

STATE OF NEVADA

BRIAN SANDOVAL  
*Governor*

MICHAEL J. WILLDEN  
*Director*



RICHARD WHITLEY, MS  
*Administrator*

TRACEY D. GREEN, MD  
*Chief Medical Officer*

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
DIVISION OF PUBLIC AND BEHAVIORAL HEALTH**

4150 Technology Way, Suite 300  
Carson City, Nevada 89706  
Telephone: (775) 684-4200 - Fax: (775) 684-4211

**ATTACHMENT D – CHILD SUPPORT VERIFICATION FORM**



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**ATTACHMENT E – REQUEST AND CONSENT TO RELEASE APPLICATION FORM**

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**Request and Consent to Release Application**  
**Form for Medical Marijuana Establishment Registration Certificate(s) - (Attachment E)**

I, \_\_\_\_\_, am the duly authorized designee of

\_\_\_\_\_ to represent and interact with the Division of Public and Behavioral Health (Division) on all matters and questions in relation to the application for a Nevada Medical Marijuana Establishment Registration Certificate(s). I understand that NRS 453A.700 makes all applications submitted to the Division confidential but that local government authorities including, but not limited to, the licensing or zoning departments of cities, towns or counties may need to review this application in order to authorize the operation of an establishment under local requirements. Therefore, I consent to the release of this application to any local governmental authority in the jurisdiction where the address listed on this application is located.

By signing this Request and Consent to Release Information I hereby acknowledge and agree that the State of Nevada, its subdivisions, including the Division of Public and Behavioral Health and its employees are not responsible for any consequences related to the release of the information identified in this consent. I further acknowledge and agree that the State and its subdivisions cannot make any guarantees or be held liable related to the confidentiality and safe keeping of this information once it is released.

\_\_\_\_\_ Date: \_\_\_\_\_

Signature of Requestor/Applicant or Designee

State of Nevada	
County of _____	
Signed and sworn to (or affirmed) before me on _____ date)	
By _____ (name(s) of person(s) making statement)	
Notary Stamp	Signature of Notarial Officer

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**ATTACHMENT F – PROPERTY OWNER APPROVAL FOR USE FORM**

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**PROPERTY OWNER APPROVAL FOR USE FORM – (Attachment F)**

TO BE COMPLETED BY THE OWNER OF THE PHYSICAL ADDRESS OF THE PROPOSED MEDICAL MARIJUANA ESTABLISHMENT.			
Name of Individual or Entity Applying for a Medical Marijuana Establishment Registration Certificate:			
Name of Owner of the Physical Address of the Proposed Medical Marijuana Establishment:			
Physical Address and Name of Proposed Medical Marijuana Establishment: <i>*This must be a Nevada address and cannot be a P.O. Box.</i>			
City:	County:	State:	Zip Code:
Legal Description of the Property:			

The individual or entity applying for a Medical Marijuana Establishment Registration Certificate is the owner of the physical address of the proposed Medical Marijuana Establishment.

OR

The owner of the physical address of the proposed Medical Marijuana Establishment gives permission to the individual or entity applying for a Medical Marijuana Establishment Registration Certificate to operate a Medical Marijuana Establishment at the physical address.

\_\_\_\_\_  
PROPERTY OWNER SIGNATURE

\_\_\_\_\_  
DATE SIGNED

\_\_\_\_\_  
PROPERTY OWNER NAME

\_\_\_\_\_  
TITLE

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**ATTACHMENT G – MULTI-ESTABLISHMENT LIMITATIONS FORM**

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**MULTI-ESTABLISHMENT LIMITATIONS FORM – (Attachment G)**

NRS 453A.324 places a limitation on the total number of certificates that can be issued within each county, and NRS 453A.326 places limitations on the number of medical marijuana dispensaries located in any one governmental jurisdiction and a limitation on the number of certificates issued to any one person. Due to these limitations, please list below all applications submitted from this business organization and/or person as identified in the Medical Marijuana Establishment Owner, Officer, and Board Member names section of Attachment A.

If this business organization were to not receive approval on all applications submitted, would the applicant still want approval on the applications determined by the ranking below?  Yes  No

**Please list in order of preference for approval (use as many sheets as needed).**

Type of Medical Marijuana Establishment: <input type="checkbox"/> Independent Testing Laboratory <input type="checkbox"/> Cultivation Facility			
<input type="checkbox"/> Medical Marijuana Dispensary <input type="checkbox"/> Marijuana Infused/Edible Production Facility			
Medical Marijuana Establishment's Name and Proposed Physical Address*: *This must be a Nevada address and cannot be a P.O. Box.			
City:	County:	State:	Zip Code:

Type of Medical Marijuana Establishment: <input type="checkbox"/> Independent Testing Laboratory <input type="checkbox"/> Cultivation Facility			
<input type="checkbox"/> Medical Marijuana Dispensary <input type="checkbox"/> Marijuana Infused/Edible Production Facility			
Medical Marijuana Establishment's Name and Proposed Physical Address*: *This must be a Nevada address and cannot be a P.O. Box.			
City:	County:	State:	Zip Code:

Type of Medical Marijuana Establishment: <input type="checkbox"/> Independent Testing Laboratory <input type="checkbox"/> Cultivation Facility			
<input type="checkbox"/> Medical Marijuana Dispensary <input type="checkbox"/> Marijuana Infused/Edible Production Facility			
Medical Marijuana Establishment's Name and Proposed Physical Address*: *This must be a Nevada address and cannot be a P.O. Box.			
City:	County:	State:	Zip Code:

Type of Medical Marijuana Establishment: <input type="checkbox"/> Independent Testing Laboratory <input type="checkbox"/> Cultivation Facility			
<input type="checkbox"/> Medical Marijuana Dispensary <input type="checkbox"/> Marijuana Infused/Edible Production Facility			
Medical Marijuana Establishment's Name and Proposed Physical Address*: *This must be a Nevada address and cannot be a P.O. Box.			
City:	County:	State:	Zip Code:

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**ATTACHMENT H – IDENTIFIER LEGEND FORM**



## **Bist, Kevin**

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**From:** George Fernandez <george@moderncanna.com>  
**Sent:** Wednesday, January 14, 2015 3:47 PM  
**To:** Nelson, Patricia A  
**Subject:** Re: MCS Formal comments  
**Attachments:** Graphs.pdf; Method - Phenomenex.pdf; Method - Restek.pdf; Method - UNODC.pdf; Standard - THC.pdf

Good afternoon Ms. Nelson,

My apologies for the late response. No, we have not consulted the U.S.P Herbal Medicines Compendium. However, we are reaching out to them now.

We plan to order the cannabis monograph from the American Herbal Pharmacopoeia website, which can be found here [http://www.herbal-ahp.org/order\\_online.htm](http://www.herbal-ahp.org/order_online.htm).

We've worked on additional method development using 3 separate methods. We've performed these trial runs with the following LC column - Phenomenex Luna 5 Micron C-18 (2)(100A) 250x30mm and using acetonitrile as the mobile phase.

I have attached all 3 methods for you to view along with the chromatograms and standard.

On the environmental side, our SOPs, methods, and QA/QC are all in compliance with NELAP (National Environmental Laboratory Accrediting Program) standards under the DOH. We've been waiting to see what the department recommends in regards to cannabis standards. I went ahead and had our lab director & QA/QC manager reach out to Restek back in July 2014 regarding cannabis testing methods (mainly potency, residual solvents, & terpene analysis). The cannabis pesticide testing shouldn't be a problem, due to the environmental background.

Restek has been one of our suppliers for years. Here is their medical cannabis landing page <http://www.restek.com/Landing-Pages/Medical-Marijuana>. It has all of their published resources for medical cannabis testing. They update it regularly.

Additionally, our QA/QC manager reached out to Absolute Standards and acquired detailed information on mycotoxin testing and it's importance.

I've listed some of the methods we've acquired from Restek below.

### **Potency Testing:**

A chromatogram with the method Restek developed here can be found on their website: [http://www.restek.com/chromatogram/view/LC\\_GN0553](http://www.restek.com/chromatogram/view/LC_GN0553). The conditions include all the associated part numbers for the column and standards. I can send you a draft extraction method that Restek has used before. We've obviously never used this method here in FL on cannabis. I'm sure you can understand why. According to Restek, it seems to work for other labs and it's very straightforward.

### **Terpenes:**

Both LC and GC methods have their drawbacks. Terpenes are hard to separate using LC, and some don't have chromophores, and they don't ionize well, ruling out LC-MS. On the GC side, the column that's most selective for terpenes does not elute the cannabinoids, so headspace injections are required. I can send you a draft technical article on terpene analysis by GC if you'd like.

### **Pesticides:**

We have an extraction/cleanup method for pesticides in cannabis plant material that we received from Restek. It should work for concentrates as well. The method addresses both GC and LC approaches, and the GC approach does require a little more cleanup than LC does. Also, there are a few pesticides that are commonly used on cannabis that cannot be analyzed by GC, most notably Abamectin, so LC-MS/MS for pesticides may be the way to go.

### **Residual Solvents**

I can send you a draft technical article on this method, as well as the full chromatogram and conditions for Figure 4 in the article. According to Restek and other labs we've reached out to, most people are doing this analysis using GC with a headspace instrument, although it may work with P&T if you can get your sample to dissolve in a solvent compatible with P&T that doesn't interfere with your residual solvents of interest. Sample dissolution for this method is the most problematic part, as you'll read in the article. When real samples are analyzed, oven programs will have to go up to 240°C and hold for about 5 minutes to elute the terpenes that will be present in the cannabis samples. The column Restek recommends is very robust and handles 240°C just fine.

Regarding heavy metals testing; we already hold the certification for solids. We're doing additional research to find the most efficient methods for extracting heavy metals from plant tissue.

I apologize for the lengthy response. I would like to help out in any way I can. If you need anything else, please feel free to contact me at your convenience.

On Tue, Jan 13, 2015 at 3:31 PM, Nelson, Patricia A <[Patricia.Nelson@flhealth.gov](mailto:Patricia.Nelson@flhealth.gov)> wrote:

Mr. Hernandez,

Has MCS consulted the U.S. Pharmacopeia Herbal Medicines Compendium for any of your SOPs, methods, or QA/QC?

Thank you,

Patty

**From:** George Fernandez [<mailto:george@moderncanna.com>]

**Sent:** Wednesday, December 31, 2014 8:17 AM

**To:** Nelson, Patricia A  
**Subject:** MCS Formal comments

Good morning,

I have attached our formal comments regarding Senate Bill 1030 that were previously submitted. I just want to make sure you have a copy in case it didn't transfer over. My colleague and I attended and spoke at each of the previous workshops in Tallahassee. Unfortunately, we were unable to attend yesterday's workshop, but I did watch the live stream online.

We own a full service quality control testing laboratory, equipped with all of the instrumentation needed for medical cannabis testing. Up until now we've specialized in environmental and petroleum analysis. I heard you mention that you have experience in a lab and ran a GC. We have GC's, LC's, ICP's, HPLC, and micro biological instrumentation at our facilities. We've created SOP's, quality assurance manuals, and safety manuals for our cannabis testing facility, based on extensive research, consultations with laboratories in CO, and protocol from our existing environmental lab. Also, we were recently inspected by the DOH and received minimal deficiencies.

It's nice to hear you have a laboratory background. We have researched cannabis testing methods thoroughly and the sample prep portion is fairly simple. The only thing left for us is equipment calibration. As I'm sure you know, in order to do that we would need to order standards (legally). This cannot be completed (legally) until testing facilities are granted immunity. I am working with Ron Watson to help write this portion of the glitch bill.

I also brought up this idea at the last hearing: We could set up a mobile testing facility and perform analysis on site at the dispensing organizations. They have been granted immunity, so perhaps this would help resolve this issue for the time being. The down side would be the cost to perform these tests would increase due to fuel charges.

I think this is an amazing opportunity for Florida to really set the bar high in this industry in terms of quality control. I would be happy to share any documents or information you need. Like everyone else, I want to see this medicine get into the hands of patients quickly.

Should you have any questions or would like to discuss these comments in further detail, please don't hesitate to contact me. Thank you for all of your hard work. I look forward to meeting you.

--

**George Fernandez**

Chief Executive Officer



3615 Century Blvd., Unit 2

Lakeland, FL 33811

(863) 797-9963



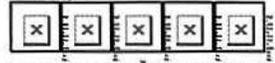
[www.moderncanna.com](http://www.moderncanna.com)

--

**George Fernandez**  
Chief Executive Officer



3615 Century Blvd., Unit 2  
Lakeland, FL 33811  
(863) 797-9963



[www.moderncanna.com](http://www.moderncanna.com)

=====  
 Calibration Table  
 =====

Calib. Data Modified : Friday, October 10, 2014 11:49:36 AM

Calculate : External Standard  
 Based on : Peak Area

Rel. Reference Window : 5.000 %  
 Abs. Reference Window : 0.200 min  
 Rel. Non-ref. Window : 5.000 %  
 Abs. Non-ref. Window : 0.200 min  
 Uncalibrated Peaks : not reported  
 Partial Calibration : Yes, identified peaks are recalibrated  
 Correct All Ret. Times: Yes, even for non-identified peaks

Curve Type : Quadratic (some peaks differ, see below)  
 Origin : Forced (some peaks differ, see below)  
 Weight : Equal

Recalibration Settings:  
 Average Response : Average all calibrations  
 Average Retention Time: Floating Average New 75%

Calibration Report Options :  
 Printout of recalibrations within a sequence:  
 Calibration Table after Recalibration  
 Normal Report after Recalibration  
 If the sequence is done with bracketing:  
 Results of first cycle (ending previous bracket)

Signal 1: FLD1 A, Ex=280, Em=389  
 Signal 2: WVD1 A, Wavelength=254 nm

RetTime [min]	Lvl Sig	Amount [mg/L]	Area	Amt/Area	Ref Grp Name
4.399	2 2	5.00000	1.41800	3.52609	CBD
	3	10.00000	3.41105	2.93164	
	4	50.00000	15.71751	3.18117	
	5	100.00000	31.20308	3.20481	
6.595	2 1	1.00000	4.64065	2.15487e-1	CBN
	2	5.00000	21.85920	2.28737e-1	
	3	10.00000	49.48243	2.02092e-1	
	4	50.00000	234.82947	2.12920e-1	
	5	100.00000	460.88614	2.16973e-1	
8.417	2 2	5.00000	1.64868	3.03272	THC
	3	10.00000	3.78019	2.64537	
	4	50.00000	19.54358	2.55839	
	5	100.00000	37.78190	2.64677	

More compound-specific settings:

Compound: CBD  
 Curve Type : Linear  
 Origin : Forced

Compound: CBN  
 Curve Type : Linear  
 Origin : Forced

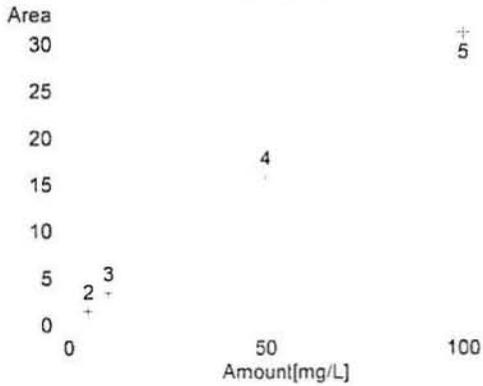
Compound: THC  
 Curve Type : Linear  
 Origin : Forced

=====

Peak Sum Table

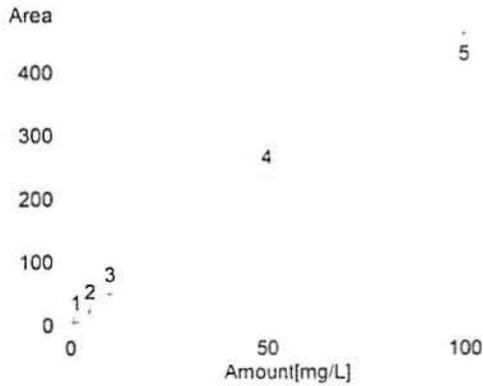
\*\*\*No Entries in table\*\*\*

Calibration Curves



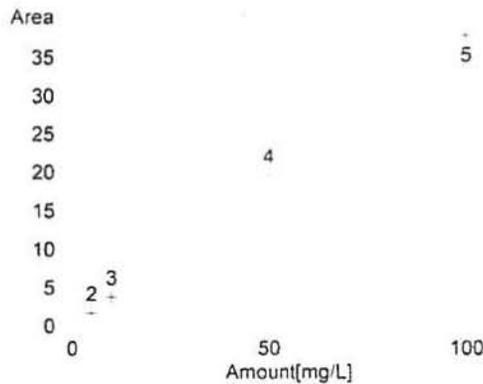
CBD at exp. RT: 4.399  
VWD1 A, Wavelength=254 nm  
Correlation: 0.99995  
Residual Std. Dev.: 0.19419  
Formula:  $y = mx$   
m:  $3.12664e-1$   
x: Amount [mg/L]  
y: Area

L2-L5  
3ppm - 100ppm  
5ppm



CBN at exp. RT: 6.595  
VWD1 A, Wavelength=254 nm  
Correlation: 0.99995  
Residual Std. Dev.: 2.61332  
Formula:  $y = mx$   
m: 4.62845  
x: Amount [mg/L]  
y: Area

L1-L5  
1ppm - 100ppm

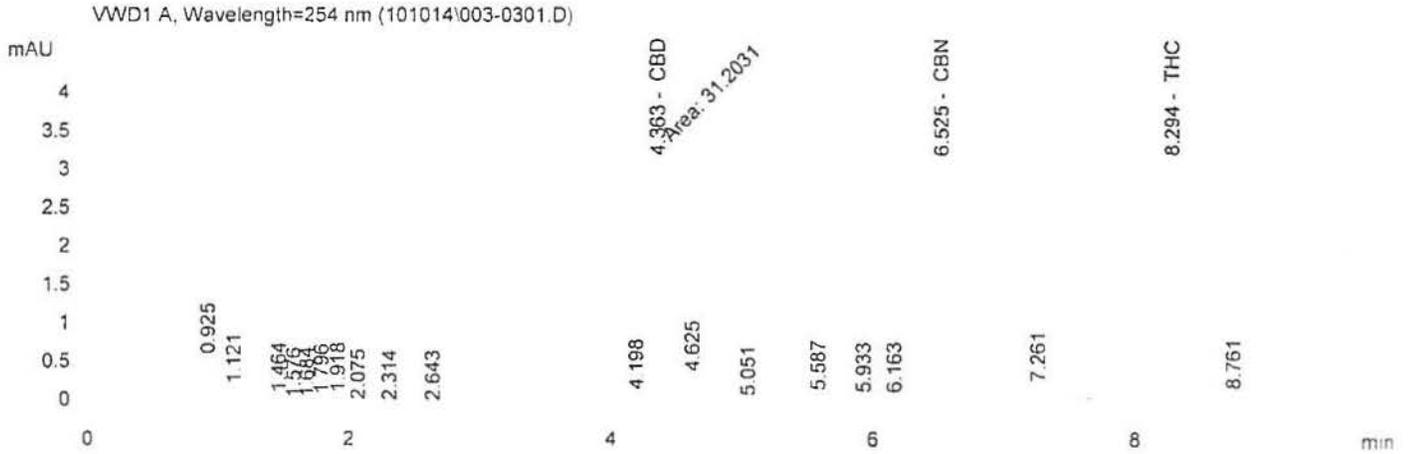


THC at exp. RT: 8.417  
VWD1 A, Wavelength=254 nm  
Correlation: 0.99989  
Residual Std. Dev.: 0.36760  
Formula:  $y = mx$   
m:  $3.80310e-1$   
x: Amount [mg/L]  
y: Area

L2-L5  
5ppm - 100ppm

```

=====
Injection Date : 10/10/2014 10:41:17 AM      Seq. Line : 3
Sample Name    : THC std 100ppm              Location  : Vial 3
Acq. Operator  : XH                          Inj      : 1
                                           Inj Volume : 10 µl
Different Inj Volume from Sequence !      Actual Inj Volume : 6 µl
Acq. Method    : C:\HPCHEM\1\METHODS\THC.M
Last changed   : 10/10/2014 9:51:49 AM by XH
Analysis Method : C:\HPCHEM\1\METHODS\THC1.M
Last changed   : 10/10/2014 11:45:52 AM by XH
                                           (modified after loading)
PAH method:EPAB310/610 Instrument:LC-1
=====
    
```



External Standard Report

```

Sorted By      : Signal
Calib. Data Modified : Friday, October 10, 2014 11:45:51 AM
Multiplier     : 1.0000
Dilution       : 1.0000
    
```

Signal 1: VWD1 A, Wavelength=254 nm

RetTime [min]	Type	Area mAU	Area *s	Amt/Area	Amount [mg/L]	Grp	Name
4.363	MM	31.20308		3.19903	99.81970		CBD
6.525	VB	460.88614		2.16057e-1	99.57775		CBN
8.294	BB	37.78190		2.65235	100.21080		THC

Totals : 299.60825

Results obtained with enhanced integrator!

\*\*\* End of Report \*\*\*

# HPLC Application

ID No.: 11085



## Cannabinols on Luna C18(2) - After SPE Cleanup

**Column:** Luna® 3 µm C18(2) 100 Å, LC Column 50 x 4.6 mm, Ea

**Dimensions:** 50 x 4.6 mm ID

**Order No:** 00B-4251-E0

**Elution Type:** Gradient

**Eluent A:** Water w/0.1% formic acid

**Eluent B:** Acetonitrile w/0.1% formic acid

Gradient Profile:	Step No.	Time (min)	Pct A	Pct B
	1	0	95	5
	2	6	5	95

**Flow Rate:** 2.5 mL/min

**Col. Temp.:** ambient

**Detection:** UV-Vis Abs.-Variable Wave.(UV) @ 285 nm (ambient)

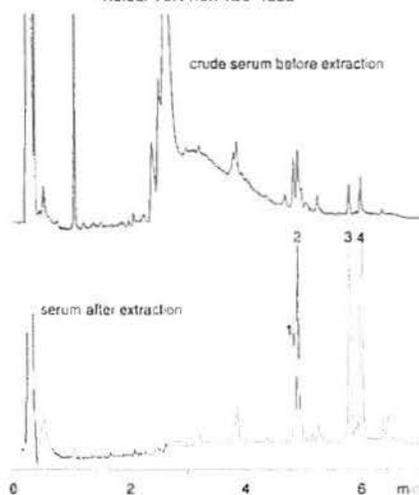
**Analyst Note:** SecurityGuard™ Guard Cartridge System extends column lifetime.

- SecurityGuard Cartridges, C18 4 x 3.0mm, 10/Pk Part No.: AJ0-4287

- Holder Part No.: KJ0-4282



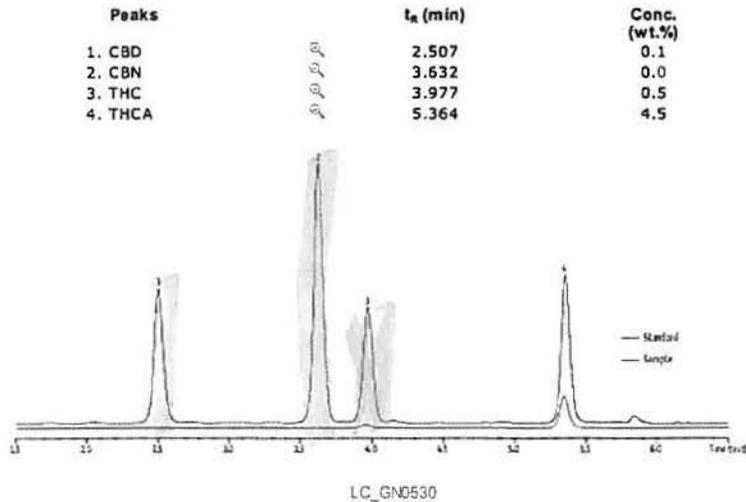
Products used in this application:



### ANALYTES:

- 1 11-Hydroxytetrahydrocannabinol
- 2 11-Nor-THC-Carboxylic acid
- 3 Cannabidiol
- 4 Tetrahydrocannabinol (THC)

## LC Potency Testing for Medical Marijuana on Ultra Aqueous C18



**Column** Ultra Aqueous C18 (cat.# 9178312)  
**Dimensions:** 100 mm x 2.1 mm ID  
**Particle Size:** 3  $\mu$ m  
**Pore Size:** 100  $\text{\AA}$   
**Temp.:** 30  $^{\circ}$ C  
**Sample**  
**Conc.:**  
**Inj. Vol.:** 10  $\mu$ L  
**Mobile Phase**  
**A:** Water + 10 mM potassium phosphate (pH = 2.5)  
**B:** Methanol

Time (min)	Flow (mL/min)	%A	%B
0.00	0.4	20	80
1.0	0.4	20	80
5.0	0.4	5	95
6.0	0.4	5	95
6.1	0.4	20	80
8.0	0.4	20	80

**Detector** UV/Vis @ 220, 4 nm  
**Cell Temp:** 40  $^{\circ}$ C  
**Instrument** Shimadzu UFLC XR  
**Notes** Blue trace = cannabinoids standards (cat.#s 34014 and 34093) diluted to 100  $\mu$ g/mL in isopropyl alcohol  
 Red trace = extracted marijuana sample

Sample extraction: Weigh 0.2 g of sample into a 40 mL VOA vial, add 40 mL of isopropyl alcohol, shake for 5 minutes, and allow sample to settle. Dilute extract 10x with isopropyl alcohol.

Quantification: Potency values (weight%) were based on a 1-point standard curve using the standard show above.

### RELATED CHROMATOGRAM LIBRARY SEARCHES

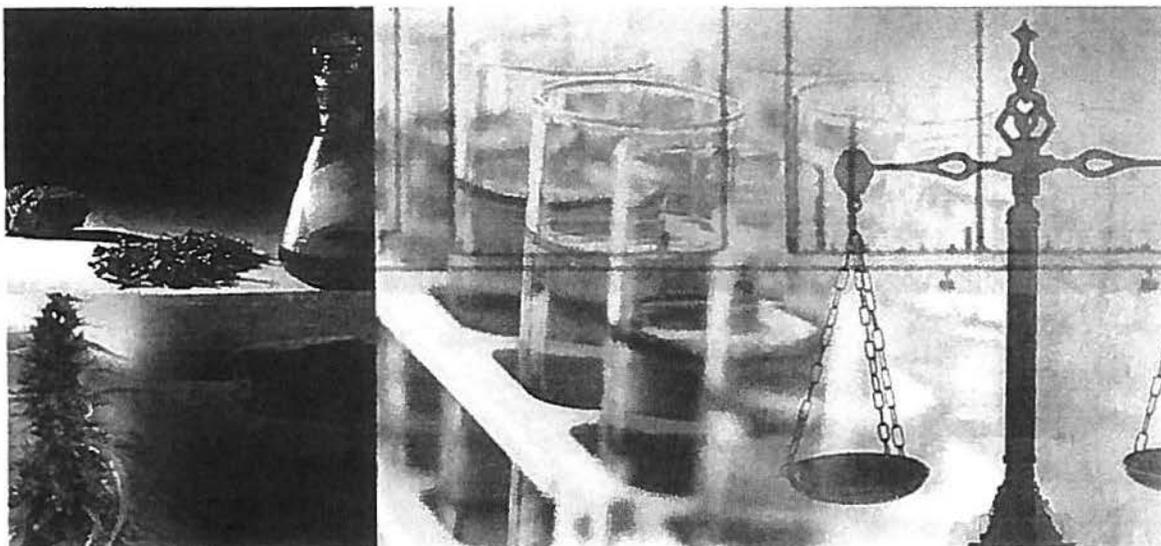
*marijuana, Ultra Aqueous C18, C18*

**Printing tips!** To print chromatograms full page, change the print settings in the print dialogue window of your PDF reader software: 1) "fit" or "fit to page", 2) "landscape" for wide chromatograms or "portrait" for tall chromatograms.



**UNODC**

United Nations Office on Drugs and Crime



Recommended methods  
for the identification and analysis  
of cannabis and cannabis products

*MANUAL FOR USE BY NATIONAL DRUG ANALYSIS LABORATORIES*

R 1/50 R+ 200

### Silylation

If THCA has to be analysed separately, i.e. without decarboxylation, 1.5 ml aliquots of the above (non-thermally decarboxylated) extract has to be derivatized before GC analysis. Derivatizing agents frequently used are:

- MSTFA: N-methyl-N-trimethylsilyltrifluoroacetamide
- BSTFA/TMCS: N,O-bis(trimethylsilyl)trifluoroacetamide/Trimethylchlorosilane (1 per cent)

Silylizable solvents such as ethanol have to be removed, usually by a gentle stream of nitrogen. The residue is taken up in 1.5 ml chloroform. 100 µl MSTFA are added and heated for 30 min at 70°C. The resulting solution can be analysed directly.

### 5.4.7 Gas chromatography-mass spectrometry (GC-MS)

The GC-MS analysis can be performed analogous to the GC-FID analysis.

Reference spectra of the most common cannabinoids, in derivatized or underivatized form, are available in common commercial MS databases.

### 5.4.8 High-performance liquid chromatography (HPLC)

The method below is a validated method for the analysis of total THC content (THC + THCOOH) in herbal cannabis after extraction with methanol/chloroform and subsequent decarboxylation [54,55]. The validation encompasses the entire process from sample preparation to HPLC analysis. Other methods may also produce acceptable results but must be validated and/or verified prior to routine use. With adequate verification, the same method can also be applied to other cannabis products.

Column type:	250x4mm RP-8 (5 µm); pre-column 4x4mm RP-8 (5 µm)
Column temperature:	30°C
Mobile phase:	Acetonitrile : water (8:2 v/v), isocratic, stop time 8 min.
Flow:	1 ml/min
Detection:	Photodiode array (PDA), 220 nm and 240 nm
Injection:	10 µl
Elution order:	CBD, CBN, THC, THCA (if decarboxylation is not performed or is incomplete)

**Sample preparation**

500 mg of dry and homogenized herbal cannabis (see section 5.4.2) are extracted with 5 ml methanol : chloroform (9:1 v/v) by the following procedure: 10 seconds on a vortex, 15 min. ultrasonic bath including again vortexing after 5, 10 and 15 minutes, then centrifugation.

**Decarboxylation**

200 µl of the above extract are transferred into a derivatization vessel. The solvent is evaporated under nitrogen gas to dryness. The sample is decarboxylated for 15 minutes at 210°C. The residue is dissolved in 200 µl methanol : chloroform (9:1 v/v).

**Preparation of the final solution**

The above decarboxylation solution is diluted with methanol by a factor of 100 (in two steps, each 100 µl + 900 µl) and is then used for the analysis.

For lower THC contents (< 0.5 per cent), a dilution factor of 10 instead of 100 is sufficient.

**Calibration**

Stock solution:	Standard solution 1 mg (-)- $\Delta^9$ -THC/ml methanol
Dilution 1:	100 µl (stock solution) + 900 µl methanol = 0.1 mg THC/ml methanol
Dilution 2:	100 µl (dilution 1) + 900 µl methanol = 0.01 mg THC/ml methanol

No.	Concentration (mg/ml)	STD (vol. of standard)	Methanol (vol. of methanol)
1	0.001	10 µl 0.01 mg/ml	90 µl
2	0.005	50 µl 0.01 mg/ml	50 µl
3	0.01	10 µl 0.1 mg/ml	90 µl
4	0.05	50 µl 0.1 mg/ml	50 µl
5	0.1	100 µl 0.1 mg/ml	0 µl

Standard solutions must be stored in a dark, cool place for up to four months.

