STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

COSTA FARMS, LLC,

Petitioner,

and

FLORIDA MEDICAL CANNABIS ASSOCIATION, INC., TORNELLO LANDSCAPE CORP., AND TREE KING-TREE FARM, INC.,

Intervenors,

vs.

Case No. 14-4296RP

DEPARTMENT OF HEALTH,

Respondent.
_____/

PLANTS OF RUSKIN, INC.,

Petitioner,

and

FLORIDA MEDICAL CANNABIS ASSOCIATION, INC., TORNELLO LANDSCAPE CORP., AND TREE KING-TREE FARM, INC.,

Intervenors,

vs.

Case No. 14-4299RP

DEPARTMENT OF HEALTH,

Respondent.
_____/

FLORIDA MEDICAL CANNABIS ASSOCIATION,

Petitioner,

vs. Case No. 14-4517RP

DEPARTMENT OF HEALTH,

Respondent.
_____/

TORNELLO LANDSCAPE CORP.,

Petitioner,

vs. Case No. 14-4547RP

DEPARTMENT OF HEALTH,

Respondent.
_____/

FINAL ORDER

Pursuant to notice, a formal hearing was held in this case before W. David Watkins, Administrative Law Judge of the Division of Administrative Hearings, on October 14 and 15, 2014, in Tallahassee, Florida.

APPEARANCES

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(Tree King-Tree Farm, Inc.)

STATEMENT OF THE ISSUE

Whether the proposed rules that comprise Florida Administrative Code Chapter 64-4 (Proposed Rules) constitute an invalid exercise of delegated legislative authority?

PRELIMINARY STATEMENT

On June 16, 2014, Governor Rick Scott signed the Compassionate Medical Cannabis Act of 2014 (Act). Ch. 2014-157, Laws of Fla. (codified at § 381.986, Fla. Stat.). The next day, the Florida Department of Health ("Department" or "DOH") commenced the statutory rulemaking process for the regulatory framework necessary to authorize the establishment of five dispensing organizations to grow and dispense low-THC cannabis to qualified patients. On August 14, 2014, the Department published a Notice of Proposed Rule that established a regulatory structure for the selection and regulation of five dispensing organizations for low-THC cannabis as required by section 381.986(5)(b). On September 9, 2014, the Department published a Notice of Change in the Florida Administrative Register, in response to comments from the Joint Administrative Procedures Committee ("JAPC"), testimony received at the public

hearing on September 5, 2014, and additional written comments received from the public after publication of the Notice.

Specific provisions of the proposed rule were challenged by Costa Farms, LLC ("Costa Farms"); Plants of Ruskin, Inc. ("Plants of Ruskin"); the Florida Medical Cannabis Association ("FMCA"); and Tornello Landscape Corp. a/k/a 3 Boys Farm Company ("Tornello Landscape"). FMCA, Tornello Landscape, and Tree King-Tree Farm, Inc., ("Tree King") were also granted permission to intervene in opposition to the proposed rules. Specifically, the challengers allege the following proposed rule provisions are invalid:

Rule 64-4.001(1), which defines "Applicant";

Rule 64-4.002(2)(j), which limits the conditions imposed on the required performance bond;

Rule 64-4.002(4)(a), providing for the use of a lottery to choose the applicants to be approved;

Rule 64-4.002(4)(b), requiring only approved applicants to pay an application fee.

In addition, Costa Farms alleges that the Department's procedure to screen applications to qualify for the lottery pool is an unadopted rule within the meaning of section 120.52(16) and (20), Florida Statutes.

Finally, Plants of Ruskin alleges that the proposed rules prescribe extensive guidelines for the grant and revocation of

authorization to become a dispensing organization which exceed those authorized by the enabling Act.

All challenges were consolidated for the purpose of final hearing, which was scheduled to commence on October 14, 2014.

On October 6, 2014, the Department moved to dismiss Costa Farms' Petition for lack of standing, which motion was denied by Order dated October 9, 2014.

On October 13, 2014, the parties filed a Joint Prehearing Stipulation, which was supplemented at the outset of the hearing. To the extent relevant, those stipulations have been incorporated in this Final Order.

The final hearing was convened as scheduled on October 14 and 15, 2014, in Tallahassee, Florida. At the hearing, Plants of Ruskin and FMCA's Motion for Partial Summary Judgment was denied, and Costa Farms' Motion to Amend Petition was granted.

Costa Farms presented the deposition testimony of Linda McMullen, Jennifer Tschetter, Pedro Freyre, and David Cooper, Ph.D, as well as the in-person testimony of one witness: Michael Rimland, Director of Research and Development for Costa Farms. Mr. Rimland was accepted as an expert in nursery operations and in the development of new non-native plant varieties for production in Florida. Costa Farms' Exhibits I – VI and VIII - XII were admitted into evidence. Plants of Ruskin and FMCA called no witnesses. Plants of Ruskin and FMCA's

Exhibits 1 - 13 and 15 - 38 were admitted into evidence. Tornello Landscape called one witness: Robert Tornello, owner of Tornello Landscape Corp., who was accepted as an expert in nursery operations. Tornello Landscape did not offer any exhibits into evidence. The Department called one witness: Jennifer Tschetter, Agency Representative for the Department. DOH Exhibits 1 – 15 and Costa Farms Exhibit VII were admitted into evidence as part of the Department's case.

All parties timely filed their Proposed Final Orders on October 27, 2014, each of which has been carefully considered in the preparation of this Final Order.

FINDINGS OF FACT

Based upon the testimony and documentary evidence presented at hearing, the demeanor and credibility of the witnesses, and on the entire record of this proceeding, the following findings of fact are made:

I. The Parties

1. The Florida Department of Health is an executive branch agency of the State of Florida created pursuant to section 20.43, Florida Statutes.[1/] The Department is primarily responsible for implementation of the Compassionate Medical Cannabis Act of 2014, as codified at section 381.986.

2. Petitioner Costa Farms, LLC, is a limited liability company with its principal place of business at 21800 S.W. 162nd

Avenue, Miami, Florida 33170. Costa Farms is a nursery that possesses a valid certificate of registration with the Department of Agriculture pursuant to section 581.131, Florida Statutes; has operated as a registered nursery for 30 years; and is operated by a nurseryman.

3. Petitioner Plants of Ruskin, Inc., is a Florida corporation whose business address is 901 4th Street, N.W., Ruskin, Florida 33570. Plants of Ruskin is a nursery that possesses a valid certificate of registration with the Department of Agriculture pursuant to section 581.131; has operated as a registered nursery for 30 years; and is operated by a nurseryman.

4. Petitioner/Intervenor, Florida Medical Cannabis Association, Inc., is a Florida corporation whose business address is 1299 Fairbanks Avenue, Suite A, Winter Park, Florida 32789. FMCA represents a substantial number of its members that will be regulated by and are substantially affected by proposed chapter 64-4. The subject matter of proposed chapter 64-4 is within the Association's general scope of interest and activity.

5. Petitioner/Intervenor Tornello Landscape Corp. a/k/a "3 Boys Farm Company," is a Florida corporation doing business at 704 21st Avenue, S.E., Post Office Box 789, Ruskin, Florida 33570. Tornello Landscape is a nursery under section 581.131;

has operated as a registered nursery for 30 years; and is operated by a nurseryman.

6. Intervenor Tree King-Tree Farm, Inc., is a Florida corporation with a principal place of business located in Pasco County, Florida, at 4903 State Road 54, New Port Richey, Florida 34652. It also alleges to have been owned and operated by a nurseryman for 30 continuous years with greater than 400,000 plants in cultivation.

II. The Compassionate Medical Cannabis Act of 2014

7. During the 2014 legislative session, the Florida Legislature passed Senate Bill 1030 entitled the "Compassionate Medical Cannabis Act of 2014," chapter 2014-157, Laws of Florida (the "Act").

8. The Act represents an historic and momentous change for the State of Florida regarding the regulation and use of cannabis, previously a Schedule-1 drug in all forms. To provide relief for patients with debilitating diseases, the Act allows for the use of low-THC cannabis by qualified patients for medical use when ordered by a Florida physician.

9. The Act authorizes licensed physicians to order low-THC cannabis beginning January 1, 2015, for qualified patients under specified conditions, primarily those suffering from cancer or severe and persistent seizures and muscle spasms.

10. The Act charges the Department with the vast majority of responsibilities associated with implementation. The Department is required to establish a compassionate-use registry by January 1, 2015. The Department is also required to establish the Office of Compassionate Use within the agency and work with the state university system to bring FDA-approved investigational new drugs for the treatment of refractory epilepsy to Florida. The Act also appropriated $1 million to the Department's Biomedical Research Council to further state university research related to cannibidiol and its effect on childhood epilepsy. Finally, the Act requires the Department to authorize, by January 1, 2015, the establishment of five dispensing organizations to grow, refine, and dispense low-THC cannabis to qualified Florida patients.

