Florida charged with administering and enforcing laws relating to the general health of the people of the state. § 381.0011(2), Fla. Stat. As part of this duty, the Department is charged with implementing the Compassionate Medical Cannabis Act of 2014 (Act). See § 381.986, Fla. Stat.

2. Baywood is a nursery located in Apopka, Florida, that grows and sells tropical and subtropical, non-cannabis foliage. Baywood has operated as a registered nursery in Florida for more than 30 consecutive years. Baywood is operated by Mr. Hogshead, a nurseryman as defined in section 581.011, Florida Statutes. Baywood intends to submit an application for approval as a medical cannabis dispensing organization under the Act and rules promulgated thereunder.

3. Baywood filed its rule challenge petition (Petition) on March 24, 2015. At the time it filed the Petition, Baywood held a Certificate of Nursery Registration from the Florida Department of Agriculture and Consumer Services (DACS) pursuant to section 581.131, issued for the cultivation of 10,001 to 25,000 plants. However, on April 10, 2015, DACS issued Baywood a Certificate of Nursery Registration to cultivate more than 400,000 plants.

## II. Background

4. In 2014, the Florida Legislature passed Senate Bill 1030, titled the "Compassionate Medical Cannabis Act of 2014." See chapter 2014-157, Laws of Florida (pertinent portions codified as section 381.986, Florida Statutes). The Act provides for the regulation and use of low-THC cannabis to provide relief for certain patients with debilitating diseases, when ordered by a Florida physician. The Act authorizes licensed physicians to order low-THC cannabis, or "Derivative Product," for qualified patients under specified conditions, primarily those suffering from cancer or other conditions that produce severe and persistent seizures and muscle spasms.

5. The Department has the majority of the responsibility for implementing the Act. The Act requires the Department to establish an Office of Compassionate Use and a compassionate use registry and to authorize the establishment of five dispensing

organizations to cultivate, process, and dispense Derivative Product to qualified Florida patients. See §§ 381.986(1)(a) - (5), Fla. Stat.

6. The Act and the proposed rules are unique in that the cultivation, processing, and dispensing of cannabis have never been legal in Florida and, except to the extent five dispensing organizations are licensed to do so with Derivative Product, will remain illegal. § 381.986, Fla. Stat.

7. The proposed rules establish a regulatory framework implementing the Act by, among other things, creating dispensing organization application, approval, and authorization procedures. Proposed rule 64-4.001 provides definitions for certain words and phrases pertinent to the Act's implementation, including "Applicant," "Approval," "Certified Financials," "Derivative Product," "Dispensing Organization," and "Financial Statements." Proposed rule 64-4.002 delineates the requirements for the dispensing organization application process, including the application fee, how an applicant may demonstrate that it best meets the statutory criteria to become a dispensing organization, the application itself and application scoring form (or scorecard), and a sample performance bond form. Proposed rule 64-4.004 sets forth the circumstances under which dispensing organization approval will be revoked. Proposed rule

64-4.005 details dispensing organization authorization and facility inspection procedures.

### III. The Rule Development Process

8. The Proposed Rules are the Department's second attempt to adopt rules implementing the Act. The first set of proposed rules (the Prior Rules) was challenged and invalidated in Costa Farms, LLC v. Department of Health, DOAH Case No. 14-4296RP (Fla. DOAH Nov. 14, 2014) (the Prior Final Order).

9. The Department began developing the Proposed Rules through a public rule development workshop held on December 30, 2014. The workshop was attended by approximately 110 people, many of whom offered comments to be considered by the Department in drafting the rules.

10. Due to the complexity of the rules to be developed, and the strong opposition anticipated, the Department decided to use a negotiated rulemaking process to develop the Proposed Rules. The Department also considered and concluded that a balanced negotiated rulemaking committee would help the Department develop mutually acceptable Proposed Rules, because committee members with competing interests could "hash things out."

11. On January 5, 2015, the Department announced that it would select a negotiated rulemaking committee composed of persons representing the following groups:



- a nursery that meets the criteria in section 381.986(5)(b)1.;
- a qualified patient or patient representative;
- a testing laboratory;
- a member of the Florida Bar experienced in administrative law;
- an individual with demonstrated experience in sound agricultural practices and necessary regulation;
- a physician authorized to order low-THC cannabis products for qualified patients;
- an individual with demonstrated experience establishing or navigating regulatory structures for cannabis in other jurisdictions; and
- Department representatives.

12. Through the notice, the Department also invited persons who believed their interests were not adequately represented by the above groups to apply to participate. The Department received approximately 10 requests from nurseries to participate in the committee – none of which came from Baywood.

13. The Department selected committee members that it believed were well informed in their fields and well equipped to bring perspectives for all of the stakeholder groups. The committee included: (1) a qualified grower (one of whom was a certified public accountant) from each of the five dispensing regions; (2) a patient's parent who worked to get the Act passed

to help her daughter; (3) a testing laboratory representative with experience with the testing the committee would be discussing; (4) a physician authorized to order low-THC cannabis products for qualified patients and who had experience in horticulture and cannabis education; (5) two Florida attorneys certified by the Florida Bar as experts in federal and state administrative law who had vast experience with rule challenges; and (6) two persons who had significant experience growing regulated cannabis legally in jurisdictions where that activity is permissible and had significant knowledge of cannabis-growing conditions.

14. The nurseries represented on the committee varied in size, ranging from the largest nursery in Florida to at least one nursery smaller than Baywood. The composition of the committee was balanced: its members held and represented different interests and were not all "of the same mind."

15. The negotiated rulemaking sessions were held on February 4 and 5, 2015, and lasted for approximately 26 total hours. Committee members were provided with a binder containing the public comments received to date, the statute, and the Prior Final Order. The sessions were mediated by a professional mediator, who ensured that the group addressed each viewpoint or concern expressed by any committee member. The committee went rule by rule, provision by provision, and discussed each

paragraph of each rule. Input that ultimately was incorporated into the proposed rules was given by each member – ranging from the growers from all five dispensing regions, to members with experience growing the pertinent cannabis strains, to the administrative law attorneys.

16. The proposed rules published on February 6, 2015, and challenged in this proceeding, are the product of the negotiated rulemaking sessions, as guided by the public rule development workshop, the public comments, the Department's research, the Act, and the Prior Final Order. No stakeholder group represented by any committee member, the Department included, got everything it wanted in the proposed rules – which underscores that the committee was balanced, that the negotiated rulemaking process worked properly, and that the developed rules reflect the interests of all represented groups.

#### IV. Baywood's Objections to the Proposed Rules

17. Baywood challenges proposed rules 64-4.001, 64-4.002, 64-4.004, and 64-4.005. Specifically, Baywood takes issue with certain definitions being omitted (rule 64-4.001); the requirement that applicants submit a \$60,063 nonrefundable application fee and certified financials with their applications (rule 64-4.002); the requirement of a \$5 million performance bond (rule 64-4.002); the application evaluation and scoring process (rule 64-4.002); dispensing organization license denial

and revocation procedures (rule 64-4.004); and dispensing organization facility inspection procedures (rule 64-4.005).

A. Definitions

18. Baywood contends that the proposed rules are defective in that although the terms "operator," "contractual agent," and "inspection" are used in the proposed rules, none of those terms is defined therein. However, at hearing, Baywood presented no evidence as to why these particular terms should have been defined.

19. The definitions listed in the Proposed Rules were developed in the negotiated rulemaking process, and the five grower representatives believed that the definitions were adequate for their representative groups to understand and know how to comply with the rules. At no time during the rulemaking process did any interested party express concern as to the meaning of the terms Baywood maintains require definition. Further, the Department's position, which the undersigned agrees is reasonable, is that not every word used in a rule requires a corresponding definition, particularly words that are commonly understood as plain English such as the terms Baywood contends should be defined.

B. The Application Fee

20. The Legislature expressly required the Department to impose an application fee that is sufficient to cover the costs

of administering the Act. § 381.986(5)(b), Fla. Stat. Proposed rule 64-4.002(1) requires applicants to submit a \$60,063 initial application fee.

21. Baywood contends that the \$60,063 fee should be refundable, is excessive, and is based on an estimated number of applicants that is inaccurate.

22. The committee determined the application fee by dividing the total cost to the Department of administering the Act by the anticipated number of applicants for a dispensing organization (D.O.) approval. The committee estimated that 15 nurseries would apply for D.O. approval.