**Results**

For a qualitative identification, the retention time as well as the DAD spectrum of the cannabinoid have to match.

<i>Substance</i>	<i>Retention time (min)*</i>	<i>Relative retention time*</i>
Cannabidiol	4.9	0.69
Cannabinol	6.0	0.85
(-)- $\Delta^9$ -THC	7.1	1.00
(-)- $\Delta^9$ -THC acid	7.4	1.04

\*Carried out on a 250-4mm LiChrospher® 60 RP-select B (5 $\mu$ m) with a pre-column 4-4 LiChrospher 60 RP-select B (5 $\mu$ m)

The calculation for the quantitative results is carried out at the wavelengths of 220 and 240 nm.



**CERTIFIED WEIGHT REPORT**

Part Number: **97837**  
 Lot Number: **081914**  
 Description: **Total THC Medicinal Cannabis Calibration**  
 3 components Lot# Solvent(s):  
 Expiration Date: 081917 DK010 Methanol (90%)  
 Recommended Storage: Freezer (0 °C) 30796EK Ethanol (10%)  
 Nominal Concentration (µg/mL): 100

<i>Gabriel Helland</i>		081914
Formulated By:	Gabriel Helland	DATE
<i>Pedro L. Rentas</i>		081914
Reviewed By:	Pedro L. Rentas	DATE

Volume(s) shown below were combined and diluted to (mL): 5.0  
 5E-05 Balance Uncertainty  
 0.006 Flask Uncertainty

Compound	Part Number	Lot Number	Dil. Factor	Initial Vol. (mL)	Uncertainty Pipette	Initial Conc. (ug/mL)	Final Conc. (ug/mL)	Expanded Uncertainty (+/-)	MSDS Information (Solvent Safety Info. On Attached pg.)		
									CAS#	OSHA PEL (TWA)	LD50
1. (-)-Δ9-THC <i>四氢大麻酚</i>	73040	040113	0.10	0.50	0.002	1002.7	100.5	0.01057	01972-08-3	N/A	N/A
2. Cannabidiol <i>大麻二酚</i>	73467	060812	0.10	0.50	0.002	1006.3	100.8	0.01068	13956-29-1	N/A	N/A
3. Cannabinol <i>大麻西酚</i>	73468	022111	0.10	0.50	0.002	1004.2	100.6	0.01066	00521-35-7	N/A	N/A

## Bist, Kevin

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**From:** Nelson, Patricia A  
**Sent:** Friday, January 16, 2015 10:23 AM  
**To:** Steven.hall@freshfromflorida.com  
**Subject:** RE: Updated List - January 9, 2015

Thank you!

---

**From:** Hall, Steven [<mailto:Steven.Hall@freshfromflorida.com>]  
**Sent:** Friday, January 16, 2015 10:22 AM  
**To:** Nelson, Patricia A  
**Subject:** FW: Updated List - January 9, 2015

Patty –

Per your request, please see the attached lists. The first document lists nurseries that have been registered with the department for 30 or more years (as of the year 2015) and meet the inventory requirement of the statute. The second document lists only the nurseries that have been registered with the department for 30 or more years whether or not they meet the inventory requirement. Both lists are updated weekly.

The information in these records is based on the department's best available records and was prepared in response to media inquiries and public records requests. The inclusion of a nursery on this list is NOT a determination of eligibility for licensure as a medical marijuana dispensary pursuant to Section 381.986, Florida Statutes.

Please let me know if you have any questions.

**Steven L. Hall**  
Senior Attorney  
Office of General Counsel  
Florida Department of Agriculture and Consumer Services

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**From:** Hamm, Denise  
**Sent:** Friday, January 09, 2015 4:07 PM  
**To:** Gillespie, Erin; Holley, Lorena; Hall, Steven; Williams, Lasharonte; Lovett, Grace; Conti, Lisa; Bevis, Amanda; Keller, Aaron; Rees, Jonathan; Joyner, Michael  
**Cc:** Emery, Tyson; Gaskalla, Richard  
**Subject:** FW: Updated List - January 9, 2015

Thanks, Tyson.

Denise

---

**From:** Emery, Tyson  
**Sent:** Friday, January 09, 2015 3:48 PM  
**To:** Hamm, Denise  
**Cc:** Benson, Bryan; McMahon, Sheila; Dixon, Wayne  
**Subject:** Updated List

Attached are our updated list of nurseries registered with the Division for 30 years and those registered for 30 years and have an inventory of 400,000 plants or more.

**Updates for 30 year list**

- 86 nurseries added, registered in year 1985

**Updates for 30 year 400,000 plant list**

- 10 nurseries added, registered in year 1985
- 1 nurseries added, increased inventory to over 400,000 plants

Tyson Emery  
Chief- Bureau of Plant and Apiary Inspection  
Division of Plant Industry  
Florida Department of Agriculture and Consumer Services

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## **Bist, Kevin**

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**From:** Nelson, Patricia A  
**Sent:** Friday, January 16, 2015 10:42 AM  
**To:** Bist, Kevin  
**Subject:** RE: List of nurseries

Thank you.

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**From:** Bist, Kevin  
**Sent:** Friday, January 16, 2015 10:41 AM  
**To:** Nelson, Patricia A  
**Subject:** FW: List of nurseries  
**Importance:** High

Per your request.

---

**From:** Emery, Tyson [<mailto:Tyson.Emery@freshfromflorida.com>]  
**Sent:** Friday, January 16, 2015 10:28 AM  
**To:** Bist, Kevin  
**Subject:** RE: List of nurseries

Kevin,

Attached is a list I ran last Friday, will be producing another this afternoon. The list has increased due to the 30 year requirement, we added all nurseries that will meet 30 years within 2015, specific date originally registered are under the column Registration Date.

Tyson Emery  
Chief- Bureau of Plant and Apiary Inspection  
Division of Plant Industry  
Florida Department of Agriculture and Consumer Services

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**From:** Bist, Kevin [<mailto:Kevin.Bist@flhealth.gov>]  
**Sent:** Friday, January 16, 2015 9:55 AM  
**To:** Emery, Tyson  
**Subject:** List of nurseries

Good Morning Mr. Tyson,

Happy Friday!

The new Director of the Office of Compassionate Use, Patty Nelson, has asked me to reach out to you to see if you could provide the latest list of nurseries that meet the definition of potential applicants for SB 1030. Would you mind sending that to me as quickly as possible?

Thank you!

Kevin

Kevin Bist  
Program Specialist  
Office of Compassionate Use  
Florida Department of Health  
850-245-4658

**Bist, Kevin**

---

**From:** ANNE <bestofalltherest@comcast.net>  
**Sent:** Friday, January 16, 2015 10:42 AM  
**To:** Nelson, Patricia A  
**Subject:** Quick inquiry fro Anne Morgan, M.D.

Good Morning,

I am certain that you are extremely busy. Is it possible that I may have your phone number to speak with you for just a moment?

If not possible, I do understand.

Or, if easier...my cell is: 954-592-0700

Thank you,

Ane Morgan, M.D.

## Bist, Kevin

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**From:** Nelson, Patricia A  
**Sent:** Friday, January 16, 2015 1:15 PM  
**To:** Steven.hall@freshfromflorida.com  
**Subject:** RE: Updated List

Thank you again!

---

**From:** Hall, Steven [<mailto:Steven.Hall@freshfromflorida.com>]  
**Sent:** Friday, January 16, 2015 1:09 PM  
**To:** Nelson, Patricia A  
**Subject:** FW: Updated List

FYI – The updated lists are attached.

**Steven L. Hall**  
Senior Attorney  
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---

Attached are our updated list of nurseries registered with the Division for 30 years and those registered for 30 years and have an inventory of 400,000 plants or more.

### Updates for 30 year list

- Three Nurseries Removed:
  - Bert Newcomb Tree and Landscaping Service, Inc.
  - Jones Nursery
  - Reedy Creek Nursery

### No Updates for 30 year 400,000 plant list

Tyson Emery  
Chief- Bureau of Plant and Apiary Inspection  
Division of Plant Industry  
Florida Department of Agriculture and Consumer Services

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**Bist, Kevin**

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**From:** julio lopez <fcd1910@gmail.com>  
**Sent:** Friday, January 16, 2015 8:11 PM  
**To:** Nelson, Patricia A  
**Subject:** Fwd: Proposed Rules

----- Forwarded message -----  
**From:** julio lopez <fcd1910@gmail.com>  
**Date:** Fri, Jan 16, 2015 at 1:04 PM  
**Subject:** Proposed Rules  
**To:** [CompassionateUse@flhealth.gov](mailto:CompassionateUse@flhealth.gov)

Ms. Nelson,

The newly proposed rules to maintain the dispensing of medical cannabis with the growers is not in accordance with the ruling from the administrative judge which dictated that dispensing should be done by multiple agencies not affiliated with the growers in order to provide convenient access to patients. Our organization strongly opposes this rule and respectfully requests that the orders of the administrative judge are reflected.

Julio A. Lopez, PhD  
President/CEO  
Florida Cannabis Dispensaries, Inc.



[Facebook](#)

## Bist, Kevin

---

**From:** Pritesh K <kpritesh2@gmail.com>  
**Sent:** Sunday, January 18, 2015 8:07 PM  
**To:** Nelson, Patricia A  
**Subject:** CBD Questions  
**Attachments:** Florida\_DPH.docx

Hi,

I'd like to informally introduce myself. My name is Dr. Pritesh Kumar. I am a research scientist at the University of Louisville in KY and have been doing medicinal cannabis research for several years and have published widely in the field. On the private side, I run a small company ([www.phytosciences.com](http://www.phytosciences.com)) with my fellow scientists and colleagues from around the world. We focus on quality control, quality assurance, and the development of safe, effective, and pure medicinal cannabis-based therapeutics from a clinical research perspective. We have always stayed on the medical side of the industry as we are scientists and do not believe in the recreational use. We have for the last two years been involved in a number consulting projects pertaining to helping companies in various states set up manufacturing sites and follow best practices for quality control.

Please forgive me but I can't disclose who sent me your question list as I consult for several companies in FL who are competitors of each other. The reason for this email is primarily out of concern from a medical perspective as the questions are very basic and should be addressed by your pharmacologist on your committee.

I recently received a copy of your question (from a client of mine in FL) and had a number of concerns. It is concerning to me that these questions have not been answered as they are relatively simple questions and the right questions are not being asked. My concern as a cannabinoid pharmacologist and toxicologist is that you are forming a committee to discuss rule-making for the State of Florida and have concerns with the scientific knowledge (or lack thereof) of some of the members nominated to your committee. Since I honestly don't care about how your state rolls out the program, I do care about the science, medical, and patient side of things. The companies you brought on to your committee (something labs.. and or the Stanley brothers) have their own agendas and don't care about the science or patient safety or best practices. They don't know the first thing about cannabinoid science or pharmacology. That lab you put on your committee is involved in legal matters that are publicly available. In the industry, we know which are the good labs and which are not (We would be happy to recommend better options for you). Here's the point - you didn't do enough due diligence and put the wrong people on your committee on the science side of things. I'd be happy to recommend any number of cannabinoid scientists and pharmacologists that can actually answer your questions and more importantly, tell you which questions need to be asked.

I have no interest in FL in any way shape or form so I don't mind being 100 % honest with you. I consult for clients who are applying for licenses there on the medical side and I don't have any personal interest in the state. Attached are the answers the questions a client of mine asked me to answer on their behalf for your department. There is no conflict for me but I would like to offer some unbiased advice. You're looking in the wrong direction for advice on the medical side of things.

I work as a consultant with clients in multiple states, and have seen many regulatory models enacted to varying degrees of success. I do not have a business interest in any of the nursery or applicants seeking to become dispensing organizations, but I would like to provide consultation on the set up and best practices for cannabis testing services in Florida. Given my experience and expertise, I believe I am in an ideal position to help the Department of Health draft the best possible rules or at least help you select appropriate committee members.

Attached is your original list of questions with answers that were sent to me by a client who needed guidance. Please keep my email confidential. I never imagined I would interfere in the political side of things, but after seeing these questions I felt it was my duty as a scientist provide assistance. I'm available to answer any questions you may have.

Best, PK

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On Mon, Jan 12, 2015 at 1:04 PM, Nelson, Patricia A <[Patricia.Nelson@flhealth.gov](mailto:Patricia.Nelson@flhealth.gov)> wrote:

Dr. Nessetti,

Thank you for your call this morning. I do have several questions regarding the production of low-THC cannabis derivative products. In my mind, the answers would affect any best practices developed for Florida growers/producers. My questions are listed below, and I appreciate any answers you or your colleagues can provide.

1. Do different production methods affect efficacy of the product ?
2. Is this true if analysis shows that the CBD levels are the same?
3. Is efficacy affected when CBD levels are constant, but the levels of other chemicals, e.g., THC, vary?
4. Do different solvents affect efficacy of the final product even if there is no residual solvent in the derivative product?
5. How many different “strains” of low-THC cannabis exist?
6. Do different strains produce different effects?
7. Are the effects still different when the level of CBD is controlled?
8. Are there any contaminants that affect the efficacy of the product (other than the inherent danger of having a contaminated product)?
9. Are there any other growing or production processes or inputs that, in your experience, affect the efficacy of the product?
10. Are there any comorbidities or coexisting conditions in a typical child with intractable epilepsy that respond negatively to any additives commonly used for agriculture?
11. Are there any comorbidities or coexisting conditions in a typical child with intractable epilepsy that respond negatively to any additives commonly used for the production of derivative products?

That is all I have for now. I will forward any other questions that I come up with.

Thank you again,

Patty

Patricia Nelson

Director

Office of Compassionate Use

Florida Department of Health

**For clarity: Questions 1,2,5 and 9 were addressed by a medicinal cannabis cultivator with extensive experience and the responses are in bold.**

Questions 3,4,6,7,8,10, and 11 were addressed by a cannabinoid pharmacologist and toxicologist and the responses are in bold (blue).

**Note: The questions presented below raised significant concern to the pharmacologist as he indicated that these are amateur questions and the individual asking these questions needs to consider consulting an expert in the field of cannabinoid pharmacology for detailed explanations and clarity.**

**Let's clarify a pharmacological concept before I answer these questions as the term efficacy is misused in nearly all of these questions: Efficacy refers to the maximum effect of a "drug" (regardless of the dose). In addition, efficacy refers to the relationship between receptor occupancy and the ability to produce a response.**

1. Do different production methods affect efficacy of the product ?

**Yes, because poor production methods will affect efficacy.**

2. Is this true if analysis shows that the CBD levels are the same?

**If poor production methods are in place, CBD levels will not be the same.**

3. Is efficacy affected when CBD levels are constant, but the levels of other chemicals, e.g., THC, vary?

**Short answer – Yes. Briefly, the specific concentration of the other cannabinoids will affect the efficacy. The pharmacological basis for this is a result of at least 7 factors: 1) Ligand-receptor affinity, 2) Receptor density (Bmax), 3) Competition for receptor binding sites, 4) Mechanism of action, 5) Delivery system, 6) Biosynthetic enzyme levels and expression levels, 7) Terpene concentration**

**You are asking the wrong question but that is the answer. The more practical and clinically relevant question that needs to be asked and addressed is**

**“What is the impact of the other cannabinoids on the efficacy?”**

**“Which enzymes are clinically relevant for efficacy?”**

**“Can these enzymes serve as potential biomarkers?”**

**Also, the question is poorly written: The term efficacy is properly defined in this context. Clinical efficacy is what I assumed? My advice – please contact a cannabinoid pharmacologist for further details.**

4. Do different solvents affect efficacy of the final product even if there is no residual solvent in the derivative product?

**Short answer – Yes. There have been several published research articles analyzing the effect of different solvents on efficacy (clinical and patient compliance).**

**Consult a cannabinoid pharmacologist for detailed answers.**

5. How many different "strains" of low-THC cannabis exist?

**>100, and cross breeding makes it so that there are new strains being developed daily.**

6. Do different strains produce different effects?

**Short Answer – Yes. Great question. But let's be even more specific: The correct question should be "Do different strains produce different effect and what factors play a role in determining this?" I will answer your question and mine for thoroughness. The correct mentality should be to think of this like a medicine and ask the same questions one would if evaluating a new medication for diabetes for example. The questions should take into account the age of the patient, dosage, strain type (e.g., Indica vs Sativa, High THC/ High CBD, High THC / Moderate CBD, High THC / Low CBD and the reverse combinations), previous history of using the medicine etc. In addition, other factors should be considered including, but not limited to, current medications patient is taking (as different strains may cause Drug-Drug Interactions), general Drug-Drug Interactions based on cannabinoid concentration specific to each strain etc etc.**

**From a pharmacological perspective, each strain is unique as the concentration of cannabinoids and ratios are different which depends on a numbers of factors (strain type – indica vs sativa, cultivation conditions, just two examples).**

**Therefore, each strain has its own pharmacology and should be considered one by one as no two strains are identical. The type of strain, dose, age of patient, pre-existing clinical conditions, and cannabinoid concentration will determine the clinical efficacy and side-effect profile.**

**The best way for me to help you understand this is by this example: Consider NSAIDs (Non-Steroidal Anti-Inflammatory Drugs) such as Ibuprofen (Advil), Naproxen (Aleve), or a COX-2 inhibitor (Celebrex) which are commonly used for pain relief. While these drugs produce their effects through a common mechanism of action (inhibition of COX1/2), each own has its own pharmacological profile and dosage indications. This is how one should view different strains and efficacy.**

7. Are the effects still different when the level of CBD is controlled?

**Short answer – Yes. The focus of these questions is on CBD which is concerning for a number of reasons. From a pharmacological perspective, the "entourage effect" is critical to the efficacy of this plant which indicates that the different cannabinoids (including CBD) interact in a multitude of ways to produce the overall effect.**

**This question can't be answered as written in its current fashion. Question is too broad and doesn't take into consideration the patient, dose, or strain type. I highly recommend you find someone who is well-versed in cannabinoid science and pharmacology to guide these questions if the goal is to set up a clinically relevant program.**

8. Are there any contaminants that affect the efficacy of the product (other than the inherent danger of having a contaminated product)?

**Short answer – Yes. This is an excellent question and should be addressed in a separate conversation. If the contaminant alters or disrupts the cannabinoid concentration in the final product then the efficacy will be at risk. There are several research studies that have already been conducted investigating this question.**

**Please consult the following people to help assist: Pharmacologist, Toxicologist, Plant Microbiologist.**

9. Are there any other growing or production processes or inputs that, in your experience, affect the efficacy of the product?

**Yes. Best methods are techniques that create the least amount of stress and provide the most super charged environment for the plant.**

10. Are there any comorbidities or coexisting conditions in a typical child with intractable epilepsy that respond negatively to any additives commonly used for agriculture?

**Short answer-Yes. This is a very broad question. A few research studies have shown that certain additives and/or pesticides can potentially trigger seizures. Please consult with pharmacologist and toxicologist with an expertise in agriculture.**

11. Are there any comorbidities or coexisting conditions in a typical child with intractable epilepsy that respond negatively to any additives commonly used for the production of derivative products?

**Please refer to the response for question 10.**

**Overall analysis: Please seek advice from people with strong backgrounds in science and cannabinoid pharmacology.**

## **Bist, Kevin**

---

**From:** Matthew Nesselletti <drmatt@allcaremedicalcenters.com>  
**Sent:** Monday, January 19, 2015 10:02 PM  
**To:** Nelson, Patricia A  
**Subject:** Re: CBD Preparation Questions  
**Attachments:** Answers to Patty Nelson's Questions - AltMed, Florida - 1-19-2015.pdf

Hi Patty,

I hope you had an awesome weekend. My wife and I traveled to Nebraska to be at my granddaughter's 2nd Birthday Party! What a blast, but, I can't believe I am a grandfather still!

I have compiled the answers I have received so far to your questions in the attached PDF. If I receive any more answers, I will forward to you. I am confident more questions will be generated from these answers and I am happy to continue to liaison. Feel free to call me at 941-685-5782 (cell) if you would like to discuss.

Best,

Matt

**Matthew B.R. Nesselletti, PHD, MD, JD (Cand), ABMP, ABFM,  
Medical Psychology/Psychopharmacology/Family Medicine  
Juris Doctor Candidate - Stetson University College of Law - 2016**

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**Unedited Answers to Questions Posed By Patty Nelson, Director, Office of Compassionate Use  
Florida Department of Health**

January 19, 2015

**For clarity: Questions 1,2,5, 6 and 9 were addressed by medicinal cannabis cultivators with extensive experience and the responses are in bold.**

Questions 3,4,6,7,8,10, and 11 were addressed by a cannabinoid pharmacologist and toxicologist and the responses are in bold (blue).

Let's clarify a pharmacological concept before answering some of these questions as the term efficacy, which might not be the exact correct term: Efficacy refers to the maximum effect of a "drug" (regardless of the dose). In addition, efficacy refers to the relationship between receptor occupancy and the ability to produce a response.

1. Do different production methods affect efficacy of the product ?

**Yes, poor production methods will affect efficacy.**

2. Is this true if analysis shows that the CBD levels are the same?

**If poor production methods are in place, CBD levels will not be the same. So, to answer your question, CBD levels will differ should inadequate or variable productions standards are in place.**

3. Is efficacy affected when CBD levels are constant, but the levels of other chemicals, e.g., THC, vary?

**Short answer – Yes. Briefly, the specific concentration of the other cannabinoids will affect the efficacy. The pharmacological basis for this is a result of at least 7 factors: 1) Ligand-receptor affinity, 2) Receptor density (Bmax), 3) Competition for receptor binding sites, 4) Mechanism of action, 5) Delivery system, 6) Biosynthetic enzyme levels and expression levels, 7) Terpene concentration**

**Some Interesting Future Research Questions Might Be:**

**"What is the impact of the other cannabinoids on the efficacy?"**

**"Which enzymes are clinically relevant for efficacy?"**

**"Can these enzymes serve as potential biomarkers?"**

4. Do different solvents affect efficacy of the final product even if there is no residual solvent in the derivative product?

**Short answer – Yes. There have been several published research articles analyzing the effect of different solvents on efficacy (clinical and patient compliance).**

5. How many different "strains" of low-THC cannabis exist?

Cultivator #1 : >100, and cross breeding makes it so that there are new strains being developed daily.

**Cultivator #2:** There is some confusion popping up I think with the term Low THC / High CBD . By FL law testing at below .8% is considered Low THC. That being said I know of about 5 strains that fall into that category. They are R-4,, AC/DC, Charlotte Web, Avi Dekel, and Hemp. There are now about 20 or so strains that are called Low THC and High CBD or High CBD strains but they test at anywhere from 3-12% THC and 8-25% CBD. Most common are Cannatonic ,Harliquin, Sour Tsunami, and Omrita to name few.

6. Do different strains produce different effects?

Short Answer – Yes. Great question. But let's be even more specific: The correct question should be "Do different strains produce different effect and what factors play a role in determining this?" I will answer your question and mine for thoroughness. The correct mentality should be to think of this like a medicine and ask the same questions one would if evaluating a new medication for diabetes for example. The questions should take into account the age of the patient, dosage, strain type (e.g., Indica vs Sativa, High THC/ High CBD, High THC / Moderate CBD, High THC / Low CBD and the reverse combinations), previous history of using the medicine etc. In addition, other factors should be considered including, but not limited to, current medications patient is taking (as different strains may cause Drug-Drug Interactions), general Drug-Drug Interactions based on cannabinoid concentration specific to each strain etc etc.

From a pharmacological perspective, each strain is unique as the concentration of cannabinoids and ratios are different which depends on a numbers of factors (strain type – indica vs sativa, cultivation conditions, just two examples).

Therefore, each strain has its own pharmacology and should be considered one by one as no two strains are identical. The type of strain, dose, age of patient, pre-existing clinical conditions, and cannabinoid concentration will determine the clinical efficacy and side-effect profile.

The best way for me to help you understand this is by this example: Consider NSAIDs (Non-Steroidal Anti-Inflammatory Drugs) such as Ibuprofen (Advil), Naproxen (Aleve), or a COX-2 inhibitor (Celebrex) which are commonly used for pain relief. While these drugs produce their effects through a common mechanism of action (inhibition of COX1/2), each has its own pharmacological profile and dosage indications. This is how one should view different strains and efficacy.

**Cultivator #2:** The answer is YES As far as R-4,AC/DC, Charlotte Web etc they will have an effect based on the higher CBD value. The more CBD the better the outcome for some patients. This does depends on their specific disease. There have been cases showing benefits from higher amounts of CBD being administered. Another example is they have been looking at Higher CBD ratios helping Autistic children. The other strains I mentioned all have different effects. Cannatonic is known to be a great calming and pain relief strain without feeling high. Omrita is known for great juicing leaves and helping with inflammation and pain for Cancer patients

7. Are the effects still different when the level of CBD is controlled?

Short answer – Yes. The focus of these questions is on CBD which is concerning for a number of reasons. From a pharmacological perspective, the “entourage effect” is critical to the efficacy of this plant which indicates that the different cannabinoids (including CBD) interact in a multitude of ways to produce the overall effect.

8. Are there any contaminants that affect the efficacy of the product (other than the inherent danger of having a contaminated product)?

Short answer – Yes. This is an excellent question and might require a long discussion, but, if the contaminant alters or disrupts the cannabinoid concentration in the final product then the efficacy will be at risk. There are several research studies that have already been conducted investigating this question.

Consult the following professionals to help assist as policies are promulgated and procedures are concretized: Pharmacologist, Toxicologist, Plant Microbiologist with expertise in Cannabis.

9. Are there any other growing or production processes or inputs that, in your experience, affect the efficacy of the product?

Cultivator #1 : Yes. Best methods are techniques that create the least amount of stress and provide the most super charged environment for the plant.

**Cultivator #2: Answered from cultivation perspective. How you grow your plants and the environment play a big role in the outcome of the final product. Like anything else if you start with bad oranges you get bad juice. Same thing applies with Cannabis. Yes it's a weed but to get the best you can out of this weed you need to give it specific nutrients at specific times and the better you control your environment the better your results will be. Keeping quality genetics and having consistent control of how the plant grows. Keeping a clean environment so. You have less of a chance for pests and other harmful diseases infecting your crop. Growing organically and keeping a clean environment will result in a superior product.**

10. Are there any comorbidities or coexisting conditions in a typical child with intractable epilepsy that respond negatively to any additives commonly used for agriculture?

Short answer-Yes. This is a very broad question. A few research studies have shown that certain additives and/or pesticides can potentially trigger seizures. Consulting with pharmacologist and toxicologist with an expertise in agriculture will ultimately be helpful in this safety concern.

11. Are there any comorbidities or coexisting conditions in a typical child with intractable epilepsy that respond negatively to any additives commonly used for the production of derivative products?

Really, same answer as #10. Greater production control with avoidance of additives and pesticides known to cause negative responses is key.

## Bist, Kevin

---

**From:** zzzz Feedback, Compassionate Use  
**Sent:** Tuesday, January 20, 2015 8:16 AM  
**To:** Nelson, Patricia A  
**Subject:** FW: Proposed Rules

Patty,

FYI. I have not responded to Mr. Lopez.

Kevin

**From:** julio lopez [<mailto:fcd1910@gmail.com>]  
**Sent:** Friday, January 16, 2015 1:04 PM  
**To:** zzzz Feedback, Compassionate Use  
**Subject:** Proposed Rules

Ms. Nelson,

The newly proposed rules to maintain the dispensing of medical cannabis with the growers is not in accordance with the ruling from the administrative judge which dictated that dispensing should be done by multiple agencies not affiliated with the growers in order to provide convenient access to patients. Our organization strongly opposes this rule and respectfully requests that the orders of the administrative judge are reflected.

Julio A. Lopez, PhD  
President/CEO  
Florida Cannabis Dispensaries, Inc.



[Facebook](#)

## Bist, Kevin

---

**From:** Nelson, Patricia A  
**Sent:** Tuesday, January 20, 2015 9:08 AM  
**To:** Bist, Kevin  
**Subject:** RE: Proposed Rules

There is no need to respond unless he follows up requesting a response. His comment will be noted.

Thank you!

---

**From:** zzzz Feedback, Compassionate Use  
**Sent:** Tuesday, January 20, 2015 8:16 AM  
**To:** Nelson, Patricia A  
**Subject:** FW: Proposed Rules

Patty,

FYI. I have not responded to Mr. Lopez.

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Julio A. Lopez, PhD  
President/CEO  
Florida Cannabis Dispensaries, Inc.



[Facebook](#)

## Bist, Kevin

---

**From:** Nelson, Patricia A  
**Sent:** Tuesday, January 20, 2015 9:09 AM  
**To:** 'Matthew Nesselletti'  
**Subject:** RE: CBD Preparation Questions

Thank you so much!

I'm sure you will hear from me soon.

Patty

**From:** Matthew Nesselletti [mailto:drmatt@allcaremedicalcenters.com]  
**Sent:** Monday, January 19, 2015 10:02 PM  
**To:** Nelson, Patricia A  
**Subject:** Re: CBD Preparation Questions

Hi Patty,

I hope you had an awesome weekend. My wife and I traveled to Nebraska to be at my granddaughter's 2nd Birthday Party! What a blast, but, I can't believe I am a grandfather still!

I have compiled the answers I have received so far to your questions in the attached PDF. If I receive any more answers, I will forward to you. I am confident more questions will be generated from these answers and I am happy to continue to liaison. Feel free to call me at 941-685-5782 (cell) if you would like to discuss.

Best,

Matt

Matthew B.R. Nesselletti, PHD, MD, JD (Cand), ABMP, ABFM,  
Medical Psychology/Psychopharmacology/Family Medicine  
Juris Doctor Candidate - Stetson University College of Law - 2016

Medical Director - AllCare Medical Centers, P.C.  
8209 Natures Way, Suite 115, Lakewood Ranch, FL 34202  
941-388-8997 (Voice)  
941-306-5876 (Fax)  
[www.AllCareMedicalCenters.com](http://www.AllCareMedicalCenters.com)

Medical Director - Hawthorne Village Healthcare & Rehabilitation  
5381 Desoto Road, Sarasota, FL 34235  
(941) 355-6111 (Voice)  
[www.hawthornevillageofsarasota.com](http://www.hawthornevillageofsarasota.com)

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On Mon, Jan 12, 2015 at 1:04 PM, Nelson, Patricia A <[Patricia.Nelson@flhealth.gov](mailto:Patricia.Nelson@flhealth.gov)> wrote:

Dr. Nessetti,

Thank you for your call this morning. I do have several questions regarding the production of low-THC cannabis derivative products. In my mind, the answers would affect any best practices developed for Florida growers/producers. My questions are listed below, and I appreciate any answers you or your colleagues can provide.

1. Do different production methods affect efficacy of the product ?
2. Is this true if analysis shows that the CBD levels are the same?
3. Is efficacy affected when CBD levels are constant, but the levels of other chemicals, e.g., THC, vary?
4. Do different solvents affect efficacy of the final product even if there is no residual solvent in the derivative product?
5. How many different "strains" of low-THC cannabis exist?
6. Do different strains produce different effects?
7. Are the effects still different when the level of CBD is controlled?
8. Are there any contaminants that affect the efficacy of the product (other than the inherent danger of having a contaminated product)?
9. Are there any other growing or production processes or inputs that, in your experience, affect the efficacy of the product?
10. Are there any comorbidities or coexisting conditions in a typical child with intractable epilepsy that respond negatively to any additives commonly used for agriculture?