III. The Department's Rule Development Process

11. Immediately after the 2014 legislative session, the Department started its work to establish a regulatory structure for approving five dispensing organizations. The Department researched statutes and rules in other states where cannabis had already been legalized in some form. None could be easily patterned because no other state had limited the number of dispensing organizations to five and restricted medical use to only low-THC cannabis derivative products.

12. Through the Department's research, it also recognized the necessity of establishing a robust regulatory structure because cannabis, in any form, remains illegal under federal law with no accepted medical use. Prior to July 1, 2014, Florida's state and local law enforcement agencies worked in partnership with federal authorities to regulate cannabis through enforcement of identical narcotics laws. The passage of the Compassionate Medical Cannabis Act of 2014 fundamentally altered the long-standing narcotics enforcement partnership between the federal law enforcement agencies and state and local law enforcement agencies.

13. The Department reviewed several memoranda and other guidance from the United States Department of Justice issued in response to laws in several other states legalizing the manufacture, distribution, dispensing, and possession of cannabis. Especially important to the Department were the eight federal enforcement priorities consistently identified by the Department of Justice in its memoranda:

- Preventing distribution of cannabis to minors;
- Preventing cannabis revenue from going to criminal enterprises such as gangs or cartels;
- Preventing the diversion of cannabis to other states;
- Preventing state-authorized cannabis activity from serving as a front for the trafficking of other illegal drugs;

- Preventing violence and the use of firearms in the cultivation and distribution of marijuana;
- Preventing drugged driving and other adverse public health consequences associated with cannabis use;
- Preventing the growing of cannabis on public lands; and
- Preventing cannabis possession or use on federal property.

14. It was clear from the federal guidance that it was the responsibility of the state to ensure protection of the eight federal enforcement priorities through the enactment of a robust regulatory structure that maintains the enforcement partnership between state and local law enforcement agencies and federal authorities. A failure to do so would create a very real risk for challenge by the federal government to the regulatory structure established by the state. Thus, in developing its proposed rules, the Department was appropriately mindful of the illegality of low-THC cannabis under federal law and the necessity for a robust regulatory structure that protected the eight federal enforcement priorities.

15. The Department estimated that the cost of setting up the "robust regulatory structure" was in the range of $750 thousand to $1.5 million.

16. Another fundamental consideration for the Department was whether any rule promulgated as part of the new regulatory structure could impose regulatory costs that would trigger the

legislative ratification requirement described in section 120.541, Florida Statutes. Because the Act required the authorization of five dispensing organizations by January 1, 2015, the Department believed it was precluded from promulgating any rule that imposed regulatory costs on the dispensing organization applicants that would trigger a legislative ratification requirement.

17. Another overall consideration for the Department was the lack of a legislative appropriation to support the Department's efforts. The Department was required to use existing resources to establish the regulatory structure and meet the other requirements of the Act. The necessity to use existing resources, the time limitation, and the unique statutory structure also limited the Department's ability to hire "cannabis experts" to assist with the rulemaking process and development of merit selection standards to be used in evaluating applications.

18. The Department issued draft proposed rules for selecting dispensing organizations and other aspects of the program on July 2, 2014. It conducted rule development workshops on July 7 and August 1, 2014. Each of the workshops was attended by over 200 people, with more than 100 persons offering verbal comments on the draft rules. On August 29, 2014, the Joint Administrative Procedures Committee (JAPC)

issued a letter commenting at length on the proposed rules, to which the Department responded on September 10, 2014. The Department held a public hearing on the proposed rules on September 5, 2014. It subsequently issued a Notice of Change/Withdrawal reflecting some technical changes to the proposed rules on September 9, 2014.

19. Department General Counsel Jennifer Tschetter had primary responsibility for preparing the proposed rules. Her career has been as a lawyer with experience in agency rulemaking; she does not claim any prior expertise in nursery operation, supply of medical cannabis, business plans, or finance. The Department had no such expertise when the bill passed in May 2014, and due to fiscal and other constraints, the Department did not hire a consultant to assist it in developing comparative review standards to be utilized in evaluating applications.

20. On July 2, 2014, the Department appointed Linda McMullen to be the Director of its Office of Compassionate Use. Ms. McMullen was previously a Department staff lawyer under Ms. Tschetter; her career has been as a lawyer. She did not claim experience in program areas relating to supplying medical cannabis.

IV. Cultivation and Production of Low-THC Cannabis

21. The low-THC cannabis product that the selected dispensing organizations will be responsible for growing, extracting, and delivering is targeted for a very vulnerable population, including children suffering from cancer and chronic and uncontrollable seizures.

22. Since the low-THC cannabis derivatives will be given to persons with serious medical conditions, it is imperative that the product not contain any impurities that could trigger an adverse reaction in the patient. However, there is a dearth of information as to what pesticides, fungicides, fertilizers, or other inputs may safely be used in cultivating cannabis in Florida. Robert Tornello, an expert in nursery operations, credibly testified about this problem as follows:

> But what this refers to in cannabis, is it's not that we are going into unknown waters as far as just the growing part of it. Where we are going is into an area, because of the amount of years that this particular plant has been labeled as a schedule 1 drug, including industrial hemp, which is grown all over the world, the problem we've got is that the Environmental Protection Agency, EPA, is the one who writes and approves guidelines for any of the inputs that you would use on a plant.
>
> For example, if you were growing apples, you could actually be able to cross reference apples with whatever visual problem that you see and you would come up with a list of -- potentially there are deficiencies that may occur and how to fix those with either

synthetic or organic compounds, or there would be a list of different possible pathogens or issues that would show you all the different pesticides that could be used, as well as fungicides.

And when we get back to cannabis, because of its being a schedule 1 drug for so many years, there are absolutely no, as in zero, chemical compounds that have been tested for rates as far as minimums or maximums, and as well as efficacy. And as well as -- now I am getting feedback (from his microphone).

So, my point is that without any testing that has ever been done on cannabis, we have a unique situation. This is one that I brought up with both Jennifer and Linda at the hearings.

And my concern is not just what growers are being told to do or suggested they can or cannot do. The most important precedent that we have to deal with is the law. And the law clearly states -- in Florida we have a statute, I believe it's 487, that the division of or actually part of the Department of Agriculture, and in that statute it tells you all about the uses of pesticides and applications, things that can be done, that can't be done, and the methods and applications. It's a little bit long-winded, almost as I am right now.

But the point is that it clearly states in several of the subchapters, as it does also with the environmental protection rules, is that if a pesticide or compound or fungicide or anything even organic compounds are not listed for that particular plant, they cannot be applied to that plant; because nobody knows, just without at least a hundred tests and those have been approved then by the departments, of what is minimums or maximums for applications and the efficacy and what amount of residual

> chemical may show up or is allowable, most importantly, a product.
>
> And where this is so critical on the Bill 1030, the Charlotte's Web law, is that we are talking about the growing of a plant that most of us -- and in this particular case with regard to cannabis, I also truthfully do not grow, but it's important to understand that with cannabis, you can't apply anything to it without -- you can't guess at it. Because if you do and you think that the application rate is safe or one that you've used on a plant that you would think is the same leaf structure or type, or genera, you could be very, very wrong and, as a result, the pesticides that are absorbed by the actual plant by contact, plus what's on there as residual, would then translocate through the extraction process.
>
> And then when we get into extraction and you have an oil, as in the case with the Charlotte's Web bill, then we are looking at -- which I was happy to see that they listed as a parts per billion test for pesticides, because any little bit of chemical that could be on any of these plants and that can be absorbed through by the caregiver to the patient, ultimately if you have an autoimmune disease or have a neurological disease, those either have metal compounds or those particular synthetics can be a trigger.

(Transcript, pgs. 107-110).

23. Many registered nurseries in Florida have experience only in growing ornamental plants. The evidence established that some of the nurseries that meet the 30-year registration requirement and the 400,000 plant threshold set forth in the Act

have little or no experience growing food products or plants that can be used for medicinal purposes or human consumption.

24. The significant chemical and safety issues inherent in growing medical cannabis require skills and expertise that are not typically required for growers of strictly ornamental (as opposed to ingestible) plants. As Mr. Tornello credibly testified:

> But knowing what we know about the nursery business in general and also enjoying those hearings which were also educational, is that quite a few of the nurserymen were very candid about speaking, and clearly stated that they are just a nurseryman and they know understand plants and, given enough time and enough money, they would develop enough experience to eventually become proficient in growing this.
>
> And to me, in my heart, I felt bad for some of these guys because, you know, this is not -- growing at these levels is not easy. It requires on average three hours of paperwork a day. It's just agonizing, the paperwork. The audits, we have 13 books that are this thick of books that are forensically gone through by the food safety people, as well as refrigeration and harvest groups and things of this nature. So when I saw all this happening, I knew that the lottery became strictly a chance-based scenario and it wasn't merit-based or experience-based. And to me, I had to object to it.

(Transcript, pgs. 121, 122).