23. Baywood asserts that the fee should be based on 99 applicants rather than the Department's estimated 15, based upon a document generated by the Department of Agriculture and Consumer Services (DACS). However, the document Baywood relies upon includes the caveat that the "information is based on [DACS]'s best available records and was prepared in response to media inquiries and public records requests. The inclusion of a nursery on this list is NOT a determination of eligibility for licensure as a medical marijuana dispensary pursuant to section 381.986, Florida Statutes."<sup>3/</sup>

24. There is no evidence in this record that all, or even a significant portion, of the nurseries appearing on the DACS list are expected to apply to become D.O.'s. There was no

evidence introduced by Baywood substantiating its allegation that a significant number of those listed nurseries have a desire or the wherewithal to apply for approval as a D.O.

25. The application fee was derived from the Revised SERC. The Department calculated the application fee by determining the estimated costs of implementing section 381.986 and dividing that number by the estimated number of D.O. applicants. In the Revised SERC, the Department stated that the expected regulatory cost imposed by the Proposed Rules was \$900,945.

26. The Revised SERC also set forth the estimated number of applicants, which was derived by consensus of the negotiated rulemaking committee. The Department asked for input from the grower members from the five dispensing regions, who were familiar with the nurseries in their region – which they compete with on a daily basis. The committee discussed the grower members' knowledge of the nurseries that exist in their region (including competitors), the likely requirements for approval as a D.O., the risks associated with underestimating the number of applicants, and section 381.986(5)(b)1.'s requirements, and determined a reasoned and credible estimate of how many qualified nurseries would apply to become D.O.'s.

27. If the Department overestimates the number of applicants – say, by assuming that a significant portion of those nurseries appearing on the DACS list will apply – the

application fees could be insufficient to cover the Department's costs of administering the Act, in violation of the Legislature's imperative. § 381.986(5)(b), Fla. Stat. For example, if the Department used a 30-applicant estimate, the fee would be approximately \$30,500 (\$900,945 divided by 30); if only 15 nurseries applied, as estimated by the Department, the Department would recover only \$457,500 – less than one-half of the expected costs of administering the Act and therefore less than one-half the sum the Act mandates the Department recover from the application fees. On the other hand, if the Department underestimates the number of applicants and captures more than its costs of administering the Act, the Department would still be in compliance with the statutory mandate.<sup>4/</sup>

### C. Certified Financials

28. A D.O. applicant must be able to demonstrate the financial ability to maintain operations for the duration of the 2-year approval cycle, including the provision of certified financials to the Department, under the express terms of the Act. An approved applicant must post a \$5 million performance bond. § 381.986(5)(b)(5), Fla. Stat.

29. Proposed rule 64-4.001(6) defines "Certified Financials" as "[f]inancial statements that have been audited in accordance with Generally Accepted Auditing Standards (GAAS) by

a Certified Public Accountant, licensed pursuant to Chapter 473, F.S.”

30. Proposed rule 64-4.002(2)(f)(1) requires that an applicant for a D.O. approval provide to the Department, as part of its completed application form, proof of “[t]he financial ability to maintain operations for the duration of the 2-year approval cycle, including the provision of Certified Financials to the department,” including “Certified Financials issued within the immediately preceding 12 months.”

31. Baywood contends that rule 64-4.002(2)(f)’s requirement that an applicant submit as part of its application certified financials issued within the immediately preceding 12 months is contrary to the Act, contrary to industry standard, and financially burdensome to applicants. Baywood contends that the Act instead requires certified financials to be submitted by a nursery only after the nursery is selected to be a dispensing organization.

32. The Department, on the other hand, interprets the Act as requiring certified financials to be submitted with the application, as part of the submittal package offered to demonstrate the applicant’s financial ability to maintain operations for the duration of the 2-year D.O. approval cycle. The Department consulted with Deborah Curry, President-CEO of the Florida Institute of Certified Public Accountants, and was



guided by the Prior Final Order when developing the certified financials portions of the rules.

33. The Department's interpretation of the Act as requiring certified financials to be submitted with the application is consistent with the testimony of expert Jeff Barbacci, a Florida-licensed certified public accountant who routinely works with certified financials, also known as "audited financial statements."

34. In layman's terms, "financial statements" are an accounting summary of the activity a business uses to create revenue (income statement); the expenses the business incurs (cash flow statement); a balance sheet, which is the cumulative results of that activity since the business's inception; and notes that help better explain the activities. "Certified financials" are financial statements that include a certified public accountant's opinion whether the financial statements are fairly presented in all material respects in accordance with generally accepted accounting principles. Proposed rule 64-4.001 defines both the terms "financial statements" and "certified financials." The "financial statements" definition mirrors the definition used by the Florida Department of Business and Professional Regulation, Board of Accountancy, an industry standard definition. The "certified financials"

definition is also an industry standard definition routinely used and understood in the field of public accounting.

35. According to the credible testimony of Mr. Barbacci, certified financials can be a forward-looking tool for assessing financial strength, as contingent liabilities are considered. And there is a presumption with certified financials that the business under scrutiny has the ability to continue as a viable entity for at least 12 months after issuance of the auditor's report. Notably, according to Mr. Barbacci, the type of business being evaluated is immaterial for the purposes of a certified financial analysis.

36. Significantly, because an industry standard is applied, one set of certified financials is comparable to another set. That industry standard is the "generally accepted auditing standards" prescribed by the American Institute of Certified Public Accountants, and delineates what evidence an auditor must examine in developing an opinion.

37. Proposed rule 64-4.002(2)(f)'s requirement of certified financials for the preceding 12 months comports with the Act and allows the Department to evaluate applicants on a one-to-one, standardized basis. From certified financials, the Department can determine whether an applicant is a financially unstable business, or is financially strong based on the

applicant's available cash, liquidities relative to liabilities, positive or negative capital, and debt.

38. Mr. Barbacci's credible, expert opinion was that the Act's requirement that an applicant demonstrate the "financial ability to maintain operations for the duration of the 2-year approval cycle" means the Legislature is requiring applicants to provide a package of information that indicates the ability to maintain operations, and part of that package is certified financials that provide a historical view. He further opined that the 13 other items required by rule 64-4.002(2)(f) (such as the applicant's projected two-year budget) work in concert with certified financials to help the Department evaluate the applicant's financial position and thus ability to perform under the Act. For example, the certified financials help the Department determine whether the applicant has the ability to make its projected budget possible.

39. Baywood contends that in order to attain certified financials, there must be a starting inventory and an ending inventory, and where it is not a common industry standard to maintain such inventories from the outset of business, it is nearly impossible for an applicant to go back in time for 12 months to speculate regarding the same.

40. Baywood's contention that it is not industry standard practice to maintain starting and ending inventories was

credibly refuted by the testimony of committee member Pedro Freyre, whose role as vice president of foliage at Costa Farms, LLC, involves overseeing inventory tracking. Mr. Freyre holds an MBA Degree from Dartmouth College. He testified that Costa Farms tracks all its plants as a matter of course and has done so for many years. In fact, at any given moment, Costa Farms can determine how many plants it has in a given location at any given facility, notwithstanding the constant fluctuations of inventory.

41. Baywood also asserts that the cost to acquire certified financials as required by the proposed rule is approximately \$125,000.00 per year, an overly burdensome requirement for applicants. Mr. Freyre also refuted this contention, testifying that the cost of obtaining certified financials ranges from \$10,000 for a small nursery such as Baywood, to upwards of \$80,000 for Costa Farms, which is the largest nursery in Florida. Costa Farms, Mr. Freyre testified, has for decades had certified financials prepared annually as part of its regular business operations, and Mr. Freyre is aware of several "small" nurseries that do the same.

42. The issue of whether the certified financials should be required at the time of application was considered at length by the negotiated rulemaking committee. The committee determined that the certified financials would enable an

historical analysis of the applicant's financial operations, and would serve as a necessary "gating constraint," as an applicant's ability to start and continue operation as a D.O. is predicated and contingent on the company's financial ability to perform under the Act.

D. Terms and Conditions of the Performance Bond

43. The Act mandates that D.O. applicants, upon their approval, secure a \$5 million performance bond.

§ 381.986(5)(b)5, Fla. Stat. However, the Act omits any definition of the specific terms and conditions that must accompany the bond.

44. Proposed rule 64-4.002(5) provides,

(e) Upon notification that it has been approved as a region's Dispensing Organization, the Applicant shall have 10 business days to post a \$5 million performance bond. The bond shall:

1. Be payable to the department in the event the Dispensing Organization's approval is revoked;
2. Be written by a surety company licensed by the Florida Office of Insurance Regulation;
3. Be written so that the nursery name on the bond corresponds exactly with the Applicant name;
4. If a bond is canceled and the Dispensing Organization fails to file a new bond with the department in the required amount on or before the effective date of cancellation, the Dispensing Organization's approval shall be revoked.

45. Proposed rule 64-4.002(5)(g) further provides, "The surety company can use any form it prefers for the performance bond as long as it complies with this rule" and includes a sample form "[f]or convenience." According to the Department's representative, Patricia Nelson, it is not mandatory for applicants to use the form, and a different bond would not be rejected as long as the bond bonded performance and complied with the statute and rule.