11. Are there any comorbidities or coexisting conditions in a typical child with intractable epilepsy that respond negatively to any additives commonly used for the production of derivative products?

That is all I have for now. I will forward any other questions that I come up with.

Thank you again,

Patty

Patricia Nelson

Director

Office of Compassionate Use

Florida Department of Health

## Bist, Kevin

---

**From:** Nelson, Patricia A  
**Sent:** Tuesday, January 20, 2015 9:18 AM  
**To:** 'Pritesh K'  
**Subject:** RE: CBD Questions

Dr. Kumar,

First, I appreciate your concern for our process. I would be happy to discuss these issues with you, especially if you have something positive to contribute to process. Please let me know when you would be available.

Patty

Patricia Nelson  
Director  
Office of Compassionate Use  
Florida Department of Health



**From:** Pritesh K [<mailto:kpritesh2@gmail.com>]  
**Sent:** Sunday, January 18, 2015 8:07 PM  
**To:** Nelson, Patricia A  
**Subject:** CBD Questions

Hi,

I'd like to informally introduce myself. My name is Dr. Pritesh Kumar. I am a research scientist at the University of Louisville in KY and have been doing medicinal cannabis research for several years and have published widely in the field. On the private side, I run a small company ([www.phytosciences.com](http://www.phytosciences.com)) with my fellow scientists and colleagues from around the world. We focus on quality control, quality assurance, and the development of safe, effective, and pure medicinal cannabis-based therapeutics from a clinical research perspective. We have always stayed on the medical side of the industry as we are scientists and do not believe in the recreational use. We have for the last two years been involved in a number consulting projects pertaining to helping companies in various states set up manufacturing sites and follow best practices for quality control.

Please forgive me but I can't disclose who sent me your question list as I consult for several companies in FL who are competitors of each other. The reason for this email is primarily out of concern from a medical perspective as the questions are very basic and should be addressed by your pharmacologist on your committee.

I recently received a copy of your question (from a client of mine in FL) and had a number of concerns. It is concerning to me that these questions have not been answered as they are relatively simple questions and the right questions are not being asked. My concern as a cannabinoid pharmacologist and toxicologist is that you are forming a committee to discuss rule-making for the State of Florida and have concerns with the scientific knowledge (or lack thereof) of some of the members nominated to your committee. Since I honestly don't care about how your state rolls out the program, I do care about the science, medical, and patient side of things. The companies you brought on to your committee (something labs.. and or the Stanley brothers) have their own agendas and don't care about the science or patient safety or best practices. They don't know the first thing about cannabinoid science or pharmacology. That lab you put on your committee is involved in legal matters that are publicly available. In the industry, we know which are the good labs and which are not (We would be happy to recommend better options for you). Here's the point - you didn't do enough due diligence and put the wrong people on your committee on the science side of things. I'd be happy to recommend any number of cannabinoid scientists and pharmacologists that can actually answer your questions and more importantly, tell you which questions need to be asked.

I have no interest in FL in any way shape or form so I don't mind being 100 % honest with you. I consult for clients who are applying for licenses there on the medical side and I don't have any personal interest in the state. Attached are the answers the questions a client of mine asked me to answer on their behalf for your department. There is no conflict for me but I would like to offer some unbiased advice. You're looking in the wrong direction for advice on the medical side of things.

I work as a consultant with clients in multiple states, and have seen many regulatory models enacted to varying degrees of success. I do not have a business interest in any of the nursery or applicants seeking to become dispensing organizations, but I would like to provide consultation on the set up and best practices for cannabis testing services in Florida. Given my experience and expertise, I believe I am in an ideal position to help the Department of Health draft the best possible rules or at least help you select appropriate committee members.

Attached is your original list of questions with answers that were sent to me by a client who needed guidance. Please keep my email confidential. I never imagined I would interfere in the political side of things, but after seeing these questions I felt it was my duty as a scientist provide assistance. I'm available to answer any questions you may have.

Best, PK

**Bist, Kevin**

---

**From:** Pritesh K <kpritesh2@gmail.com>  
**Sent:** Tuesday, January 20, 2015 11:04 AM  
**To:** Nelson, Patricia A  
**Subject:** RE: CBD Questions

**Follow Up Flag:** Follow up  
**Flag Status:** Completed

Hi Patricia,

Thanks for your response. I am available this Friday for a phone call if that works for you.

Best, PK

On Jan 20, 2015 9:18 AM, "Nelson, Patricia A" <[Patricia.Nelson@flhealth.gov](mailto:Patricia.Nelson@flhealth.gov)> wrote:

Dr. Kumar,

First, I appreciate your concern for our process. I would be happy to discuss these issues with you, especially if you have something positive to contribute to process. Please let me know when you would be available.

Patty

Patricia Nelson

Director

Office of Compassionate Use

Florida Department of Health



**From:** Pritesh K [<mailto:kpritesh2@gmail.com>]  
**Sent:** Sunday, January 18, 2015 8:07 PM  
**To:** Nelson, Patricia A  
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Best, PK

**Bist, Kevin**

---

**From:** Nelson, Patricia A  
**Sent:** Tuesday, January 20, 2015 11:53 AM  
**To:** 'Pritesh K'  
**Subject:** RE: CBD Questions

Friday afternoon works for me. Let me know a time so I can put it on my calendar.

**From:** Pritesh K [mailto:kpritesh2@gmail.com]  
**Sent:** Tuesday, January 20, 2015 11:04 AM  
**To:** Nelson, Patricia A  
**Subject:** RE: CBD Questions

Hi Patricia,

Thanks for your response. I am available this Friday for a phone call if that works for you.

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On Jan 20, 2015 9:18 AM, "Nelson, Patricia A" <[Patricia.Nelson@flhealth.gov](mailto:Patricia.Nelson@flhealth.gov)> wrote:

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Patricia Nelson

Director

Office of Compassionate Use

Florida Department of Health



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**To:** Nelson, Patricia A

**Subject:** CBD Questions

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Best, PK

## Bist, Kevin

---

**From:** Michael Sjuggerud <Mike@cflawoffice.com>  
**Sent:** Tuesday, January 20, 2015 11:58 AM  
**To:** Nelson, Patricia A  
**Subject:** RE: Application to serve on negotiated rulemaking committee to address the regulatory structure for dispensing organizations of low-THC cannabis

Patty,

While it's unfortunate that I wasn't chosen to serve on the committee, I'll be glad to provide you with my thoughts on the rules. From what I have observed in other jurisdictions, the more restrictions that are placed on the process to cultivate, harvest, transport, dispense, and possess cannabis in a lawful manner under state and local law, the greater the likelihood that the black market will thwart the success of the program.

Regards,

Michael Sjuggerud, Esq.  
Cantwell & Goldman, P.A.  
96 Willard Street, Suite 302  
Cocoa, Florida 32922

321-639-1320 x 108  
321-639-9950 (fax)  
[mike@cflawoffice.com](mailto:mike@cflawoffice.com)

---

**From:** Nelson, Patricia A [<mailto:Patricia.Nelson@flhealth.gov>]  
**Sent:** Tuesday, January 20, 2015 9:22 AM  
**To:** 'Michael Sjuggerud'  
**Subject:** RE: Application to serve on negotiated rulemaking committee to address the regulatory structure for dispensing organizations of low-THC cannabis

Mr. Sjuggerud,

The negotiating committee was named Friday. We had a lot of interest from many very qualified people. You were not chosen for the committee, but I encourage you to contact me with thoughts on the rules as I prepare drafts for the negotiation. I am happy to accept all the help I can get.

Thank you,  
Patty

Patricia Nelson  
Director  
Office of Compassionate Use  
Florida Department of Health



---

**From:** Michael Sjuggerud [<mailto:Mike@cflawoffice.com>]

**Sent:** Friday, January 16, 2015 4:34 PM

**To:** Nelson, Patricia A

**Subject:** FW: Application to serve on negotiated rulemaking committee to address the regulatory structure for dispensing organizations of low-THC cannabis

Ms. Nelson,

Regarding my application to serve on the negotiated rulemaking committee to address the regulatory structure for dispensing organizations of low-THC cannabis, would you please let me know when the Department intends to make its final decision with respect to applicants? I am trying to plan my work schedule for early February.

Regards,

Michael Sjuggerud, Esq.  
Cantwell & Goldman, P.A.  
96 Willard Street, Suite 302  
Cocoa, Florida 32922

321-639-1320 x 108  
321-639-9950 (fax)  
[mike@cflawoffice.com](mailto:mike@cflawoffice.com)

---

**From:** Michael Sjuggerud [<mailto:Mike@cflawoffice.com>]

**Sent:** Thursday, January 08, 2015 1:15 PM

**To:** 'Patricia.Nelson@flhealth.gov'

**Subject:** Application to serve on negotiated rulemaking committee to address the regulatory structure for dispensing organizations of low-THC cannabis

Dear Ms. Nelson,

Please consider this as my application to serve on the negotiated rulemaking committee to address the regulatory structure for dispensing organizations of low-THC cannabis pursuant to the attached Notice of Development of Rulemaking.

I understand that the negotiated rulemaking committee will be selected from a variety of representative groups. I am eligible to serve on the negotiated rulemaking committee because I satisfy the requirements of two of the representative groups:

- I am member of the Florida Bar with experience in administrative law, and
- I am an individual with experience navigating regulatory structures for cannabis in other jurisdictions inasmuch as my legal practice includes assisting Florida clients with cannabis-related laws in Washington state, California, Oregon, and Colorado.

Regarding my credentials, attached please find a copy of my resume (also available at the following link: [Bio for Michael Sjuggerud, Esq.](#))

Please let me know if you have any questions or further information about the negotiated rulemaking committee. I look forward to hearing from you.

Regards,

Michael Sjuggerud, Esq.  
Cantwell & Goldman, P.A.  
96 Willard Street, Suite 302  
Cocoa, Florida 32922

321-639-1320 x 108  
321-639-9950 (fax)  
[mike@caglawoffice.com](mailto:mike@caglawoffice.com)

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Version: 2014.0.4800 / Virus Database: 4257/8959 - Release Date: 01/19/15

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Checked by AVG - [www.avg.com](http://www.avg.com)

Version: 2014.0.4800 / Virus Database: 4257/8965 - Release Date: 01/20/15

**Bist, Kevin**

---

**From:** Pritesh K <kpritesh2@gmail.com>  
**Sent:** Tuesday, January 20, 2015 11:58 AM  
**To:** Nelson, Patricia A  
**Subject:** RE: CBD Questions

Hi,

Does 330 PM EST on Friday work for you?

Best, PK

On Jan 20, 2015 11:52 AM, "Nelson, Patricia A" <[Patricia.Nelson@flhealth.gov](mailto:Patricia.Nelson@flhealth.gov)> wrote:

Friday afternoon works for me. Let me know a time so I can put it on my calendar.

**From:** Pritesh K [<mailto:kpritesh2@gmail.com>]  
**Sent:** Tuesday, January 20, 2015 11:04 AM  
**To:** Nelson, Patricia A  
**Subject:** RE: CBD Questions

Hi Patricia,

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On Jan 20, 2015 9:18 AM, "Nelson, Patricia A" <[Patricia.Nelson@flhealth.gov](mailto:Patricia.Nelson@flhealth.gov)> wrote:

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Patty

Patricia Nelson

Director

Office of Compassionate Use

Florida Department of Health



**From:** Pritesh K [mailto:kpritesh2@gmail.com]

**Sent:** Sunday, January 18, 2015 8:07 PM

**To:** Nelson, Patricia A

**Subject:** CBD Questions

Hi,

I'd like to informally introduce myself. My name is Dr. Pritesh Kumar. I am a research scientist at the University of Louisville in KY and have been doing medicinal cannabis research for several years and have published widely in the field. On the private side, I run a small company ([www.phytosciences.com](http://www.phytosciences.com)) with my fellow scientists and colleagues from around the world. We focus on quality control, quality assurance, and the development of safe, effective, and pure medicinal cannabis-based therapeutics from a clinical research perspective. We have always stayed on the medical side of the industry as we are scientists and do not believe in the recreational use. We have for the last two years been involved in a number consulting projects pertaining to helping companies in various states set up manufacturing sites and follow best practices for quality control.

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Best, PK

## Bist, Kevin

---

**From:** Nelson, Patricia A  
**Sent:** Tuesday, January 20, 2015 12:00 PM  
**To:** 'Michael Sjuggerud'  
**Subject:** RE: Application to serve on negotiated rulemaking committee to address the regulatory structure for dispensing organizations of low-THC cannabis

I appreciate your insight. Is there currently a black market for low-THC cannabis?

---

**From:** Michael Sjuggerud [<mailto:Mike@cfqlawoffice.com>]  
**Sent:** Tuesday, January 20, 2015 11:58 AM  
**To:** Nelson, Patricia A  
**Subject:** RE: Application to serve on negotiated rulemaking committee to address the regulatory structure for dispensing organizations of low-THC cannabis

Patty,

While it's unfortunate that I wasn't chosen to serve on the committee, I'll be glad to provide you with my thoughts on the rules. From what I have observed in other jurisdictions, the more restrictions that are placed on the process to cultivate, harvest, transport, dispense, and possess cannabis in a lawful manner under state and local law, the greater the likelihood that the black market will thwart the success of the program.

Regards,

Michael Sjuggerud, Esq.  
Cantwell & Goldman, P.A.  
96 Willard Street, Suite 302  
Cocoa, Florida 32922

321-639-1320 x 108  
321-639-9950 (fax)  
[mike@cfqlawoffice.com](mailto:mike@cfqlawoffice.com)

---

**From:** Nelson, Patricia A [<mailto:Patricia.Nelson@flhealth.gov>]  
**Sent:** Tuesday, January 20, 2015 9:22 AM  
**To:** 'Michael Sjuggerud'  
**Subject:** RE: Application to serve on negotiated rulemaking committee to address the regulatory structure for dispensing organizations of low-THC cannabis

Mr. Sjuggerud,

The negotiating committee was named Friday. We had a lot of interest from many very qualified people. You were not chosen for the committee, but I encourage you to contact me with thoughts on the rules as I prepare drafts for the negotiation. I am happy to accept all the help I can get.

Thank you,  
Patty

Patricia Nelson

Director  
Office of Compassionate Use  
Florida Department of Health



---

**From:** Michael Sjuggerud [<mailto:Mike@cfglawoffice.com>]  
**Sent:** Friday, January 16, 2015 4:34 PM  
**To:** Nelson, Patricia A  
**Subject:** FW: Application to serve on negotiated rulemaking committee to address the regulatory structure for dispensing organizations of low-THC cannabis

Ms. Nelson,

Regarding my application to serve on the negotiated rulemaking committee to address the regulatory structure for dispensing organizations of low-THC cannabis, would you please let me know when the Department intends to make its final decision with respect to applicants? I am trying to plan my work schedule for early February.

Regards,

Michael Sjuggerud, Esq.  
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96 Willard Street, Suite 302  
Cocoa, Florida 32922

321-639-1320 x 108  
321-639-9950 (fax)  
[mike@cfglawoffice.com](mailto:mike@cfglawoffice.com)

---

**From:** Michael Sjuggerud [<mailto:Mike@cfglawoffice.com>]  
**Sent:** Thursday, January 08, 2015 1:15 PM  
**To:** 'Patricia.Nelson@flhealth.gov'  
**Subject:** Application to serve on negotiated rulemaking committee to address the regulatory structure for dispensing organizations of low-THC cannabis

Dear Ms. Nelson,

Please consider this as my application to serve on the negotiated rulemaking committee to address the regulatory structure for dispensing organizations of low-THC cannabis pursuant to the attached Notice of Development of Rulemaking.

I understand that the negotiated rulemaking committee will be selected from a variety of representative groups. I am eligible to serve on the negotiated rulemaking committee because I satisfy the requirements of two of the representative groups:

- I am member of the Florida Bar with experience in administrative law, and
- I am an individual with experience navigating regulatory structures for cannabis in other jurisdictions inasmuch as my legal practice includes assisting Florida clients with cannabis-related laws in Washington state, California, Oregon, and Colorado.

Regarding my credentials, attached please find a copy of my resume (also available at the following link: [Bio for Michael Sjuggerud, Esq.](#))

Please let me know if you have any questions or further information about the negotiated rulemaking committee. I look forward to hearing from you.

Regards,

Michael Sjuggerud, Esq.  
Cantwell & Goldman, P.A.  
96 Willard Street, Suite 302  
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321-639-1320 x 108  
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[mike@cfglawoffice.com](mailto:mike@cfglawoffice.com)

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No virus found in this message.

Checked by AVG - [www.avg.com](http://www.avg.com)

Version: 2014.0.4800 / Virus Database: 4257/8959 - Release Date: 01/19/15

No virus found in this message.

Checked by AVG - [www.avg.com](http://www.avg.com)

Version: 2014.0.4800 / Virus Database: 4257/8965 - Release Date: 01/20/15

## Bist, Kevin

---

**From:** Pritesh K <kpritesh2@gmail.com>  
**Sent:** Tuesday, January 20, 2015 12:03 PM  
**To:** Nelson, Patricia A  
**Subject:** RE: CBD Questions

Scheduled. Look forward to speaking with you.

On Jan 20, 2015 12:00 PM, "Nelson, Patricia A" <[Patricia.Nelson@flhealth.gov](mailto:Patricia.Nelson@flhealth.gov)> wrote:

Yes.

**From:** Pritesh K [<mailto:kpritesh2@gmail.com>]  
**Sent:** Tuesday, January 20, 2015 11:58 AM  
**To:** Nelson, Patricia A  
**Subject:** RE: CBD Questions

Hi,

Does 330 PM EST on Friday work for you?

Best, PK

On Jan 20, 2015 11:52 AM, "Nelson, Patricia A" <[Patricia.Nelson@flhealth.gov](mailto:Patricia.Nelson@flhealth.gov)> wrote:

Friday afternoon works for me. Let me know a time so I can put it on my calendar.

**From:** Pritesh K [<mailto:kpritesh2@gmail.com>]  
**Sent:** Tuesday, January 20, 2015 11:04 AM  
**To:** Nelson, Patricia A  
**Subject:** RE: CBD Questions

Hi Patricia,

Thanks for your response. I am available this Friday for a phone call if that works for you.

Best, PK

On Jan 20, 2015 9:18 AM, "Nelson, Patricia A" <[Patricia.Nelson@flhealth.gov](mailto:Patricia.Nelson@flhealth.gov)> wrote:

Dr. Kumar,

First, I appreciate your concern for our process. I would be happy to discuss these issues with you, especially if you have something positive to contribute to process. Please let me know when you would be available.

Patty

Patricia Nelson

Director

Office of Compassionate Use

Florida Department of Health



**From:** Pritesh K [mailto:kpritesh2@gmail.com]

**Sent:** Sunday, January 18, 2015 8:07 PM

**To:** Nelson, Patricia A

**Subject:** CBD Questions

Hi,

I'd like to informally introduce myself. My name is Dr. Pritesh Kumar. I am a research scientist at the University of Louisville in KY and have been doing medicinal cannabis research for several years and have published widely in the field. On the private side, I run a small company ([www.phytosciences.com](http://www.phytosciences.com)) with my fellow scientists and colleagues from around the world. We focus on quality control, quality assurance, and the development of safe, effective, and pure medicinal cannabis-based therapeutics from a clinical research perspective. We have always stayed on the medical side of the industry as we are scientists and do not believe in the recreational use. We have for the last two years been involved in a number consulting projects pertaining to helping companies in various states set up manufacturing sites and follow best practices for quality control.

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**Bist, Kevin**

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**From:** Pritesh K <kpritesh2@gmail.com>  
**Sent:** Tuesday, January 20, 2015 12:04 PM  
**To:** Nelson, Patricia A  
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What is the best number to reach you at? I understand if you wish to not provide a phone number - my personal cell is 7164005274. If you prefer, you can call me at the scheduled time.

On Jan 20, 2015 12:00 PM, "Nelson, Patricia A" <Patricia.Nelson@flhealth.gov> wrote:

Yes.

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Patty

**Bist, Kevin**

---

**From:** Pritesh K <kpritesh2@gmail.com>  
**Sent:** Tuesday, January 20, 2015 12:10 PM  
**To:** Nelson, Patricia A  
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Perfect. That works for me.

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**Sent:** Tuesday, January 20, 2015 12:10 PM  
**To:** Nelson, Patricia A  
**Subject:** RE: Application to serve on negotiated rulemaking committee to address the regulatory structure for dispensing organizations of low-THC cannabis

Patty,

I don't know whether there is a black market for low-THC cannabis.

Mike

---

**From:** Nelson, Patricia A [mailto:Patricia.Nelson@flhealth.gov]  
**Sent:** Tuesday, January 20, 2015 12:00 PM  
**To:** 'Michael Sjuggerud'  
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Office of Compassionate Use  
Florida Department of Health



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**From:** Michael Sjuggerud [<mailto:Mike@cflawoffice.com>]

**Sent:** Friday, January 16, 2015 4:34 PM

**To:** Nelson, Patricia A

**Subject:** FW: Application to serve on negotiated rulemaking committee to address the regulatory structure for dispensing organizations of low-THC cannabis

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- I am an individual with experience navigating regulatory structures for cannabis in other jurisdictions inasmuch as my legal practice includes assisting Florida clients with cannabis-related laws in Washington state, California, Oregon, and Colorado.

Regarding my credentials, attached please find a copy of my resume (also available at the following link: [Bio for Michael Sjuggerud, Esq.](#))

Please let me know if you have any questions or further information about the negotiated rulemaking committee. I look forward to hearing from you.

Regards,

Michael Sjuggerud, Esq.  
Cantwell & Goldman, P.A.  
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Version: 2014.0.4800 / Virus Database: 4257/8965 - Release Date: 01/20/15

## Bist, Kevin

---

**From:** Nelson Jimenez <Nelson.Jimenez@co2meter.com>  
**Sent:** Wednesday, January 21, 2015 3:00 PM  
**To:** zzzz Feedback, Compassionate Use  
**Cc:** Michele Ferioli  
**Subject:** CO2 Meter Ormond Beach, FL

**Importance:** High

Hello & Good Day Compassionate Use Office,

CO2Meter, Inc., is an Ormond Beach, FL based designer and manufacturer of gas detection and monitoring devices. The majority of our work is for scientific organizations and medical companies. That intelligence finds its way into devices for agriculture, hospitality, and HVAC.

We are aware you have put together a council who will pick five nurseries to grow, process & dispense medical marijuana under the revamped rule released recently by the Florida Department of Health.

As the leading manufacturer of CO2 monitoring equipment in the US, we would like the opportunity to introduce ourselves to not only your division but to the growers who will be selected. We work with grow houses in various states providing them with the necessary equipment to safely monitor for CO2. As you know, CO2 is used in grow houses for the enhancement of the plants. Introduction of CO2 into the environment needs to be carefully monitored not only for the growth process but for the safety of those working in the area.

Some municipalities including Denver, Colorado have adopted regulations for the enhancement systems & the storage of CO2 which provides direction to the grow houses to ensure safety.

We would be happy to set up a conference call with your team to answer any questions you may have & provide you with any additional information.

Looking forward to working with you, your team & the growers as this process unfolds.

Thank you & have a safe day!

Nelson Jiménez Rosado  
Sales and Marketing Assistant  
English/Spanish Sales  
CO2Meter, Inc.  
131 Business Center Drive  
Ormond Beach, FL 32174  
Office Hours: M-F 8:30am-5:00pm EST  
[nelson.jimenez@co2meter.com](mailto:nelson.jimenez@co2meter.com)  
Office: 386-872-7667  
Fax: 866-422-2356



Follow us on LinkedIn: [www.linkedin.com/company/co2meter.com](http://www.linkedin.com/company/co2meter.com)

Follow us on Facebook: [www.facebook.com/co2meter](http://www.facebook.com/co2meter)

Follow us on Twitter: [www.twitter.com/co2meter](http://www.twitter.com/co2meter)

Follow us on YouTube: <http://www.youtube.com/CO2Meter>

**Bist, Kevin**

---

**From:** Arianna Cabrera <arianna@costafarms.com>  
**Sent:** Wednesday, January 21, 2015 3:49 PM  
**To:** Nelson, Patricia A  
**Subject:** Draft Rule

Hi, Patricia. Would it be possible to get a Word version of the draft rule?

Thanks!

Arianna

**Bist, Kevin**

---

**From:** robert tornello <roberttornello@me.com>  
**Sent:** Thursday, January 22, 2015 9:54 AM  
**To:** Nelson, Patricia A  
**Subject:** Truth behind the C. Web strains.

This is an in depth report on the development and current issues I thought you should be aware of.  
R

[http://blogs.westword.com/latestword/2014/12/charlottes\\_web\\_miracle\\_marijuana\\_drug\\_seizures.php](http://blogs.westword.com/latestword/2014/12/charlottes_web_miracle_marijuana_drug_seizures.php)

**Bist, Kevin**

---

**From:** Nelson, Patricia A  
**Sent:** Thursday, January 22, 2015 10:34 AM  
**To:** 'robert tornello'  
**Subject:** RE: Truth behind the C. Web strains.

Thank you!

---

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This is an in depth report on the development and current issues I thought you should be aware of.  
R

[http://blogs.westword.com/latestword/2014/12/charlottes\\_web\\_miracle\\_marijuana\\_drug\\_seizures.php](http://blogs.westword.com/latestword/2014/12/charlottes_web_miracle_marijuana_drug_seizures.php)

## Bist, Kevin

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**From:** Kostas Stoilas <stoilas@yahoo.com>  
**Sent:** Thursday, January 22, 2015 1:50 PM  
**To:** Nelson, Patricia A  
**Subject:** Re: Low-THC Cannabis Rulemaking

Thanks Patty. The nurses association is disappointed they couldn't have more time to make the committee but should still attend.

To confirm, you had told me that the public could attend but only the committee can negotiate the rules. Whether that means that the public can testify to the committee before they go into negotiations, is what we would like to determine. Is that the case, that you will still take input from the audience at the workshop on Feb 4?

Sent via mobile device...please excuse abbreviated responses & grammar.

Kostas Stoilas  
239.822.7816 cell

[www.CauseToFund.com](http://www.CauseToFund.com)

[www.WarehouseRealEstateBlog.com](http://www.WarehouseRealEstateBlog.com)

[www.Linkedin.com/in/stoilas](http://www.Linkedin.com/in/stoilas)

On Jan 22, 2015, at 10:32 AM, "Nelson, Patricia A" <[Patricia.Nelson@flhealth.gov](mailto:Patricia.Nelson@flhealth.gov)> wrote:

The committee has been selected. I have attached the Department's press release.  
Patty

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**From:** Kostas Stoilas [<mailto:stoilas@yahoo.com>]

**Sent:** Thursday, January 22, 2015 8:16 AM

**To:** Nelson, Patricia A

**Subject:** Re: Low-THC Cannabis Rulemaking

Patty - good morning. Just checking in after the holiday. Is the committee fully selected? A couple of the board members from the nurses association are curious and I believe they would be very worthwhile as committee members. Thank you.

Sent via mobile device...please excuse abbreviated responses & grammar.

Kostas Stoilas

239.822.7816 cell

[www.CauseToFund.com](http://www.CauseToFund.com)

[www.WarehouseRealEstateBlog.com](http://www.WarehouseRealEstateBlog.com)

[www.Linkedin.com/in/stoilas](http://www.Linkedin.com/in/stoilas)

On Jan 5, 2015, at 5:11 PM, "Nelson, Patricia A" <[Patricia.Nelson@flhealth.gov](mailto:Patricia.Nelson@flhealth.gov)> wrote:

Dear Interested Parties,

Please see the attached Notice of Negotiated Rulemaking (on page 1 of the attached document) scheduled for February 4 and 5, 2015, in Tallahassee.

Sincerely,

Patty  
Patricia Nelson  
Director  
Office of Compassionate Use

**Bist, Kevin**

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**From:** zzzz Feedback, Compassionate Use  
**Sent:** Thursday, January 22, 2015 1:57 PM  
**To:** Nelson, Patricia A  
**Subject:** FW: Proposed Rules

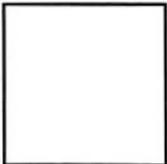
FYI.

**From:** julio lopez [<mailto:fcd1910@gmail.com>]  
**Sent:** Friday, January 16, 2015 1:04 PM  
**To:** zzzz Feedback, Compassionate Use  
**Subject:** Proposed Rules

Ms. Nelson,

The newly proposed rules to maintain the dispensing of medical cannabis with the growers is not in accordance with the ruling from the administrative judge which dictated that dispensing should be done by multiple agencies not affiliated with the growers in order to provide convenient access to patients. Our organization strongly opposes this rule and respectfully requests that the orders of the administrative judge are reflected.

Julio A. Lopez, PhD  
President/CEO  
Florida Cannabis Dispensaries, Inc.



[Facebook](#)

## **Bist, Kevin**

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**From:** Chris Finkbeiner <chris@rubingroup.com>  
**Sent:** Thursday, January 22, 2015 2:27 PM  
**To:** Nelson, Patricia A  
**Subject:** Suggested Revisions  
**Attachments:** Draft Rule Revisions - 1-22-2015.pdf

Patty,

Thank you for your call this morning. I very much appreciate you getting back to me.

On behalf of our client, Surterra, we would like to submit the attached suggested revisions to the rule.

If you have any questions, or would like to discuss any of these changes further, please don't hesitate to contact me. We would be happy to walk through our arguments and rationale whenever is convenient for you.

Thank you.

Chris Finkbeiner  
The Rubin Group  
(c) 850-570-4747  
(o) 850-681-9111  
(e) [chris@rubingroup.com](mailto:chris@rubingroup.com)

RULE NO.:	RULE TITLE:
64-4.001	Definitions
64-4.002	Initial Application Requirements for Dispensing Organizations
64-4.003	Biennial Renewal Requirements for Dispensing Organizations
64-4.004	Revocation of Dispensing Organization Approval
64-4.005	Inspection Procedures
64-4.006	Identification, Labeling and Testing
64-4.007	Recordkeeping and Reporting Requirements
64-4.008	Procedural Requirements
64-4.009	Compassionate Use Registry

64-4.001 Definitions.

For the purposes of this chapter, the following words and phrases shall have the meanings indicated:

(1) Applicant – An organization that meets the requirements of Section 381.986(5)(b)1., F.S., applies for approval as a dispensing organization, and identifies a nurseryman as defined in s. 581.011 who will serve as the operator.

(2) Approval – Written notification from the department to an applicant that its application for dispensing organization approval has been found to be in compliance with the provisions of this chapter and that the department is awaiting notification that it is prepared to be inspected and authorized to begin cultivation and other operations.

(3) Authorization – Written notification by the department to a dispensing organization that it may begin specific phases of operation including cultivation, harvesting, processing, dispensing and other activities authorized by this chapter involving the possession of low-THC cannabis and the production of low-THC cannabis derivative products. Authorization may be requested and given in stages as the infrastructure and staffing requirements of the operation are completed.

(4) Banking Relationship – means a Federal or State chartered bank that provides a letter to the Applicant stating it is ready and willing to receive cash deposits from sale of low-THC cannabis.

(4)(5) Batch - means a specific lot of low-THC cannabis derivative product produced from one or more harvests of low-THC cannabis plants that are processed or blended into a uniform mixture before portioning such that all products bearing the same batch number would be expected to be representative of the entire batch for the purpose of laboratory testing.

(5)(6) Batch number - means a unique numeric or alphanumeric identifier assigned to a batch by a dispensing organization when the batch is portioned and packaged for dispensing.