25. Cannabis is a product that is not native to Florida, and the ability to grow the product safely and effectively depends on a number of complex factors which are not addressed

in the proposed rules. Michael Rimland, accepted as an expert in nursery operations and in the development of new non-native plant varieties for production in Florida, described the risks in growing low-THC cannabis in Florida for a nursery that does not have experience in introducing and cultivating non-native varieties:

> First would be failure, actually crop loss, not be able to actually produce the plant. And the plant would die from cultural conditions not being adapted properly, physiological conditions not being adapted properly, or some other type of issue that they just have not learned how to produce it. Or it could be crop timing; the crop is a very sensitive crop when it comes to timing. Basically it's eight weeks. Eight weeks in one vegetative form, eight to ten weeks in flowering form. Could also be in the quality of the product that's produced, without understanding again the protocols that are required to produce it perfectly and timing is a huge factor in producing it perfectly.

(Transcript, p. 64).

26. Mr. Rimland also testified that not all nurseries with 30 years' experience in Florida will have the same likelihood of success in efficiently producing low-THC cannabis for medical use. Because cannabis is not native to Florida, an important factor in predicting success is the nursery's demonstrated ability to successfully produce a large number and variety of non-native genera and species. It is not sufficient simply to hire someone who has produced medical cannabis in another state,

because growing conditions in Florida such as humidity, temperature, light conditions, and insect and disease thresholds are very different from those found elsewhere. Mr. Rimland testified that there are at least 20 different varieties of low-THC cannabis, all of which have different production requirements, so the dispensing organization will have to address these issues in introducing different varieties to meet patient needs. A lack of specialized knowledge regarding introduction of non-native genera and species in Florida risks inability to produce the plant at all; delays in production; reduced crop quality; and increased price for the product, all of which may affect patient access.

27. Additionally, the infrastructure required to safely and successfully cultivate cannabis is significantly different than what is required to grow ornamental plants. As explained by Mr. Tornello:

> The things that are different are primarily going to be the first initial set up. The greenhouses, as I said earlier, need to be pretty much hermetically sealed to avoid any pests or any kinds of problems; and you have to have vestibules again with alcohol mats so people don't track in anything from the ground, because there's a lot of different soil-borne pathogens that can come into a humid or a growing situation that could become virile.

(Transcript, p. 130).

28. Pedro Freyre, Costa Farms' Vice President of its Foliage Division, also credibly testified concerning factors that predict whether a nursery will be able to dependably produce medical cannabis. According to Mr. Freyre, nurseries with established operations and experience in introducing new varieties of plants are better prospects for success in producing medical cannabis. Mr. Freyre agreed that there are numerous challenges to growing medical cannabis in Florida, such as climate control, pest control, contamination controls, establishing correct and adequate patient protocols, security structure, source materials, risk of loss of key personnel, and financial perils. A nursery with substantial financial resources, according to Mr. Freyre, is better able to weather initial growing pains, comply with regulations, and produce consistent high-quality products. Such nurseries may be better equipped and staffed to provide reliable inventory control. The nursery's location, transportation system, and costs would all affect patients' access to the product.

V. Selection of Medical Cannabis Dispensing Organizations

29. Section 381.986(5) directs, in pertinent part, that "by January 1, 2015, the Department shall" do the following:

> (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.
>
> * * *
>
> (d) Adopt rules necessary to implement this section.

30. There are approximately 75 nurseries that possess a valid certificate of registration for the cultivation of more than 400,000 plants, are operated by a nurseryman as defined in section 581.011, and have been operated as a registered nursery in Florida for at least 30 continuous years. These 75 nurseries represent the potential pool of applicants seeking to become one of the five dispensing organizations authorized under the Act.

31. Proposed rule 64-4.002(4)(a) provides that "[i]f more than one applicant for a dispensing region is qualified and its application is timely received, the department will provide a computer program method for a double random lottery-type selection by public drawing to designate the approved applicant and the order of the other applications within each dispensing region."

32. Pursuant to proposed rule 64-4.002(1), the Department will require applicants to submit a one-page application form which identifies the applicant and key personnel, with attached exhibits prescribed by the proposed rules as follows:

- Plan for cultivating, processing, and dispensing low-THC cannabis, including a business plan showing the applicant's expected production, rule 64-4.002(2)(b);

- Security and safety plan with at least certain listed features, rule 64-4.002(2)(c);

- Quality assurance plan, rule 64-4.002(2)(d);

- Documentation of the applicant's ability to obtain and maintain the premises, facilities, resources, and personnel necessary to operate a dispensing organization, with, at a minimum, specific disclosures regarding facilities and employees, rule 64-4.002(2)(e);

- Inventory control plan documenting the applicant's ability to maintain accountability of all raw materials, finished products, and any byproducts, rule 64-4.002(2)(f);

- Documentation that the applicant possesses infrastructure reasonably located to dispense products to registered patients, and a transportation plan, if applicable, 64-4.002(2)(g);

- Documentation that the applicant has equipment, training, ability, and personnel necessary to safely produce

low-THC cannabis derivative products, rule 64-4.002(2)(h);

- Documentation of the applicant's financial ability to maintain operations for the two year approval cycle, rule 64-4.002(2)(i);

- Documentation of the applicant's ability to post a $5 million performance bond, the sole condition of which is to cover any cost incurred in disposing of inventory should the applicant fail to perform and need to be replaced, rule 64-4.002(2)(j).

33. The above-listed nine categories of documentation are the only guidance to applicants on what information they must submit in order to be found qualified to be randomly selected by lottery as a dispensing organization under the rule. Likewise, this is the only guidance to Department evaluators on what they should consider in order to pass or fail applications for random selection approval. Ms. McMullen could not elaborate on what would specifically qualify an applicant for the lottery under the rule. Ms. Tschetter explained that evaluators will not be using any guidelines other than these rules to determine which applications qualify for random selection.

34. JAPC asked the Department how it intended to apply these general standards to evaluate applications:

> 64-4.002(4)(a): This rule paragraph indicates that the department will substantively review and evaluate all timely received applications to determine if the applicant is qualified . . . . To

> substantively evaluate the applications and exhibits, it appears that there must be stated standards and criteria in the rule text. See § 120.52(8)(d), Fla. Stat.

(emphasis added).

35. Ms. Tschetter's response to JAPC's inquiry did not identify any specific standards or criteria, but rather stated:

> 7. 64-4.002(2), 64-4.003 -- Evaluation Criteria
>
> Each of the documentation requirements identified in proposed rule 64-4.002(2), as changed, will be evaluated on a pass/fail basis. The documentation will either be present; or it will not. Each of the Department's decisions about whether the documentation is sufficient will be subject to review at the Division of Administrative Hearings pursuant to section 120.57, Florida Statutes. Similarly, the evaluation of biennial renewal applications will be on a pass/fail basis and subject to review at DOAH. There is no need for additional criteria.

36. The rules give no specific direction as to what financial information is required of an applicant, or for what period of time. There is no minimum requirement for applicants' financial ability. The financial information can be either historical or projected. There is no requirement that the financial statements be audited to assure the information is accurate.

37. The Department intends to evaluate each application independently, not comparatively, to determine if the applicant has the ability to provide the low-THC product for two years

under its specific business plan. The Department anticipates that financial requirements will vary from applicant to applicant, and should be determined independently for each business plan. Thus, requirements will be ad hoc and non-uniform, floating with the unique features of each proposed business plan. Ms. McMullen explained that each applicant will be judged on its own proposal.

38. Prior to an applicant being selected as a dispensing organization, evaluators will not visit the nursery site to verify the applicants' capabilities. And although applicants must theoretically demonstrate the ability to perform in their application, the Department does not require that an operation be up and running prior to approval.

39. The applicant must have a licensed M.D. or D.O. as its medical director, but there is no specific required medical experience, duties, or work hours.

40. When asked about the Department's "qualitative analysis" of applications, Ms. McMullen testified that the screening panel will only check the applications for minimum qualifications or requirements:

> Q: So the qualitative analysis that you're speaking of here is simply are they minimally qualified under our interpretation of the statute, which have they met the statutory criteria sufficient to be an applicant?

A: Correct. (Costa Farms Ex. I: McMullen Dep. p. 86)

* * *

Q: Would you agree that the absence of any fee requirement would encourage someone who has minimal qualifications to apply when there's really nothing to lose, you don't have an application fee to lose?

A: All this – if they meet the minimum requirements of the statute and the rule, then their application will be accepted. (Costa Farms Subst. Exh. II, McMullen Dep. p. 63)

41. Ms. Tschetter did not interpret the statute to require the Department to pick the best or most dependable applicant. Rather, she felt that the screening process will ensure that applicants that are passed to the lottery pool will be "good enough" and that whether one applicant is better than another is just a matter of opinion.