46. Baywood contends that rule 64-4.002(5)(e)'s performance bond provision is overly burdensome and inequitable given the alleged difficulty companies will have in obtaining a bond where all marijuana activity is a federal crime. Baywood also contends the bond provision should include exceptions for circumstances beyond a dispensing organization's control, such as hurricanes and other "acts of God," and that the bond should be invoked only upon revocation of a dispensing organization's registration. Baywood further questions how invocation of the bond would be applied – for example, how the amount of damages would be determined and what constitutes a valid recoverable cost?

47. The Department reasonably interprets the Act as requiring a performance bond that guarantees performance and does not carve out exceptions that undermine the purpose of the bond. The Department does not believe it has the authority to

create such exceptions, including exceptions accounting for enforcement of federal laws relating to cannabis. Similarly, the Department does not believe it has the authority to include in the rules a process for a dispensing organization to appeal if it believes the bond was improperly invoked. Further, the Department is cognizant of the fact that the dispensing organization would have a right to administratively challenge bond invocation as agency action.

48. In developing its position on the bond requirements of the statute and in drafting the rule's bond provision, the Department considered the bond-related conclusions in the Prior Final Order. Under the Prior Rules, the performance bond was conditioned solely on the expense of destroying low-THC cannabis inventory if the dispensing organization failed to perform or failed to destroy its inventory when required. Costa, DOAH Case No. 14-4296RP, ¶ 64. The Prior Final Order concluded that the Prior Rules ignored the potential significant delays in appointing a new dispensing organization and having it become operational should a dispensing organization default, and a conclusion that the Prior Rules "dilute[d] the purpose and effect of the required performance bond to the point that 'performance' [was] not being bonded." Id. ¶¶ 65, 110.

49. The Department also consulted with a bond brokerage firm when drafting the Proposed Rules. The brokerage firm,

including its attorneys, provided input that helped the Department draft a sample bond form that complies with the Act and the rule and would be palatable to sureties.

50. The bond provision was discussed during the negotiated rulemaking sessions, and none of the growers on the committee – regardless of their nursery’s size – voiced any objection to the bond rule or the bond form.

E. Biennial Renewal Requirements

51. The Act mandates that the Department “shall develop an application form and impose an initial application and biennial renewal fee that is sufficient to cover the costs of administering this section.” In its Proposed Final Order, Baywood argues that applicants are entitled to know the financial burden to be imposed by the renewal fee, and that the failure to include renewal costs and fees in rule 64-4.003(4) is in contravention of the Act.

52. At hearing, the undersigned took official recognition of the Department’s published withdrawal of proposed rule 64-4.003 which addressed the biennial renewal requirements for D.O.’s. Accordingly, Baywood’s challenge to proposed rule 64-4.003 is moot.

53. To the extent Baywood faults the remaining proposed rules for failing to include mention of the renewal fee, the undersigned notes that the Department will have at least two



years to determine the appropriate amount of the renewal fee. In doing so, the Department will be required to take into consideration the cost of administering the Act during that period, as well as the amount of revenue received from the initial application fees.

54. Baywood's challenge to the proposed rules based upon the absence of the biennial renewal fee amount is rejected, since approved D.O.'s will have the option to renew their D.O. approval or not, once the amount of the renewal fee is determined and announced by the Department.

F. Application Evaluation and Scoring

55. Proposed rule 64-4.002(2) lists the seven statutory criteria that an applicant must demonstrate to become a dispensing organization:

- the technical and technological ability to cultivate and produce low-THC cannabis;
- the ability to secure the premises, resources, and personnel necessary to operate as a dispensing organization;
- the ability to maintain accountability of all raw materials, finished products, and any byproducts to prevent diversion or unlawful access to or possession of these substances;
- an infrastructure reasonably located to dispense low-THC cannabis to registered patients statewide or regionally as determined by the department;

- the financial ability to maintain operations for the duration of the two-year approval cycle;
- that all owners and managers have been fingerprinted and have successfully passed a level 2 background screening pursuant to section 435.04, Florida Statutes; and
- the employment of a medical director who is a physician licensed under chapter 458 or chapter 459, Florida Statutes, to supervise the dispensing organization's activities.

See § 381.986(5)(b), Fla. Stat. These criteria are carried over into the dispensing organization application incorporated into the rule in the form of five categories and subcategories developed during the negotiated rulemaking sessions.

56. The rule also lists for most statutory criteria numerous "items," also developed in part by the negotiated rulemaking committee, which will help the Department assess each applicant's ability to meet the statutory criteria. The application reiterates these items under the five categories and the subcategories. For example, the rule, under the statutory criterion "technical and technological ability to cultivate and produce low-THC cannabis," lists "experience cultivating cannabis," "experience cultivating in Florida plants not native to Florida," and "experience cultivating plants for human consumption such as food or medicine products" as some of the items. The application repeats these three items under the

"cultivation" category (worth 30 percent of the applicant's score), and the "technical ability" subcategory (worth 25 percent of the cultivation score). As expressly provided in the application, the application is organized differently than the rule because the application is based on the scoring system the Department will use to evaluate applications. But the application nevertheless covers and cites to all seven criteria from the statute and every item in the rule.

57. Every applicant is required to address each of the items, as provided in rule 64-4.002(2), even if just to state that, for example, it has no experience or knowledge in a given area. As stated in the application, however, having knowledge or experience relating to these items "is not mandatory but is designed to elicit information" that will help the Department select the most qualified dispensing organizations from the pool of applications.

58. Baywood contends that the rule and application conflict as to whether addressing each item is mandatory. Baywood also contends that rule 64-4.002(2) and the application fail to set forth the required level of experience or knowledge relating to each item. Finally, Baywood contends that the incorporated application scorecard fails to disclose what percentage of an applicant's score corresponds with each item.

59. Baywood's contention as to each point is rejected. First, the rule and application do not conflict, as the former unambiguously requires applicants to address each item and the latter unambiguously repeats this requirement, stating that the applicant is required to provide the Department with all items listed, and informs applicants that it is not mandatory to have knowledge of and experience with each item.

60. Second, there is no required minimum level of experience or knowledge for any item. As provided in the application, a description of the items is mandatory, but an applicant need not possess each item in its experience or operation. Thus, each applicant is competing with other applicants, not with any mandatory minimum criteria set by the Department. In fact, to make any of the items mandatory would exceed the Department's authority under the Act, as only the basic elements, such as "cultivation," are listed in the Act. See also Costa, DOAH Case No. 14-4296RP, ¶ 81 (concluding that imposing mandatory qualifications not specified in Act impermissibly modifies or enlarges Act).

61. Third, there is no percentage score assigned to every single item in the application (only the categories and subcategories are assigned percentages); the items are not weighted, but are simply things each applicant must address to demonstrate its knowledge of and experience in an area. This

will allow the Department to evaluate the applicant against other applicants in predictable areas and will inform the applicant as to what the Department is looking for. The decision not to assign weights or percentages to items (as opposed to categories and subcategories) was made by the negotiated rulemaking committee, whose grower members believed the Department's expectations as to how applications would be evaluated were made clear in the rule and application. In developing this evaluation system, the Department was guided by the Prior Final Order, which concluded that the Act required the Department to undertake a comparative, qualitative review of each applicant. Costa, DOAH Case No. 14-4296RP ¶¶ 84-87.

G. Inspection and License Revocation

62. The Act expressly requires an "approved dispensing organization [to] maintain compliance with the criteria demonstrated for selection and approval . . . at all times." § 381.986(6), Fla. Stat.

63. Proposed rule 64-4.004 provides that the Department "shall" revoke a D.O.'s approval if the D.O. "[c]ultivates low-THC cannabis before obtaining Department authorization" or "[k]nowingly dispenses 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." That rule also provides that

the Department "may" revoke approval if any of four other events occurs and is not corrected within the applicable cure period specified in the rule – for example, if a dispensing organization fails "to comply with the requirements in [the Act or the rules]" or fails "to implement the policies and procedures or comply with the statements provided to the department with the original or renewal application" and does not correct the failure within 30 calendar days after notification.

64. Proposed rule 64-4.005 provides in part that submission of an application constitutes permission for entry by the Department at any reasonable time during the approval or renewal process into any D.O. facility to inspect any portion of the facility, review the records required by the Act or the rules, and identify samples of any low-THC cannabis for laboratory analysis. That rule also provides that if, during an inspection, the Department identifies a violation of the Act or the rules, the D.O. must notify the Department in writing within 20 calendar days after receipt of written notice of the violation what corrective action was taken and when.