(6)(7) Certified financials – ~~[FBD]~~ means 2-year financial projections prepared by a registered CPA, including all itemized capital expenditures, construction, renovation and build-out costs, reasonable production and yield estimates in grams, revenue estimates based on a \$6 dollars per gram market price, and all variable operating costs including salaries, fertilizer, electricity and corporate overhead. Projections should show total upfront cash outlays required and maximum cash drawdown under a “Stress Test” scenario. Certified Financials must include a certified Letter of Credit from a Banking Relationship showing the Applicant possesses the necessary cash on hand to fund all upfront cash outlays and maximum cash drawdown under the Stress Test.

(7)(8) Cultivation - means the growth of source plant or tissue culture material.

(8)(9) Derivative product – means forms of low-THC cannabis suitable for routes of administration, e.g., vapor, resins, salts, extracts, capsules, oral sprays, nasal sprays, and any compound, manufacture, mixture or preparation derived from low-THC cannabis that is dispensed by a dispensing organization.

(9)(10) Dispensing Region – A geographical area where the growing and production of low-THC cannabis under the control of a dispensing organization occurs. The five dispensing regions shall be identified as follows:

(a) Northwest Florida Region consisting of Bay, Calhoun, Escambia, Franklin, Gadsden, Gulf, Holmes, Jackson, Jefferson, Leon, Liberty, Madison, Santa Rosa, Okaloosa, Taylor, Wakulla, Walton, and Washington counties.

(b) Northeast Florida Region consisting of Alachua, Baker, Bradford, Clay, Columbia, Dixie, Duval, Flagler, Gilchrist, Hamilton, Lafayette, Levy, Marion, Nassau, Putnam, St. Johns, Suwannee, and Union counties.

(c) Central Florida Region consisting of Brevard, Citrus, Hardee, Hernando, Indian River, Lake, Orange, Osceola, Pasco, Pinellas, Polk, Seminole, St. Lucie, Sumter, and Volusia counties.

(d) Southwest Florida Region consisting of Charlotte, Collier, DeSoto, Glades, Hendry, Highlands, Hillsborough, Lee, Manatee, Okeechobee, and Sarasota counties.

(e) Southeast Florida Region consisting of Broward, Dade, Martin, Monroe, and Palm Beach counties.

(10)(11) Dispensing Organization – an organization that meets the requirements of Section 381.986(5)(b)1., F.S., which has been approved by the department to cultivate, process and dispense low-THC cannabis.

(11) Dispensing Organization Facility – One or multiple structures on contiguous properties that are used

by the dispensing organization for the preparation, cultivation, storage, processing, or dispensing of low-THC —  
cannabis.

(12)

~~Harvest — A specific lot of low-THC cannabis plants grown from one or more seeds, cuttings or tissue cultures, that are planted, cloned or cultured and harvested at the same time such that any plant in the harvest is expected to be representative of the entire harvest for the purposes of laboratory testing.~~

(13) Harvest – A specific lot of low-THC cannabis plants grown from one or more seeds, cuttings or tissue cultures, that are planted, cloned or cultured and harvested at the same time such that any plant in the harvest is expected to be representative of the entire harvest for the purposes of laboratory testing.

~~(12)~~(14) Harvest number - means a unique numeric or alphanumeric identifier assigned to a harvest by a dispensing organization when the harvest is planted.

~~(13)~~(15) Inventory Agent – An employee of the dispensing organization who has been designated in writing to have oversight of the inventory control system.

~~(14)~~(16) Manager – Any person with the authority to exercise operational direction or management of the dispensing organization or the authority to supervise any employee of the dispensing organization such as, the following:

(a) All directors, officers, board members and managers identified in the most recent annual report filed with the Florida Division of Corporations;

(b) The inventory agent;

(c) The security director;

(d) The medical director; and

(e) If the dispensing organization is a joint venture, all persons who have a direct or indirect interest in each joint venture partner as well as all persons who have the authority to exercise operational direction or management of the dispensing organization or have the authority to supervise any employee of the dispensing organization.

~~(15)~~(17) Owner – Any person, including any individual or other legal entity, with a direct or indirect ownership interest of 5% or more in the applicant, including the possession of stock, equity in capital, or any interest in the profits of the applicant.

~~(16)~~(18) Permanent resident – A person has his or her true, fixed and permanent home in Florida to which, whenever absent, he or she has the intention of returning. Once a permanent residence is established in Florida it is presumed to continue until the resident shows that a change has occurred. Any person who has established a residence in this state may manifest and evidence the same by filing a sworn statement pursuant to Section 222.17, F.S.

~~(17)~~(19) Routes of administration – means the path by which a low-THC cannabis derivative product is ordered by a physician to be taken into the body, and includes oral, topical, transdermal, and nasal administration.

~~(18)~~(20) Sanitation Protocol - A set of identified policies and procedures of an applicant or dispensing organization that details required sanitation procedures within the dispensing organization facility including personnel and visitor dress protocols, equipment sanitation requirements, facility sanitation requirements, disposal procedures, and employee hygiene requirements.

(21) Stress Test – means a financial projection scenario prepared by a CPA where the market price of low-THC cannabis is forecast to decline by 50% and the operating costs to produce low-THC cannabis increase by 50%.

~~(19)~~(22) Tissue culture – Technique of cultivating low-THC cannabis plant tissue in a prepared medium and the low-THC cannabis plant tissue so cultivated.

~~—Transportation plan—Method of transporting up to a 90-day supply of low-THC cannabis derivative product for each qualified patient served on the trip from the dispensing organization to qualified patients in the state which documents, at a minimum, confirmation of the order from the registry, confirmation from the qualified patient that he or she requests delivery, place of delivery, date and time of trip, route of transportation, security of the low-THC cannabis product or products being transported, signature of the qualified patient or the qualified patient's legal representative receiving the order, and creation and maintenance of a log of all low-THC derivative products transported.~~

Rulemaking Authority 381.986(5)(d) FS. Law Implemented 381.986(5)(b) FS. History—New \_\_\_\_\_.

#### 64-4.002 Initial Application Requirements for Dispensing Organizations.

Each nursery that meets the requirements of Section 381.986(5)(b)1., F.S., desiring to be approved as a dispensing organization shall make application to the department using Form DH8006-OCU-12/2014, "Application for Low-THC Cannabis Dispensing Organization Approval" herein incorporated by reference and available at <https://flrules.com/gateway/reference.asp?No=Ref-####>. The completed application form must include the following:

(1) An initial application fee of \$x.xx;

(2) An explanation or written documentation, as applicable, showing how the Applicant meets the statutory criteria listed in section 381.986(5)(b), F.S. In any explanation, the Applicant must address each item listed for each criterion below. The Applicant must disclose the name, position, and resume of the employee(s) who provides the knowledge or experience explained for each item.

(a). The technical and technological ability to cultivate and produce low-THC cannabis. Please address the following items:

1) Cultivation Experience, including:

a) Experience cultivating plants most similar in genetic structure to cannabis;

- b) Experience cultivating plants for human consumption such as food or medicine products;
  - c) Experience with tissue culturing or plant genetics;
  - d) Experience using clean growing rooms;
  - e) Knowledge of cannabis cultivation, including proper cultivation conditions and techniques, additives that can be used when growing cannabis and pests and nutritional deficiencies common for cannabis; and
  - f) Demonstrable access to the greatest number of strains of low-THC cannabis.
- 2) Technological Experience, including:
- a) Experience tracking each plant in a harvest;
  - b) Experience tracking every employee's interaction with each plant in a harvest;
  - c) Experience in automation of cultivation, processing and packaging; and
  - d) Experience employing state-of-the-art greenhouse technology.
- 3) Compounding Pharmaceutical Experience, including:
- a) Experience handling DEA scheduled substances;
  - b) Experience managing employees who handle DEA scheduled substances;
  - c) Experience delivering DEA scheduled substances through multiple routes of administration;
  - d) Experience compounding custom medicines for individual patients;
  - e) Experience managing licenses pharmacists in Florida;
  - f) Experience gathering, managing and handling confidential patient data;
  - g) Knowledge of low-THC extraction techniques;
3. Experience cultivating cannabis;
- 4. Experience growing plants not native to Florida;
5. Experience cultivating plants for human consumption such as food or medicine products;

6. ~~Experience with tissue culturing or plant genetics;~~
7. ~~Experience using clean growing rooms;~~
8. ~~Knowledge of cannabis cultivation, including:~~
  - ~~— Proper cultivation conditions and techniques;~~
  - ~~— Additives that can be used when growing cannabis;~~
  - ~~— Pests and nutritional deficiencies common for cannabis;~~
  - ~~— Production of high quality product in a short time.~~
13. ~~Experience with tracking each plant in a harvest;~~
14. ~~Experience with good manufacturing practices;~~
15. ~~Experience with analytical and organic chemistry;~~
16. ~~Experience with analytical laboratory methods;~~
17. ~~Experience with analytical laboratory quality control, including maintaining a chain of custody;~~
18. ~~Knowledge of and experience with CBD/low-THC extraction techniques;~~
19. ~~Knowledge of CBD/low-THC routes of administration;~~
20. ~~Knowledge of and experience with producing CBD/low-THC products;~~
21. ~~Experience interacting with patients;~~
22. ~~Experience with handling confidential information;~~
23. ~~Experience gathering and managing data, i.e. data on patient reactions to products dispensed; and~~
24. ~~Any awards or recognition received for relevant expertise.~~

~~(y)(b)~~ Written documentation demonstrating that 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, is operated by a nurseryman as defined in s. 581.011, and has been operated as a registered nursery in this state for at least 30 continuous years.

~~(z)(c)~~ The ability to secure the premises, resources, and personnel necessary to operate as a dispensing organization. Please address the following items, and include resumes, maps and/or photos for each:

1. Location of all properties Applicant proposes to utilize to cultivate, produce, and distribute low-THC cannabis, including ownership information for the properties and any lease terms if applicable;
2. Site plan for each property proposed;
3. Description of the areas proposed for the cultivation of low-THC cannabis, including the following:
  - a. Capacity, in number of plants;
  - b. Cultivation environment, e.g., greenhouse, clean room, aseptic, et cetera;
  - c. Irrigation system(s);
  - d. Lighting control system(s);
  - e. Temperature control system(s); and
  - f. Any equipment or processes designed to reduce the environmental impact of the chosen cultivation technique(s);
4. Back-up systems for all cultivation and processing systems;
5. Description of any onsite laboratory facilities, including the following:
  - a. Extraction equipment and location;
  - b. Concentration equipment and location;
  - c. Analytical equipment, including separators and detectors, and location;
  - d. Safety equipment and facilities and location;
  - e. Computer systems and software;
  - f. Any equipment or processes designed to reduce the environmental impact of the any laboratory processes, e.g., solvent recapture;
6. Description of the areas proposed for the production of low-THC cannabis derivative products, including the following:
  - a. Production equipment; and
  - b. Any equipment designed to reduce the environmental impact of the chosen production technique(s).
7. Description of the areas proposed for the distribution of low-THC cannabis derivative products, including the following:
  - a. Accessibility of dispensing facilities, e.g., centrally located to several populated areas, located on a main roadway, not in a high crime area, et cetera; and
  - b. Proximity of dispensing facilities to patient populations.
8. Employment of a Pharmacist licensed to practice in Florida;
- 8.9. A list of current and proposed staffing including position, duties and responsibilities;

9-10. An organizational chart illustrating the supervisory structure of the proposed dispensing organization;  
and

11. Plans and procedures for loss of key personnel.

12. Banking Relationships that will allow for the deposit of cash sales and acceptance of debit and credit payments from qualified patients.

~~10.~~

~~(aa)(d)~~ 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. Please address the following items for each property or location:

1. Experience and qualification of the Security Director and support staff;

~~1-2.~~ Floor plan of each facility or proposed floor plans for proposed facilities, including the following:

a. Locking options for each means of ingress and egress;

b. Alarm systems;

c. Video surveillance;

d. Name and function of each room;

e. Layout and dimensions of each room;

~~2-3.~~ Diversion and trafficking prevention procedures;

~~3-4.~~ A facility emergency management plan;

~~4-5.~~ System for tracking cuttings, seedlings, or seeds throughout the cultivation, processing, and distribution processes;

~~5-6.~~ Vehicle tracking systems;

~~6-7.~~ Vehicle security systems;

~~7-8.~~ Methods of screening and monitoring employees;

~~8-9.~~ Personnel qualifications and experience with chain of custody or other tracking mechanisms;

~~9-10.~~ Personnel reserved solely for inventory control purposes; and

~~10-11.~~ Access to specialized resources or expertise regarding security or tracking.

~~(bb)(e)~~ An infrastructure reasonably located to dispense low-THC cannabis to registered patients statewide or regionally as determined by the department. Please address the following items:

1. Access to a salesforce of experience pharmaceutical sales representatives;

2. Access to a courier delivery service for distributing medicines;

~~1-3.~~ A map showing the location of the applicant's proposed dispensing facilities;

~~2-4.~~ A site plan of the actual or proposed dispensing location showing streets; property lines; buildings; parking areas; outdoor areas, if applicable; fences; security features; fire hydrants, if applicable; and access to water and sanitation systems; and

~~3-5.~~ A floor plan of the actual or proposed building or buildings where dispensing activities will occur showing:

a. Areas designed to protect patient privacy;

b. Areas designed for patient consultation;

~~4-6.~~ A centralized computer system or network utilized by all facilities;

~~5-7.~~ Vehicles that will be used to transport product among cultivating, producing, and dispensing facilities;

~~6-8.~~ Communication systems;

~~7-9.~~ Vehicle tracking and security systems; and

~~8-10.~~ Hours of operation of each dispensing facility.

~~(ee)(f)~~ The financial ability to maintain operations for the duration of the 2-year approval cycle, including the provision of certified financials to the department. In addition to submitting certified financials, please address the following items (or reference to where that item appears in the certified financials):

1. Bank Letter of Credit showing Applicant's ability to fund proposed cash outlays and maximum cash drawdown in a Stress Test with existing cash on hand;

~~1-2.~~ Applicant's corporate structure;

~~2-3.~~ All owners of the Applicant;

4. Combined net assets of all owners of the Applicant;

~~3-5.~~ All subsidiaries of the Applicant;

~~4-6.~~ Any other individuals or entities for which the Applicant is financially responsible;

~~5-7.~~ Net Assets of the Applicant and Applicant's subsidiaries;

~~6-8.~~ Liabilities of the Applicant and Applicant's subsidiaries;

~~7-8.~~ Any pending lawsuits to which the Applicant is a party;

~~8-9.~~ Any lawsuits within the past 10 years to which the Applicant was a party; and

~~9-10.~~ All financial obligations of Applicant that are not listed as a "liability" in the certified financials.

~~(dd)(g)~~ That all owners and managers have been fingerprinted and have successfully passed a level 2 background screening pursuant to s. 435.04, F.S. within the calendar year prior to application. Please submit the

screening report for each owner and manager , including a list of all owners and managers indicating the date of each individual's most recent Level-2 background screening.;

(ee)(h) The employment of a medical director who is a physician licensed pursuant to chapter 458 or chapter 459, F.S. to supervise the activities of the proposed dispensing organization.

(ff)(i) The ability to post a \$5 million performance bond [conditions TBD] for the biennial approval cycle.  
The performance bond shall be posted via deposit into an escrow account held by the Florida Department of Health.

(3) If the applicant intends to claim any exemption from public records disclosure under Section 119.07, F.S., or any other exemption from public records disclosure provided by law for any part of its application, it shall indicate on the application the specific sections for which it claims an exemption and the basis for the exemption.

(4) Failure to submit the \$x.xx application fee or documentation sufficient to establish the applicant meets the requirements of section 381.986(5)(b), F.S., shall result in the application being denied prior to any scoring as contemplated in section (5) of this rule.

(5) Any "Application for Low-THC Cannabis Dispensing Organization Approval" and all required exhibits and supporting documents shall be delivered to the Agency Clerk of the Department of Health physically located at 2585 Merchants Row Boulevard in Tallahassee, Florida, no earlier than 10:00 AM, Eastern Time, on the effective date of this rule and no later than 5:00 PM, Eastern Time, xx calendar days after the effective date of this rule.

(a) The department will substantively review, evaluate, and score applications using Form DH8007-OCU-12/2014, "Scorecard for Low-THC Cannabis Dispensing Organization Selection" herein incorporated by reference and available at <https://flrules.com/gateway/reference.asp?No=Ref-#####>. The scorecard includes each of the items listed above with each item weighted [TBD]. Each item will be scored on a scale of [TBD] then multiplied by the weighting factor [TBD]. The department's substantive review will be completed by:

1. Director of the Office of Compassionate Use;
2. A member of the Drug Policy Advisory Council appointed by the State Surgeon General; and
3. A Certified Public Accountant appointed by the State Surgeon General.

Scorecards from each of the three substantive review panel members will be combined to generate an aggregate score for each application. The applicant with the highest aggregate score in each dispensing region shall be selected as the region's dispensing organization.

(b) Upon notification that it has been selected as a region's dispensing organization, the applicant shall have 10 calendar days to post a \$5 million performance bond.

(c) If the selected applicant fails to post the bond within the required timeframe, the applicant with the next highest score in the dispensing region shall be selected and notified.

Rulemaking Authority 381.986(5)(d) FS. Law Implemented 381.986(5)(b) FS. History--New \_\_\_\_\_.

#### 64-4.003 Biennial Renewal Requirements for Dispensing Organizations.

(1) No less than six months prior to the expiration of an existing dispensing organization's two year authorization to dispense low-THC cannabis derivative products, the dispensing organization shall make application for renewal of the dispensing organization approval using Form DH8006-OCU-096/2014, "Application for Low-THC Cannabis Dispensing Organization Approval" herein incorporated by reference and available at <https://flrules.com/gateway/reference.asp?No=Ref-#####>, indicating that the application is a renewal application.

(2) In addition to the completed application form, dispensing organization renewal applicants shall:

(a) Demonstrate that they continue to meet the requirements of Section 381.986(5)(b)1.-7., F.S., by updating the documentation submitted with the original application or providing a notarized statement that there have been no changes;

(b) Provide written documentation that any violations noted during any inspections or investigations by the department have been corrected;

(c) Provide written documentation of compliance with the financial requirements of Section 381.986(5)(b)5., F.S., for the previous two years;

(d) Report how much cannabis oil was produced in the previous two years of operation; and

(e) Report how many patients were served in the previous two years of operation.

(3) If the dispensing organization meets the requirements of Section 381.986(5)(b), F.S., and this chapter, the department shall notify the dispensing organization that it intends to renew the approval.

(4) Upon notification that its renewal will be approved, the dispensing organization shall have 30 calendar days to pay a nonrefundable \$xx renewal fee to the department and to provide proof that its \$5 million performance bond remains in effect.

(5) If the dispensing organization fails to renew within the required timeframes, the department shall seek new applications for a dispensing organization in the applicable dispensing region by posting notice in the Florida Administrative Register and thereafter following the procedures in rule 64-4.002, F.A.C.

(6) A dispensing organization that fails to renew its approval shall not dispense low-THC cannabis products after midnight local time on the date that its authorization expires and shall destroy through incineration all low-THC cannabis in its possession within 48 hours of the last dispensing day. Any undestroyed low-THC cannabis

remaining under the control of the dispensing organization more than 48 hours after the last dispensing day shall be seized and destroyed by the department.

#### 64-4.004 Revocation of Dispensing Organization Approval.

- (1) The department shall revoke its approval of the dispensing organization if the dispensing organization:
  - (a) Cultivates low-THC cannabis before obtaining department authorization; or
  - (b) Knowingly dispenses, delivers, or otherwise transfers low-THC cannabis derivative product to an individual other than a qualified patient or a qualified patient's legal representative; or
- (2) The department may revoke a dispensing organization's approval or authorization if the dispensing organization does not:
  - (a) Comply with the requirements in Section 381.986, F.S., or this rule chapter;
  - (b) Implement the policies and procedures or comply with the statements provided to the department with the original or renewal application;
  - (c) Seek authorization to begin cultivation within 75 calendar days of application approval; or
  - (d) Begin dispensing within 150 calendar days of the authorization granted pursuant to subsection 64-4.005(2), F.A.C.

Rulemaking Authority 381.986(5)(d) FS. Law Implemented 381.986(5)(b) FS. History--New

#### 64-4.005 Inspection and Authorization Procedures.

- (1) Submission of an application for dispensing organization approval constitutes permission for entry by the department at any reasonable time into any dispensing organization facility to inspect any portion of the facility; review the records required pursuant to Section 381.986, F.S., or this chapter; and collect samples of any low-THC cannabis or low-THC cannabis derivative product for laboratory analysis. All inspectors shall follow the dispensing organization's sanitation protocol when conducting any inspection.
- (2) No less than 30 calendar days prior to the initial cultivation of low-THC cannabis, the dispensing organization shall notify the department that the dispensing organization is ready to begin cultivation, the dispensing organization is in compliance with Section 381.986, F.S., and this rule chapter and is seeking authorization to begin cultivation. No low-THC cannabis, including seeds, tissue culture, and cuttings, may be present in any dispensing organization facility prior to authorization by the department.
- (3) No less than 10 calendar days prior to the initial production or dispensing of low-THC cannabis, the dispensing organization shall notify the department that the dispensing organization is ready to begin production or dispensing, the dispensing organization is in compliance with Section 381.986, F.S., and this chapter and is seeking authorization to begin production or dispensing.
- (4) If the department identifies a violation of Section 381.986, F.S., or this chapter during an inspection of a dispensing organization facility, the dispensing organization shall notify the department in writing, within 20 business days after the date of receipt of the written notice of violation, identifying the corrective action taken and the date of the correction.

Rulemaking Authority 381.986(5)(d) FS. Law Implemented 381.986(5)(b) FS. History--New

#### 64-4.006 Identification, Labeling and Testing Low-THC Cannabis Seeds, Dried Flowers and Derivative Products.

- (1) A dispensing organization shall ensure that the low-THC cannabis derivative product provided to a qualified patient is in medical grade, childproof containers labeled with:
  - (a) The dispensing organization name and location;
  - (b) The amount, harvest number, and batch number of the low-THC cannabis derivative product being dispensed;
  - (c) The date of product processing or production;
  - (d) A list of all additives, including pesticides, herbicides, fertilizers, and solvents, used in the cultivation and production of the low-THC cannabis derivative product;
  - (e) A list of all matrix ingredients used to make the low-THC cannabis derivative product, e.g., olive oil, canola oil, et cetera;
  - (f) The percent by weight of tetrahydrocannabinol (THC) and cannabidiol (CBD);
  - (g) Identification and percentages of all specific cannabinoids in the low-THC cannabis derivative product, if known;
  - (h) The name of the ordering physician; and
  - (i) The registry identification number of the qualified patient.

(2) Prior to dispensing any low-THC derivative product, a dispensing organization shall sample and have tested by a [TBD] each batch of each product to be distributed. The testing laboratory shall file with the department an electronic copy of each laboratory test result for any batch that does not pass the microbial, mycotoxin, heavy metal, pesticide, chemical residue or residual solvents levels test or meet the composition requirements required by s. 381.986(1)(b), F.S. Dispensing shall not occur until the test results have been received by the dispensing organization. Testing shall include at a minimum [use *U.S. Pharmacopeia Herbal Medicines Compendium?*]:

- (a) Tetrahydrocannabinol concentration reported as a percentage by weight;
- (b) Cannabidiol concentration reported as percentage by weight;
- (c) Bacteria and molds, including aerobic bacteria, *E. coli*, enterobacteria, powdery mildew, penicillium, yeast, aspergillus, cladosporin, fusarium, botrytis, aureobasidium and acremonium;
- (d) Heavy metals; and
- (e) All chemical additives, including nonorganic pesticides, herbicides, and fertilizers, and solvents used in the cultivation and production of the low-THC cannabis reported as parts per billion.

(3) The dispensing organization shall provide copies of any test results to the department upon request.

(4) If any batch sample test result shows the presence of any bacteria, mold, heavy metal, or chemical additive over the Health Advisory Level (HAL) as provided in the department's Environmental Chemistry Analyte List [use *U.S. Pharmacopeia Herbal Medicines Compendium?*], dated July 31, 2014, herein incorporated by reference and available at <https://flrules.com/gateway/reference.asp?No=Ref-#####>, the entire batch from which the sample was derived shall be identified and segregated to prevent further processing or distribution. The entire batch shall be [TBD].

(5) Any batch sample or any other sample that exceeds 0.8% tetrahydrocannabinol by weight or has 10% or less of cannabidiol by weight shall be segregated to prevent further processing or dispensing. If the batch cannot be made to conform to the requirements of section 381.986(1)(b), F.S., within 10 days, the batch shall be destroyed.

(6) Upon request from the department, a dispensing organization shall submit a sample of any specific seed, dried flower or derivative product from the low-THC cannabis inventory to a laboratory selected by the department for analysis and reporting to the department.

(7) Laboratories shall immediately destroy any untested low-THC cannabis or low-THC cannabis derivative product upon the completion of the testing. Laboratories shall retain the tested sample for 30 calendar days to allow for retesting before destroying the sample. If the low-THC cannabis or low-THC cannabis derivative product is destroyed, the time and method of destruction or disposal shall be documented.

(8) All low-THC derivative products shall be maintained in an appropriately climate-controlled environment.

Rulemaking Authority 381.986(5)(d) FS. Law Implemented 381.986(5)(b) FS. History—New

#### 64-4.007 Recordkeeping and Reporting Requirements.

(1) A dispensing organization shall designate in writing an inventory agent who has oversight of the inventory control system.

(2) A dispensing organization shall establish and implement an inventory control system for the low-THC cannabis plants and derivative products that documents:

(a) Each day's beginning and ending inventory of seeds, tissue cultures, cuttings, plants harvests, processed low-THC cannabis derivative products, sales, disbursements, and disposed, unusable plants or low-THC cannabis derivative products;

(b) For each harvest of low-THC cannabis cultivated:

- 1. The harvest number;
- 2. Whether the harvest originated from seeds, tissue culture, or cuttings;
- 3. The strain of the seeds, tissue culture, or cuttings planted;
- 4. The number of seeds, tissue culture, or cuttings planted;
- 5. The date the seeds, tissue culture, or cuttings were planted;
- 6. A list of all additives, including pesticides, herbicides, and fertilizers used in the cultivation;
- 7. The number of low-THC plants grown to maturity and harvested;
- 8. Method and date of disposal of plants not grown to maturity;
- 9. Date of harvest;
- 10. Final harvest yield weight - gross;
- 11. Weight of low-THC plants or plant parts not used for the production of dispensable products;
- 12. Final harvest yield weight - net;
- 13. Name of the inventory agent responsible for the harvest, and

14. The disposal through incineration or composting of low-THC plants or plant parts not used for the production of dispensable products including the:

a. Description of and reason for disposal including, if applicable, the number of failed or other unusable plants;

b. Date of disposal;

c. Method of disposal; and

d. Name of the employee responsible for the disposal.

(c) For each batch of low-THC cannabis derivative product produced:

1. The batch number;

2. The harvest number(s) of the low-THC plants incorporated into the batch;

3. The name (if applicable) of the low-THC cannabis derivative product produced;

4. Form and quantity of low-THC cannabis derivative product produced;

5. Date sampled for laboratory analysis;

6. Laboratory sample results; and

7. Date laboratory results were received.

(d) For each low-THC cannabis derivative product dispensed:

1. Name (if applicable) of the low-THC cannabis derivative product;

2. Form of the low-THC cannabis derivative product;

3. Batch number;

4. A list of all matrix ingredients used to make the low-THC cannabis derivative product, e.g., olive oil, canola oil, et cetera;

5. The percent by weight of tetrahydrocannabinol (THC) and cannabidiol (CBD);

6. Identification and percentages of all specific cannabinoids in the low-THC cannabis derivative product, if known;

7. Amount of each low-THC cannabis derivative product dispensed;

8. The name of the ordering physician;

9. The registry identification number of the qualified patient; and

10. The price of the low-THC cannabis derivative product dispensed.

(e) For low-THC cannabis derivative products disposed:

1. Name (if applicable) of the low-THC cannabis derivative product, form, batch number and amount;

2. Reason for disposal; and

3. Method of disposal.

(3) The inventory agent shall conduct and document an audit of the dispensing organization's inventory at least once every 30 days. If the audit identifies a discrepancy in the amount of low-THC cannabis or low-THC cannabis derivative product, the dispensing organization shall determine where the discrepancy has occurred and take and document immediate corrective action. The dispensing organization shall notify the department of any identified discrepancy and the corrective action taken within five business days of the identification of the discrepancy. If criminal activity is suspected, the dispensing organization shall immediately report the suspicion to law enforcement officials.

(4) The dispensing organization shall maintain the required documentation for a minimum of five years from the date of the document and provide the documentation to the department upon request.

Rulemaking Authority 381.986(5)(d) FS. Law Implemented 381.986(5)(b) FS. History—New

#### 64-4.008 Procedural Requirements.

(1) A dispensing organization shall:

(a) Ensure that dispensing hours of operation, at a minimum, adhere to the dispensing availability proposed in the approved application, and that its dispensary is operating and available to dispense low-THC cannabis derivative product to any qualified patient on a regular schedule. The dispensing hours of operation shall be prominently displayed in the dispensary, posted on the dispensing organization's website, and available upon request to qualified patients, their legal representatives, the department, and ordering physicians;

(b) Develop, document, and implement policies and procedures regarding:

1. Training and adherence to requirements for protecting patient privacy;

2. Inventory control; and

3. Patient records;

(c) Maintain policies and procedures and provide copies to the department upon request;

(d) Post the following information in a place that can be viewed by individuals entering the dispensing facility:

1. Name of the dispensing organization;
2. Name of the medical director and the medical director's license number; and
3. Hours of operation;

(e) Limit access to all dispensing organization facilities to owners, managers, dispensing organization employees, qualified patients, legal representatives of qualified patients, authorized inspectors, and authorized visitors. Authorized visitors must wear an identifying badge and be escorted and monitored at all times by an owner, manager, or employee. The dispensing organization shall create and maintain a visitor log and the name of any visitor and the date and duration of the visit shall be entered in the log. All authorized visitors must comply with the sanitation protocol of the dispensing organization; and

(f) Advise the department within seven calendar days of any change in medical director. A dispensing organization cannot operate in the absence of a medical director.

(2) The dispensing organization shall cultivate, process, store, dispense, and perform any other activity involving low-THC cannabis in [TBD].

(3) The dispensing organization shall make reasonable efforts to mitigate odors.

(4) The dispensing organization shall ensure that all buildings and equipment used for the cultivation, harvest, preparation, packaging, storage, or sale of low-THC cannabis and low-THC cannabis derivative products are maintained [TBD].

(a) Low-THC cannabis in the process of preparation, production, packing, storage, sale or dispensing shall be protected from insects, dust, dirt and other contamination in fully enclosed rooms.

(b) Refuse or waste products incident to the manufacture, preparation, packing, selling, or distribution of low-THC cannabis and low-THC cannabis derivative products shall be [TBD].

(c) All trucks, trays, buckets, other receptacles, platforms, racks, tables, shelves, knives, saws, cleavers, other utensils, or the machinery used in moving, handling, cutting, chopping, mixing, canning, packaging, or other processes shall be cleaned at least once every 24 hours.