42. At the public hearing held on September 5, 2014, the Department made a PowerPoint presentation. Included in the presentation was a description of the "Qualification Process – 64-4.002" with bullet points stating "At least 3 Department evaluators," "Public meeting" and "Will comply with requirements of section 120.60(1), Florida Statutes." If the Department finds an application is defective, incomplete, or insufficient to qualify, it intends to allow

the applicant 15 days to correct, supplement, or remedy the application, under authority of section 120.60(1).

43. The proposed rules do not contain any guidance on procedures to be used in this evaluation – for example, who appoints the panel members, who the panel members will be, whether the panel members will have any expertise, whether panel members' evaluations are independent or joint, whether panel decisions to disqualify an applicant must be unanimous or majority vote, whether panel decisions will be subject to further administrative review and by what process, and when decisions may be challenged.

44. Ms. McMullen confirmed that the Department intends to appoint a three-person panel to screen applications to determine if they meet basic requirements to be eligible for the lottery pool. She expects to participate in the screening process, but did not know how this screening process will work or what her role will be.

45. The Department did not propose rules, nor does it plan to adopt rules to elucidate its panel-review procedure to determine if applicants are qualified for the lottery.

46. Under proposed rule 64-4.002(4)(a), all applicants that are deemed to pass general minimum requirements will qualify to be placed in the lottery pool, and the winner then selected at random:

> If more than one applicant for a dispensing region is qualified and its application is timely received, the department will provide a computer program method for a double blind random lottery-type selection by public drawing to designate the approved applicant and the order of the other applications within each dispensing region. (emphasis added).

47. Each applicant in the lottery pool will have an equal chance to be selected. Applicants not selected by the lottery will not be approved as a dispensing organization.

48. Applicants are not required to pay any application fee to have their applications reviewed and placed into the lottery pool. Only the lottery winner is required to pay an "application fee," in the amount of $150,000 before it is authorized to be the exclusive dispensing organization for its region. If the winner fails to pay the application fee, the applicant picked second in the lottery is selected; if a default occurs later, a new lottery is conducted for that region.

49. Although the license is granted for two years, pursuant to proposed rule 64-4.003, an approved dispensing organization will have perpetual renewal rights, unless it commits a serious violation or is unwilling or unable to continue.

50. Costa Farms' Pedro Freyre has a background in finance and the business side of operating nurseries. Mr. Freyre testified it was not clear to him what the

proposed rule requires applicants to provide as a "business plan," a "quality assurance plan," "reasonably located infrastructure" or "financial statements" in connection with the application.

51. Mr. Freyre also testified that in order to attract established Florida nurseries to become dispensing organizations for lawful cannabis products, the Department should allow a winning applicant to assign its operating rights to a related single-purpose entity owned by the same owners, so the existing nursery can maintain its banking relationships.

52. Ms. Tschetter agreed that a qualified nursery selected as a dispensing organization will be allowed to transfer operating rights to an affiliated single-purpose entity, under the Department's form to request to alter a dispensing organization.

53. David Cooper, Ph.D., professor of economics at Florida State University, credibly summarized the likely economic effects of the lottery system as reducing competition between providers and raising prices to consumers, which could potentially impair access to the medication:

> [U]se of a random selection process (i.e. a lottery) to select an oligopolistic and permanent regional franchise under a general qualifications standard . . . will encourage inefficient (i.e. high cost) providers to

> enter the lottery. The likely outcome is a reduction in the disciplining effect of competition and, as a direct result, higher prices in all regions of the state. Consumers who would benefit from access to this medication will either be forced to pay higher prices or, even worse, be unable to afford the product. Poor choice of a mechanism to choose providers means that access will be denied to some patients who would receive medication under a better system.
>
> * * *
>
> Unfortunately it is extremely unlikely that the low cost providers are chosen under the lottery system . . . .
>
> Even if we get lucky, the outcome is still likely to be worse with the lottery . . . because of a lack of effective competition . . . .
>
> The lottery system leads to even worse outcomes when potential providers are uncertain about their costs, testing standards and potential demand. Because the costs of entry are low due to the structure of the bond and the low filing fees, this becomes much like the old lottery ad where "all you need is a dollar and a dream." The lottery is likely to be flooded with inefficient producers. The best case scenario is that these providers become weak competitors who do little to discipline pricing. The worst case scenario is that they have underestimated their costs and rapidly go bankrupt, leaving a void in their territory and reducing competition across the state. (CF Ex. VI -20 pp. 1-2).

According to Dr. Cooper, the proposed rules also promote collusion among providers, which can artificially restrict competition and consumer access to the product:

> The preceding assumes that the five providers are acting independently and competing prices down. Matters become far worse if the 25% rule is in place, [proposed rule 64.001(1)][2/] as this makes it relatively easy for providers to collude. The worst case scenario is that 75% of each provider is held by an outside entity. At this point, providers have little incentive to undercut the prices of other competitors as they are essentially robbing profits from themselves . . . . This once again reduces their incentives to compete . . . . (Id. p.2)

And the proposed rules discourage competition in product quality:

> The adherence to a quality threshold to qualify for the lottery is potentially harmful as well. With no incentive to provide anything other than minimum acceptable quality, there is little reason for providers to research methods of improving quality or to invest in equipment to improve their quality . . . . It is safe to assume that efficient providers not only have lower costs for minimal quality, but also have better capability to provide high quality at a reasonable cost. By randomly tossing these providers out of the market, it becomes less likely that high quality will be provided even if consumers might be willing to pay more for access to a higher quality product. (Id. p.2)

54. Dr. Cooper concluded that the proposed lottery rule, alone and in combination with other proposed rules, will not promote consumers' access to the medication:

> [I]f potential providers with efficient operations (i.e. low costs, ability to provide high quality) are given no advantage in entering the market, the likely outcome

> is lack of competition and low access to a needed medication. (Id. p.2)

55. Using standard economic analysis, Dr. Cooper testified that the Department should want five efficient low-cost providers that are financially stable, willing and able to compete statewide on price and quality; but that the proposed lottery rule and related rules enlarging the lottery pool (such as no application fee and limited performance bond) will encourage inefficient nurseries to apply, and encourage more efficient nurseries to offer less competitive proposals than they would if selection were based on competitive review of the merits. He explained the dangers arising from rules relating to applicants' ownership or financial control structure that permit and encourage providers to have common ownership and to collude as to price, which can reduce consumers' access to the product, or to collude by territorial allocation if providers decline to compete in one another's regions.

56. The price that patients must pay for the low-THC cannabis is a factor in accessibility, particularly as insurance does not cover this medication.

57. The uncertainty over whether the five chosen suppliers will be able to meet demand for the product magnifies concerns over access and price. Ms. McMullen was uncertain that the five dispensing organizations will be able to supply enough product

to meet the need of eligible patients, noting there is a waiting list for this product in Colorado. She assumed that dispensing organizations will expand to meet whatever demand arises. Even so, a dispensing organization may fail to produce an adequate or timely supply, and shortages can occur without warning if a product batch fails testing. Moreover, the proposed rules require destruction of all inventory if a license is revoked or a dispensing organization does not stay in business. None of the proposed rules require applicants to show ability to cover any particular number of patients or any increase in number, or to cover patients in other regions in the event one or more other regional dispensing organizations cannot meet all needs in that region or cannot perform at all.

58. Ms. McMullen confirmed that nothing in the rules prevents collusive applications in which one nursery or one out-of-state investor owns 75% of all applicants.

59. For its part, the Department believes lottery selection is appropriate because applicants may propose different approaches to producing medical cannabis, and it is difficult for the Department to adopt uniform standards to evaluate all approaches. Ms. Tschetter and Ms. McMullen both expressed an opinion that all applicants who pass general standards in the proposed rules are equally qualified, using

variations on the phrase, "different but not better" and "they are all great . . . just different".

60. The undersigned rejects as non-credible the proposition that all applicants who meet the minimum initial application requirements set forth in rule 64-4.002 are equally qualified to cultivate, process, and dispense low-THC cannabis. Rather, many of the general statutory criteria – e.g., the applicant's security and safety plan, inventory control plan, location and transportation plan, and financial ability – can be compared on the merits using ordinary business judgment without special knowledge of technical methods of production or preference for any one technical approach. While the Department's present inexperience in technical program areas may make comparison more difficult, it can avail itself of expert assistance to determine which applicants have superior programs and the best chance of success.

61. Without the lottery system for choosing dispensing organizations, one of the Department's concerns is that the selection process would be drawn out into an extended review period followed by legal challenges to the ultimate selection. Thus, the Department's objective is to establish a regulatory structure that neither invites litigation nor prolongs the process. The Department concluded that the lottery system would provide the fairest way to choose among qualified applicants,

and would provide the best mechanism to get the medicine to patients as quickly as possible.

VI. The Initial Application Fee

62. Proposed rule 64-4.002(4)(b) requires only the five chosen applicants to pay the $150,000.00 application fee; all other applicants who are not selected are not to be charged anything.