65. Baywood contends rule 64-4.004 fails to include any standards or protocol for violation correction or license revocation, allows the Department to revoke a license "based on a whim," and fails to include a revocation appeal mechanism.

Baywood contends rule 64-4.005 fails to include any parameters or criteria for inspections, leaving D.O.'s to wonder what will be inspected, what testing protocols will be used, and against what standards their facilities will be measured; fails to specify what records a D.O. must keep; and fails to provide an appeal process.

66. The Department, interpreting a statute the Department is charged with implementing, believes section 381.986(6) obligates the Department to monitor each dispensing organization's compliance with the Act and that proposed rules 64-4.004 and -.005 implement that statutory provision. The Department is confident that these rules, which were developed by a negotiated rulemaking committee that included five grower members, clearly delineate what a D.O. is expected to do and what the repercussions of failing to comply are. Indeed, the negotiated rulemaking committee discussed the rules' inspection and revocation provisions in great detail, and the grower members' concerns, in particular, were a factor in drafting those provisions.

67. For example, if the Department identified samples of product for laboratory analysis, those samples would be required to meet the Act's requirements for low-THC cannabis, which is defined in part as containing "0.8 percent or less of tetrahydrocannabinol and more than 10 percent of cannabidiol

weight for weight.” § 381.986(1)(b), Fla. Stat. And if a D.O. failed to comply with this standard and did not correct the failure within the cure period delineated in the rule, the Department could initiate the revocation process.

68. By the same token, a license may be revoked upon a D.O.’s failure to implement the policies and procedures or comply with the statements provided to the Department in the D.O.’s application. Clearly, a D.O. would look to its own approved application to determine what policies, procedures, and statements it needs to comply with to avoid revocation on such grounds.

#### CONCLUSIONS OF LAW

69. The Division of Administrative Hearings has jurisdiction over the subject matter and the parties hereto pursuant to sections 120.56, 120.569, and 120.57(1), Florida Statutes. Jurisdiction attaches when a person who is substantially affected by an agency’s rule claims that it is an invalid exercise of delegated legislative authority.

#### V. Baywood’s Standing

70. As noted, the Act sets forth three threshold requirements for D.O. applicants: (1) the applicant must possess a valid certificate issued by the Florida Department of Agriculture and Consumer Services that is issued for the cultivation of more than 400,000 plants; (2) the applicant must



be operated by a nurseryman as defined in section 581.011, Florida Statutes; and (3) the applicant must have been operated as a registered nursery in Florida for at least 30 continuous years. § 381.986(5)(b)1., Fla. Stat.

71. It is undisputed, however, that on March 24, 2015, the day Baywood filed its Petition, Baywood was missing one of the statutory "three threshold prerequisites": it did not possess a valid certificate issued by DACS for the cultivation of more than 400,000 plants. Thus, according to the Department, on March 24, 2015, Baywood could not be a D.O. as a matter of law, and therefore lacks standing to maintain this challenge.

72. Section 120.56, Florida Statutes, establishes both the jurisdictional deadline for filing a rule challenge petition and who has standing to file that petition – that is, only a party that is "substantially affected" by the proposed rules. § 120.56(1)(a), Fla. Stat.

73. To establish that it is "substantially affected," a party must show (1) that the rule or policy will result in a real or immediate injury in fact and (2) that the alleged interest is within the zone of interest to be protected or regulated. Off. of Ins. Reg. & Fin. Servs. Comm'n v. Secure Enters., L.L.C., 124 So. 3d 332, 336 (Fla. 1st DCA 2013). A "real or immediate injury in fact" does not include an injury that is abstract, conjectural, speculative, or hypothetical.

See Vill. Park Mobile Home Ass'n, Inc. v. State of Fla., Dep't of Bus. Reg., 506 So. 2d 426, 433 (Fla. 1st DCA 1987). Rather, a rule challenge petitioner must allege that it has sustained or is immediately in danger of sustaining some direct injury as a result of the challenged official conduct. Id. Stated differently, the petitioner's allegations must be of sufficient immediacy and reality to confer standing. Id. (citing Fla. Dep't of Offender Rehab. v. Jerry, 353 So. 2d 1230, 1236 (Fla. 1st DCA 1978) (disapproved on other grounds by Fla. Home Builders Ass'n v. Dep't of Labor & Emp. Sec., 412 So. 2d 351 (Fla. 1982))).

74. Without question, standing and the timely filing of a petition are jurisdictional. See State of Fla., Dep't of Health & Rehab. Servs. v. Alice P., 367 So. 2d 1045, 1052-53 (Fla. 1st DCA 1979); see also Abbott Labs. v. Mylan Pharm., Inc., 15 So. 3d 642, 651 n.2 (Fla. 1st DCA 2009).

75. The Department strenuously argues that a petitioner must have standing during the window in which a petition may be filed, and that the lack of such standing is fatal to a rule challenge. Citing, Alice P., 367 So. 2d at 1053 ("Failure to file a valid petition or request within that . . . period is grounds for dismissal upon proper motion directed to jurisdiction."). Here, the Department argues that Baywood must have met the statutory "three threshold prerequisites" by no

later than March 24, 2015, the day Baywood filed its petition, and that since it did not, the Division lacks jurisdiction to entertain the instant challenge.

76. Alice P. involved a challenge to the Florida Department of Health and Rehabilitative Services' adoption of rules concerning abortion funding. 367 So. 2d at 1048. The Alice P. court held that because Alice P. was not pregnant at the time of filing her challenge petition and because her chances or intentions of getting pregnant again were based on speculation and conjecture, she could not demonstrate any "real and immediate injury" necessary to make her a "substantially affected party" as required by section 120.56(1)(a), Florida Statutes.

77. Citing Alice P., the Department concludes Baywood is not a "substantially affected" party because it did not possess a certificate of nursery registration for the cultivation of more than 400,000 plants on the date it filed its rule challenge petition. In other words, as the Department put it at final hearing, Baywood was not "pregnant" when its petition was filed.

78. The Alice P. court relied on Florida Department of Offender Rehabilitation v. Jerry, 353 So. 2d 1230 (Fla. 1st DCA), cert. denied, 359 So. 2d 1215 (Fla. 1978). Jerry, like Alice P., hinged in part on the future actions or intentions of the petitioning party. In Jerry, an inmate filed a petition

challenging a prison rule streamlining procedures for fact finding by prison officials of alleged inmate offenses. Id. at 1230-1231. The inmate, Jerry, had been found guilty of an assault on another inmate and, by the time Jerry filed his petition challenging the rule, Jerry had already served his penalty. Id. at 1235.

79. The First District Court of Appeal held that Jerry lacked standing because he could not demonstrate an injury of "sufficient immediacy and reality." Id. at 1232, 1235 ("[Jerry] failed to demonstrate, either at the time his petition for administrative relief was filed or at the time of the hearing, that he was then serving disciplinary confinement or that his existing prison sentence had been subjected to loss of gain-time.") (emphasis added). Just as the Alice P. court found the odds of a future pregnancy too speculative, the Jerry court declined to presume that Jerry would again violate the rules and commit another assault. Id. at 1236.

80. Jerry and Alice P. dictate that a rule challenger cannot be "substantially affected" if he or she was previously injured by the challenged rule but is no longer so affected at the time of the rule challenge and is unlikely to be affected in the future.

81. The circumstances presented in Jerry and Alice P. are the converse of the facts presented in the matter sub judice.

In Jerry and Alice P., standing existed at some time prior to the filing of the rule challenges, but was subsequently lost, since no real and immediate "injury in fact" remained by the time of hearing. Here, Baywood may not have met all three statutory prerequisites to apply for D.O. approval when it filed its rule challenge petition. However, by the time of hearing DACS had issued Baywood a Certificate of Nursery Registration to cultivate more than 400,000 plants, thereby rendering Baywood eligible to apply for D.O. approval.<sup>5/</sup>

82. Access to a rule challenge is a forward-looking concept,<sup>6/</sup> not to be confused with prevailing on the merits. Guardian Interlock, Inc. v. Dep't. of High. Saf. & Motor Veh., Case No. 13-3685RX (Fla. DOAH Jan. 10, 2014), ¶ 152. As observed by Judge Meale in Guardian, in "substantial interest" cases, the question is whether, at the outset, the party's substantial interests "could be" affected by the proposed agency action, St. John's Riverkeeper, Inc. v. St. Johns River Water Management District, 54 So. 3d 1051, 1054 (Fla. 5th DCA 2011) (citing Peace River/Manasota Regional Water Supply Authority v. IMC Phosphates Co., 18 So. 3d 1079, 1084 (Fla. 2d DCA 2009)), or whether, at the outset, the party's substantial interests "could reasonably be affected by the proposed activities." Palm Beach Cnty. Envtl. Coal. v. Dep't of Envtl. Prot., 14 So. 3d 1076, 1078 (Fla. 4th DCA 2009) (citing Peace River/Manasota, at 1084).