(6) The medical director must be [TBD- and must designate a back-up medical director when not so available. The medical director shall provide for standards and protocols that ensure proper testing of low-THC medical cannabis derivative products for potency and contamination. The medical director shall assist with the development and implementation of policies and procedures regarding, at a minimum, emergency responses, sanitation protocols, compliance with state and federal regulations regarding confidentiality of personally identifiable health information, quality assurance, and disease prevention. The medical director shall also respond to the department and local municipalities regarding compliance with rules and regulations and community health and public safety concerns. If the medical director determines that any employee of the dispensing organization has a health condition that may adversely affect the safety or quality of the low-THC cannabis or derivative products, the employee shall be prohibited from direct contact with any product or equipment or materials for processing low-THC cannabis until the medical director determines that the employee's health condition will not adversely affect the safety and quality of the low-THC cannabis.]

Rulemaking Authority 381.986(5)(d) FS. Law Implemented 381.986(5)(b) FS. History—New

#### 64-4.009 Compassionate Use Registry.

(1) Ordering physicians licensed under Chapter 458 or 459, F.S., meeting the educational requirements of Section 381.986(4), F.S., may access the Compassionate Use Registry using their existing MQA Services credentials.

(2) Designated persons may request access to the Compassionate Use Registry by completing form DH8008-OCU-12/2014, "Request for Access to the Compassionate Use Registry," herein incorporated by reference and available at <https://flrules.com/gateway/reference.asp?No=Ref-#####>. Those requesting access must meet one of the following criteria:

(a) Authorized employee of a dispensing organization - each dispensing organization may have up to five employees with access to the Compassionate Use Registry;

(b) Law enforcement official; or

(c) Authorized employee of the department.

(3) Persons seeking to access to the registry shall have successfully completed a department-approved course in their responsibilities related to patient confidentiality and shall make documentation of completion available to the department upon request.

(4) Before dispensing any low-THC cannabis derivative product to a qualified registered patient or the patient's legal guardian, the dispensing organization must verify that the patient has an active registration, the order presented matches the order contents as recorded by the physician in the registry, and the order has not already been dispensed.

(5) The dispensing organization shall enter a dispensing action into the registry immediately upon dispensing the low-THC cannabis to the qualified registered patient or the patient's legal guardian.

Rulemaking Authority 381.986(5)(d) FS. Law Implemented 381.986(5)(a); 837.06 FS. History—New \_\_\_\_\_.

## Bist, Kevin

---

**From:** Nelson, Patricia A  
**Sent:** Thursday, January 22, 2015 2:39 PM  
**To:** stoilas@yahoo.com  
**Subject:** RE: Low-THC Cannabis Rulemaking

We have no plans take testimony from the public prior to the negotiation. It would be best to submit any comments in writing prior to the negotiation.

---

**From:** Kostas Stoilas [<mailto:stoilas@yahoo.com>]  
**Sent:** Thursday, January 22, 2015 1:50 PM  
**To:** Nelson, Patricia A  
**Subject:** Re: Low-THC Cannabis Rulemaking

Thanks Patty. The nurses association is disappointed they couldn't have more time to make the committee but should still attend.

To confirm, you had told me that the public could attend but only the committee can negotiate the rules. Whether that means that the public can testify to the committee before they go into negotiations, is what we would like to determine. Is that the case, that you will still take input from the audience at the workshop on Feb 4?

Sent via mobile device...please excuse abbreviated responses & grammar.

Kostas Stoilas  
239.822.7816 cell

[www.CauseToFund.com](http://www.CauseToFund.com)

[www.WarehouseRealEstateBlog.com](http://www.WarehouseRealEstateBlog.com)

[www.Linkedin.com/in/stoilas](http://www.Linkedin.com/in/stoilas)

On Jan 22, 2015, at 10:32 AM, "Nelson, Patricia A" <[Patricia.Nelson@flhealth.gov](mailto:Patricia.Nelson@flhealth.gov)> wrote:

The committee has been selected. I have attached the Department's press release.

Patty

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**From:** Kostas Stoilas [<mailto:stoilas@yahoo.com>]  
**Sent:** Thursday, January 22, 2015 8:16 AM  
**To:** Nelson, Patricia A  
**Subject:** Re: Low-THC Cannabis Rulemaking

Patty - good morning. Just checking in after the holiday. Is the committee fully selected? A couple of the board members from the nurses association are curious and I believe they would be very worthwhile as committee members. Thank you.

Sent via mobile device...please excuse abbreviated responses & grammar.

Kostas Stoilas

239.822.7816 cell

[www.CauseToFund.com](http://www.CauseToFund.com)

[www.WarehouseRealEstateBlog.com](http://www.WarehouseRealEstateBlog.com)

[www.Linkedin.com/in/stoilas](http://www.Linkedin.com/in/stoilas)

On Jan 5, 2015, at 5:11 PM, "Nelson, Patricia A" <[Patricia.Nelson@flhealth.gov](mailto:Patricia.Nelson@flhealth.gov)> wrote:

Dear Interested Parties,

Please see the attached Notice of Negotiated Rulemaking (on page 1 of the attached document) scheduled for February 4 and 5, 2015, in Tallahassee.

Sincerely,  
Patty

Patricia Nelson  
Director  
Office of Compassionate Use

**Bist, Kevin**

---

**From:** zzzz Feedback, Compassionate Use  
**Sent:** Thursday, January 22, 2015 1:57 PM  
**To:** Nelson, Patricia A  
**Subject:** FW: Proposed Rules

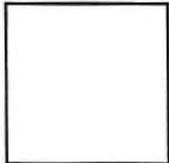
FYI.

**From:** julio lopez [<mailto:fcd1910@gmail.com>]  
**Sent:** Friday, January 16, 2015 1:04 PM  
**To:** zzzz Feedback, Compassionate Use  
**Subject:** Proposed Rules

Ms. Nelson,

The newly proposed rules to maintain the dispensing of medical cannabis with the growers is not in accordance with the ruling from the administrative judge which dictated that dispensing should be done by multiple agencies not affiliated with the growers in order to provide convenient access to patients. Our organization strongly opposes this rule and respectfully requests that the orders of the administrative judge are reflected.

Julio A. Lopez, PhD  
President/CEO  
Florida Cannabis Dispensaries, Inc.



[Facebook](#)

**Bist, Kevin**

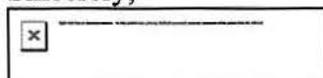
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**From:** Gary Greenwood <gary.greenwood@biotrackthc.com>  
**Sent:** Thursday, January 22, 2015 3:50 PM  
**To:** Nelson, Patricia A  
**Cc:** Steven Siegel; Patrick Vo; Moe Afaneh  
**Subject:** Rulemaking Session Feb 4th & 5th Suggestions  
**Attachments:** Florida Needs State Monitoring System.pdf

Hi Patricia

As "Director of the Office of Compassionate Use" I was told to forward suggestions (attached) to you for the new panel to consider. Please review and contact me with any questions.

Sincerely,



Gary Greenwood • EVP of Business Development & Government Affairs

3101 North Federal Highway, Suite 400, Fort Lauderdale, FL 33306

Web: <http://www.BioTrackTHC.com> • Phone: (954) 303-2270 • Fax: (954) 206-0200

## Why Florida State Needs a Monitoring/Traceability System

To enable a State agency to capture, monitor, and analyze all marijuana inventory activity data reported in real time. To know where every plant and gram of legal marijuana is, in the production lifecycle within the state in order to enforce regulations, collect taxes, prevent illegal marijuana activity, and promote public safety. System must be able to generate unique inventory identifiers to prevent duplication and maintain tracking integrity.

- **Cultivation** – Track and monitor each plant grown and forward-trace in real-time every gram to where it is still in inventory.
- **Harvest** – Track and monitor each gram of flower, trim, waste, and destruction.
- **Production** – Track and monitor how harvest is being measured, validate lab results, packaged and produced into CBD oils.
- **Dispensing** – Validate doctors licenses. Monitor in real-time a prescription presented is determined compliant, and ensure the prescription hasn't been previously filled (control doctor shopping).
- **Patient** – Monitor patients are registered, orders entered for patients, and orders filled for patients
- **Additional modules to consider:**
  - o Testing Lab Reports
  - o Transportation Manifests
  - o Tax Obligation Reports
  - o Patient Database
  - o Annual Reports to State Governor, House & Senate

### Federal Government

A strong state monitoring system is key to satisfying the guidance as detailed in the **Department of Justice released in August 29, 2013:**

- o “In jurisdictions that have enacted laws legalizing marijuana in some form and that have also implemented strong and effective regulatory and enforcement systems to control the cultivation, distribution, sale, and possession of marijuana, conduct in compliance with those laws and regulations is less likely to threaten the federal priorities.

- o “If state enforcement efforts are not sufficiently robust to protect against the harms set forth above, the federal government may seek to challenge the regulatory structure itself in addition to continuing to bring individual enforcement actions, including criminal prosecutions, focused on those harms.”
- o **Cole Memorandum February 14, 2014**
  - “ The August 29 guidance rested on the expectation that states that have enacted laws authorizing marijuana-related conduct will implement clear, strong and effective regulatory and enforcement systems in order to minimize the threat posed to federal enforcement priorities. Consequently, financial institutions and individuals choosing to service marijuana-related businesses that are not compliant with such state regulatory and enforcement systems, or that operate in states lacking a clear and robust regulatory scheme, are more likely to risk entanglement with conduct that implicates the eight federal enforcement priorities.”

### Value Proposition

- **Financially speaking**, a state monitoring system pays for itself many times over as the tax revenues associated with a healthy industry that is reporting its inventory and sales. Ways of paying for a system;
  - o **Up Front**
    - The state can pay for system configuration and deployment up front and then pay an annual maintenance and support fee, both of which are mutually agreed upon.
  - o **Percentage of Activity**
    - The state pays nothing up front and pays for the system based on usage; Grams Tracked, Dollars Collected, or any other proxy for activity may be used.
- **Politically, both supporters and opponents of legal marijuana - can get behind technology that brings transparency, and therefore accountability, to the marijuana industry.**

## **Bist, Kevin**

---

**From:** Kelly, Veloria <Veloria.Kelly@myfloridalicense.com>  
**Sent:** Friday, January 23, 2015 2:26 PM  
**To:** Nelson, Patricia A  
**Subject:** Requested Correspondence  
**Attachments:** SPGVCPA0415012314220.pdf

Hi Patty:  
Here is the copy of the letter that you requested.

Thanks  
Veloria

Veloria A. Kelly  
Director  
Division of Certified Public Accounting  
240 NW 76 Drive Suite A  
Gainesville, Florida 32607  
352.333.2505 (telephone) 352.333.2508 (fax)

"If you are going to achieve excellence in big things, you develop the habit in little matters. Excellence is not an exception, it is a prevailing attitude." Colin Powell

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August 12, 2014

Linda McMullen  
Director  
Office of Compassionate Use  
Florida Department of Health  
4052 Bald Cypress Way  
Tallahassee, FL 32399

**RE: Comments on Draft Revisions to Rules 64-4.001 to 64-4.009, F.A.C.**

Dear Ms. McMullen:

Regulated under chapter 473, F.S., both individual CPAs as well as CPA firms adhere to the highest level of professional standards and are regulated by a nine-member Board of Accountancy. The Florida Institute of Certified Public Accountants (FICPA) - the advocacy arm of the CPA profession - has long held the policy position to *"support legislation and regulatory initiatives that promote efficient and appropriate delivery of government services through privatization and which do not conflict with professional standards or create an expectation gap that ultimately reflects poorly on the profession."*

In support of this policy, the FICPA has continued to actively participate in the drafting of any legislation or agency rules that require participation of a CPA. The goal of this policy is to ensure that the Legislative or regulatory entity drafting the law or rules understand what kinds of services can be provided by a CPA and what level of assurance (or not) the CPA can provide with regard to the financial information.

We understand that the passage of CS/CS/SB 1030 required the department to complete several items by January 1, 2015 including establishing rules to implement the legislation, the application and approval process for dispensing organizations, and demonstration of the financial viability of these organizations. While the legislation did not specifically require a CPA to prepare or assess the financial viability of an applying dispensing organization, the draft rules under 64-4.001 through 64-4.009, F.A.C. do establish requirements for a CPA. Therefore, to ensure a CPA regulated under chapter 473, F.S. completely understands what the department expects and what the CPA can provide under their current regulatory framework and

professional standards, we offer for your consideration the following questions and comments to the above named Florida Department of Health draft rule revisions workshopped on July 7, 2014 and August 1, 2014:

**1) Draft revision to 64-4.002 F.A.C. - Applicant's Financial Strength:**

~~(e) (k) Written documentation of the applicant's financial strength compliance with the financial requirements of as required by Section 381.986(3)(b)5., F.S. All financial statements and other documents shall be prepared by a Certified Public Accountant licensed pursuant to Chapter 473, F.S., who has performed an audit of the organization within one year of the application date;~~

First, there is a difference between "preparation of financial statements" versus an audit, review or compilation which might be contemplated in the rules as referenced by the term "certified financials". Under professional standards and chapter 473, F.S. an audit provides a specific level of assurance as a CPA expresses an opinion as to the reliability of the information presented in an audit. A review provides limited assurance to the financial statements, but not to the extent of expressing an opinion as is provided in an audit. A compilation is defined as financial statements that have been compiled and presented by the CPA with no level of assurance. The level of assurance required by the department should be established. Regardless of the level of assurance the department chooses to require for application and renewal, the CPA would be providing said level of assurance as to the accuracy of the financial information presented in the historical financial statements but could not provide a financial forecast or provide assurance on the future financial viability of the organization. We would strongly suggest the department determine the level of assurance they want with regard to the financial information and consider the following revisions:

**Suggestion A:** If the department determines that it wants financial statements prepared by a CPA and a level of assurance as to the reliability of the financial statements, an audit "prepared in accordance with generally accepted auditing standards" should be required. The rule should be revised to say "all financial statements prepared in accordance with generally accepted accounting principles shall be prepared by a Certified Public Accountant practicing under chapter 473, F.S."

**Suggestion B:** If the department determines that it does not want the level of assurance provided by an audit, it should specify that "all financial statements prepared in accordance with generally accepted accounting principles..." and also specify what the department means by "other documents." Leaving these two terms up for interpretation does not provide guidance to the CPA as to what is exactly expected nor do the terms have meaning within professional standards under chapter 473, F.S.

**2) Draft revision to 64-4.002 F.A.C. - Public Lottery:**

We heard discussion during the August 1, 2014 workshop regarding having a CPA "certify" these lottery results. While we appreciate the confidence the department has in the CPA profession, we again are not clear on what level of assurance is to be provided or professional standards the CPA would have to adhere to and apply in order to "certify" this lottery.

**3) Draft revision to 64-4.003 F.A.C. - Biennial Renewal Requirements for Dispensing Organizations:**

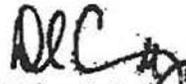
Once the department determines the level of assurance needed as discussed in A and B, the language should be changed to reflect either a "financial statement prepared in accordance with generally accepted accounting principles" or "an audit prepared in accordance with generally accepted auditing standards."

**4) Draft revision to 64-4.007 F.A.C. - Recordkeeping and Reporting Requirements:**

We are assuming that the department intends for the designated "inventory agent" who will also conduct an inventory audit to be someone other than the CPA who has prepared a financial statement on behalf of the dispensing organization. In addition, if a financial "audit" is required for the dispensing organization's application, the CPA conducting the financial audit will have some responsibility in viewing the organization's inventory records and would also need to have this separation of responsibility from the inventory agent's role so as not to impair independence.

Thank you for the opportunity to provide comments and feedback on this issue. Should you need any additional information regarding this issue or accounting standards in general, please do not hesitate to contact me via email at [curryd@ficpa.org](mailto:curryd@ficpa.org) or my consultant, Jennifer J. Green, Liberty Partners of Tallahassee at [jennifer@libertypartnersfl.com](mailto:jennifer@libertypartnersfl.com).

Regards,



Deborah L. Curry, CPA, CGMA  
President and CEO

cc: FICPA Executive Committee  
Florida Board of Accountancy

## **Bist, Kevin**

---

**From:** Nelson, Patricia A  
**Sent:** Friday, January 23, 2015 3:31 PM  
**To:** 'Kelly, Veloria'  
**Subject:** RE: Requested Correspondence

Thank you!

---

**From:** Kelly, Veloria [<mailto:Veloria.Kelly@myfloridalicense.com>]  
**Sent:** Friday, January 23, 2015 2:26 PM  
**To:** Nelson, Patricia A  
**Subject:** Requested Correspondence

Hi Patty:  
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## **Bist, Kevin**

---

**From:** MDAttorneyatLaw@aol.com  
**Sent:** Friday, January 23, 2015 3:50 PM  
**To:** Bist, Kevin  
**Subject:** Interested Parties List - Florida Medical Marijuana Group (FMMG)

Good afternoon, Kevin.

Thanks so much for bringing me up to date and clarifying where everything stands. It looks like I missed out on Florida Medical Marijuana Group serving on the committee. I hope we can avoid that in the future. You now have my email address to be included on the interested parties distribution list for the Office of Compassionate Use.

Please anytime do not hesitate to contact me particularly when the application is in its final version and ready to be submitted.

I can't emphasize enough how much I appreciate how you always make yourself available to take my phone calls and keep me in the loop. As I'm sure you can understand the extent to which we are interested in obtaining the license for Low THC Cannabis dispensing.

Again, I appreciate your continued assistance.

Sincerely,

Lumi.  
Legal Counsel, Florida Medical Marijuana Group

**Luminica M. Djulvezan, Esq.**  
Law Offices of Luminica M. Djulvezan, P.L.  
P.O. Box 1912  
Hallandale, Florida 33008

Phone: 954.646.1844  
Fax: 877.863.8149  
[mdattorneyatlaw@aol.com](mailto:mdattorneyatlaw@aol.com)

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## Bist, Kevin

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**From:** MDAttorneyatLaw@aol.com  
**Sent:** Tuesday, January 27, 2015 3:14 PM  
**To:** Bist, Kevin  
**Subject:** Re: Interested Parties List - Florida Medical Marijuana Group (FMMG)

I'm so very grateful, Kevin.

I look forward to our future interactions.

Sincerely,

Lumi.

In a message dated 1/26/2015 1:15:57 P.M. Eastern Standard Time, [Kevin.Bist@flhealth.gov](mailto:Kevin.Bist@flhealth.gov) writes:

Hi Lumi,

I've submitted your email to be included on the interested parties list. Sorry for the confusion on my part. I'll blame in on being too early on a Monday morning.

Kevin

---

**From:** MDAttorneyatLaw@aol.com [mailto:MDAttorneyatLaw@aol.com]  
**Sent:** Friday, January 23, 2015 3:50 PM  
**To:** Bist, Kevin  
**Subject:** Interested Parties List - Florida Medical Marijuana Group (FMMG)

Good afternoon, Kevin.

Thanks so much for bringing me up to date and clarifying where everything stands. It looks like I missed out on Florida Medical Marijuana Group serving on the committee. I hope we can avoid that in the future. You now have my email address to be included on the interested parties distribution list for the Office of Compassionate Use.

Please anytime do not hesitate to contact me particularly when the application is in its final version and ready to be submitted.

I can't emphasize enough how much I appreciate how you always make yourself available to take my phone calls and keep me in the loop. As I'm sure you can understand the extent to which we are interested in obtaining the license for Low THC Cannabis dispensing.

Again, I appreciate your continued assistance.

Sincerely,

Lumi.

Legal Counsel, Florida Medical Marijuana Group

**Luminica M. Djulvezan, Esq.**  
Law Offices of Luminica M. Djulvezan, P.L.

P.O. Box 1912

Hallandale, Florida 33008

Phone: 954.646.1844

Fax: 877.863.8149

[mdattorneyatlaw@aol.com](mailto:mdattorneyatlaw@aol.com)

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**Bist, Kevin**

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**From:** Chris Hansen <chansen@ballardfl.com>  
**Sent:** Friday, January 23, 2015 4:06 PM  
**To:** Nelson, Patricia A  
**Subject:** FW:  
**Attachments:** Summary of Florida Application Requirement Changes.docx

Patti:

Thank you for the call this afternoon, as I stated on the phone our client wants to be part of the Florida solution and enclosed is a quick overview.

The Draft rule ( new ) does not emphasize operation plans and business plans which is a very important component of the application. The Corporate / financial sections are much lighter than before which weighs on the merit of the applicant. And in our opinion the draft adds a lot more technical specifications that are a little over the top and not necessarily an indicator of an applicant's ability to produce the product and work in a highly regulated market.

Chris

PS We will work with Austin in your office going forward.

CH

---

**From:** Samantha Robbins  
**Sent:** Friday, January 23, 2015 3:36 PM  
**To:** Chris Hansen  
**Subject:**

Samantha Robbins  
Ballard Partners  
Administrative Assistant  
(850) 577-0444

## Changes to Florida Application for Low-THC Cannabis Dispensing Organization

Prior Application Requirements	Changes
1. Application Form	Still required
2. Documentation that applicant meets nursery requirements	Still required
3. <u>Plan</u> for cultivating low-THC cannabis and processing and dispensing low-THC cannabis derivative products including a <u>Business Plan</u> showing expected production	Replaced with detailed information on applicant experience and extensive detail on systems and equipment (see item 6)
4. <u>Security and Safety Plan</u> to include at least the following: <ul style="list-style-type: none"> <li>• Locking options, alarm systems and video surveillance</li> <li>• Diversion and trafficking prevention procedures</li> <li>• A facility emergency management plan</li> </ul>	Expanded to include layout and dimensions of each room, vehicle tracking and security, employee screening and qualifications for chain of custody, access to specialized security resources
5. <u>Quality Control Plan</u> to ensure the quality and consistency of low-THC cannabis grown, processed and dispensed	Deleted from application
6. Ability to obtain and maintain the premises, facilities, resources and personnel to operate as a dispensing organization to include: <ul style="list-style-type: none"> <li>• <u>Map</u> showing the location of the proposed dispensing facility</li> <li>• <u>Site plan</u> of actual or proposed cultivation, processing and dispensing location showing streets, property lines, building, parking areas, outdoor areas, if applicable, fences, security features, fire hydrants and access to sewer and water mains</li> <li>• <u>Floor plan</u> of the actual or proposed building or buildings where the cultivation, processing and dispensing activities will occur: <ul style="list-style-type: none"> <li>➤ Layout and dimensions of each room</li> <li>➤ Name and function of each room</li> <li>➤ Location of each hand-washing sink</li> <li>➤ Location of each toilet room</li> <li>➤ Means of ingress and egress</li> <li>➤ Location of natural and artificial lighting sources</li> </ul> </li> <li>• A list of current and <u>proposed staffing</u> including: <ul style="list-style-type: none"> <li>➤ Position, duties and responsibilities</li> <li>➤ The age in years of each current employee</li> <li>➤ Date and status of each individuals most recent Level-2 background screening</li> </ul> </li> </ul>	Significantly expanded to include detailed information on systems and equipment – including maps and photo’s for each (cultivation, back-up systems, laboratory facilities, areas for production and distribution)  Added plan for loss of key personnel
7. <u>Inventory Control Plan</u> that meets the requirements of Rule 64-4.007.F.A.C. (“maintain accountability of all raw materials, finished products and by products”).	Renamed to “system for tracking cuttings, seedlings or seeds throughout the cultivation, processing and distribution process”

Prior Application Requirements	Changes
8. Infrastructure to dispense low-THC cannabis products: <ul style="list-style-type: none"> <li>• Physical Address</li> <li>• Photographs or drawings showing the proposed driveway, parking and public access to the dispensary</li> <li>• <u>Transportation plan</u> for delivery to qualified patients</li> </ul>	Expanded to include information on centralized computer system or network, vehicles, communications systems, vehicle tracking and security systems, hours of operation
9. Documentation showing Good Chemistry has the equipment, training, ability and personnel necessary to safely produce low-THC cannabis products	Replaced with documentation showing experience and staffing in 18 specific areas
10. Documentation of financial ability to maintain operations for the two year approval cycle including a <u>financial statement</u> prepared by a CPA licensed pursuant to Chapter 473,F.S	Expanded to include information on corporate structure, applicant information, owners and subsidiaries
11. Documentation of the ability to post \$5 million performance bond for the biennial approval period	Still required
12. Documentation that all owners and managers have successfully completed Level-2 background screening within the calendar year prior to application	Still required
13. Organizational chart illustrating the supervisory structure of the dispensing organization	Still required
14. Documentation that applicant employs or will employ a <u>medical doctor</u> who is a licensed physician	Still required
15. Any exemptions	Still required

**Summary of Changes: focus on systems/equipment/infrastructure rather than policies/procedures/plans for complying with Florida regulations and meeting patient needs**

- Replaced operating and business plans for detailed facility, equipment and system information
- Excluded requirement for quality control plan (which includes product testing, storage, sanitary protocols, etc.)
- Expanded information requirements on applicant corporate structure, financial assets, liabilities and obligations – but excludes business planning info (projected capital expenditures, revenue)
- At a minimum – no mention of independent laboratory product testing, waste disposal methods, compassion program, staff training, regulatory compliance relative to coordination with Office of Compassionate Care, labeling/packaging, patient education, potential medical research

## Bist, Kevin

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**From:** Chris Finkbeiner <chris@rubingroup.com>  
**Sent:** Friday, January 23, 2015 4:48 PM  
**To:** Nelson, Patricia A  
**Subject:** Re: Suggested Revisions

**Importance:** High

Patty,

As a follow up to our suggested revisions, we would appreciate the following comments being considered for future rule drafts and by the committee members. Please feel free to contact me with any questions. Thank you!

### Financial requirements

- a. Applicants should be required to provide a Bank Letter of Credit showing their ability to fund capital expenditures and cash drawdown from existing cash-on-hand prior to their application.
- b. Applicants should be required to provide a letter showing they have a preexisting banking relationship that will accept credit cards and cash deposits from low-THC cannabis sales. This reduces the likelihood of violence related to holding large stockpiles of cash.
- c. Applicants should be required to post the entire \$5 million performance bond in an escrow account with the Florida DOH.

### "Technological and Technical Abilities" used to score applicants

- a. The current metrics are heavily weighted toward experience cultivating cannabis. By definition, it is impossible for any 30 year nursery to have experience legally producing low-THC cannabis in Florida.
- b. Knowledge of cannabis cultivation should be included, but actual experience should not be included.
- c. Thus, "Technological and Technical Abilities" should be based on experience in fields most similar to cannabis cultivation & processing:
  - i. Experience cultivating plants most similar to cannabis (i.e. tomatoes)
  - ii. Experience with high tech greenhouse cultivation techniques
  - iii. Experience processing, compounding and delivering DEA scheduled pharmaceutical products

Chris Finkbeiner  
The Rubin Group  
(c) 850-570-4747  
(o) 850-681-9111  
(e) [chris@rubingroup.com](mailto:chris@rubingroup.com)

---

**From:** Chris Finkbeiner <[chris@rubingroup.com](mailto:chris@rubingroup.com)>  
**Date:** Thursday, January 22, 2015 at 2:27 PM  
**To:** "[patricia.nelson@flhealth.gov](mailto:patricia.nelson@flhealth.gov)" <[patricia.nelson@flhealth.gov](mailto:patricia.nelson@flhealth.gov)>  
**Subject:** Suggested Revisions

Patty,

Thank you for your call this morning. I very much appreciate you getting back to me.

On behalf of our client, Surterra, we would like to submit the attached suggested revisions to the rule.

If you have any questions, or would like to discuss any of these changes further, please don't hesitate to contact me. We would be happy to walk through our arguments and rationale whenever is convenient for you.

Thank you.

Chris Finkbeiner  
The Rubin Group  
(c) 850-570-4747  
(o) 850-681-9111  
(e) [chris@rubingroup.com](mailto:chris@rubingroup.com)

**Bist, Kevin**

---

**From:** Lcr5002@aol.com  
**Sent:** Monday, January 26, 2015 9:27 AM  
**To:** Nelson, Patricia A  
**Subject:** Rule Comments  
**Attachments:** flmcaletterheadword12615.doc

Patty  
As we discussed.  
Louis Rotundo

Ms. Patricia Nelson  
Office of Compassionate Use  
Department of Health  
Tallahassee, Fl.  
January 24, 2015

Patty;

Below are my comments regarding the first proposed new rule:

**64-4-001:**

(1) Applicant: I believe the applicant definition needs an additional clarification consistent with the administrative law judges' ruling that nurseries may not be restricted to once in applying for licenses. However, he also indicated that his concerns over lottery also included a danger of monopolies being created by awarding the licenses. So my suggestion:

"The nursery applicant must in its initial application identify its organization and key owners, partners and related affiliated parties as identified in IRS SS 267 and 1563(a), individuals and supporting operations. Failure to completely do so is legal grounds for license denial or revocation of the awarded license. No applicant or the listed organization and key owners, partners and related affiliated parties as identified in IRS SS 267 and 1563(a), individuals and supporting operations may be issued more than one license by the state of Florida.

RESULT: This goes directly with 64-4.002 (e) of measurable criteria. You may apply as many times as you wish, but you and your *hidden* associates and partners may only win one license in Florida, not one in each or any district. Grounds = Better Competition. It also makes each applicant self-policing as the danger of post-award loss is significant.

(5) The distinction between batch and harvest may be confusing and unnecessary. If the product is the end product not the process product, it may lead to additional testing not required and expensive. This carries over to 64-4.006 (5).

(11) "Contiguous" should be dropped as some nursery's have multiple locations that grow and process. They win once but should operate most efficiently regardless of location(s) as long as they identify to the department and their local law enforcement what is their business plan.

(18) Fine with that broad definition. Since we have excluded smoking in the past, I would believe that should continue and the issue might be expanded to include any electronic ignition delivery in public locations to strengthen the point against electronic cigarettes. Is vaping really going to be done in public?

(21) Change "Transportation plan" to "Delivery Plan" to better match the allowances in 64-4.002 (e). Transportation implies vehicles whereas the method of delivery may include transportation and location delivery.

**64-4.002:** I am fine with the criteria listed except (e) is still confusing with the interchangeability of the words dispensing and distribution. Perhaps better to match the exact wording of the law. Thus it would read "distribute low THC cannabis".

Also, the issue of setbacks still needs to be addressed by the Department since the state legislature has created this conflict issue. Local zoning should prevail, but the state must give guidance. Perhaps:

"The infrastructure shall include separate physical locations for multiple establishments that allow the licensee to facilitate the distribution of low THC cannabis to the designated patients. These retail establishments must comply with local zoning requirements; however local zoning may not completely

prohibit the establishment of retail distribution locations nor treat them differently than any other allowed pharmaceutical dispensaries.

The Department of Health should also adopt restrictions on the allowed number of facilities per county and local governments could still adopt additional requirements consistent with local code practices and the intent of this section.

If you have any questions, please feel free to call me.

Thank you,

Louis Rotundo

**Bist, Kevin**

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**From:** Nelson, Patricia A  
**Sent:** Monday, January 26, 2015 10:55 AM  
**To:** Tschetter, Jennifer  
**Subject:** FW: New Rule Version

---

**From:** Chris Finkbeiner [<mailto:chris@rubingroup.com>]  
**Sent:** Monday, January 26, 2015 10:06 AM  
**To:** Nelson, Patricia A  
**Subject:** New Rule Version

Patty,

When the new rule draft becomes available, can you please send it to me, so that we can review it?

Thank you.