63. JAPC asked the Department to explain why, when the statute requires an initial application fee, the proposed rule imposes an application fee only after applicants are selected? Ms. Tschetter responded that she believed it was reasonable to impose the initial application fee as a post-approval condition since the Legislature made the performance bond a post-approval condition. Ms. Tschetter's rationale in this regard is rejected inasmuch as the initial application fee to cover the Department's regulatory costs has no logical connection to the $5 million performance bond.

VII. The Performance Bond

64. Section 381.986(5)(b)5. requires each dispensing organization to post a $5 million performance bond, with no limiting condition. Yet proposed rule 64-4.002(2)(j) limits the condition of the performance bond to the expense of destroying low-THC cannabis inventory if the dispensing organization fails to perform or fails to destroy its inventory when required. The

performance bond will not guarantee performance or cover costs of default or increased cost to patients. Ms. Tschetter candidly acknowledged that she was uncertain as to why the Legislature chose to require a $5 million performance bond, particularly in light of other states' bond requirements which are as low as $10,000.00.

65. The Department's reason for proposing a rule to limit this bond is that it did not want to force anyone to deliver these services, and that it seemed "illogical" and "unnecessary" to do so because, if one dispensary defaults, the Department can appoint a successor, or consumers can just look to one of the other regional dispensing organizations to fill their prescriptions. The Department's reasoning ignores the potential that there will be significant delays in appointing a new dispensing organization and having it become operational. In the meantime, other regional dispensing organizations may elect not to serve that territory, or do so only at an increased price.

CONCLUSIONS OF LAW

I. Jurisdiction, Standing, and Burden of Proof

66. The Division of Administrative Hearings has jurisdiction over the parties and the subject matter of this proceeding. § 120.56, Fla. Stat.

67. As stipulated by the parties, the Petitioners and Intervenors have standing pursuant to section 120.56(1), Florida Statutes, to participate in this proceeding as persons substantially affected by the proposed rules.

68. Petitioners seek a Final Order determining that the Department's proposed chapter 64-4 constitutes an invalid exercise of delegated legislative authority in violation of section 120.52(8), Florida Statutes. Subsections (1) and (2) of section 120.56, Florida Statutes, provide in pertinent part, as follows:

> 120.56 Challenges to rules.-
>
> (1) GENERAL PROCEDURES FOR CHALLENGING THE VALIDITY OF A RULE OR A PROPOSED RULE.
>
> (a) Any person substantially affected by a rule or a proposed rule may seek an administrative determination of the invalidity of the rule on the ground that the rule is an invalid exercise of delegated legislative authority.
>
> * * *
>
> (e) Hearings held under this section shall be de novo in nature. The standard of proof shall be the preponderance of the evidence . . . . Other substantially affected persons may join the proceedings as intervenors on appropriate terms which shall not unduly delay the proceedings . . . .
>
> (2) CHALLENGING PROPOSED RULES/SPECIAL PROVISIONS.
>
> (a) . . . The petitioner 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.
>
> * * *
>
> (c) When any substantially affected person seeks determination of the invalidity of a proposed rule pursuant to this section, the proposed rule is not presumed to be valid or invalid.

69. Petitioners met their initial burden of going forward in this case through the presentation of their cases-in-chief. The burden therefore shifts to the Department to prove by a preponderance of the evidence that the proposed rules are not an invalid exercise of delegated legislative authority. Id.; see also Fla. Bd. of Med. v. Fla. Academy of Cosmetic Surgery, Inc., 808 So. 2d 243, 251 (Fla. 1st DCA 2002).

II. Rulemaking Standards

70. Rulemaking is a legislative function, and as such, it is within the exclusive authority of the Legislature under the separation of powers provision of the Florida Constitution. See S.W. Fla. Water Mgmt. Dist. v. Save the Manatee Club, Inc., 773 So. 2d 594, 598-99 (Fla. 1st DCA 2000). An administrative rule is valid only if adopted under a proper delegation of legislative authority. See id., Chiles v. Children A, B, C, D, E, and F, 589 So. 2d 260 (Fla. 1991); Askew v. Cross Keys Waterways, 372 So. 2d 913 (Fla. 1978).

71. A proposed rule may be challenged pursuant to section 120.56, Florida Statutes, only on the ground that it is an "invalid exercise of delegated legislative authority." Invalid exercise of delegated legislative authority is defined in section 120.52(8), Florida Statutes, as follows:

> "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 . . . .

Petitioners do not allege that the Department's rules deviate from procedural requirements or impose impermissible regulatory costs.

72. There are limits on judicial authority to invalidate agency rules. Thus, for example, an ALJ may not invalidate a proposed rule simply because, in the judge's opinion, it does not present the wisest or best policy choice. See Citizens of Fla. v. Mayo, 357 So. 2d 731, 733 (Fla. 1970)("[T]he agency rulemaking function involves the exercise of agency discretion and this Court will not substitute its judgment for that of the agency on an issue of discretion."); Bd. of Trs. of Internal Improvement Trust Fund v. Levy, 656 So. 2d 1359, 1364 (Fla. 1st DCA 1995)("The issue before the hearing officer in this [rule challenge] case was not whether the Trustees made the best choice in limiting the lengths of docks within the preserve, or whether their choice is one that the appellee finds desirable for his particular location."); Dravo Basic Materials Co. v. State, Dep't. of Transp., 602 So. 2d 632, 634 (Fla. 2d DCA 1992)("It is not our task, however, to write the best rule for DOT. That was not the task of the hearing officer."). Courts have no authority to compel an agency to adopt a rule which represents a policy choice in the area of the agency's statutory concern. Mayo, 357 So. 2d at 733 (citing FEA/United v. PERC, 346 So. 2d 551 (Fla. 1st DCA 1977)).

73. 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 alternative rules exist. Atlantic 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); Board of Trustees, 656 So. 2d at 1363.

74. Likewise, agency rulemaking efforts are afforded deference. Agrico Chemical Co. v. State, 365 So. 2d 759 (Fla. 1st DCA 1978). "Agencies are accorded wide deference in the exercise of lawful rulemaking authority which is clearly conferred or fairly implied and consistent with the agency's general statutory duties." Charity v. Fla. State Univ., 680 So. 2d 463, 466 (Fla. 1st DCA 1996). Petitioner's burden to establish that an agency's rulemaking efforts are an invalid exercise of delegated legislative authority "is a stringent one indeed." Agrico, 365 So. 2d at 763.

III. Proposed Rule 64-4.002(4)(a) - Lottery Selection

75. Proposed rule 64-4.002(4)(a) provides for random selection of minimally qualified dispensing organizations, rather than selection by reasonable discretionary evaluation of

applications in consideration of the statutory objectives and general criteria provided. Considering the general statutory criteria to be demonstrated by a qualified applicant, the statute necessarily delegates reasonable discretion to the Department to select the five dispensing organizations consistent with these stated parameters to further the statutory objective of ensuring accessibility and availability of low-THC cannabis to needy patients. See N. Broward Hosp. Dist. v. Mizell, 148 So. 2d 1, 4, n.11 (Fla. 1962)(courts infer standard of reasonableness to be applied where the statute protects public safety and general welfare).

76. The statute's language requires the Department to determine, with regard to demonstrable facts, which statutorily qualified applicant for each region best promotes the statutory interests, including ability and financial strength to undertake a new operation, to promote accessibility and availability of low-THC cannabis. This necessarily requires the Department to engage in discretionary evaluation to determine which eligible applicants to approve as a dispensing organization for each region. See Shands Jacksonville Med. Center, Inc. v. State Dep't. of Health, 123 So. 3d 86, 93 (Fla. 1st DCA 2013)(statute requires agency to engage in evaluation functions that are more than ministerial).

77. The statute's manifest intent also requires the Department to qualitatively evaluate applicants for each of the five dispensing organizations. See State Bd. of Optometry v. Fla. Soc. of Ophthalmology, 538 So. 2d 878, 886, 888 (Fla. 1st DCA 1988)(the statute must be read with reference to its manifest intent and spirit and interpreted according to the ordinary sense in which the words of common usage were employed; agency cannot invoke its "expertise" to supplant the plain intent of the statute). There is no discernable reason why the exercise of the Department's reasonable discretion in applying the criteria should not determine which applicants are approved.

78. The proposed rule for selection of dispensing organizations also contravenes a basic expectation of law for reasoned agency decision-making. See Agrico Chem. Co. v. State Dep't of Env. Reg., 365 So. 2d 759, 763 (Fla. 1st DCA 1979)("[a]dministrative discretion must be reasoned and based on substantial evidence," and "[a]n arbitrary decision is one not supported by facts or logic."); § 120.60(3), Fla. Stat., (applicant for licensure must be informed with particularity of the grounds or basis for the agency's decision for license denial).