83. Unlike the petitioners in Alice P. and Jerry, the potential adverse impact on Baywood imposed by the Proposed Rules create more than a sufficient probability that Baywood will suffer real and immediate injury regardless of the status of Baywood's nursery registration when it filed its Petition. At hearing Baywood established that it intends to apply for D.O. approval and that it currently meets all statutory criteria to be able to do so once the Department adopts final rules.

84. Baywood's future application will be approved or denied by the Department in accordance with the rules under challenge. In essence, Baywood will be vying for a one-time opportunity to obtain one of five coveted, exclusive, and potentially very valuable D.O. franchises to be awarded by the Department. Since the approval or denial of its application will "substantially affect" Baywood, Baywood has established its standing to maintain this challenge. Bio-Med. Applications of Ocala v. Off. of Cmty. Med. Facilities, 374 So. 2d 88 (Fla. 1st DCA 1979).

#### VI. Burden of Proof and Applicable Legal Standards

85. The party challenging a proposed agency rule has the burden of going forward. The agency then has the burden to prove by a preponderance of the evidence that the proposed rule is not an invalid exercise of delegated legislative authority as to the objections raised. § 120.56(2)(a), Fla. Stat. When any

substantially affected person seeks a determination of the invalidity of a proposed rule pursuant to section 120.56(2), the proposed rule is not presumed to be valid or invalid.

§ 120.56(2)(b), Fla. Stat.

86. A petitioner satisfies its burden of going forward by establishing a factual basis for the objections to the proposed rule. See St. Johns River Water Mgmt. Dist. v. Consol.-Tomoka Land Co., 717 So. 2d 72, 76 (Fla. 1st DCA 1998) (superseded on other grounds by chapter 99-379, §§ 2, 3, Laws of Fla.). This requires the petitioner to offer more than mere conclusions or allegations that a rule is arbitrary or capricious or is an invalid exercise of delegated legislative authority in some other way. See Combs Oil Co. v. Dep't of Fin. Servs., Div. of State Fire Marshall, Case No. 11-3627RP, ¶ 14 (Fla. DOAH Mar. 9, 2012). Rather, the petitioner must offer expert testimony, documentary evidence, or other competent evidence – otherwise, the petitioner's objections amount to nothing more than conjecture and speculation. Id. Only after the petitioner has met its burden of going forward does the burden shift to the agency to demonstrate by a preponderance of the evidence that the proposed rule is not an invalid exercise of delegated legislative authority as to the objections raised.

§ 120.56(2)(a), Fla. Stat.

87. Section 120.52(8) defines what constitutes an "invalid exercise of delegated legislative authority":

(8) "Invalid exercise of delegated legislative authority" means action that goes beyond the powers, functions, and duties delegated by the Legislature. A proposed or existing rule is an invalid exercise of delegated legislative authority if any one of the following applies:

(a) The agency has materially failed to follow the applicable rulemaking procedures or requirements set forth in this chapter;

(b) The agency has exceeded its grant of rulemaking authority, citation to which is required by s. 120.54(3)(a)1.;

(c) The rule enlarges, modifies, or contravenes the specific provisions of law implemented, citation to which is required by s. 120.54(3)(a)1.;

(d) The rule is vague, fails to establish adequate standards for agency decisions, or vests unbridled discretion in the agency;

(e) The rule is arbitrary or capricious. A rule is arbitrary if it is not supported by logic or the necessary facts; a rule is capricious if it is adopted without thought or reason or is irrational; or

(f) The rule imposes regulatory costs on the regulated person, county, or city which could be reduced by the adoption of less costly alternatives that substantially accomplish the statutory objectives.

A grant of rulemaking authority is necessary but not sufficient to allow an agency to adopt a rule; a specific law to be implemented is also required. An agency may adopt only rules that implement or interpret the specific powers and duties granted by



the enabling statute. No agency shall have authority to adopt a rule only because it is reasonably related to the purpose of the enabling legislation and is not arbitrary and capricious or is within the agency's class of powers and duties, nor shall an agency have the authority to implement statutory provisions setting forth general legislative intent or policy. Statutory language granting rulemaking authority or generally describing the powers and functions of an agency shall be construed to extend no further than implementing or interpreting the specific powers and duties conferred by the enabling statute.

88. The Department's interpretation of section 381.986, a statute it is charged with administering, is entitled to great deference. Verizon Fla., Inc. v. Jacobs, 810 So. 2d 906, 908 (Fla. 2002); Bellsouth Telecomms., Inc. v. Johnson, 708 So. 2d 594, 596 (Fla. 1998). The deference to an agency interpretation of a statute it is charged with enforcing applies even if other interpretations or alternatives exist. Atl. Shores Resort v. 507 S. St. Corp., 937 So. 2d 1239, 1245 (Fla. 3d DCA 2006); Miles v. Fla. A & M Univ., 813 So. 2d 242, 245 (Fla. 1st DCA 2002); Int. Improv. Tr. Fd. v. Levy, 656 So. 2d 1359, 1364 (Fla. 1st DCA 1995). When an agency committed with authority to implement a statute construes the statute in a permissible way, that interpretation must be sustained even though another interpretation may be possible or even, in the view of some, preferable. Humhosco, Inc. v. Dep't of Health and Rehab. Svcs., 476 So. 2d 258, 261 (Fla. 1st DCA 1985).

89. Historically, courts have given deference to agencies based on agency expertise in the areas regulated. See, e.g., Wallace Corp. v. City of Miami Beach, 793 So. 2d 1134 (Fla. 1st DCA 2001) (noting that an agency's construction of a statute it is given power to administer will not be overturned unless clearly erroneous). Traditionally, agencies generally have more expertise in a specific area they are charged with overseeing, and courts have noted the benefit of the agency's technical and/or practical experience in its field. Rizov v. Bd. of Prof'l Eng'rs, 979 So. 2d 979 (Fla. 3d DCA 2008).

90. Stated otherwise, an agency is accorded broad discretion and deference in the interpretation of the statutes which it administers, and an agency's interpretation should be upheld when it is within a range of permissible interpretations and unless it is clearly erroneous. Pan Am. World Airways, Inc. v. Fla. Pub. Serv. Comm'n, 427 So. 2d 716 (Fla. 1983); see also Bd. of Podiatric Med. v. Fla. Med. Ass'n, 779 So. 2d 658, 660 (Fla. 1st DCA 2001).

91. Notwithstanding the deference owed to the Department's interpretation of section 381.986, it has no authority as a matter of law to further limit a statutory term beyond its plain meaning. Courts employ a fundamental precept arising from the separation of powers doctrine that an agency may not redefine statutory terms to modify the meaning of a statute. See Campus

Commc'ns, Inc. v. Dep't of Rev., 473 So. 2d 1290 (Fla. 1985) (department rule defining "newspaper" for purposes of a statutory sales tax exemption invalid for adding criteria to statute); see also State, Dep't of Bus. Reg. v. Salvation Ltd. Inc., 452 So. 2d 65 (Fla. 1st DCA 1984) (providing that a rule which added a fifth criterion that meals must be prepared and cooked on the premises to the existing statutory criteria for a special restaurant beverage license "enlarged upon the statutory criteria and, thus, exceeded the 'yardstick' laid down by the legislature"); Pedersen v. Green, 105 So. 2d 1 (Fla. 1958) (where statute excepted "feed" from sales tax, agency cannot adopt rule limiting exemption to feed for animals kept for agricultural purposes thereby excluding feed for zoo animals). Nor may an agency apply a construction which conflicts with the plain language of the statute. Holly v. Auld, 450 So. 2d 217, 219 (Fla. 1984) (citing A.R. Douglass, Inc. v. McRainey, 102 Fla. 1141, 1144, 137 So. 157, 159 (1931)).

#### VII. The Merits of Baywood's Challenge

92. An agency is empowered to adopt rules where there is both (1) a statutory grant of rulemaking authority, or statutory language explicitly authorizing or requiring the agency to adopt rules, and (2) a specific law to be implemented. Whiley v. Scott, 79 So. 3d 702, 710 (Fla. 2011). The Legislature delegates rulemaking authority to agencies because agencies

generally have expertise in the particular area for which they are given oversight. Id.

93. Section 381.986 embodies both the statutory authority for and the law implemented by the Proposed Rules. Section 381.986 states, in pertinent part:

(5) DUTIES OF THE DEPARTMENT.—By January 1, 2015, the department shall:

(a) Create a secure, electronic, and online compassionate use registry for the registration of physicians and patients as provided under this section. The registry must be accessible to law enforcement agencies and to a dispensing organization in order to verify patient authorization for low-THC cannabis and record the low-THC cannabis dispensed. The registry must prevent an active registration of a patient by multiple physicians.