Chris Finkbeiner  
The Rubin Group  
850-570-4747  
[chris@rubingroup.com](mailto:chris@rubingroup.com)

**Bist, Kevin**

---

**From:** Gary Greenwood <gary.greenwood@biotrackthc.com>  
**Sent:** Monday, January 26, 2015 1:10 PM  
**To:** Nelson, Patricia A  
**Subject:** Compassionate Use Rulemaking

Dear Ms Nelson

It has come to our attention that the rulemaking panel (other than the Florida growers) is seated mainly by Colorado consultants. The Colorado Governor recently stated "that his state's decision to legalize marijuana was a "bad idea" highlighting the difficulties of creating a regulatory structure "from scratch". I would like to suggest that you watch the USATODAY investigation video below showing how two Colorado's Senators wish they had a regulatory system more like Washington State. I would strongly suggest you and the panel to duplicate Washington States succesful model rather than Colorado's inadequet system.

<http://www.9news.com/story/news/investigations/2014/12/29/marijuana-contaminants-testing/21019837/>



Gary Greenwood • EVP of Business Development & Government Affairs  
3101 North Federal Highway, Suite 400, Fort Lauderdale, FL 33306  
Web: <http://www.BioTrackTHC.com> • Phone: (954) 303-2270 • Fax: (954) 206-0200

## Bist, Kevin

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**From:** Nelson, Patricia A  
**Sent:** Tuesday, January 27, 2015 10:02 AM  
**To:** Sachs, Taylor  
**Subject:** FW: RULEMAKING COMMITTEE as a Infrastructure and testing laboratory EXPERT: UGrow  
**Attachments:** UGrow on Florida.pdf

Will you please make sure this is counted as a comment even though it was sent as a request to be on the negotiating committee?

Thank you!  
Patty

**From:** Sam Harris III [mailto:sam@ugrowflorida.com]  
**Sent:** Friday, January 16, 2015 1:19 PM  
**To:** Nelson, Patricia A  
**Subject:** RULEMAKING COMMITTEE as a Infrastructure and testing laboratory EXPERT: UGrow

Dear Ms. Patricia Nelson,

It would be an honor to serve on the panel, as CEO/President of UGrow, Inc. with many of the aspects of medical marijuana being considered across the US the need for a robust research & development laboratory solution is necessary at the state level. Now that Florida is moving forward with its Medical Marijuana plan here are some bullet points that outline an approach that UGrow might take in providing professional service to Florida Department of Health Panel as member with Industry leaders. UGrow, Inc. has a state of the art network of Cannabis Infrastructure and lab partners that operate at the current medical laboratory standards. Our network of scientist, possess an extensive background in plant genetics as well as agriculture science and organic chemistry. Having a medical standards lab ensures the reliability of testing and ultimately the safety of all patients' medicine at the highest level.

Our approach in testing is on a consultative level with our clients grow operations and processor facilities. We do not just see the lab as simply a vehicle for testing. UGrow is a partner with the labs, growers, dispensaries, and manufacturing processors to help them when things do not go right to work through and arrive at a solution. Our door is always open to them to help problem solve. We have staff experienced cultivators, soil scientist, extractors and our science team to continually improve outcomes for the client. Test results would be yielded back to the grow facilities and the state through the Bio Track reporting system or an equivalent online portal. UGrow could develop a lab quality mobile extraction service to go to each facility and perform extraction service to yield oils for edible products, infusions and the like (**This could also be accomplished at a centralized lab quality facility depending on the State's transportation policies**).

As for packaging we are not totally aware of what the state's expectation is as it pertains to flower product vs. edibles. The flower product could be packaged in several ways and standards depending on state requirements. This could be accomplished at either a central facility specifically connected with the main lab. Most edibles manufacturing processors are responsible for their respective packaging at point of origin then those products are tested. The advantage with UGrow's lab partners is advanced microbial testing is that it has fast turnaround times (**around 24 hours**). This will result

in those products arriving on the dispensary shelves quickly ensuring a fresh and safe product, extending shelf life and reducing degradation. I'm looking forward to working with you and the panel, and please call me if you have any question.

Best Regards,

Sam Harris III

CEO/President

UGrow, Inc.

**The UGrow Tracking System:**

- BTM Software system for Medical dispensaries is the industry leader.
- Preferred testing laboratory vendor.
- The laboratory module has integrated testing and seamless RFID tracking seed to sell solution.

**Comprehensive approach:**

- Here are some of the analysis and services we offer whether the product is Flower, Extract or Edible type :
  - Qualitative/Quantitative Microbial Analysis
  - Pesticide testing
  - Heavy metals testing
  - Potency testing
  - Visual inspection with moisture analysis,
  - Residual solvent testing in extracted products.

- Terpene Profile analysis
- Development of Genetic Strain Analysis
- Extraction Services

**Methodology:**

Florida Specific's: Given the size of the state and considering 5 separate grow facilities one in each region. Logistics and transport will be important. The sheer cost of building laboratories, it is important that the State of Florida considers a more centralized solution.

**Advantages:**

- Ensures a standardized testing facility with the exact same methodologies
- Reduce the overall cost outlays while allow for equipment redundancies to ensure no down time.
- Deploy lab trained personnel to the grow facility to accomplish sample collection to ensure non-bias collections
- Allows for continual facility inspection and conditions.
- Run routine soil or medium analysis for non-approved chemicals
- Quality assurance of the end product. The quality of the extraction is only as good as the base material it came from
- Reduces the cost of expensive extraction equipment to the grower/processor.
- Safety and Laboratory Quality/Expertise
- Testing of final product is automatic
- Ensures inventory controls.

**Disadvantage:** is having the entire states crop in a single facility as it pertains to crop safety and isolation/contamination. The alternative would be to develop a mobile packaging facility that can roll into a grow operation and accomplish this on-site.

- Product never leaves the grower's premise's
- Lower cost to the grower to maintain the equipment and personnel

- o Each facility could still maintain branding specific to that grow

--

Sam Harris III,

CEO/President

UGrow, Inc.

10006 Cross Creek Blvd #,

Tampa, FL, 33647

O. 813-510-0982

**[WWW.ugrowflorida.com](http://WWW.ugrowflorida.com)**

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Sam Harris III  
CEO/President  
UGrow, Inc.

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- Lower cost to the grower to maintain the equipment and personnel
- Each facility could still maintain branding specific to that grow

## Bist, Kevin

---

**From:** Curry, Deborah <CurryD@ficpa.org>  
**Sent:** Tuesday, January 27, 2015 5:58 PM  
**To:** Nelson, Patricia A  
**Subject:** CPAs - Rules 64-4.001 to 64-4.009 - Language recommendations

Patricia,

Thank you for contacting me regarding terms related to Certified Public Accountants and the services that may be provided in accordance with professional standards. Referencing our discussion this morning, I have provided the language that would be appropriate under the specific circumstances we explored.

Please let me know if I can provide additional clarification or assistance.

*With respect to the preparation of financial statements that could be prepared on a comparable basis from one entity to another and provide adequate data, the following terminology could apply:*

Written documentation of the applicant's financial strength as required by Section 381.986(5)(b)5., F.S. All financial statements shall be prepared in accordance with "generally accepted accounting principles" pursuant to Chapter 61H1, F.A.C.

*With respect to any requirement that an audit is to be performed, if that is the desire of the department, the rule should reference:*

An audit performed in accordance with "generally accepted auditing standards" pursuant to Chapter 61H1, F.A.C. prepared by a Certified Public Accountant authorized to practice under Chapter 473 F.S.

Best regards,  
Deborah

**Deborah L. Curry, CPA, CGMA | President-CEO**  
Florida Institute of CPAs | 325 W. College Ave. | Tallahassee, FL 32301  
800.342.3197 | 850.224.2727, x240 | Fax : 850.222.8190 | [www.ficpa.org](http://www.ficpa.org)



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**Bist, Kevin**

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**From:** Tobynuber <tobynuber@gmail.com>  
**Sent:** Tuesday, January 27, 2015 9:58 PM  
**To:** Nelson, Patricia A  
**Cc:** Toby Nuber; Matt Huron  
**Subject:** Good Chemistry follow up

Patty,

It was a pleasure to meet with you in person and we thank you again for your time.

Please do not hesitate to call Matthew or me with any questions. We're happy to try to be helpful here in anyway possible.

We are committed to patient access in Florida and look forward to the opportunity to work with you.

Best regards,

Toby

Toby Nuber  
CFO  
Good Chemistry  
(415) 713-7613

**Bist, Kevin**

---

**From:** Scott <scott@skdgrp.com>  
**Sent:** Wednesday, January 28, 2015 8:33 AM  
**To:** Nelson, Patricia A  
**Subject:** FW: Suggested additions to Rules  
**Attachments:** Additions to Rules - 2.docx

Patty, please see suggested additions to the proposed rule drafts. Thanks for your consideration. Scott Dick

Scott Dick  
SKD Consulting Group, Inc.  
210 South Monroe Street  
Tallahassee, FL 32301  
O: 850-421-9100 C: 850-545-4526



#### 64-4.002 Initial Application Requirements for Dispensing Organizations.

If planned as part of the dispensing operation, additional points will be awarded for:

(j) The technical and technological ability to produce medical products with low-THC cannabis. Please address the following items:

1. Knowledge and experience producing medical products
2. Technological protocols for manufacturing and production of medical products
3. Knowledge and experience with laboratory procedures for analysis of plant material and medical products for THC/CBD composition
4. The safety of the medical products for patients, consistency, predictability and efficacy
5. Knowledge and experience in management and of medical products production operation

(k) The scientific knowledge and technological ability to research and develop products and treatments for medical symptoms, conditions and diseases. Please address the following:

1. Knowledge and experience with medical symptoms, conditions and diseases that are potentially treatable with cannabis formulas and products
2. Knowledge and experience in conducting research on plant and medical products
3. Availability of research facilities and funding for research activities
4. Partnerships or collaboration with research institutions and private organizations

## **Bist, Kevin**

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**From:** robert tornello <roberttornello@me.com>  
**Sent:** Wednesday, January 28, 2015 12:09 PM  
**To:** Nelson, Patricia A  
**Subject:** Re: Truth behind the C. Web strains.

Patty, When we last spoke I asked if I could send you any additional information I thought relevant and informative to your steering the committee.

You were kind enough to state you would read and review, also asked, since the committee will be closed to questions unless solicited,

I asked if I could send you my questions in advance so you could vet them and ask the panel member(s) for their response.

You acknowledged that that would be acceptable.(to follow)

[http://www.projectcbd.org/wp-content/uploads/2014/10/ProjectCBD\\_Special-Report\\_Medical-Marijuana-Inc-HempMeds-Kannaway1.pdf](http://www.projectcbd.org/wp-content/uploads/2014/10/ProjectCBD_Special-Report_Medical-Marijuana-Inc-HempMeds-Kannaway1.pdf)

This link above is to a Project CBD report is so important/mandatory to read. It serves several important purposes.

First, it exposes companies involvement with marketing patient sourced products, the real motivation behind the CBD oil industry.

Second, it shows the levels of contamination and misrepresentation as to source, part of the plant derived, and their motive.

I have to professionally ask the question(s) below because I honestly value your judgement and intellectual ability to see beyond the obvious, and know you are right person for this Bills final outcome.

---

After reading and vetting the Joel Warren report in Westword, It is presumed that the Stanley's saw the enormous opportunity that fell on their laps with the original formulated oil they produced that was effective for some cases of seizures. The problem was how to supply the demand when so many others were making claims to a similar nature. The only way was to take the MMJ regulated R-4 strain and cross it with non regulated industrial Hemp.

However to be able to mass produce and compete in the industry that the Project CBD report is citing, industrial hemp breeding was selected to circumvent the Co laws pertaining to numbers of plants you can grow for patients, and the mandatory RFID identifiers required for cannabis products including low THC.

They were successful in their efforts to grow around the law, as their new cultivar tested as industrial hemp with lower CBD levels than the original plant, but now way below the threshold levels of THC.

What they are producing is in the eyes and laws of the DEA, and Colorado marijuana cultivation laws, is classified as industrial hemp.

I have to ask as a qualified grower and on behalf of all potential licensees, with great financial exposure and risk, are questions that need a clear and definitive answer.

Also SB1030 timing and structure would make reference to the ORIGINAL strain of C. Web as produced by the Stanley's, verified by numerical valuations to that strain, one that is still above federally legal THC requirements, (as we know to be effective some THC must be coupled with the CBD for stated seizures).

However, the current strain they grow is by their own assertion and exemption under the laws, is an industrial Hemp, not a regulated strain of MMJ.

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My questions.

Are we working a bill that is Industrial Hemp, or Medical Marijuana?

The seed and clone stock the Stanley's will now provide Florida growers will be Industrial Hemp by their own admission and state crop filing.

SB1030 is MMJ regulation, requiring the 150K licensee fees, and a 5 million dollar bond above all security concerns, as are not required for Industrial Hemp producers as defined by USDA.

So why are we being asked to pay and invest millions into nothing more than industrial hemp?

We need to have a clear direction here, as fortunes will be spent by growers on equipment and facilities to grow Industrial Hemp for CBD oil, that has at best anecdotal not Medical proof of its effectiveness. Medical Marijuana that was Low in THC, High CBD has proven effective for some cases, while the Hemp oil derivative is just a dietary supplement with extracted CBD added without all the other mandatory cannabinoids necessary to deliver its effective treatment potential to patients as prescribed.

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It is my personal opinion the Stanley's should recuse themselves from this process, as well as the Mosley's as this is misleading to the real patient needs we are seeking to help.

Their current hybridized product has been revealed to have lower efficacy, and higher cost and is by their demonstration, Not medical cannabis.

SB1030 is a medical cannabis bill, and they have by their own hands changed the plants genetics to industrial hemp classification.

We cannot endorse a hybridized impostor as the original plant the bill is based upon.

As you saw by testimony and comments most Florida growers do not understand the dynamics of cannabis in any form, and for this committee to endorse the Stanley's, and what will be their current offerings of seeds to Florida Growers as Industrial Hemp, frightens me.

Thank you for listening to my concerns.

Robert

On Jan 22, 2015, at 10:34 AM, Nelson, Patricia A wrote:

Thank you!

---

**From:** robert tornello [mailto:roberttornello@me.com]

**Sent:** Thursday, January 22, 2015 9:54 AM

**To:** Nelson, Patricia A

**Subject:** Truth behind the C. Web strains.

This is an in depth report on the development and current issues I thought you should be aware of.

R

[http://blogs.westword.com/latestword/2014/12/charlottes\\_web\\_miracle\\_marijuana\\_drug\\_seizures.php](http://blogs.westword.com/latestword/2014/12/charlottes_web_miracle_marijuana_drug_seizures.php)

## Bist, Kevin

---

**From:** Nelson, Patricia A  
**Sent:** Wednesday, January 28, 2015 4:32 PM  
**To:** Nelson, Patricia A  
**Subject:** FW: Rules

**From:** anthony ardizzone [<mailto:tvanursery@yahoo.com>]  
**Sent:** Wednesday, January 28, 2015 1:52 PM  
**To:** Nelson, Patricia A  
**Subject:** Rules

Patty,

Thank you for taking my call, and one again it was a pleasure.

I believe an Applicant is exactly what SB1030 calls it a Nursery.

Definitions 64-4001 1 Applicant

I believe the definition of an Applicant should read: A nursery that meets the requirements. Not an organization

Also be cautious when using the word Experience. I had this conversation with Linda McMullen. Sb1030 does not call for experience it says an applicant must demonstrate the technical and technological ability to grow low the cannabis, not experience. However I do believe experience should have bonus points given to an applicant

Lastly I would like to make the request again as per FDOH notice of rule making development (posted below) and my statement below falls within the parameters of the notice giving me the right to apply by the FDOH notice and the right to be on the committee

If you believe that your interests are not adequately represented by the committee members listed above, you may apply to participate within 30 days of the date of publication of this notice. Your application must contain the following information: your name, business address, and telephone number; the name of any organization you are representing; a description of the organization or the members of the organization; a description of how the proposed rulemaking proceedings will affect you or the parties that you represent; a statement identifying the reasons why you believe the representative groups listed above will not adequately represent your interests; and a statement that you are willing to negotiate in good faith and can attend the scheduled meeting. Please submit your application to Patricia Nelson, Department of Health, 4052 Bald Cypress Way, Bin A-02, Tallahassee, Florida 32399, email address: [Patricia.Nelson@flhealth.gov](mailto:Patricia.Nelson@flhealth.gov).

In my opinion based on past statements, and actions of Costa Farms, Costa Farms has only their self

interest in rule development. Costa Farms does not adequately represent Ed Miller & Sons, and many other nurseries intrests.

I am willing to negotiate in good faith, and I am able to attend all meetings.

I will stand by this statment publicly.

Therefore I respectfully request to be appointed to the committee

You will not be disappointed we will get this right!

Anthony Ardizzone

Ed Miller & Son

772-201-3065

Sent from Yahoo Mail on Android

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**From:** Curry, Deborah [<mailto:CurryD@ficpa.org>]  
**Sent:** Thursday, January 29, 2015 3:04 PM  
**To:** Nelson, Patricia A  
**Subject:** FICPA - Auditor Opinion Letter Example for language

Patricia,

I have attached an example of the language that is included in standards for CPAs as it relates to issuing an opinion on the fair presentation of financial statements. This is standard language used in audit opinions.

According to standards, the CPA may attest that the financial statements, present fairly, the financial position of the entity as of a date certain.

Please let me know if I can provide additional assistance.

Best regards,  
Deborah Curry

Deborah L. Curry, CPA, CGMA | President-CEO  
Florida Institute of CPAs | 325 W. College Ave. | Tallahassee, FL 32301  
800.342.3197 | 850.224.2727, x240 | Fax : 850.222.8190 | [www.ficpa.org](http://www.ficpa.org)



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**Illustration 2—An Auditor's Report on a Single Year Prepared in Accordance With Accounting Principles Generally Accepted in the United States of America**

Circumstances include the following:

- Audit of a complete set of general purpose financial statements (single year).
- The financial statements are prepared in accordance with accounting principles generally accepted in the United States of America.

**Independent Auditor's Report**

[Appropriate Addressee]

**Report on the Financial Statements<sup>1</sup>**

We have audited the accompanying financial statements of ABC Company, which comprise the balance sheet as of December 31, 20X1, and the related statements of income, changes in stockholders' equity, and cash flows for the year then ended, and the related notes to the financial statements.

**Management's Responsibility for the Financial Statements**

Management is responsible for the preparation and fair presentation of these financial statements in accordance with accounting principles generally accepted in the United States of America; this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error.

**Auditor's Responsibility**

Our responsibility is to express an opinion on these financial statements based on our audit. We conducted our audit in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control.<sup>2</sup> Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

<sup>1</sup> The subtitle "Report on the Financial Statements" is unnecessary in circumstances when the second subtitle, "Report on Other Legal and Regulatory Requirements," is not applicable.

<sup>2</sup> In circumstances when the auditor also has responsibility to express an opinion on the effectiveness of internal control in conjunction with the audit of the financial statements, this sentence would be worded as follows: "In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the financial statements in order to design audit procedures that are appropriate in the circumstances." In addition, the next sentence, "Accordingly, we express no such opinion." would not be included.

***Opinion***

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of ABC Company as of December 31, 20X1, and the results of its operations and its cash flows for the year then ended in accordance with accounting principles generally accepted in the United States of America.

**Report on Other Legal and Regulatory Requirements**

*[Form and content of this section of the auditor's report will vary depending on the nature of the auditor's other reporting responsibilities.]*

*[Auditor's signature]*

*[Auditor's city and state]*

*[Date of the auditor's report]*

## Bist, Kevin

---

**From:** Nelson, Patricia A  
**Sent:** Thursday, January 29, 2015 3:39 PM  
**To:** 'Curry, Deborah'  
**Subject:** RE: FICPA - Auditor Opinion Letter Example for language

Thank you!

Do you have one for a review that is short of an audit?

Patty

---

**From:** Curry, Deborah [<mailto:CurryD@ficpa.org>]  
**Sent:** Thursday, January 29, 2015 3:04 PM  
**To:** Nelson, Patricia A  
**Subject:** FICPA - Auditor Opinion Letter Example for language

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Please let me know if I can provide additional assistance.

Best regards,  
Deborah Curry

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Florida Institute of CPAs | 325 W. College Ave. | Tallahassee, FL 32301  
800.342.3197 | 850.224.2727, x240 | Fax : 850.222.8190 | [www.ficpa.org](http://www.ficpa.org)



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## Bist, Kevin

---

**From:** Curry, Deborah <CurryD@ficpa.org>  
**Sent:** Thursday, January 29, 2015 3:48 PM  
**To:** Nelson, Patricia A  
**Subject:** RE: FICPA - Auditor Opinion Letter Example for language  
**Attachments:** Sample review report language.pdf

Patricia,  
See attached.

To illustrate a major difference between an audit and a review, a review will provide for analytical procedures and inquiries of management but will not involve testing of specific transactions. In general, a review does not generally provide for an actual inventory observation.

Our Director of Technical Services can explain in detail if you would like to talk with him. Just let me know.

**Deborah L. Curry, CPA, CGMA | President-CEO**  
Florida Institute of CPAs | 325 W. College Ave. | Tallahassee, FL 32301  
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**From:** Nelson, Patricia A [<mailto:Patricia.Nelson@flhealth.gov>]  
**Sent:** Thursday, January 29, 2015 3:39 PM  
**To:** Curry, Deborah  
**Subject:** RE: FICPA - Auditor Opinion Letter Example for language

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Patty

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**To:** Nelson, Patricia A  
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Please let me know if I can provide additional assistance.

Best regards,  
Deborah Curry

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## Review Exhibit D—Illustrative Review Reports

*Standard accountant's review report on financial statements prepared in accordance with accounting principles generally accepted in the United States of America*

### Independent Accountant's Review Report

[Appropriate Salutation]

I (We) have reviewed the accompanying balance sheet of XYZ Company as of December 31, 20XX, and the related statements of income, retained earnings, and cash flows for the year then ended. A review includes primarily applying analytical procedures to management's (owners') financial data and making inquiries of company management (owners). A review is substantially less in scope than an audit, the objective of which is the expression of an opinion regarding the financial statements as a whole. Accordingly, I (we) do not express such an opinion.

Management (owners) is (are) responsible for the preparation and fair presentation of the financial statements in accordance with accounting principles generally accepted in the United States of America and for designing, implementing, and maintaining internal control relevant to the preparation and fair presentation of the financial statements.

My (our) responsibility is to conduct the review in accordance with Statements on Standards for Accounting and Review Services issued by the American Institute of Certified Public Accountants. Those standards require me (us) to perform procedures to obtain limited assurance that there are no material modifications that should be made to the financial statements. I (We) believe that the results of my (our) procedures provide a reasonable basis for our report.

Based on my (our) review, I am (we are) not aware of any material modifications that should be made to the accompanying financial statements in order for them to be in conformity with accounting principles generally accepted in the United States of America.

[Signature of accounting firm or accountant, as appropriate]

[Date]

*Standard accountant's review report on financial statements prepared in accordance with the income tax basis of accounting*

### Independent Accountant's Review Report

[Appropriate Salutation]

I (We) have reviewed the accompanying statement of assets, liabilities, and equity—income tax basis of XYZ Company as of December 31, 20XX, and the related statement of revenue and expenses—income tax basis for the year then ended. A review includes primarily applying analytical procedures to management's (owners') financial data and making inquiries of company management (owners). A review is substantially less in scope than an audit, the objective of which is the expression of an opinion regarding the financial statements as a whole. Accordingly, I (we) do not express such an opinion.

Management (owners) is (are) responsible for the preparation and fair presentation of the financial statements in accordance with the income tax basis for accounting and for designing, implementing, and maintaining

## Bist, Kevin

---

**From:** Nelson, Patricia A  
**Sent:** Thursday, January 29, 2015 3:49 PM  
**To:** 'Curry, Deborah'  
**Subject:** RE: FICPA - Auditor Opinion Letter Example for language

Thank you very much!

I'll let you know after I have a chance to review these. I really appreciate all your help.

Patty

---

**From:** Curry, Deborah [<mailto:CurryD@ficpa.org>]  
**Sent:** Thursday, January 29, 2015 3:48 PM  
**To:** Nelson, Patricia A  
**Subject:** RE: FICPA - Auditor Opinion Letter Example for language

Patricia,  
See attached.

To illustrate a major difference between an audit and a review, a review will provide for analytical procedures and inquiries of management but will not involve testing of specific transactions. In general, a review does not generally provide for an actual inventory observation.

Our Director of Technical Services can explain in detail if you would like to talk with him. Just let me know.

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**From:** Nelson, Patricia A [<mailto:Patricia.Nelson@flhealth.gov>]  
**Sent:** Thursday, January 29, 2015 3:39 PM  
**To:** Curry, Deborah  
**Subject:** RE: FICPA - Auditor Opinion Letter Example for language

Thank you!

Do you have one for a review that is short of an audit?

Patty

**Bist, Kevin**

---

**From:** david.roberts@akerman.com  
**Sent:** Friday, January 30, 2015 2:53 PM  
**To:** Nelson, Patricia A  
**Cc:** info@pure-analytics.com; armen@pure-analytics.com; eli.nortelus@akerman.com  
**Subject:** FW: Final Draft  
**Attachments:** Comments For the Office of Compassionate Use \_2014.pdf; Pure Analytics Amendments to Proposed Rule Feb 4 and 5\_Revised JZ.DOCX

Director Nelson – For your consideration, I have attached comments from Pure Analytics, LLC, and their Laboratory Director Jose A. Zavaleta, regarding the draft rule language that is being considered during the February 4<sup>th</sup> & 5<sup>th</sup> meeting of the Negotiated Rulemaking Committee here in Tallahassee. Also, attached is proposed amendment language that we request to be considered by the Negotiated Rulemaking Committee.

Please let me know if you have any questions. Thank you,

Dave Roberts

**David J. Roberts**

Public Policy Advisor

Akerman LLP | Suite 1200 | 106 East College Avenue | Tallahassee, FL 32301

Dir: 850.521.8009 | Main: 850.224.9634 | Cell: 850.443.4820 | Fax: 850.325.2548

[david.roberts@akerman.com](mailto:david.roberts@akerman.com)



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Pure Analytics, LLC  
1 Hartford Square  
New Britain, CT 06052  
Ph. 860-224-6668  
30 January 2015

The Office of Compassionate Use/Florida Department of Health  
Negotiated Rulemaking Session Committee

Dear Committee Members:

Pure Analytics, LLC is writing this letter in respond to the *"1-15-15 draft of Chapter 64-4, Florida Administrative Code"* addressing the use of medical marijuana.

Pure Analytics, LLC is a privately owned medical marijuana testing laboratory. We are currently servicing the medical marijuana program (MMP) in Connecticut, which is ran by the Connecticut Department of Consumer Protection (DCP). In November 2013, Pure Analytics, LLC was the first lab in Connecticut, **and in the country**, to be awarded a Controlled Substance License (CSL 0001049) specific for medical marijuana testing. We have collaborated extensively with former DCP Commissioner William M. Rubenstein, Drug Control Director John Gadea, and the Connecticut Medical Marijuana Program Director Xaviel Soto. Our collaboration efforts with the DCP resulted in setting up various standards that are currently used, including standards in microbiology testing, heavy metal testing, and pesticide residue limits (tolerances).

Our laboratory has been responsible for testing 75% of **ALL** pharmaceutical grade medical marijuana products made available to Connecticut patients thus far and continue to do so.

We are very confident that our experience in servicing a pharmaceutical grade medical marijuana program, such as the one in Connecticut, can assist with drafting testing guidelines that will not only ensure that the Florida program excels, but also, most importantly, help keep patients safe. With this in mind, we have outlined below a few issues that we believe will make your testing guidelines stronger and more efficient:

I. **Microbiology Testing**

- a. For purposes of the microbiological test, we believe that it is best to follow USP <1111> instead of the USP Herbal Medicine Compendium. USP <1111> better addresses the different routes of administration, i.e. oral use, oromucosal use, gingival use, cutaneous use, etc. Our data obtained from research and actual products tested, which can be provided upon request, strongly suggests that the limits described in USP 1111 are realistically achievable for “none-usable flower” products.

II. **Pesticide Residue Limits**

- a. For purposes of the pesticide usage on any plant harvest, we have attached a table outlining the “most common” pesticides used in the medical marijuana industry as described in the *“American Herbal Pharmacopeia, Cannabis Inflorescence”*. The table also includes the tolerances allowed by the EPA for non-meat products. The attached table was suggested by us and is currently used by the CT-DCP.

III. **Heavy Metals**

- a. For purposes of the heavy metal test, we suggest that this test be nullified. Our data obtained from research, and from actual products tested, demonstrates that when the active ingredients (cannabinoids) in marijuana are extracted, no heavy metals are extracted. In fact, the extracted material from the marijuana plant is almost 100% free from the “big four” heavy metals, lead (Pb), arsenic (As), cadmium (Cd), and mercury (Hg).

**IV. Batch Size and Sampling**

- a. For purposes of batch size, we suggest that a batch be limited to 1,000 grams of any extract, oil, and concentrate. For tinctures, we suggest a “batch” to be limited to 1.00 liter.
- b. For purposes of sampling any product that is sold as a “unit”, we suggest that a minimum of 1.0% of the total “batch” size be sampled and tested.
- c. The above sampling and batch size suggestions are in reference to USP 1111 for proper microbiological testing. Furthermore, it will ensure that pharmaceutical grade product is properly manufacture and a representative sample of the batch is tested.

**V. Laboratory Requirements**

- a. We suggest that any laboratory that handles and test any medical marijuana product should be ISO 17025 certified. The scope of the laboratory’s certification should include all of the tests being performed on any medical marijuana product.

We at Pure Analytics strongly believe that if the medical marijuana industry looks to obtain a serious and credible standing with the public, then it should be held to the same standards as any other pharmaceutical company in the business of making medical drugs.

Please, do not hesitate to contact me may you have any questions regarding any of the suggestions above. I look forward to witnessing and potentially be part of a thriving pharmaceutical grade medical marijuana program in Florida!

Sincerely,



Jose A. Zavaleta  
Laboratory Director  
Pure Analytics, LLC

**Attachment A**

<b>Pesticide</b>	<b>Residue limits according to EPA in parts per billion (ppb)</b>
<b>Avermectin (abamectin)</b>	< 10
<b>Acequinocyl</b>	< 20
<b>Bifenazate</b>	< 100
<b>Bifenthrin (synthetic pyrethroid)</b>	< 50
<b>Cyfluthrin (synthetic pyrethroid)</b>	< 20
<b>Etoxazole</b>	< 10
<b>Imazalil</b>	< 100
<b>Imidacloprid</b>	< 50
<b>Myclobutanil</b>	< 20
<b>Paclobutrazol</b>	< 400
<b>Pyrethrins (synthetic)</b>	< 50
<b>Spinosad</b>	< 10
<b>Spiromesifen</b>	< 20
<b>Spirotetramat</b>	< 200
<b>Trifloxystrobin</b>	< 50

64.4001 Definitions. – Below are new (6) and (7), and then renumber subsequent subsections.

**(6) Batch Size – For the purposes of testing, a batch shall be limited to 1,000 grams of any extract, oil, and concentrate, and a batch shall be limited to 1.00 liter for any tinctures, as referenced in USP 1111 for proper microbiological testing.**

**(7) Batch Sample – For purposes of sampling any product that is sold as a unit, a minimum of 1.0% of the total batch size shall be sampled and tested, as referenced in USP 1111 for proper microbiological testing.**

64-4.006 Identification, Labeling and Testing Low-THC Cannabis Seeds, Dried Flowers and Derivative Products.