79. By definition, "lottery" is a device whereby value is allotted by chance, or where result is reached by means in which human choice or will has no part, and human reason does not

enable determination of results. Black's Law Dictionary (5th ed. 1979). Because arbitrary selection of dispensing organizations as provided by proposed rule 64-4.002(4)(a) is not supported by logic, reason or facts, the proposed rule itself is arbitrary, and invalid. § 120.52(8)(e), Fla. Stat. See Fla. Inst. of Neurologic Rehab. v. Dep't. of Health, Case No. 12-3463RX (Fla. DOAH Jan. 25, 2013)(holding rule invalid as arbitrary where agency offered no factual support for the rule other than its incorrect interpretation of law).

80. The Department's position that it is unable to score or comparatively evaluate dispensing organization applications because they will advance different approaches is unsupported and illogical. Different proposals can be evaluated in the exercise of reasoned judgment as to which will best serve the need identified consistent with the statutory objectives and criteria. If necessary, the Department can recruit or engage expertise (paid from application fees) to evaluate aspects that are harder to judge, such as technical methods and business models.

81. Proposed rule 64-4.002(4)(a) is also invalid because it modifies or enlarges the enabling statute. First, as discussed above, the proposed rule creates a lottery selection of dispensing organizations instead of approval of applicants pursuant to statutory objectives and criteria, as contemplated

by the statute. Second, the proposed rule imposes a "qualification" regime for applicants that is not part of the statute. The statute's only specified qualification for an applicant to be considered for approval as a dispensing organization is 30 years of continuous operation as a nursery with large certified plant capacity. The proposed rule requires another qualification based on application feasibility and sufficiency determined by the Department in order for an applicant to be considered for random selection approval. This additional "qualification" of applicants modifies or enlarges the statute. § 120.52(8)(c), Fla. Stat. See Subirats v. Fidelity National Property, 106 So. 3d 997, 1001 (Fla. 3d DCA 2013)(scope of the statute cannot be enlarged by adding a manner to proceed not authorized in the statute)(citing Lamar Outdoor Advertising-Lakeland v. Fla. Dept. of Transp., 17 So. 3d 799 (Fla. 1st DCA 2009)(rule invalid where statute confers certain duties but does not authorize particular rule)).

82. Even assuming the proposed rule's additional "qualification" of applicants were valid, the proposed rule fails to establish adequate standards for the Department's decision to qualify applicants for lottery selection. This vests unbridled discretion in the agency to qualify applicants for selection, including the ability to discriminate among applicants as to what is sufficient to qualify for lottery

selection. Without specific standards as to how a nursery will be deemed qualified to participate in the random selection process, the Department is free to qualify applicants for such selection as it sees fit. The proposed rule is thus vague in respect to its requirement for applicant qualification, and is invalid for that reason as well. § 120.52(8)(d), Fla. Stat. See Cortes v. State Bd. of Regents, 655 So. 2d 132, 138 (Fla. 1st DCA 1995)(challenged rule that confers unbridled discretion not given by statute and creates standardless discretion not implicit in the statute is invalid); Grove Isle, Ltd. v. State Dep't of Env. Prot., 454 So. 2d 571, 574 (Fla. 1st DCA 1984)(rule is vague because criteria are not provided to enable determination whether requirement for permit applicant is satisfied).

83. Costa Farms argues that proposed rule 64-4.002(4)(a) is also invalid because the Department failed to follow rulemaking procedures as to the qualification review procedure for random selection. It asserts that the procedure is not established by the proposed rules, but rather, is left for invalid non-rule policy. DBPR Const. Lic. Bd. v. Harden, 10 So. 3d 647, 648-49 (Fla. 1st DCA 2009)(review committee procedures must be adopted as rule where neither statute nor rule authorizes application review committee). Costa Farms argues that an agency cannot fail to adopt an integral element of a

rule, such as how the process of application review qualification is given effect, by instead relying on non-rule policy. In its allegation, Costa Farms admits that "[i]t is unclear how the panel will be constituted and proceed; and whether panel decisions (however reached) will be final administrative action or whether such decisions will be in essence a recommendation subject to final internal review at some supervisory level in the Department, and if so, what review process and standards will be applied." In effect, Costa Farms is challenging a process that does not yet exist. As such, Costa Farms has failed to meet the requirements for an unpromulgated rule challenge as established by section 120.56(4), Florida Statutes, as it cannot identify the "statement" that constitutes an unpromulgated rule. Moreover, even had Costa Farms been able to identify the suspect "statement," it has not established that its interests have been substantially affected by an agency statement, at least at this juncture. While the undersigned has concluded that proposed rule 64-4.002(4)(a) is invalid on several other grounds, the challenge brought by Costa Farms pursuant to section 120.56(4) is not yet ripe.

84. Proposed rule 64-4.002(4)(a) is also invalid because lottery selection for entitlement to licensure is contrary to established law that requires reasoned licensure decisions, and

due process and comparative review. There is no question the licensure requirements of section 120.60, Florida Statutes, are controlling with respect to dispensing organizations.

85. "License" is defined in section 120.52(10) to mean a franchise, permit, certification . . . or similar form of authorization required by law (not including a ministerially-issued revenue license). Section 120.60(3) requires a written notice by the agency to an applicant (for licensing) that must state with particularity the grounds or basis for issuance or denial of the license (except when a ministerial act), and that informs of the right to an administrative hearing. Pursuant to that statute, an agency denying a license has the burden to produce substantial evidence at hearing to support denial. Comprehensive Med. Access, Inc. v. Ofc. of Ins. Reg., 983 So. 2d 45, 46 (Fla. 1st DCA 2008).

86. Where the substantial interest of an applicant is determined by denial upon review of mutually exclusive applications, applicants are entitled to a comparative review hearing. Bio-Med. Applications of Clearwater, Inc. v. Dep't. of Health & Rehab. Servs., Office of Cmty. Med. Facilities, 370 So. 2d 19 (Fla. 2d DCA 1979). Applications are "mutually exclusive" where the decision on one application will substantially prejudice another pending application because all applicants are competing for the right to serve a market that only one of them

can in practical effect be authorized to serve. Id. at 23. Thus, when an applicant is able to show that the granting of authority to some other applicant would substantially prejudice his or her application, fairness requires that the agency conduct a comparative hearing pursuant to section 120.57 at which the competing applications are considered simultaneously. Id.

87. Chapter 120 requires that reasoned justification be given for denial of licensure, with opportunity for hearing at which the agency must support its denial with substantial evidence. The proposed rule's lottery selection precludes such review, including required comparative review of mutually exclusive applications, and thereby deprives the losing applicant of the due process opportunity which the Legislature saw fit to extend. See Ashbacker Radio Corp. v. F.C.C., 326 U.S. 327, 333 (1945)(deprives the loser of the opportunity Congress chose to give the applicant). See also Fed. Prop. Mgmt. Corp. v. Health Care & Ret. Corp. of Am., 462 So. 2d 493, 496 (Fla. 1st DCA 1984)(intervention required in later batched applications to prevent "circumvention of the fundamental doctrine of fair play laid down by the Supreme Court in Ashbacker 'which administrative agencies must diligently respect and the courts must be ever alert to enforce.'").

88. In its Proposed Final Order, the Department argues that there are significant distinctions between the factual scenario that led to the Supreme Court's decision in Ashbacker and the factual scenarios that are likely to result from the implementation of the proposed rules. The Department asserts that unless there are only two applicants in a dispensing region, it would be difficult for an applicant to prove that any two applications share mutual exclusivity, which is fundamental to the Supreme Court's analysis in Ashbacker. According to the Department, courts that have distinguished Ashbacker have done so for lack of mutual exclusivity of the applications. See Keystone Raceway Corp. v. State Harness Racing Comm'n, 173 A.2d 97, 102, (Pa. 1961)(distinguishing Ashbacker in a case involving four available licenses by holding that a hearing was not required to challenge the approval of one license when there were still three licenses available).

89. The Department's reliance on Keystone in support of its argument is misplaced. While the Keystone Court did distinguish Ashbacker from the factual scenario before it, the court's opinion clearly reaffirmed the right of comparative review when multiple applicants are competing for a single license:

> Considering all of the relevant facts and the pertinent language of the Act, we believe that the present appellant does not

> have a direct, immediate and substantial interest in the grant of a license to Liberty Bell Racing Association. This is not the case of two or more persons (or corporations) applying for a license when only one license is available. Three licenses are still available for issuance by the Commission. Moreover, since the Philadelphia metropolitan area contains a very large percentage of the Commonwealth's population, it is not unlikely that the Commission would allocate another license to this area. In this respect Ashbacker Radio Corp. v. F.C.C., 326 U.S. 327, relied on by appellants, is readily distinguishable. In that case only *one* license was available and the Federal Communications Commission conceded that the two applications for that one radio license were *mutually exclusive.* No such situation arises in the present case. There is nothing in the record in this case which demonstrates or indicates that the grant of a license to Liberty Bell automatically excludes Keystone from consideration for a license. We believe this case is ruled in principle by Ritter Finance Company, Inc. v. Myers, 401 Pa., supra.