(b) Authorize the establishment of five dispensing organizations to ensure reasonable statewide accessibility and availability as necessary for patients registered in the compassionate use registry and who are ordered low-THC cannabis under this section, one in each of the following regions: northwest Florida, northeast Florida, central Florida, southeast Florida, and southwest Florida. The department shall develop an application form and impose an initial application and biennial renewal fee that is sufficient to cover the costs of administering this section. An applicant for approval as a dispensing organization must be able to demonstrate:

1. The technical and technological ability to cultivate and produce low-THC cannabis. The applicant must possess a valid certificate of registration issued by the Department of Agriculture and Consumer

Services pursuant to s. 581.131 that is issued for the cultivation of more than 400,000 plants, be operated by a nurseryman as defined in s. 581.011, and have been operated as a registered nursery in this state for at least 30 continuous years.

2. The ability to secure the premises, resources, and personnel necessary to operate as a dispensing organization.

3. The ability to maintain accountability of all raw materials, finished products, and any byproducts to prevent diversion or unlawful access to or possession of these substances.

4. An infrastructure reasonably located to dispense low-THC cannabis to registered patients statewide or regionally as determined by the department.

5. The financial ability to maintain operations for the duration of the 2-year approval cycle, including the provision of certified financials to the department. Upon approval, the applicant must post a \$5 million performance bond.

6. That all owners and managers have been fingerprinted and have successfully passed a level 2 background screening pursuant to s. 435.04.

7. The employment of a medical director who is a physician licensed under chapter 458 or chapter 459 to supervise the activities of the dispensing organization.

(c) Monitor physician registration and ordering of low-THC cannabis for ordering practices that could facilitate unlawful diversion or misuse of low-THC cannabis and take disciplinary action as indicated.

(d) Adopt rules necessary to implement this section.

(6) DISPENSING ORGANIZATION.—An approved dispensing organization shall maintain compliance with the criteria demonstrated for selection and approval as a dispensing organization under subsection (5) at all times. Before dispensing low-THC cannabis to a qualified patient, the dispensing organization shall verify that the patient has an active registration in the compassionate use registry, the order presented matches the order contents as recorded in the registry, and the order has not already been filled. Upon dispensing the low-THC cannabis, the dispensing organization shall record in the registry the date, time, quantity, and form of low-THC cannabis dispensed.

A. The Negotiated Rulemaking Process

94. Baywood relies in large part on allegations relating to the negotiated rulemaking process to support this rule challenge. More specifically, Baywood challenges the selection and composition of the negotiated rulemaking committee, the negotiated rulemaking process, and Baywood's and Master Growers' alleged exclusion from the negotiated rulemaking process.

95. In section 120.54, the Florida Legislature set forth detailed parameters for the agency rulemaking process. Included within section 120.54 is the option for an agency to use the "negotiated rulemaking" process in promulgating rules. Section 120.54(2) provides in relevant part:

(d)1. An agency may use negotiated rulemaking in developing and adopting rules. The agency should consider the use of negotiated rulemaking when complex rules are being drafted or strong opposition to the

rules is anticipated. The agency should consider, but is not limited to considering, whether a balanced committee of interested persons who will negotiate in good faith can be assembled, whether the agency is willing to support the work of the negotiating committee, and whether the agency can use the group consensus as the basis for its proposed rule. Negotiated rulemaking uses a committee of designated representatives to draft a mutually acceptable proposed rule.

2. An agency that chooses to use the negotiated rulemaking process described in this paragraph shall publish in the Florida Administrative Register a notice of negotiated rulemaking that includes a listing of the representative groups that will be invited to participate in the negotiated rulemaking process. Any person who believes that his or her interest is not adequately represented may apply to participate within 30 days after publication of the notice. All meetings of the negotiating committee shall be noticed and open to the public pursuant to the provisions of this chapter. The negotiating committee shall be chaired by a neutral facilitator or mediator.

3. The agency's decision to use negotiated rulemaking, its selection of the representative groups, and approval or denial of an application to participate in the negotiated rulemaking process are not agency action. Nothing in this subparagraph is intended to affect the rights of an affected person to challenge a proposed rule developed under this paragraph in accordance with s. 120.56(2).

96. The statute's plain language addressing negotiated rulemaking unequivocally evidences the Legislature's intent that the selection and composition of a negotiated rulemaking

committee, the negotiated rulemaking process, and a party's exclusion from the negotiated rulemaking process cannot be grounds for challenging or invalidating a proposed rule. This intent is underscored by the legislative history behind the enactment of the "not agency action" language, which reads:

The amendment to s. 120.54(2)(d), F.S., 1996 Supp., creates a new paragraph 3. It clarifies that an agency's decision to utilize negotiated rulemaking, its selection of representative groups, and its approval or denial of applications to participate in the negotiated rulemaking process are not actions that constitute "agency action." Agency action normally may be challenged in the DOAH and, upon appeal, to the District Court of Appeal. The clarification that these types of determinations in the negotiated rulemaking process are not agency action restricts the ability to challenge those determinations, but persons still may challenge a proposed rule. The amendment is in keeping with the standard used for mediation under the act.

Ch. 97-176, Laws of Fla., Sen. Staff Analysis & Economic Impact Statement at 8 (emphasis added).

97. The Administrative Procedure Act delineates detailed, specific requirements for rulemaking, which is "a complex process, but . . . also a flexible one with room for agency discretion." Whiley v. Scott, supra at 720 (citing Patricia A. Dore, Access to Florida Administrative Proceedings, 13 Fla. St. U.L. Rev. 965, 988-1018 (1986)). While chapter 120 includes numerous provisions agencies are required to comply with, such



as providing notice, holding public hearings, and publishing and filing proposed rules, that chapter “establishes no particular procedure to be followed by an agency during the original drafting of the proposed rule.” Id. at 721-23 (detailing chapter 120’s discretionary and required rulemaking procedures). Put differently, the Legislature has not imposed any specific requirements that an agency must comply with when drafting a proposed rule – including when that drafting derives from the negotiated rulemaking process. The resulting rule must, of course, be a valid exercise of delegated legislative authority; for example, the rule may not enlarge the law implemented, be vague, or be arbitrary or capricious. See § 120.52(8), Fla. Stat. But the agency has considerable discretion in how it drafts the rule, and a discretionary process like negotiated rulemaking is not one that imposes “rulemaking procedures or requirements” that an agency must follow to avoid invalidly exercising its delegated legislative authority. See Whiley, Id. at 721 (noting that under section 120.54, Florida Statutes, agency may choose to develop proposed rule on its own, may choose to hold a public workshop, or may choose to utilize negotiated rulemaking).

98. Baywood asserts that the Department failed to follow the applicable rulemaking procedures or requirements mandated by section 120.54. Specifically, Baywood contends that the

Department failed to convene a "balanced" committee, and that the members of the committee failed to adequately represent the interests of all other stakeholders in the formulation of the Proposed Rules.

99. Section 120.56(1)(c) provides in relevant part:

The failure of an agency to follow the applicable rulemaking procedures or requirements set forth in this chapter shall be presumed to be material; however, the agency may rebut this presumption by showing that the substantial interests of the petitioner and the fairness of the proceedings have not been impaired.

100. At hearing, Baywood did not establish that the Department failed to follow the applicable rulemaking procedures required by chapter 120, including the manner in which it utilized the negotiated rulemaking process. To the contrary, the evidence established that the Department considered whether a balanced committee could be assembled, and indeed did assemble such a committee. See § 120.54(2)(d), Fla. Stat. The Department worked to support the committee and used the committee consensus as the basis for the Proposed Rules. See Id. The Department published the required notice of negotiated rulemaking and of committee meetings, and the meetings were chaired by a neutral mediator. See Id. The negotiated rulemaking committee the Department selected was balanced and composed of a diverse group of stakeholders with wide-ranging

experience and expertise, including persons representing the interests of nurseries like Baywood.<sup>7/</sup> Over the course of some 26 hours the negotiated rulemaking committee conducted a reasoned, thoughtful, rational rulemaking process and helped develop a similarly reasoned, thoughtful regulatory framework for implementing the Act.

B. Definitions

101. The definitions provided in rule 64-4.001 are more than sufficient to allow applicants to know how to comply with the rules. The definitions were developed with input from negotiated rulemaking committee members representing potential applicants and do not leave any doubt as to the meaning of any term used in the rules.