(1) A dispensing organization shall ensure that the low-THC cannabis derivative product provided to a qualified patient is in medical grade, childproof containers labeled with:

- (a) The dispensing organization name and location;
- (b) The amount, harvest number, and batch number of the low-THC cannabis derivative product being dispensed;
- (c) The date of product processing or production;
- (d) A list of all additives, including pesticides, herbicides, fertilizers, and solvents, used in the cultivation and production of the low-THC cannabis derivative product;
- (e) A list of all matrix ingredients used to make the low-THC cannabis derivative product, e.g., olive oil, canola oil, et cetera;
- (f) The percent by weight of tetrahydrocannabinol (THC) and cannabidiol (CBD);
- (g) Identification and percentages of all specific cannabinoids in the low-THC cannabis derivative product, if known;
- (h) The name of the ordering physician; and
- (i) The registry identification number of the qualified patient.

(2) Prior to dispensing any low-THC derivative product, a dispensing organization shall sample and have tested by a **testing laboratory that is ISO 17025 certified and the certification scope must include all tests being performed on** each batch of each product to be distributed. The testing laboratory shall file with the department an electronic copy of each laboratory test result for any batch that does not pass the microbial, mycotoxin, heavy metal, pesticide, chemical residue or residual solvents levels test or meet the composition requirements required by s. 381.986(1)(b), F.S. Dispensing shall not occur until the test results have been received by the dispensing organization. Testing shall include **minimum requirements found in USP 1111 for microbiological testing of any low-THC derivative product:** ~~at a minimum~~ ~~{use U.S. Pharmacopeia Herbal Medicines Compendium?}~~:

- (a) Tetrahydrocannabinol concentration reported as a percentage by weight;
- (b) Cannabidiol concentration reported as percentage by weight;
- (c) Bacteria and molds, including aerobic bacteria, E. coli, enterobacteria, powdery mildew, penicillium, yeast, aspergillus, cladosporin, fusarium, botrytis, aureobasidium and acremonium;
- (d) Heavy metals; and

(e) All chemical additives, including nonorganic pesticides, herbicides, and fertilizers, and solvents used in the cultivation and production of the low-THC cannabis reported as parts per billion.

(3) The dispensing organization shall provide copies of any test results to the department upon request.

(4) If any batch sample test result shows the presence of any bacteria, mold, heavy metal, or chemical additive over the Health Advisory Level (HAL) as provided in the department's Environmental Chemistry Analyte List based on **USP 1111 and EPA minimum requirements** [~~use U.S. Pharmacopeia Herbal Medicines Compendium?~~], dated July 31, 2014, herein ~~incorporated by reference and available at <https://flrules.com/gateway/reference.asp?No=Ref#####>~~, the entire batch from which the sample was derived shall be identified and segregated to prevent further processing or distribution. The entire batch shall be [TBD].

(5) Any batch sample or any other sample that exceeds 0.8% tetrahydrocannabinol by weight or has 10% or less of cannabidiol by weight shall be segregated to prevent further processing or dispensing. If the batch cannot be made to conform to the requirements of section 381.986(1)(b), F.S., within 10 days, the batch shall be destroyed.

(6) Upon request from the department, a dispensing organization shall submit a sample of any specific seed, dried flower or derivative product from the low-THC cannabis inventory to a laboratory selected by the department for analysis and reporting to the department.

(7) Laboratories shall immediately destroy any untested low-THC cannabis or low-THC cannabis derivative product upon the completion of the testing. Laboratories shall retain the tested sample for 30 calendar days to allow for retesting before destroying the sample. If the low-THC cannabis or low-THC cannabis derivative product is destroyed, the time and method of destruction or disposal shall be documented.

(8) All low-THC derivative products shall be maintained in an appropriately climate-controlled environment.

## Bist, Kevin

---

**From:** Nelson, Patricia A  
**Sent:** Friday, January 30, 2015 3:35 PM  
**To:** david.roberts@akerman.com  
**Cc:** info@pure-analytics.com; armen@pure-analytics.com; eli.nortelus@akerman.com  
**Subject:** RE: Final Draft

Thank you!

---

**From:** [david.roberts@akerman.com](mailto:david.roberts@akerman.com) [<mailto:david.roberts@akerman.com>]  
**Sent:** Friday, January 30, 2015 2:53 PM  
**To:** Nelson, Patricia A  
**Cc:** [info@pure-analytics.com](mailto:info@pure-analytics.com); [armen@pure-analytics.com](mailto:armen@pure-analytics.com); [eli.nortelus@akerman.com](mailto:eli.nortelus@akerman.com)  
**Subject:** FW: Final Draft

Director Nelson – For your consideration, I have attached comments from Pure Analytics, LLC, and their Laboratory Director Jose A. Zavaleta, regarding the draft rule language that is being considered during the February 4<sup>th</sup> & 5<sup>th</sup> meeting of the Negotiated Rulemaking Committee here in Tallahassee. Also, attached is proposed amendment language that we request to be considered by the Negotiated Rulemaking Committee.

Please let me know if you have any questions. Thank you,

Dave Roberts

**David J. Roberts**  
Public Policy Advisor  
Akerman LLP | Suite 1200 | 106 East College Avenue | Tallahassee, FL 32301  
Dir: 850.521.8009 | Main: 850.224.9634 | Cell: 850.443.4820 | Fax: 850.325.2548  
[david.roberts@akerman.com](mailto:david.roberts@akerman.com)



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## Bist, Kevin

---

**From:** Jorge Chamizo <jorge@flapartners.com>  
**Sent:** Friday, January 30, 2015 5:52 PM  
**To:** Nelson, Patricia A  
**Subject:** RE: Updated Draft Text for 64-4, F.A.C.  
**Attachments:** Jorge Chamizo.vcf

Patty:

Is this the same draft that was circulated by your office previously (January 5<sup>th</sup>) or different version?



---

**From:** Nelson, Patricia A [<mailto:Patricia.Nelson@flhealth.gov>]  
**Sent:** Friday, January 30, 2015 5:44 PM  
**To:** DL 64-4 Interested Parties; DL 64-4 Interested Parties 2  
**Cc:** Dunn, Nathan P; Cowie, Tiffany C  
**Subject:** Updated Draft Text for 64-4, F.A.C.

Please see the attached updated draft text.

Have a great weekend!

Patricia Nelson  
Director  
Office of Compassionate Use  
Florida Department of Health



STATE & FEDERAL  
GOVERNMENT &  
ADMINISTRATIVE  
PRACTICE

## **Bist, Kevin**

---

**Full Name:** Jorge Chamizo  
**Last Name:** Chamizo  
**First Name:** Jorge  
**Company:** Floridian Partners, LLC

**Business Address:** 108 South Monroe Street  
Tallahassee, FL 32301

**Business:** (850) 681-0024

**E-mail:** jorge@flapartners.com  
**E-mail Display As:** Jorge Chamizo (jorge@flapartners.com)

**Web Page:** [www.flapartners.com](http://www.flapartners.com)

## Bist, Kevin

---

**From:** Nelson, Patricia A  
**Sent:** Friday, January 30, 2015 6:25 PM  
**To:** Jorge@flapartners.com  
**Subject:** RE: Updated Draft Text for 64-4, F.A.C.

It is different. That's why it has a dated watermark.

---

**From:** Jorge Chamizo [<mailto:jorge@flapartners.com>]  
**Sent:** Friday, January 30, 2015 5:52 PM  
**To:** Nelson, Patricia A  
**Subject:** RE: Updated Draft Text for 64-4, F.A.C.

Patty:

Is this the same draft that was circulated by your office previously (January 5<sup>th</sup>) or different version?



---

**From:** Nelson, Patricia A [<mailto:Patricia.Nelson@flhealth.gov>]  
**Sent:** Friday, January 30, 2015 5:44 PM  
**To:** DL 64-4 Interested Parties; DL 64-4 Interested Parties 2  
**Cc:** Dunn, Nathan P; Cowie, Tiffany C  
**Subject:** Updated Draft Text for 64-4, F.A.C.

Please see the attached updated draft text.

Have a great weekend!

Patricia Nelson  
Director  
Office of Compassionate Use  
Florida Department of Health



**Bist, Kevin**

---

**From:** Desiree Mufson <desireemufson@gmail.com>  
**Sent:** Saturday, January 31, 2015 12:50 PM  
**To:** Nelson, Patricia A  
**Subject:** Re: Low-THC Cannabis Rulemaking

Absolutely..I am open anytime...  
Let me know so I will be by my phone..

Best,  
Desiree

On Fri, Jan 30, 2015 at 3:34 PM, Nelson, Patricia A <Patricia.Nelson@flhealth.gov> wrote:

Thank you, Desiree. Do you have time for a quick call on Monday?

Patty

**From:** Desiree Mufson [mailto:[desireemufson@gmail.com](mailto:desireemufson@gmail.com)]  
**Sent:** Friday, January 30, 2015 2:50 PM  
**To:** Nelson, Patricia A  
**Subject:** Re: Low-THC Cannabis Rulemaking

Hello Ms. Nelson;

Thank you for replying to my email. I would be delighted to participate by offering any additional information that you may need.

I am quite impressed that you are gathering a committee of well versed individuals to aid you in drafting the proposed rules for Medical Marijuana. I am quite familiar with CannLabs out of Denver as I have met Genifer Murray several times and know that she will be an asset to the committee.

I am available to help you anytime.

Best,

Desiree Ardito Mufson

Coastal Cannalabs

[772-260-8636](tel:772-260-8636)

On Tue, Jan 27, 2015 at 5:09 PM, Nelson, Patricia A <Patricia.Nelson@flhealth.gov> wrote:

Ms. Mufson,

The negotiating committee has already been chosen. We chose CannLabs out of Colorado as the laboratory representative. Although your lab was not chosen for the committee, that does not mean you will not be part of

the process. In fact, as a laboratory that will be operating in Florida, I think you can help me a lot. As I am drafting the rules to use as a starting point for the negotiation, I find that I need some information in the laboratory area. It would be great if you could help me understand some of the best laboratory practices you have learned, including methods, standards, equipment, etc. If I receive your information prior to the negotiation, I will be able to draw from it for the draft rules, and the group can use it during the negotiation process. Please let me know if you can offer this type of assistance.

Thank you,

Patty

Patricia Nelson

Director

Office of Compassionate Use

Florida Department of Health



**From:** Desiree Mufson [mailto:[desireemufson@gmail.com](mailto:desireemufson@gmail.com)]

**Sent:** Tuesday, January 27, 2015 3:17 PM

**To:** Nelson, Patricia A

**Subject:** Fwd: Low-THC Cannabis Rulemaking

-

Hello Ms. Nelson;

I wish to be considered as one of the committee members to represent the laboratory portion for the Medical Marijuana Rule Revision to be held on February 4-5 in Tallahassee.

Please see enclosed on why I feel I can make a difference.

Best,

Desiree Ardito Mufson

Coastal Cannalabs

772-260-8636

Desireemufson@gmail.com

On Mon, Jan 5, 2015 at 5:11 PM, Nelson, Patricia A <Patricia.Nelson@flhealth.gov> wrote:

Dear Interested Parties,

Please see the attached Notice of Negotiated Rulemaking (on page 1 of the attached document) scheduled for February 4 and 5, 2015, in Tallahassee.

Sincerely,

Patty

Patricia Nelson

Director

Office of Compassionate Use

--

*Desiree Ardito Mufson*

*New Vision Productions, Inc.*

Stuart, Fl

772-219-0140

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*Desiree Ardito Mufson*

*New Vision Productions, Inc.*

Stuart, Fl

772-219-0140

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*Desiree Ardito Mufson*

*New Vision Productions, Inc.*

Stuart, Fl

772-219-0140

--

*Desiree Ardito Mufson*

*New Vision Productions, Inc.*

Stuart, Fl

772-219-0140

**Bist, Kevin**

---

**From:** Kostas Stoilas <stoilas@yahoo.com>  
**Sent:** Sunday, February 01, 2015 5:29 PM  
**To:** Nelson, Patricia A  
**Cc:** Cowie, Tiffany C; Dunn, Nathan P  
**Subject:** Re: Updated Draft Text for 64-4, F.A.C.  
**Attachments:** FL App Criteria Suggestions (Feb1-15).docx; ATT00001.htm

Patty - thanks for the email. I have a couple questions, just to understand if this is a new point we're starting from for Rule 64 or if this picks up somewhere from where we left off in the Fall of 2014. In previous drafts/revisions, it was noted whether subsequent drafts changed language in the prior draft or simply added to existing language. For example, I don't see any mention of the "nursery block number" that would allow cultivation to happen at multiple facilities as long as they fell under the nursery's control and their Dept of Agr block number. Does this mean the block number carries over from the last rule draft from Fall 2014, or has it been struck off and now we start over with new rule-making?

In addition, I've attached an update to my written comments from early January, due to added input from others and personal research. I've highlighted the added comments in yellow, and you'll see most of page 4 is input from a nursery we are working with. Consider this "food for thought" since we are not able to participate in verbal testimony this week in Tallahassee.

One final question, based on process. Will the results of the Feb 4-5 workshop go into some planning material for committee review at the Legislative level, or is Legislature no longer involved in this rule making process?

### Criteria and Research from other States:

- States should DEFINITELY include compliance with the Cole Memo into their criteria.

### **Cole Memorandum 8 Priorities:**

- Preventing the distribution of marijuana to minors.
  - Accounted for through distance from schools, etc.
- Preventing revenue from the sale of marijuana from going to criminal enterprises, gangs and cartels.
  - Accounted for through background checks of owners.
- Preventing the diversion of marijuana from states where it is legal under state law in some form to other states.
- Preventing state-authorized marijuana activity from being used as a cover or pretext for the trafficking of other illegal drugs or other illegal activity.
- Preventing violence and the use of firearms in the cultivation and distribution of marijuana.
- Preventing drugged driving and the exacerbation of other adverse public health consequences associated with marijuana use.
  - Accounted for by showing community education plans.
- Preventing the growing of marijuana on public lands and the attendant public safety and environmental dangers posed by marijuana production on public lands.
- Preventing marijuana possession or use on federal property.
- o Points should be accounted for in terms of proximity/distance from schools, etc., as well as how much control the applicant has over the property in terms of leased or owned.
- o Points for marketing plans, packaging/labeling plans.
- o Points for security procedures, physical access, exceptions and post-event scenarios if something goes wrong.
- o Points for training staff and tracking product.
- Those individuals that rate and qualify the applications should be trained on how to review the applications.
  - o This comes highly recommended.
  - o Could use other states' processes as a starting point for review/training.
- Consider bringing in or talking with the Association of American Cannabis Nurses, as they have been building up curriculum in this area.
- There HAS to be a way to keep some info confidential and NOT accessible to the public through sunshine laws, in order to maintain the security and proprietary nature of that particular info (i.e. the security plan and facility layout).

- Thoughts on medicinal administration:
  - o It's an expensive proposition due to how patients take the drug and how quickly they feel relief.
  - o Patients don't feel relief as quickly with edible or ingested methods because of the lag to get into the bloodstream, so some high-pain, quick relief needs are met with vaporizing.
  - o Extraction to oil is more expensive for less patient demand, as compared to vaporizing flower for quicker relief.
  - o Juicing the plant as an administration method removes the euphoria because it doesn't activate the THCA (acid) into the euphoric THC, so "juice" should be added to the list of DOH accepted Derivative Products.
- Minnesota is close to Florida's program in terms of how the product is administered to patients.
- Pennsylvania has been going back and forth on which conditions qualify for legal use of prescribed cannabis, as well as how to administer the drug
  - o Currently they are working to push through an amendment that eliminate enumerated conditions, leaving the decision to medical professionals as to what could qualify.
  - o <http://www.post-gazette.com/news/health/2015/01/29/Support-surfaces-for-Pennsylvania-medical-marijuana-bill/stories/201501290182>
- Iowa and Maine are good examples as well.
- Illinois allows a business applicant to own both the cultivation and dispensary operations, and they can be separate locations/facilities not tied to the same parcel.
- Illinois also designated a Security Officer that would, in addition to other duties, accompany any transported product from grow to dispensary.
  - o Seed to Sale tracking helps this process if there aren't many dispensary locations, along with lockboxes in the vehicles, but if transport to patients is part of the program then the Security Officer will have to track product differently because they can't be on every delivery route.
- New Jersey is a tough model to follow because it wasn't very well received, and some believe it was set up for failure.
- Michigan supposedly has set up good testing procedures.
- Application Fee Examples:
  - o Massachusetts: \$31,000
  - o Illinois: \$25,000 for cultivation; \$5,000 for each dispensary
  - o New Jersey: \$20,000 with \$18,000 refundable
  - o Colorado: \$7,500 – 18,000
  - o Arizona: \$5,000
  - o \*Fee should depend on if there's state funding in place.
- An attending MD on site at all times could be overkill and expensive for the operation, where a nurse is almost better, more effective and typical of other states.

- Better to have a medical professional on the board, and then it can be an MD, nurse, pharmacist, etc.
- Some states actually go as far as to NOT have a Dr on site at all.
- Should be modeled after a clinical intake process, which is designed by the applicant and judged by the state against the application criteria. This leaves the applicant free to come up with a well thought out and designed plan that the state can judge for appropriateness.
- Bonus points have been given in other states:
  - for research plans and other agreements in place with researchers within the medical and horticulture fields,
  - for “community outreach” plans, which also address and cover the Cole Memo,
  - for environmental controls, such as energy savings plans and waste disposal/reuse,
  - where there were economically positive benefits to state grown businesses:
    - You can’t exclude out of state entrants, but can rather incentivize in-state developed businesses.
- Offer alternative ways to satisfy the financial review, such that if there are audited financials versus certified, then the applicant can submit whichever they have and the state can judge them each.
- Show flowcharts of how the product moves through the facility, physically through vegetation to flower to harvest, etc.
- It should be mandatory to have inclusion of how discounts are given to patients with financial hardship, and how they would qualify for discounted product (i.e. are they already on a public assistance program?).

Other things to think about:

- Will FL consider zoning needs, county code enforcement and building permit timeframes so building the right grow houses is accounted for, and so facilities fall under light-industrial areas?
  - This would apply to the 150-day timeline to dispense, so that it can be revised to an appropriate timeframe and not restrict applicants from building the right facility from the start.
- Can DOs sell to each other in the state if demand and production capacity shifts per region?
- How will FL license the testing labs (important)?
  - Lab testing becomes even more important when you move past growing just flowers, and start getting into edible/ingestible product.
- Will there be dosage criteria or a review of how DO’s plan their patient dosage?
- Will DOH change the nursery ownership percentage based on the Administrative Law Judge’s ruling, or will they work with the State Legislature to explain why they chose 25% ownership?
  - 25% ownership was chosen by the DOH after the first rule-making workshop in the summer of 2014 because someone mentioned it

would not be fair to the nursery to apply for this license and risk losing their primary business and livelihood because it was still Federally illegal to grow cannabis.

- The solution was to make the nursery part owner in the applicant company, so that the entity that applies is the only one at risk, Federally, and the nursery can still operate its normal business without risk of losing it.

#### ADDED FEB 1, 2015;

Input from an approved nursery that meets Section 381.986(5)(b)1., F.S.:

- 150 days is plenty of time to grow, however from the minute we get the go ahead we need equipment to be ordered, shipped, installed, and running, not to mention working out any problems.
  - A lot has to happen perfectly to meet the 150 day deadline.
  - The warehouse must be ready, harvest and drying time, systems for oil extraction tested, sales and delivery set up, ID cards in place for the customers.
  - Will the state have that in place on time? Could they let the growers on the list get started with some experimental crops for learning and then destroy? I know all of the growing information is available, however with failure not an option, the hands-on approach is without a doubt the best teacher.
- The University of Florida has extension offices all over the state and could do all of this research, however with the federal laws being what they are they wouldn't touch it.
- Spring is the time to start this program.
- What are the minimum amounts of production to keep the license? If you have a crop failure what are your options?

There is a concern that the nurseries on the committee could be positioning criteria into the application that only they can meet rather than be fair to all applicable nurseries.

Also, the state should look into and consider pitfalls and lessons learned from other states such as Illinois, New Jersey and Massachusetts, which are having problems getting their programs off the ground.

Resources and Knowledgeable Groups:

- Kalyx Development: performed thorough state-by-state process reviews.
- CannLabs: independent lab testing of cannabis flower and oils.
- American Cannabis Nurses Assoc: building curriculum for this area.

## Bist, Kevin

---

**From:** Nelson, Patricia A  
**Sent:** Monday, February 02, 2015 11:25 AM  
**To:** stoilas@yahoo.com  
**Subject:** RE: Updated Draft Text for 64-4, F.A.C.

Mr. Stoilas,

Thank you for your comments. I am unclear on some of your questions. I cannot find the term "nursery block number" in any of the previous draft rules. Can you please identify for me the part of the rules that addressed that topic? Regarding your process question, the remainder of the rulemaking will proceed according to the requirements of section 120.54, F.S. The Legislature is normally not involved in the rulemaking process. Its only involvement is to ratify rules that exceed certain regulatory cost thresholds.

Patty

---

**From:** Kostas Stoilas [<mailto:stoilas@yahoo.com>]  
**Sent:** Sunday, February 01, 2015 5:29 PM  
**To:** Nelson, Patricia A  
**Cc:** Cowie, Tiffany C; Dunn, Nathan P  
**Subject:** Re: Updated Draft Text for 64-4, F.A.C.

Patty - thanks for the email. I have a couple questions, just to understand if this is a new point we're starting from for Rule 64 or if this picks up somewhere from where we left off in the Fall of 2014. In previous drafts/revisions, it was noted whether subsequent drafts changed language in the prior draft or simply added to existing language. For example, I don't see any mention of the "nursery block number" that would allow cultivation to happen at multiple facilities as long as they fell under the nursery's control and their Dept of Agr block number. Does this mean the block number carries over from the last rule draft from Fall 2014, or has it been struck off and now we start over with new rule-making?

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One final question, based on process. Will the results of the Feb 4-5 workshop go into some planning material for committee review at the Legislative level, or is Legislature no longer involved in this rule making process?

## Bist, Kevin

---

**From:** Kostas Stoilas <stoilas@yahoo.com>  
**Sent:** Monday, February 02, 2015 2:49 PM  
**To:** Nelson, Patricia A  
**Subject:** Re: Updated Draft Text for 64-4, F.A.C.

Sorry, should've noted where it was. In the previous draft was in the last sentence of the first paragraph of 64-4.002 section (1).

Sent via mobile device...please excuse abbreviated responses & grammar.

Kostas Stoilas  
239.822.7816 cell

[www.CauseToFund.com](http://www.CauseToFund.com)

[www.WarehouseRealEstateBlog.com](http://www.WarehouseRealEstateBlog.com)

[www.Linkedin.com/in/stoilas](http://www.Linkedin.com/in/stoilas)

On Feb 2, 2015, at 11:24 AM, "Nelson, Patricia A" <[Patricia.Nelson@flhealth.gov](mailto:Patricia.Nelson@flhealth.gov)> wrote:

Mr. Stoilas,

Thank you for your comments. I am unclear on some of your questions. I cannot find the term "nursery block number" in any of the previous draft rules. Can you please identify for me the part of the rules that addressed that topic? Regarding your process question, the remainder of the rulemaking will proceed according to the requirements of section 120.54, F.S. The Legislature is normally not involved in the rulemaking process. Its only involvement is to ratify rules that exceed certain regulatory cost thresholds.

Patty

---

**From:** Kostas Stoilas [<mailto:stoilas@yahoo.com>]

**Sent:** Sunday, February 01, 2015 5:29 PM

**To:** Nelson, Patricia A

**Cc:** Cowie, Tiffany C; Dunn, Nathan P

**Subject:** Re: Updated Draft Text for 64-4, F.A.C.

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One final question, based on process. Will the results of the Feb 4-5 workshop go into some planning material for committee review at the Legislative level, or is Legislature no longer involved in this rule making process?

## Bist, Kevin

---

**From:** Latresia Wilson <redbirdllc@gmail.com>  
**Sent:** Monday, February 02, 2015 11:34 AM  
**To:** Bist, Kevin  
**Subject:** Re: Florida Channel Link

Thanks Kevin  
Dr Wilson

On Monday, February 2, 2015, Bist, Kevin <[Kevin.Bist@flhealth.gov](mailto:Kevin.Bist@flhealth.gov)> wrote:

Hi Dr. Wilson,

Nice to speak with you this morning!

The Negotiated Rulemaking meeting February 4<sup>th</sup> and 5<sup>th</sup> will be streamed via the Florida Channel. Here is the link for your convenience:

<http://thefloridachannel.org/>

Please let me know if I may be of additional assistance.

Kind Regards,

Kevin

Kevin Bist

Program Specialist

Office of Compassionate Use

Florida Department of Health

850-245-4658

**Bist, Kevin**

---

**From:** Nelson, Patricia A  
**Sent:** Monday, February 02, 2015 4:40 PM  
**To:** jeffreysark@gmail.com  
**Subject:** RE: sharkey question

There will be no opportunity for public comment at the negotiation. We need all the time we can get for actual negotiation. The time to comment is now via written comment. I am collecting all the comment and we will have it at the negotiation. The feedback I got at the workshop was that we did not need any more workshops. This will be a negotiation only. We will have to file a Notice of Proposed Rule pursuant to section 120.54, F.S., and I assume someone will request a hearing. Though, for the sake of time, that is not my preference, and it will be disappointing if someone does it solely for delay purposes.

**From:** Jeffrey Sharkey [<mailto:jeffreysark@gmail.com>]  
**Sent:** Monday, February 02, 2015 4:05 PM  
**To:** Nelson, Patricia A  
**Subject:** sharkey question

**Patti**

Know you are busy but had a quick question.

There is some confusion about whether or not any other public comment will be allowed at the negotiating committee meeting. My assumption is no.

Should they finish the final draft, my assumption is that the DOH would have to hold a final rule hearing.

Let me know  
Thanks

**Dr. Jeffrey Sharkey**  
**Managing Partner**  
**Capitol Alliance Group, Inc**  
**106 E. College Avenue, Suite 640**  
**Tallahassee, FL 32301**  
**850.224.1660 office**  
**850.224.6785 fax**  
**850.443.3355 cell**

**jeffreysark@gmail.com**

**www.capitolalliancegroup.com**

## Bist, Kevin

---

**From:** John Dial <johndialmarine@hotmail.com>  
**Sent:** Monday, February 02, 2015 7:23 PM  
**To:** Nelson, Patricia A  
**Cc:** Ken Sumner  
**Subject:** comments

Ms Nelson;

First I would like to thank you and the DOH for taking on this issue with open mind and a sense of fair play. I was at the last DOH meeting and think you are definitely heading in the right direction. It is our opinion that this process should be about not who is the biggest flower grower or vegetable grower but who will assemble the best team to grow, process and distribute as well as track the effects and successes of the cannabis medicines which will be produced. Sometimes bigger is not always better. For example General Motors or Tesla Motors both are car companies but very different in product and quality controls.

My name is John Dial with Florida Organic Products and I am in a partnership with Ken Sumner with Gator Growers with operations in 2 sectors of the 5. We are in the central and the north east zones. Our position is that since we are in 2 sections we should have the ability to apply in two zones. Also we realize we may only be awarded one license and are fine with this as it may be only one license per entity but you can clarify this it would help. Our remote location should not be a penalty against us and want to have clarification of the offsite dispensary language and number if in fact this is the way it is going to go. In our opinion off site dispensaries are the only real way to serve the patient base effectively.

Next I would like to address the 5 million dollar bond this I think we all agree will be much more than needed to destroy a crop and dismantle a grow operation. This will prove costly and what I am finding hard to obtain. This will have to be passed down to the patient with inflated medicine costs.

Third we are of the belief that under the current rule that although the governor signed the law for 5 licenses in the each of the 5 regions we feel this would create a monopoly in each area and would urge you to allow state wide market and sales to create competition and across the board even pricing. As with the exclusive area price fixing could occur as there is no competition in the zone. Obviously more than one license in each area would be better of course but you have only the signed rule you have only to deal with I suppose.

Lastly I have read the latest version of the draft and want you to be more clear on the language of "leased property" terms as this is a little ambiguous. It is not clear if this has to be at the licenses growers location or can these mentioned entities (processing and packaging) be off site at a leased operation?

In respect with all of the grow operations they can be modified to grow effectively but none are set up for the antiseptic facility required to process, extract and package medical grade products in a clinically clean environment. It is my opinion this will have to be customized for the process and in fact offsite may be better. The same goes for the lab process which should be independent from the grower and accountable only to the DOH.

Thank you and best Regards;  
John Dial  
Florida Organic Products  
Gator Growers Nursery

Sent from my iPad

**Bist, Kevin**

---

**From:** Kostas Stoilas <stoilas@yahoo.com>  
**Sent:** Monday, February 02, 2015 8:54 PM  
**To:** Nelson, Patricia A  
**Subject:** Re: Updated Draft Text for 64-4, F.A.C.  
**Attachments:** 64-4.001.doc; ATT00001.htm

Patty - to make it easier, please find towards the top of page 3, the definition under (16) for Nursery Block Number. It's right above the definition for Owner, which was revised from 5% to 7%. Who updated the chapter, such that this removal wasnt noted? The administrative law judge didnt have a problem with Nursery Block Number, so I'm concerned that other things might have been left out.

## NOTICE OF PROPOSED RULE

### DEPARTMENT OF HEALTH

#### Office of Compassionate Use

#### RULE NOS.:RULE TITLES:

- 64-4.001 Definitions
- 64-4.002 Initial Application Requirements for Dispensing Organizations
- 64-4.003 Biennial Renewal Requirements for Dispensing Organizations
- 64-4.004 Denial or Revocation for Dispensing Organization Approval
- 64-4.005 Inspection Procedures
- 64-4.006 Identification, Labeling and Testing Low-THC Cannabis Plants and Products
- 64-4.007 Recordkeeping and Reporting Requirements
- 64-4.008 Procedural Requirements
- 64-4.009 Compassionate Use Registry

**PURPOSE AND EFFECT:** This rulemaking establishes a comprehensive regulatory framework for implementing the Compassionate Medical Cannabis Act of 2014. It establishes the requirements for persons who cultivate and produce the medical cannabis as well as the requirements for dispensing and use of the cannabis.

**SUMMARY:** The rulemaking establishes, licensure and biennial licensure renewal requirements for dispensing organizations, reasons for denial or revocation of dispensing organization approval, inspection procedures for dispensing organization facilities, medical direction for dispensing organizations, requirements for pre-dispensing identification, testing and labelling of low THC cannabis and derivative products, inventory control, recordkeeping and reporting requirements, procedural requirements including dispensing facility hours, policies and procedures for inventory control and patient records, facility security, staffing, facility cleanliness, and refuse removal, requirements for accessing and inputting information as well as maintenance of the compassionate use registry.

**SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS AND LEGISLATIVE RATIFICATION:** The agency has determined that seven of the nine rules associated with the regulatory framework will not have an adverse impact on small business or likely increase directly or indirectly regulatory costs in excess of \$200,000 in the aggregate within one year after the implementation of the rule. The agency has determined that two of the nine rules associated with the regulatory framework, Rules 64-4.002 and 64-4.003, F.A.C., will have an adverse impact on small business or likely increase directly or indirectly regulatory costs in excess of \$200,000 in the aggregate within one year after the implementation of the rule. A SERC has been prepared by the agency for Rules 64-4.002 and 64-4.003, F.A.C. The Agency has determined that proposed Rule 64-4.003, F.A.C., is expected to require legislative ratification based on the statement of estimated regulatory costs. Based on the SERC checklist, this rulemaking, except for proposed Rule 64-4.003, F.A.C., will not have an adverse impact or regulatory costs in excess of \$1 million within five years as established in Section 120.541(2)(a), F.S. Proposed section 64-4.003 will have an adverse impact or regulatory costs in excess of \$1 million within five years as established in Section 120.541(2)(a), F.S.