(Id. at 102). (emphasis added).

90. The Department's argument that unless there are only two applicants in a dispensing region, it would be difficult for an applicant to prove that any two applications share mutual exclusivity, is not persuasive. To the contrary, any time there are two or more applications competing for a single license or franchise, all applications share mutual exclusivity with one another, since the approval of one necessarily results in the denial of all others. Such is the situation with the

Department's proposed lottery which would approve but a single license for each of the five designated regions. In any of the five regions in which more than a single application is submitted, Ashbacker and its Florida progeny mandate comparative review of all competing applications. As Florida's First District Court of Appeal noted in Federal Property Management Corporation v. Health Care and Retirement Corporation, 462 So. 2d 493 (Fla. 1st DCA 1984):

> In Bio-Medical Applications of Clearwater, Inc. v. Department of Health and Rehabilitative Services, Office of Community Medical Facilities, 370 So. 2d 19 (Fla. 2d DCA 1979), the court relied upon the "Ashbacker" doctrine in holding that denial of a competing applicant's motion for consolidation constituted a material error in procedure requiring that the matter be remanded for further agency action. In Ashbacker Radio Corporation v. Federal Communications Commission, 326 U.S. 327, 66 S. Ct. 148, 90 L. Ed. 108 (1945), the Supreme Court laid down a general principle that an administrative agency is not to grant one application for a license without some appropriate consideration of another bona fide and timely filed application to render the same service. The Second District Court of Appeal observed that where a need is determined in accordance with a quantitative standard, opposing applicants necessarily become competitors for the fixed pool of needed investments, so that their applications are mutually exclusive within the meaning of Ashbacker.

(Id. at 495) (emphasis added).

91. Need is fixed by the Act for only one dispensing organization in each of the five designated areas of the State. Under the proposed rule, an applicant can only apply for one of the franchises, and when approval is granted, the right to be a dispensing organization is renewable indefinitely, absent default or non-compliance. As a practical matter, the opportunity to enter the new medical cannabis market is foregone if the applicant is not among the five applicants initially selected. Especially given these circumstances, the Department must offer a comparative review hearing on the merits of an application pursuant to section 120.57, so each applicant has a fair opportunity to persuade the agency that its application should be granted over competing applicants. See Gulf Court Nursing Center v. Dep't of HRS, 483 So. 2d 700, 705 (Fla. 1st DCA 1985)(citing BioMedical)(where need is quantitatively set, opposing applications necessarily become competitors and filling the established need effectively denies pending applications, entitling comparative review which advances the public interest to assure that the agency makes the best choice when several alternatives are available).

92. Because the proposed lottery selection rule contravenes rights conferred by law, it is invalid as contrary to law. § 120.52(8)(c), and (e), Fla. Stat. See Willette v. Air Prods., 700 So. 2d 397, 399 (Fla. 1st DCA

1997)(administrative rule "must give way . . . to any contradictory statute that applied"). See also Ariz. State Bd. of Regents v. Ariz. State Pers. Bd., 985 P. 2d 1032, 1034-35 (Ariz. 1999)(agency rule must yield; while agency rule may grant rights in addition to Administrative Procedure Act, it may not diminish rights conferred by the Act or any provision of law). See generally, 2 Am. Jur. 2d Admin. Law § 218 (a rule may not contravene, conflict with, or be contrary to an existing statute; rules that violate, conflict with or contravene statutory enactments governing the same subject matter are invalid as a matter of law and generally declared void).

93. The express intent of the Act was to ensure that low-THC cannabis is reasonably available and accessible to patients needing this medicine. The evidence adduced at hearing supports the common sense notion that this objective requires selecting the most dependable, most qualified dispensing organizations to cultivate, process, and dispense low-THC cannabis as prescribed by physicians. The proposed lottery rule to select these special franchises by chance creates risks that substantially reduce the likelihood of this objective being met.

94. The danger that the Department's lottery system will not result in the selection of qualified dispensing organizations is exacerbated by the fact that the proposed rules would not impose an initial application fee for applicants vying

for lottery approval. Thus, with little or no investment, a marginally-qualified applicant who barely meets the general minimum requirements is equally as likely to be approved as a clearly superior applicant. This scenario is made all the more likely by the lack of clear standards and criteria that will be used by the Department to evaluate the applications and determine whether the minimum requirements for entry into the lottery have been met by an applicant.

95. The Department's representative testified that all applicants that meet the minimum qualifications (however that is ultimately determined) would qualify for the lottery. This approach does not ensure that the most qualified candidates will be approved, only that the luckiest five applicants that meet the minimum requirements will be approved. Assuring the dependable delivery of consistently high-quality, low-THC medicine is too important to be left to chance. Rather than minimally qualified applicants, citizens of the State of Florida, including sick and vulnerable children, deserve approval of the most qualified growers, processors and dispensers of low-THC cannabis.

96. The Department's lottery selection process set forth in proposed rule 64-4.002(4)(a) is invalid because it is vague, fails to establish adequate standards for agency decisions, and vests unbridled discretion in the agency, in contravention of

section 120.52(8)(d). In addition, the proposed rule is arbitrary, in contravention of section 120.52(8)(e), in that the ultimate decision as to which applicant will be approved is left to chance, rather than logic and an evaluation of all necessary facts.

IV. Proposed Rule 64-4.001(1) - Definition of Applicant

97. Section 381.986 provides the specific requirements for an applicant seeking approval as a dispensing organization. Section 381.986(5)(b) states in relevant part:

> 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.

98. Specifically, section 381.986(5)(b)1. provides three limiting requirements: (1) the applicant must possess a valid certificate of registration issued by the Department of Agriculture and Consumer Services for the cultivation of more than 400,000 plants; (2) the applicant must be operated by a nurseryman; and, (3) the applicant must have been operated as a registered nursery in Florida for at least 30 continuous years.

In effect, section 381.986(5)(b)1. excludes all businesses that are not prequalified as or do not meet the requirements of being a high volume, certified nursery in the State of Florida for at least 30 years. Proposed rule 64-4.001(1) contravenes the statutory requirements and arbitrarily deviates from those requirements, proposing criteria beyond the statutorily-delegated authority, and opens the application process to entities that are not nurseries. Despite the express statutory language, the Department proposes to relax the statutory mandate that the applicant meet the three requirements in order to allow entities that otherwise do not qualify to be approved as "dispensing organizations" by redefining the qualification for applicants as follows:

> (1) Applicant – An organization with at least 25% ownership by either a nursery that meets the requirements of Section 381.986(5)(b)1., Florida Statutes, or 100% of the owners of a nursery that meets the requirements of Section 381.986(5)(b)1., Florida Statutes, that applies for approval as a dispensing organization and identifies a nurseryman as defined in Section 581.011, Florida Statutes, who will serve as the operator.

99. As explained by Ms. Tschetter, the proposed definition makes "it possible for the [applicant] to be something other than just a nursery, but instead an organization owned by a nursery." While the proposed definition is intended to facilitate dispensing organizations' relationships with entities

squeamish about doing business with cannabis growers, the Act does not authorize an "organization" owned at any level by a nursery to be an applicant. The Legislature expressly required the "applicant" to be the party possessing "a valid certificate of registration issued by the Department of Agriculture and Consumer Services issued for the cultivation of more than 400,000 plants . . . and have been operated as a registered nursery in this state for at least 30 continuous years," in other words, a nursery.

100. When construing a statute, one looks first to the statute's plain meaning. Moonlit Waters Apartments, Inc. v. Cauley, 666 So. 2d 898, 900 (Fla. 1996). Furthermore, "[w]hen the language of the statute is clear and unambiguous and conveys a clear and definite meaning, there is no occasion for resorting to the rules of statutory interpretation and construction; the statute must be given its plain and obvious meaning." Holly v. Auld, 450 So. 2d 217, 219 (Fla. 1984), citing A.R. Douglass, Inc., v. McRainey, 137 So. 157, 159 (1931). Fla. Hosp. v. Ag. for Health Care Admin., 823 So. 2d 844, 848 (Fla. 1st DCA 2002).

101. In this instance, the clear meaning of the statute is that the applicant, to be a dispensing organization, must be the entity that possesses the certificate of registration and has been operating as a nursery for 30 years. Because the proposed

rule contravenes the express statutory requirements as to who may be an applicant, the proposed rule is invalid.

§ 120.52(8)(c), Fla. Stat.

V. Proposed Rule 64-4.002(4)(b) – Application Fee

102. Proposed rule 64-4.002(4)(b) provides for an application fee of $150,000 to be paid only by approved applicants. There is no provision to assess an initial application fee on each applicant.

103. Section 381.986(5)(b) requires the Department to impose initial application and biennial renewal fees sufficient to cover the cost of administering the statute.