102. The terms "operator," "contractual agent" and "inspection" do not require definition, as in this context their plain English meaning applies and is sufficient to enable applicants to understand what the rules mean and require. These terms of common usage are not vague, nor do they fail to establish adequate standards for the Department's decisions or vest unbridled discretion in the Department.<sup>8/</sup>

C. The Application Fee

103. Baywood asserts that with the potential for 99 applications for D.O. approval the Department is obligated to adjust the proposed fee to a more reasonable amount that

accurately reflects the "exact number" of actual applicants. Baywood also posits that the members of the rulemaking committee, some of whom represent some of the largest nurseries in Florida, wanted to ensure that the initial application fee was "robust" enough to eliminate other nursery competition for D.O. approval in their region. Finally, Baywood argues that upon request, an applicant's application fee should be refundable.

104. Baywood has failed to offer any persuasive evidence that the \$60,036 application fee is an invalid exercise of delegated legislative authority. The fee amount was determined by dividing the estimated costs of implementing section 381.986 by the estimated number of D.O. applicants. In point of fact, it is unknown how many applications for D.O. approval will be submitted to the Department, and therefore an estimate must be used.

105. Baywood did not offer any competent evidence that would render the Department's estimate of 15 applicants unreasonable. The mere fact that substantially more than 15 nurseries may be eligible to apply does not invalidate the Department's estimate. Rather, the 15-applicant estimate developed at the negotiated rulemaking sessions is a reasonable, rational estimate based on sound input and should allow the

Department to recover its costs of administering the statute, as required by the Act.

106. Baywood presented no evidence to support its theory that grower members of the committee had nefarious intent in estimating the number of potential applicants in order to inflate the application fee.

107. As to the argument that application fees should be refundable, the Department does not have the statutory spending authority to refund the application fee, nor does the Act confer the power to refund fees. Agencies are creatures of statute and have only those powers conferred on them by the Legislature.

State of Fla., Dep't of Env'tl. Reg. v. Puckett Oil Co., 577 So. 2d 988, 991 (Fla. 1st DCA 1991). The Florida Constitution; chapter 215, Florida Statutes; and the rules implementing that chapter impose specific limitations on how an agency may spend its money, including that agencies may not spend - even to refund - money unless the expenditure is expressly authorized by the Legislature. See, e.g., § 215.31, Fla. Stat.

108. Finally, Baywood waived any right to challenge this aspect of proposed rule 64-4.002, as Baywood failed to submit a lower cost regulatory alternative - which is a precondition to challenging the rule on the grounds relating to the regulatory costs imposed. See § 120.541(1), Fla. Stat.; Fla. Bd. of Med. v. Fla. Acad. of Cosmetic Surg., Inc., 808 So. 2d 243, 258 (Fla.

1st DCA 2002) (superseded on other grounds by ch. 2003-94 §§ land 3, Laws of Fla., as noted in Dep't of Health v. Merritt, 919 So. 2d 561, 564 (Fla. 1st DCA 2006)).

D. Certified Financial Statements

109. Baywood next argues that rule 64-4.002(2)(f)1. misinterprets the statutory requirement of certified financials, and therefore the rule violates section 120.52(8)(d)-(e). Specifically, Baywood contends that while the Act requires the submission of certified financials to the Department, the Act neither mandates exactly when the applicant or D.O. must submit those certified financials to the Department nor dictates how far back in time, if at all, the certified financials must date. According to Baywood, the plain meaning of the Act dictates that certified financials should be submitted two years after the D.O. has been in existence, because the Act states that certified financials must demonstrate an applicant's ability to sustain two years of operation as a D.O. For the reasons set forth below, Baywood's arguments in this regard are unpersuasive and are rejected.

110. The requirement that applicants submit certified financials with their application is a reasonable, rational interpretation of a statute the Department is charged with implementing. Section 381.986(5)(b)1. provides,

An applicant for approval as a dispensing organization must be able to demonstrate . . . [t]he financial ability to maintain operations for the duration of the 2-year approval cycle, including the provision of certified financials to the department. Upon approval, the applicant must post a \$5 million performance bond.

(Emphasis added). The next subsection, titled "Dispensing Organization," provides, "An approved dispensing organization shall maintain compliance with the criteria demonstrated for selection and approval as a dispensing organization under subsection (5) at all times." § 381.986(6), Fla. Stat.

(emphasis added).

111. Contrary to Baywood's interpretation of this provision, the only logical way to read the provision is as the Department does: as requiring an applicant to, at the time of application, submit certified financials as part of demonstrating its financial ability to maintain operations for the two-year approval cycle if selected to be a D.O. Here, the statute lists two items an applicant must furnish: certified financials and a performance bond. Significantly, the provision specifies that the performance bond must be posted "[u]pon approval" – but does not include that condition precedent "upon approval" when imposing the certified financials requirement. Under long-standing statutory construction principles, certified financials are not required to be furnished "upon approval," but

at another time. See S. Alliance for Clean Energy v. Graham, 113 So. 3d 742, 749 (Fla. 2013) (construing statute by applying doctrines of negative implication and in pari materia).

112. The Department's interpretation also comports with statutory construction principles by avoiding an absurd result. See Barber v. State, 988 So. 2d 1170, 1174 (Fla. 4th DCA 2008). It is logical to read the statute as requiring an applicant to submit certified financials with its application because that allows the applicant's financial ability to be assessed; it would be absurd to construe the statute as requiring certified financials to be submitted only after an applicant is selected to become a D.O., particularly after two years of cultivating, processing, and dispensing product to qualified patients as Baywood asserts. At that point, the Department would already have evaluated the company's application, and any information revealed after-the-fact in certified financials would do nothing to help this assessment.

113. The Department has reasonably interpreted the Act to require certified financials to be submitted with the application. The Department has no authority to omit that statutory requirement from the proposed rules.

E. The Performance Bond

114. The performance bond is intended to ensure the security of "performance" by a D.O. The Department created the



performance bond form and its terms and conditions based largely upon the Prior Final Order. Baywood argues that while the Act demands that applicants post a \$5 million performance bond upon approval, the Act includes none of the specific terms and conditions created by the Department and included on the performance bond form.

115. By definition, a performance bond is designed to guarantee performance, and the performance bond required by the Act is no different from any other performance bond. A performance bond is a contract in which one party (the surety) guarantees to another party (the obligee – here, the Department) that a third party (the principal – here, the D.O.) will complete the work under the bonded agreement. See Shannon R. Ginn Constr. Co. v. Reliance Ins. Co., 51 F. Supp. 2d 1347, 1350 (S.D. Fla. 1999); Am. Home Assurance Co. v. Larkin Gen. Hosp., Ltd., 593 So. 2d 195, 197, 198 (Fla. 1992). As concluded in the Prior Final Order, by requiring a performance bond in the amount of \$5 million, the Legislature unquestionably intended the bond to cover losses to cure a D.O.'s default and ensure complete performance of the license term obligation, including loss to patients whose needs may otherwise not be met. Costa ¶ 111.

116. Finally, the Proposed Rules' bond provisions comport with the Prior Final Order in that the new provisions assure performance by fulfilling approved application requirements and

not defaulting, as a performance bond would be expected to do. A bond that could be invoked only upon a D.O.'s license revocation, as Baywood believes is appropriate, would ignore the potential "significant delays in appointing a new dispensing organization and having it become operational" should a D.O. default and "dilute[] the purpose and effect of the required performance bond to the point that 'performance' is not being bonded." Costa, ¶¶ 65, 110.

117. A D.O. is not without recourse if it disagrees with the Department revoking the D.O.'s approval or invoking the bond: such an event would be agency action, and the D.O. could pursue administrative review under chapter 120, Florida Statutes. See e.g., § 120.569, Fla. Stat.

118. Here, too, Baywood essentially challenges the Act's requirements, not the Proposed Rules' requirements. The Act expressly requires each approved dispensing organization to furnish a \$5 million performance bond. § 381.986(5)(b)5., Fla. Stat. The Department has reasonably interpreted its statutory obligation and the Proposed Rules appropriately codify that statutory charge.

#### F. Inspection and License Revocation

119. Baywood challenges proposed rule 64-4.004 governing the revocation of D.O. approval, and proposed rule 64-4.005 governing the inspection of D.O. facilities. With respect to

proposed rule 64-4.004, Baywood asserts that it fails to set forth minimum thresholds and parameters for revocation, and as to both rules, Baywood faults them for failing to provide an appeal mechanism for challenging a failed inspection or revocation of D.O. approval.

120. Proposed rule 64-4.004 provides as follows:

64-4.004 Revocation of Dispensing  
Organization Approval.

(1) The department shall revoke its approval of the Dispensing Organization if the Dispensing Organization does any of the following:

(a) Cultivates low-THC cannabis before obtaining department authorization;

(b) Knowingly dispenses 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;

(2) The department may revoke its approval of the Dispensing Organization if any of the following failures impact the accessibility, availability, or safety of the Derivative Product and are not corrected within 30 calendar days after notification to the Dispensing Organization of the failure;

(a) Failure to comply with the requirements in Section 381.986, F.S., or this rule chapter;

(b) Failure to implement the policies and procedures or comply with the statements provided to the department with the original or renewal application;

(3) The department may revoke its approval of the Dispensing Organization for failure to meet the following deadlines if failure is not corrected within 10 calendar days:

(a) Failure to seek Cultivation Authorization within 75 calendar days of application approval; or

(b) Failure to begin dispensing within 210 calendar days of being granted the Cultivation Authorization requested in subsection 64-4.005(2), F.A.C.

121. As to proposed rule 64-4.005, Baywood contends that D.O.'s are unable to know against what standards exactly the Department is inspecting their facilities and against what measurable thresholds the facilities are being assessed. Baywood further argues that, for a given inspection of "any portion of the facility," the Department has failed to set forth minimum thresholds for a passing inspection of each "portion of the facility."

122. Proposed rule 64-4.005(1) provides that:

Submission of an application for Dispensing Organization approval or renewal constitutes permission for entry by the department at any reasonable time during the approval or renewal process, into any Dispensing Organization facility to inspect any portion of the facility; review the records required pursuant to Section 381.986, F.S., or this chapter; and identify samples of any low-THC cannabis or Derivative Product for laboratory analysis, the results of which shall be forwarded to the department. All inspectors shall follow the Dispensing Organization's Visitation Protocol when conducting any inspection.

123. At hearing, Baywood failed to present any persuasive evidence that proposed rules 64-4.004 and 64-4.005 are an invalid exercise of delegated legislative authority. Rather, the undersigned finds that those rules appropriately implement the Act's directive that a D.O. maintains compliance with the statutory criteria for selection at all times. § 386.981(6), Fla. Stat. The Department, therefore, needs a mechanism to determine whether such compliance is occurring and to take action if a failure to comply occurs.

124. Both of the above rules fairly and adequately inform D.O.'s of what is expected of them and what will happen if they fail to meet the Act's and the rules' requirements. Rule 64-4.005 unambiguously explains what may be inspected (any portion of the facility, the records required by the Act and the rules, and product) and what standards will be applied (the Department will inspect for violations of the Act or the rules). And rule 64-4.004 clearly delineates the circumstances under which a D.O. approval will or may be revoked and provides specific time periods for curing such a violation.

125. Finally, the Department has no authority under the Act to create a separate appeal process for challenging the revocation of D.O. approval or inspection failure. Moreover, there is no need for the Department to create an appeal process for inspection failure or license revocation, as such a process

already is provided in chapter 120, which authorizes any licensee whose license has been revoked to challenge agency action.

G. Application Evaluation and Scoring

126. Baywood next claims that the application and scorecard forms and the corresponding portions of rule 64-4.002 as drafted by the Department neglect to detail for applicants exactly how and by what methodology the Department will select the D.O. in each of the five regions. Without any defined scoring or weighting mechanism, Baywood argues, it is unclear how the Department will objectively assess the total points awarded to applicants and within each category and subcategory on the scorecard in the scoring matrix.

127. The application form developed by the Department, incorporated by reference in proposed rule 64-4.002, assigns relative weight to the five major categories (cultivation, processing, dispensing, medical director, and financials), and within three of those categories (cultivation, processing, dispensing) subcategories are identified and assigned relative weights.

128. The weighting system clearly set forth in the application form sufficiently informs would-be applicants as to the relative importance of each category and subcategory. The decision not to assign weights or percentages to individual

items (as opposed to categories and subcategories) was made by the negotiated rulemaking committee, is reasonable, and does not vest unbridled discretion in the Department. The application form and scorecards, in conjunction with the proposed rule, adequately inform D.O. applicants as to criteria to be considered and comparatively evaluated among competing applicants. In developing this evaluation system, the Department was guided by the Prior Final Order, which concluded that the Act required the Department to undertake a comparative, qualitative review of each applicant. Costa, ¶¶ 84-87.

#### H. Biennial Renewal Fee

129. Finally, Baywood asserts that the failure to include renewal costs and fees in the proposed rules is in contravention of the Act, is arbitrary and capricious, and fails to establish adequate standards for agency decisions, vesting unbridled discretion in the Department regarding such fee. According to Baywood, D.O. applicants are entitled to know the financial burden to be imposed by the renewal fee.

130. Baywood's contention in this regard is rejected. The Act requires that the cost of administering the program be borne by the imposition of initial and renewal fees. Inasmuch as the biennial renewal fee will not be assessed until two years following D.O. approval, it would be impossible at this point in time for the Department to determine the appropriate amount of

the renewal fee. The failure to include the specific amount of the biennial renewal fee within the proposed rules does not render them defective.

#### CONCLUSION

131. With due deference to the Department's interpretation of the statute the Department is charged with implementing, it is concluded that the Proposed Rules are a reasonable, rational interpretation of the Department's rulemaking authority that is clearly conferred by and consistent with the Department's general duties under the Compassionate Medical Cannabis Act, section 381.986.

132. Further, the Department's interpretation of the statute it is responsible for implementing is consistent with the Department's general duties under section 381.0011(2). The Proposed Rules do not enlarge, modify, or contravene the authority and discretion granted to the Department in section 381.986.

133. The Department has been vested with the important responsibility to develop the regulatory platform for implementation of the Compassionate Medical Cannabis Act. While the Department's first attempt to do so was unsuccessful, the fruit of its second effort, which was well-reasoned, deliberative, and thorough, represents a rational and coherent regulatory framework.



ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, it is ORDERED that proposed rules 64-4.001, 64-4.002, 64-4.004, and 64-4.005 do not constitute an invalid exercise of delegated legislative authority. Accordingly, Baywood's Petition is dismissed.

DONE AND ORDERED this 27th day of May, 2015, in Tallahassee, Leon County, Florida.



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Filed with the Clerk of the  
Division of Administrative Hearings  
this 27th day of May, 2015.

ENDNOTES

<sup>1/</sup> Unless otherwise noted, all statutory references are to the 2014 version of the Florida Statutes.

<sup>2/</sup> At one point, this case was consolidated with a rule challenge brought by the Medical Cannabis Trade Association of Florida, LLC (MCTA), Case No. 15-1693RP. MCTA voluntarily dismissed its petition prior to final hearing.

<sup>3/</sup> The untitled document lists 98 Florida nurseries having a "total inventory" of at least 400,000 plants, presumably as of January 9, 2015, the date the document was revised. The

document also includes the "registration date" for each of the nurseries listed. The undersigned notes that 10 of the nurseries on the list have registration dates that are less than 30 years prior to January 9, 2015.

<sup>4/</sup> Section 381.986(5)(b) provides that the cost of administering the Act shall be covered by both initial application fees and biennial renewal fees. If indeed the Department's estimate of D.O. applications is low, any excess funds received from initial application fees can be applied to the calculation of the biennial renewal fees, since the number of biennial renewals is fixed at five.

<sup>5/</sup> The undersigned rejects the Department's contention that a petitioner's standing to bring a rule challenge is fixed as of the date the petition is filed. Rather, as noted in Jerry, a petitioner may demonstrate injury either at the time the petition is filed or at the time of the hearing. Fla. Dep't. of Offender Rehab. v. Jerry, supra., at 1235.

<sup>6/</sup> Forward-looking decisions on access to rule challenges include Department of Administration v. Harvey, 356 So. 2d 323 (Fla. 1st DCA 1977); Professional Firefighters of Florida, Inc. v. Department of Health and Rehabilitative Services, 396 So. 2d 1194 (Fla. 1st DCA 1981); Montgomery v. Department of Health and Rehabilitative Services, 468 So. 2d 1014 (Fla. 1st DCA 1985); Cole Vision Corp. v. Department of Business and Professional Regulation, 688 So. 2d 404 (Fla. 1st DCA 1997); and NAACP v. Board of Regents, 863 So. 2d 294 (Fla. 2003).

<sup>7/</sup> Baywood itself did not apply to be part of the negotiated rulemaking committee.

<sup>8/</sup> The Legislature used the closely related terms "operated" and "operations" in the Act, and did not deem it necessary to define the meaning of those terms within the Act.

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NOTICE OF RIGHT TO JUDICIAL REVIEW

A party who is adversely affected by this Final Order is entitled to judicial review pursuant to section 120.68, Florida Statutes. Review proceedings are governed by the Florida Rules of Appellate Procedure. Such proceedings are commenced by filing the original notice of administrative appeal with the agency clerk of the Division of Administrative Hearings within 30 days of rendition of the order to be reviewed, and a copy of the notice, accompanied by any filing fees prescribed by law, with the clerk of the District Court of Appeal in the appellate district where the agency maintains its headquarters or where a party resides or as otherwise provided by law.