104. The word "initial" means "of or related to the beginning; placed at the beginning; first." Webster's 9th New Collegiate Dictionary (1983). An application fee charged to an applicant after approval is not an initial application fee. It is a license fee. An initial application fee is charged at the beginning of the application process for all applications submitted. It is commonplace to require such application fees to assure the applicant is serious and to cover the cost of processing and review. The Department cannot change the statutory requirement to assess an initial application fee as required by the statute.

105. The proposed rule places the recovery of the cost of administering the new program only on those entities that were

successful in obtaining a license. The Department estimated that the cost of setting up the "robust regulatory structure" was in the range of $750 thousand to $1.5 million dollars. Instead of calculating the cost per "application," the Department calculated the cost per license of the five approved nurseries, charging each $150,000 to fund the program. The Department was not authorized to adopt a licensure fee. Had the Legislature intended there to be a licensure fee, it would have adopted such language as it has done in numerous other statutes. See, e.g., §§ 457.015, 466.0067, 468.508, 478.55, 480.044 and 484.0447, Fla. Stat.

106. The omission of an initial application fee and provision only for a license approval fee modifies the statutory requirement, and is thus invalid. § 120.52(8)(c), Fla. Stat.

VI. Proposed Rule 64-4.002(2)(i) – Financial Statements

107. Section 381.986(5)(b)5. requires "certified financials" to demonstrate the applicant's financial ability to maintain operations for the 2-year approval cycle. The term "certified" means the financials must be attested, i.e., verified by audit or sworn. See U.S. v. Mateo-Mendez, 215 F.3d 1039, 1043 (9th Cir. 2000)(certify means "to attest as being true," citing Black's Law Dictionary). This requirement must be construed with subparagraph (5)(b)1. requiring that the applicant be a nursery with 30 years' experience. Proposed rule

64-4.002(2)(i) requiring that a CPA prepare the financials in accordance with GAAP does not meet this standard. Financials must certify (attest) that the applicant has the financial stability, resources and capability to maintain low-THC cannabis operations for at least a minimum of two years from approval. Because the proposed rule eliminates the requirement for certified financial statements the proposed rule modifies the statute and is invalid.

VII. Proposed Rule 64-4.002(2)(j) – Performance Bond Condition

108. Section 381.986(5)(b)5. requires as part of financial ability that "upon approval the applicant must post a $5 million performance bond."

109. Proposed rule 64-4.002(2)(j) modifies this requirement by providing: "[t]he condition of the bond shall be that in the event the dispensing organization fails to renew its approval or its approval is revoked, it shall destroy all low-THC cannabis remaining under its control. The bond . . . shall be paid to the Office of Compassionate Use in an amount necessary to cover the costs of securing and destroying all low-THC cannabis not so destroyed and remaining under the control of the dispensing organization."

110. The proposed rule condition dilutes the purpose and effect of the required performance bond to the point that "performance" is not being bonded. The condition provided by

the proposed rule is readily met simply by destroying inventory. This is not the same as assuring performance by fulfilling approved application responsibilities and not defaulting, as a "performance bond" would be expected to do. See Black's Law Dictionary (5th ed. 1979) ("performance bond" guarantees contractor will perform); Wikipedia, "Surety Bond" (license and permit bonds are required by law as prerequisites to receipt of a license or permit to engage in certain business activities, and "function as a guaranty from a surety to government . . . that a company (Principal) will comply with an underlying statute . . . or regulation.").

111. By requiring a performance bond in the amount of $5 million – an amount much greater than is likely to be needed for the destruction of inventory – the Legislature obviously intended the bond to cover losses to cure default and to ensure complete performance of the license term obligation, including loss to consumers whose needs may otherwise not be met.

112. The proposed rule cannot lessen the explicit statutory financial requirement of a $5 million performance bond by diluting its effect through an easily satisfied condition of destroying inventory. This changes what the statute intended to require. An administrative rule must comply with the particular requirements in the authorizing statute; it is not enough that a rule be reasonably related to the statutory provision. See GB

v. Ag. for Pers. with Disab., 143 So. 3d 454, 457 (Fla. 1st DCA 2014). There is no room for deviation from the particular requirement contemplated by the statute, Id. at 458. The proposed rule's attempt to do so is invalid. § 150.52(8)(c), Fla. Stat.

VIII. Proposed Rules 64-4.002, .004 and .005 - Lack of Statutory Authority

113. The enabling Act authorizes the Department to adopt rules in furtherance of the programmatic requirements listed in section 381.986(5). These requirements include such matters as 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 by-products; to maintain the infrastructure reasonably located to dispense low-THC cannabis to registered patients statewide or regionally; the financial ability to maintain operations for the duration of the 2-year approval cycle, including the posting of a $5 million performance bond; the fingerprinting and background checks of all owners and managers; and the employment of a medical director. § 381.986(5), Fla. Stat. However, on its own initiative and without statutory authority, the Department has prescribed extensive guidelines for the grant and revocation of authorization to become a dispensing organization which far

exceed those authorized by the enabling Act. See proposed rules 64-4.002 and .004. Specifically, the requirements which are not supported by statutory authority are:

- limiting nursery ownership to only one application [proposed rule 64-4.002(1)]
- requiring cultivation, processing and dispensing to occur on the same, or contiguous, property [proposed rule 64-4.002(1)]
- Level-2 background screening for employees [proposed rules 64-4.002(2)(e)4.c. and .008(7)]
- limitations on the activities of medical directors [proposed rule 64-4.002(2)(m)]
- setback requirements [proposed rule 64-4.004(1)(a)]
- limitations on ownership and management [proposed rules 64-4.004(1)(b), (2)(b) and .008(7)]
- warrantless entry and searches by law enforcement officials and agents [proposed rule 64-4.005(1)]

114. In support of these additional requirements and prohibitions, the Department asserts that it holds an "inherent authority" and "general rulemaking authority" from "the State of Florida's decision to legalize cannabis in some form and [its] responsibility to set up a robust regulatory structure." However, it is well settled that agencies do not have inherent rulemaking authority. § 120.54(1)(e), Fla. Stat.; see also,

Fla. Elec. Comm'n v. Blair, 52 So. 3d 9, 12 (Fla. 1st DCA 2010). Further, since the 1999 amendments to chapter 120, a general grant of rulemaking authority is no longer sufficient. § 120.52(8) and 120.536(1), Fla. Stat.; see also, Bd. of Tr. of the Internal Improvement Trust Fund v. Day Cruise Ass'n, Inc., 794 So. 2d 696, 700-704 (Fla. 1st DCA 2001).

115. In attempting to codify the above-referenced provisions, the Department has taken upon itself to implement policies which the Legislature has expressly rejected, or for which the Legislature chose not to grant the Department authority. See § 381.986, Fla. Stat. Through its representative, the Department acknowledged that it has no express or specific authority to enact the above referenced proposed rules and, instead, relies upon its "inherent authority" to create a robust regulatory structure and its general rulemaking authority. As stated above, agencies have no inherent authority to conduct rulemaking and a general grant of rulemaking authority is insufficient. Fla. Elec. Comm'n v. Blair, 52 So. 3d 9 (Fla. 1st DCA 2010); § 120.52(8) and 120.536(1), Fla. Stat.; see also, Bd. of Tr. of the Internal Improvement Trust Fund v. Day Cruise Ass'n, Inc., 794 So. 2d 696, 700-704 (Fla. 1st DCA 2001). As such, proposed rules 64-4.002(1), 4.002(2)(e)4.c., 4.002(2)(m), 4.004(1)(a), 4.004(1)(b), 4.004(2)(b), 4.005(1) and 4.008(7) violate section

120.52(8)(b), Florida Statutes, and are invalid as they exceed the limited statutory authority granted the Department.

CONCLUSION

Based on the foregoing Findings of Fact and Conclusions of Law, it is

ORDERED that challenged proposed rules 64-4.001(1), 4.002(2)(i), 4.002(2)(j), 4.002(4)(a), 4.002(4)(b), 4.002(1), 4.002(2)(e)4.c., 4.002(2)(m), 4.004(1)(a), 4.004(1)(b), 4.004(2)(b), 4.005(1), and 4.008(7) are declared to be invalid exercises of delegated legislative authority. Jurisdiction is reserved to consider any motions for fees and costs.

DONE AND ORDERED this 14th day of November, 2014, in Tallahassee, Leon County, Florida.

W. DAVID WATKINS
Administrative Law Judge
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Filed with the Clerk of the
Division of Administrative Hearings
this 14th day of November, 2014.

ENDNOTES

[1/] All references to Florida Statutes are to the 2014 version unless otherwise noted.

[2/] Proposed rule 64-4.002(1) only limits nurseries to one application to avoid them submitting "shell" applications to "game the system." Tr. 188-89, 218; CF Exhibit VIII (Ardizzone colloquy). No one else is so limited, so an "organization" other than a nursery can submit multiple applications by pairing with a different front nursery for each application. This could lead to one organization owning or controlling a majority part of more than one or all five dispensing organizations. CF Exhibit VIII (Ardizzone colloquy); Tschetter Dep. 70-72.

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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.