Any person who wishes to provide information regarding the statement of estimated regulatory costs, or to provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

**RULEMAKING AUTHORITY:** 381.986(5)(d) FS.

**LAW IMPLEMENTED:** 381.986(5)(b) FS.

**A HEARING WILL BE HELD AT THE DATE, TIME AND PLACE SHOWN BELOW:**

**DATE AND TIME:** September 5, 2014, 9:00 a.m. – 5:00 p.m., Eastern Time or until the hearing is concluded

**PLACE:** Room 152, Betty Easley Conference Center, Esplanade Way, Tallahassee, Florida 32399

Any person wanting to request a hearing regarding the proposed rule must do so within 21 days of the date of publication of this notice by contacting the agency's designated contact, as described herein.

**THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS:** Linda N. McMullen, Director of Office of Compassionate Use, 4052 Bald Cypress Way, Bin A-02, Tallahassee, Florida 32399-1703, E-mail: linda.mcmullen@flhealth.gov

**THE FULL TEXT OF THE PROPOSED RULE IS:**

64-4.001 Definitions.

For the purposes of this chapter, the following words and phrases shall have the meanings indicated:

(1) Applicant – An entity with at least 25% ownership by a nursery that meets the requirements of Section 381.986(5)(b)1., F.S., that applies for approval as a dispensing organization.

(2) Approval – Written notification from the department to an applicant that its application for dispensing organization approval has been found to be in compliance with the provisions of this chapter and that the department is awaiting notification from the applicant that it is prepared to be inspected and authorized to begin cultivation and other operations.

(3) Authorization – Written notification by the department to a dispensing organization that it may begin specific phases of operation including cultivation, harvesting, processing, dispensing and other activities authorized by this chapter involving the possession of low-THC cannabis and the manufacturing of low-THC cannabis derivative products. Authorization may be requested and given in stages as the infrastructure and staffing requirements of the operation are completed.

(4) Batch – means a specific lot of low-THC cannabis derivative product produced from one or more harvests of low-THC cannabis plants that are processed or blended into a uniform mixture before portioning such that all products bearing the same batch number would be expected to be representative of the entire batch for the purpose of laboratory testing.

(5) Batch number – means a unique numeric or alphanumeric identifier assigned to a batch by a dispensing organization when the batch is portioned and packaged for dispensing.

(6) Cultivation – means the reproduction of source plant or tissue culture material.

(7) Derivative product – means forms of low-THC cannabis suitable for routes of medical administration, including but not limited to vapor, resins, salts, extracts, capsules, oral sprays and any compound, mixture or preparation derived from low-THC cannabis plants that is dispensed only from a dispensing organization.

(8) Dispensing Region – A geographical area where the growing, production and dispensing of Low-THC cannabis under the control of a dispensing organization shall occur. The five dispensing regions shall be identified as follows:

(a) Northwest Florida Region consisting of Bay, Calhoun, Escambia, Franklin, Gadsden, Gulf, Holmes, Jackson, Jefferson, Leon, Liberty, Madison, Santa Rosa, Okaloosa, Taylor, Wakulla, Walton, and Washington counties.

(b) Northeast Florida Region consisting of Alachua, Baker, Bradford, Clay, Columbia, Dixie, Duval, Flagler, Gilchrist, Hamilton, Lafayette, Levy, Marion, Nassau, Putnam, St. Johns, Suwannee, and Union counties.

(c) Central Florida Region consisting of Brevard, Citrus, Hardee, Hernando, Indian River, Lake, Martin, Orange, Osceola, Pasco, Pinellas, Polk, Seminole, St. Lucie, Sumter, and Volusia counties.

(d) Southwest Florida Region consisting of Charlotte, Collier, DeSoto, Glades, Hendry, Highlands, Hillsborough, Lee, Manatee, Okeechobee, and Sarasota counties.

(e) Southeast Florida Region consisting of Broward, Dade, Monroe, and Palm Beach counties.

(9) Dispensing Organization – an entity which has been approved by the department to cultivate, process and dispense organically grown low-THC cannabis.

(10) Dispensing Organization Facility – One or multiple structures within the same contiguous property that are used by the dispensing organization for the preparation, cultivation, storage, processing, dispensing, or any other action in the presence of or involving low-THC cannabis.

(11) Edible food product – Food products made with low-THC cannabis such as cakes, cookies, candies, brownies and other food items intended to be taken into the mouth, chewed and swallowed. Low-THC cannabis derivative products such as pills or ingestible substances used as delivery agents for low-THC cannabis such as olive oil are not considered edible food products.

(12) Harvest – A specific lot of low-THC cannabis plants grown from one or more seeds, cuttings or tissue cultures, that are planted, cloned or cultured and harvested at the same time such that any plant in the harvest is expected to be representative of the entire harvest for the purposes of laboratory testing.

(13) Harvest number – means a unique numeric or alphanumeric identifier assigned to a harvest by a dispensing organization when the harvest is planted.

(14) Inventory Agent – An employee of the dispensing organization who has been designated in writing to have oversight of the inventory control system.

(15) Manager – Any person with the authority to exercise operational direction or management of the dispensing organization or the authority to supervise any employee of the dispensing authority, including but not limited to the following:

(a) All directors, officers, board members and managers identified in the most recent annual report filed with the Florida Division of Corporations;

(b) The inventory agent;

(c) The security director;

(d) The medical director; and

(e) If the dispensing organization is a joint venture, all persons associated with each joint venture partner who have the authority to exercise operational direction or management of the dispensing organization or have the authority to supervise any employee of the dispensing organization.

(16) Nursery block number – Subpart of a nursery certificate of registration that identifies where plants or grown or produced.

(17) Owner – Any person, including any individual or other legal entity, with a direct or indirect ownership interest of 5% of more in the applicant, including the possession of stock, equity in capital, or any interest in the profits of the applicant.

(18) Permanent resident – A person has his or her true, fixed and permanent home and principal establishment in Florida to which, whenever absent, he or she has the intention of returning. Once a permanent residence is established in Florida it is presumed to continue until the resident shows that a change has occurred. Any person who has established a residence in this state may manifest and evidence the same by filing a sworn statement pursuant to Section 222.17, F.S.

(19) Routes of administration – means the path by which a low-THC cannabis derivative product is taken into the body, and includes oral, topical, transdermal, and nasal administration.

(20) Tissue culture – Technique of cultivating low-THC cannabis plant tissue in a prepared medium and the low-THC cannabis plant tissue so cultivated.

(21) Transportation plan – Method of transporting up to a 90-day supply of low-THC cannabis derivative product for each qualified registered patient served on the trip from the dispensing organization to qualified registered patients in the state which documents, at a minimum, confirmation of the order from the registry, confirmation from the qualified registered patient that he or she requests delivery, place of delivery, date and time of trip, route of transportation, security of the low-THC cannabis product or products being transported, signature of the qualified registered patient or the qualified registered patient’s legal guardian receiving the order, and creation and maintenance of a log of all low-THC derivative products transported on an annual basis.

Rulemaking Authority 381.986(5)(d) FS. Law Implemented 381.986(5)(b) FS. History–New \_\_\_\_\_.

#### 64-4.002 Initial Application Requirements for Dispensing Organizations.

(1) An entity desiring to be authorized as a dispensing organization shall make application to the department using Form DH8006-OCU-06/2014, “Application for Low-THC Cannabis Dispensing Organization Approval” herein incorporated by reference and available at <https://flrules.com/gateway/reference.asp?No=Ref-#####>. Each nursery that meets the requirements of Section 381.986(5)(b)1., F.S., may have an ownership interest in only one application per qualifying nursery registration. The qualifying nursery certificate of registration or nursery block thereof must be located within the dispensing region applied for.

(2) In addition to the completed application form, applicants shall provide the following exhibits:

(a) Written documentation demonstrating that the applicant meets the requirements of Section 381.986(5)(b)1., F.S.;

(b) Written documentation of the applicant’s plan for cultivating low-THC cannabis, and processing and dispensing low-THC cannabis derivative products, including a business plan showing applicant’s expected production.

(c) Written documentation of a detailed security and safety plan to include, but not be limited to:

1. Locking options, alarm systems, and video surveillance;

2. Diversion and trafficking prevention procedures;
3. A facility emergency management plan;
4. Proof of compliance or the ability to comply with the current local and state building codes, fire codes and electric codes.

(d) Written documentation of the applicant's quality assurance plan to ensure the quality and consistency of low-THC cannabis grown, processed and dispensed.

(e) Written documentation demonstrating the applicant's ability to obtain and maintain the premises, facilities, resources, and personnel necessary to operate as a dispensing organization. At a minimum, documentation shall include:

1. A map showing the location of the applicant's dispensing organization facility;
2. A site plan drawn to scale of the actual or proposed cultivation, processing and dispensing location showing streets, property lines, buildings, parking areas, outdoor areas if applicable, fences, security features, fire hydrants if applicable, and access to water mains; and
3. A floor plan drawn to scale of the actual or proposed building or buildings where the cultivation, processing, and dispensing activities will occur showing the:

- a. Layout and dimensions of each room;
- b. Name and function of each room;
- c. Location of each hand-washing sink;
- d. Location of each toilet room;
- e. Means of ingress and egress; and
- f. Location of natural and artificial lighting sources;

4. A list of current and proposed staffing including:

- a. Position, duties and responsibilities;
- b. The age in years of each current employee; and
- c. Written documentation that each employee has successfully completed Level-2 background screening within the last year;

(f) Written documentation that the applicant has the ability to maintain accountability of all raw materials, finished products, and any byproducts by submission of an inventory control plan that meets the requirements of this chapter;

(g) Written documentation that the applicant possesses an infrastructure reasonably located to dispense low-THC cannabis derivative products to registered patients in the state. At a minimum, such documentation shall include the physical address of the dispensing organization's dispensing facility and photographs showing the public access, driveway, parking and public access to the dispensary location and a transportation plan, if applicable, for delivery to qualified registered patients;

(h) Written documentation that the applicant has the experience, equipment, training, ability and personnel necessary to safely manufacture or produce low-THC cannabis derivative products that will be ingested by qualified registered patients.

(i) Written documentation of the applicant's financial strength as required by Section 381.986(5)(b)5., F.S., including a financial statement prepared in accordance with generally accepted auditing standards by a Certified Public Accountant licensed pursuant to Chapter 473, F.S.

(j) Written documentation of the ability to post a \$5 million performance bond for the biennial approval period. The 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, or a portion thereof, 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.

(k) Written documentation that all owners and managers of the dispensing organization have successfully completed Level-2 background screening pursuant to Section 435.04, F.S., within the last year, to include:

1. An organizational chart illustrating the supervisory structure of the dispensing organization; and
2. A list of all owners and managers indicating the date and status of each individual's most recent Level-2 background screening.

3. For the purposes of this chapter, the following individuals are considered owners or managers:

- a. If an individual is applying to become a dispensing organization, the individual;
- b. The dispensing organization's inventory agent;
- c. The dispensing organization's security director; and
- d. The dispensing organization's medical director.

(1) Written documentation that the organization employs a medical director who is a physician licensed pursuant to Chapter 458 or 459, F.S., who does not register qualified patients or place orders for low-THC cannabis derivative products in the Compassionate Use Registry. For the purposes of this chapter, employment means a relationship evidenced by an independent contract or where compensation can be documented by the regular deduction of FICA and federal withholding tax as required by law.

(3) If the applicant intends to claim any exemption from public records disclosure under Section 119.07, F.S., or any other exemption from public records disclosure provided by law for any part of its application, it shall indicate on the application the specific sections for which it claims an exemption and the basis for the exemption.

(4) Any completed "Application for Low-THC Cannabis Dispensing Organization Approval" and all required exhibits and supporting documents shall be delivered to the Agency Clerk of the Department of Health physically located at 2585 Merchants Row Boulevard in Tallahassee, Florida, no earlier than 10:00 AM, Eastern Time, on the effective date of this rule and no later than 5:00 PM, Eastern Time, 15 calendar days after the effective date of this rule. A courtesy copy of the completed application shall also be delivered to the Sheriff of the county in which the dispensing organization facility is located.

(a) The Department will substantively review and evaluate all timely received applications to determine if the applicant is qualified by meeting the requirements of Section 381.986(5)(b), F.S., and this Chapter. 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 random lottery-type selection by public drawing to designate the approved applicant and the rank order of other applications within each dispensing region.

(b) Upon notification that it has been selected as a region's dispensing organization, the applicant shall have ten calendar days to pay a non-refundable \$150,000 application fee to the department and post a \$5 million performance bond.

(c) If the selected applicant fails to pay the application fee and post the bond within the required timeframes, the applicant next in rank order and located in the applicable dispensing region shall be selected and the selected applicant notified.

Rulemaking Authority 381.986(5)(d) FS. Law Implemented 381.986(5)(b) FS. History—New \_\_\_\_\_.

#### 64-4.003 Biennial Renewal Requirements for Dispensing Organizations.

(1) No less than 60 calendar days prior to the expiration of an existing dispensing organization's authorization to dispense low-THC cannabis derivative products, the dispensing organization shall make application for renewal of the dispensing organization approval using Form DH8006-OCU-06/2014, "Application for Low-THC Cannabis Dispensing Organization Approval" herein incorporated by reference and available at <https://flrules.com/gateway/reference.asp?No=Ref-#####>, indicating that the application is a renewal application.

(2) In addition to the completed application form, dispensing organization renewal applicants shall:

(a) Demonstrate that they continue to meet the requirements of Section 381.986(5)(b)1.-7., F.S., by updating the documentation submitted with the original application or providing a notarized statement that there have been no changes;

(b) Provide written documentation that any violations noted during any inspections or investigations by the department, Department of Agriculture and Consumer Services or law enforcement officials have been corrected; and

(c) Provide written documentation of compliance with the financial requirements of Section 381.986(5)(b)5., F.S., including a financial report of an audit by a Florida Certified Public Accountant of the financial statement for the previous two years.

(3) If the dispensing organization meets the requirements of Section 381.986(5)(b), F.S., and this chapter, the department shall notify the dispensing organization that it intends to renew the approval.

(4) Upon notification that its renewal will be approved, the dispensing organization shall have 30 calendar days to pay a nonrefundable \$300,000 renewal fee to the department and to provide proof that its \$5 million performance bond remains in effect.

(5) If the applicant fails to renew within the required timeframes, the department shall seek new applications for a dispensing organization in the applicable dispensing region.

(6) A dispensing organization that fails to renew its approval shall not dispense low-THC cannabis products after midnight local time on the date that its authorization expires and shall destroy all low-THC cannabis in its possession within 24 hours of the last dispensing day. Any undestroyed low-THC cannabis remaining under the control of the dispensing organization more than 24 hours after the last dispensing day shall be seized and destroyed by the Department.

PROPOSED EFFECTIVE DATE: Upon Legislative ratification.

Rulemaking Authority 381.986(5)(d) FS. Law Implemented 381.986(5)(b) FS. History--New \_\_\_\_\_.

#### 64-4.004 Denial or Revocation of Dispensing Organization Approval.

(1) The department shall deny an application for a dispensing organization approval or renewal if:

(a) Any dispensing organization facility is within 1000 feet, as measured from the primary dispensing organization structure to the nearest property line of an elementary, middle or secondary school, day care facility as defined in Section 402.302, F.S., county or municipal park, or place of worship that existed before the date the dispensing organization submitted its initial application for approval;

(b) Any owner or manager:

1. Has been convicted of a felony offense;

2. Has served as an owner or manager for any entity or organization in any state that has had its authority to cultivate, harvest, process or dispense low-THC cannabis or low-THC cannabis derivative product revoked;

3. Is under 21 years of age;

4. Is a physician currently ordering low-THC cannabis derivative products for use by qualified registered patients;

5. Is a law enforcement official; or

6. Is an employee or contractor of the department;

(c) The application of the dispensing organization does not comply with the requirements Section 381.986, F.S., or this chapter;

(d) The dispensing organization has failed to correct any violation noted during an inspection in accordance with its corrective action plan; or

(e) The applicant provides false or misleading information to the department.

(2) The department shall revoke its approval of the dispensing organization if:

(a) The dispensing organization:

1. Cultivates low-THC cannabis before obtaining department authorization; or

2. Knowingly dispenses, delivers, or otherwise transfers low-THC cannabis derivative product to an individual or entity other than a qualified registered patient or a qualified registered patient's legal guardian; or

(b) An owner or manager has been convicted of a felony offense; or

(3) The department may revoke a dispensing organization's approval or authorization if the dispensing organization does not:

(a) Comply with the requirements in Section 381.986, F.S., or this chapter;

(b) Implement the policies and procedures or comply with the statements provided to the department with the dispensing organization's application;

(c) Seek authorization to begin cultivation within 75 calendar days of application approval; or

(d) Begin dispensing within 150 calendar days of the authorization granted pursuant to subsection 64-4.005(2),

F.A.C.

Rulemaking Authority 381.986(5)(d) FS. Law Implemented 381.986(5)(b) FS. History--New \_\_\_\_\_.

#### 64-4.005 Inspection Procedures.

(1) Submission of an application for dispensing organization approval constitutes permission for entry by the department, the Department of Agriculture and Consumer Services or law enforcement officials and agents into any dispensing organization facility to inspect any portion of the facility, review the records required pursuant to Section 381.986, F.S., or this chapter, and collect samples of any low-THC cannabis for laboratory examination at any reasonable time. All inspectors shall follow the dispensing organization's sanitation protocol when conducting any inspection.

(2) No less than 30 calendar days prior to the initial cultivation of low-THC cannabis, the dispensing organization shall notify the department and the sheriff of the county in which the dispensing organization facility is located that the dispensing organization facility is complete, the dispensing organization is in compliance with Section 381.986, F.S., and this chapter and is seeking authorization to begin operation. No low-THC cannabis, including seeds, tissue culture, and cuttings, may be present in any dispensing organization facility prior to authorization by the department.

(3) If the department identifies a violation of Section 381.986, F.S., or this chapter during an inspection of a dispensing organization facility, the dispensing organization shall notify the department in writing, with a postmark date within 20 working days after the date of receipt of the written notice of violations, identifying the corrective actions taken and the date of the correction.

Rulemaking Authority 381.986(5)(d) FS. Law Implemented 381.986(5)(b) FS. History—New \_\_\_\_\_.

#### 64-4.006 Identification, Labeling and Testing Low-THC Cannabis Seeds, Dried Flowers and Derivative Products.

(1) A dispensing organization shall ensure that the low-THC cannabis derivative product provided to a qualified patient is in medical grade, childproof containers labeled with:

(a) The dispensing organization name and location;

(b) The amount, harvest number, and batch number of the low-THC cannabis derivative product being dispensed;

(c) The date of product processing or manufacture;

(d) A list of all additives, including pesticides, herbicides, and fertilizers, used in the cultivation and production of the low-THC Cannabis;

(e) The percent by weight of tetrahydrocannabinol and cannabidiol; and

(f) The registry identification number of the qualified registered patient.

(2) Prior to dispensing any low-THC derivative product, a dispensing organization shall sample and have tested by a department approved testing laboratory each batch of each product to be distributed. The testing laboratory shall file with the department an electronic copy of each laboratory test result for any batch that does not pass the microbial, mycotoxin, heavy metal, pesticide, chemical residue or residual solvents levels test or meet the composition requirements required by s. 381.986(1)(b), F.S. Dispensing shall not occur until the test results have been received by the dispensing organization. Testing shall include, but is not limited to:

(a) Tetrahydrocannabinol concentration reported as a percentage by weight;

(b) Cannabidiol concentration reported as percentage by weight; and

(c) Bacteria and molds, including aerobic bacteria, e coli, enterobacteria, powdery mildew, penicillium, yeast, aspergillus, cladosporin, fusarium, botrytis, aureobasidium and acremonium.

(d) Heavy metals;

(e) All chemical additives, including nonorganic pesticides, herbicides, and fertilizers, and solvents used in the cultivation and production of the low-THC Cannabis reported as parts per billion.

(3) The dispensing organization shall provide copies of any test results to the department upon request.

(4) If any batch sample test result shows the presence of a chemical additive over the Health Advisory Level (HAL) as provided in the department's Environmental Chemistry Analyte List, the entire batch from which the sample was derived shall be identified and segregated to prevent further processing or distribution. The entire batch and harvest shall be destroyed.

(5) Any batch sample or any other sample that exceeds 0.8% tetrahydrocannabinol by weight or 10% or less of cannabidiol by weight shall be reported immediately to law enforcement officials. The entire batch or other material from which the sample was derived shall be identified and segregated to prevent further processing or dispensing. If

the batch cannot be made to conform in a reasonable period of time, any further handling and destruction of the material shall be conducted with the consent of law enforcement officials.

(6) Upon request from the department, a dispensing organization shall submit a sample of any specific seed, dried flower or derivative product from the low-THC cannabis inventory to a laboratory selected by the department for analysis and reporting to the department.

(7) Laboratories shall immediately destroy any untested low-THC cannabis or low-THC cannabis derivative product upon the completion of the testing. Laboratories shall retain the tested sample for 30 calendar days to allow for retesting before destroying the sample. If the low-THC cannabis or low-THC cannabis derivative product is destroyed, the time and method of destruction or disposal shall be documented.

(8) Compliance with the testing requirements constitutes the legal authority to possess and transmit low-THC cannabis and low-THC cannabis derivative products under Florida law.

(9) All low-THC derivative products shall be maintained in a climate-controlled and appropriate environment.  
Rulemaking Authority 381.986(5)(d) FS. Law Implemented 381.986(5)(b) FS. History--New \_\_\_\_\_.

#### 64-4.007 Recordkeeping and Reporting Requirements.

(1) A dispensing organization shall designate in writing an inventory agent who has oversight of the inventory control system.

(2) A dispensing organization shall establish and implement an inventory control system for the low-THC cannabis plants and derivative products that documents:

(a) Each day's beginning and ending inventory of, seeds, tissue culture, cuttings, harvests, processed low-THC cannabis derivative products, sales, disbursements, and disposal of unusable plants or low-THC cannabis derivative products:

(b) For each harvest of low-THC cannabis cultivated:

1. The harvest number;

2. Whether the harvest originated from seeds, tissue culture or cuttings;

3. The strain of the seeds, tissue culture or cuttings planted;

4. The number of seeds, tissue culture or cuttings planted;

5. The date the seeds, tissue culture or cuttings were planted;

6. A list of all chemical additives, including organic pesticides, herbicides, and fertilizers used in the cultivation;

7. The number of low-THC plants grown to maturity;

8. Date of harvest;

9. Final harvest yield weight;

10. Name of the inventory agent responsible for the harvest, and

11. The disposal of low-THC plants or plant parts not used for the production of dispensable products including

the:

a. Description of and reason for disposal including, if applicable, the number of failed or other unusable plants;

b. Date of disposal;

c. Method of disposal; and

d. Name of the inventory agent responsible for the disposal.

(c) For each batch of low-THC cannabis produced:

1. The batch number;

2. The harvest number(s) of the low-THC plants incorporated into the batch;

3. The name (if applicable) of the low-THC cannabis derivative product produced;

4. Form and quantity of low-THC cannabis derivative product produced;

5. Date sampled for laboratory analysis;

6. Laboratory sample results; and

7. Date laboratory results were received.

(d) For low-THC cannabis derivative products dispensed:

1. Name (if applicable) of the low-THC cannabis derivative product;

2. Form of the low-THC cannabis derivative product;

3. Batch number;

4. Amount of each low-THC cannabis derivative product dispensed; and

5. Price of the low-THC cannabis derivative product dispensed

(e) For low-THC cannabis derivative products disposed:

1. Name (if applicable) of the low-THC cannabis derivative product, form, batch number and amount;

2. Reason for disposal; and

3. Method of disposal.

(3) The inventory agent shall conduct and document an audit of the dispensing organization's inventory at least once every 30 days. If the audit identifies a discrepancy in the amount of low-THC cannabis or low-THC cannabis derivative product, the dispensing organization shall determine where the discrepancy has occurred and take and document immediate corrective action. The dispensing organization shall notify the department of any identified discrepancy and the corrective action taken within 5 working days of the identification of the discrepancy. If criminal activity is suspected, the dispensing organization shall immediately report the suspicion to law enforcement officials.

(4) The dispensing organization shall maintain the required documentation for a minimum of five years from the date of the document and provide the documentation to the department upon request.

Rulemaking Authority 381.986(5)(d) FS. Law Implemented 381.986(5)(b) FS. History—New \_\_\_\_\_.

#### 64-4.008 Procedural Requirements.

(1) A dispensing organization shall:

(a) Ensure that dispensing hours of operation, at a minimum, adhere to the dispensing availability proposed in the approved application, and that its dispensary is operating and available to dispense low-THC cannabis derivative product to any qualified registered patient on a regular schedule which shall be prominently displayed in the dispensary, posted online and available upon request to qualified registered patients, their legal guardians and ordering physicians;

(b) Develop, document, and implement policies and procedures regarding:

1. Training and adherence to confidentiality requirements;

2. Inventory control; and

3. Patient records;

(c) Maintain policies and procedures and provide copies to the department upon request;

(d) Post the following information in a place that can be viewed by individuals entering the dispensary:

1. Name of the dispensing organization;

2. Name of the medical director and the medical director's license number; and

3. Hours of operation;

(e) Limit access to the dispensing organization to owners, agents, managers, designated employees and qualified registered patients, their legal guardians, authorized inspectors and authorized visitors. Authorized visitors must wear an identifying badge and be escorted and monitored at all times by an owner, manager, agent or employee. The dispensing organization shall create and maintain a visitor log and the name of any visitor and the date and duration of the visit shall be entered the log. All authorized visitors must comply with the sanitary protocol of the dispensing organization; and

(f) Advise the department within seven calendar days of any change in medical director. A dispensing organization cannot operate in the absence of a contracted or employed medical director.

(2) The dispensing organization shall cultivate, process, store, dispense, and perform any other activity involving low-THC cannabis in an enclosed and locked facility that protects the growing and processing operations from view.

(3) The dispensing organization shall make reasonable efforts to mitigate odors.

(4) Dispensing organizations shall not produce or provide low-THC cannabis that is part of, mixed with, or added to an edible food product.

(5) The dispensing organization shall ensure that all buildings and equipment used for the cultivation, harvest, preparation, packaging, storage, or sale of low-THC cannabis and low-THC cannabis derivative products are maintained in a clean and sanitary condition.

(a) Low-THC cannabis in the process of preparation, production, packing, storage, sale or dispensing shall be protected from insects, dust, dirt and other contamination in fully enclosed rooms.

(b) Refuse or waste products incident to the manufacture, preparation, packing, selling, or distribution of low-THC cannabis and low-THC cannabis derivative products shall be destroyed on-site at least once every 24 hours.

(c) All trucks, trays, buckets, other receptacles, platforms, racks, tables, shelves, knives, saws, cleavers, other utensils, or the machinery used in moving, handling, cutting, chopping, mixing, canning, packaging, or other processes shall be cleaned at least once every 24 hours.

(6) The medical director must be onsite or available by telephone, pager or other electronic communication and must designate a back-up medical director when not so available. The medical director shall provide for standards and protocols that ensure proper testing of low-THC medical cannabis derivative products for potency and contamination. The medical director shall assist with the development and implementation of policies and procedures regarding, at a minimum, emergency responses, sanitary practices, compliance with state and federal regulations regarding confidentiality of personally identifiable health information, quality assurance, and disease prevention. The medical director shall also respond to the Department of Health and local municipalities regarding compliance with rules and regulations and community health and public safety concerns. If the medical director determines that any employee of the dispensing organization has a health condition that may adversely affect the safety or quality of the low-THC cannabis or derivative products, the employee shall be prohibited from direct contact with any product or equipment or materials for processing low-THC cannabis until the medical director determines that the employee's health condition will not adversely affect the safety and quality of the low-THC cannabis.

(7) Dispensing organizations shall ensure that all owners, managers and employees are at least 21 years of age and have successfully completed Level-2 background screening within the last year before commencing employment. Any owner, manager or employee arrested for a disqualifying felony shall be immediately suspended. Any owner, manager or employee shall be immediately terminated upon conviction of a disqualifying felony.

(8) With approval from the Department, dispensing organizations may alter, expand or consolidate their infrastructure, operations or staffing structure in order to better serve patients, provided the changes comply with the requirements of Section 381.986(5)(b), F.S., and this chapter. Dispensing organizations shall request approval using Form DH8007-OCU-06/2014, "Request to Alter, Expand or Consolidate Dispensing Organization" herein incorporated by reference and available at <https://flrules.com/gateway/reference.asp?No=Ref-####>. Rulemaking Authority 381.986(5)(d) FS. Law Implemented 381.986(5)(b) FS. History—New \_\_\_\_\_.

#### 64-4.009 Compassionate Use Registry.

(1) Ordering physicians licensed under Chapter 458 or 459, F.S., meeting the educational requirements of Section 381.986(4), F.S., may access the Compassionate Use Registry using their existing MQA Services credentials.

(2) Designated persons may request access to the Compassionate Use Registry by completing form DH8008-OCU-06/2014, "Request for Access to the Compassionate Use Registry", herein incorporated by reference and available at <https://flrules.com/gateway/reference.asp?No=Ref-#####>. Those requesting access must meet one of the following criteria:

(a) Authorized employee of a dispensing organization - Each dispensing organization may designate up to five employees for access to the Compassionate Use Registry;

(b) Law enforcement official;

(c) Authorized employee of the University of Florida, College of Pharmacy Program – The University of Florida College of Pharmacy may designate up to five employees for access to the Compassionate Use Registry;

(d) Authorized employee of the department; or

(e) A person authorized by the department to conduct research pursuant to Section 381.987(3)(f), F.S.

(3) Persons seeking to access to the registry shall have successfully completed a department-approved course in their responsibilities related to patient confidentiality and shall make documentation of completion available to the department upon request.

(4) Before dispensing any low-THC cannabis derivative product to a qualified registered patient or the patient's legal guardian, the dispensing organization must verify that the patient has an active registration, the order presented matches the order contents as recorded by the physician in the registry and the order has not already been filled.

(5) The dispensing organization shall enter a dispensing action into the registry immediately upon dispensing the low-THC cannabis to the qualified registered patient or the patient's legal guardian.

Rulemaking Authority 381.986(5)(d) FS. Law Implemented 381.986(5)(a) FS. History—New \_\_\_\_\_.

NAME OF PERSON ORIGINATING PROPOSED RULE: Linda N. McMullen

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: John H. Armstrong, MD, FACS,  
Surgeon General and Secretary

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: August 13, 2014

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: June 18, 2014

**Bist, Kevin**

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**From:** Kostas Stoilas <stoilas@yahoo.com>  
**Sent:** Tuesday, February 03, 2015 6:33 AM  
**To:** Nelson, Patricia A  
**Subject:** Re: Updated Draft Text for 64-4, F.A.C.

I attached the document it was in. We provided testimony regarding the block number at the September 2014 workshop, so whichever draft was reviewed for that day is where you will find it.

Sent via mobile device...please excuse abbreviated responses & grammar.

Kostas Stoilas  
239.822.7816 cell

[www.CauseToFund.com](http://www.CauseToFund.com)

[www.WarehouseRealEstateBlog.com](http://www.WarehouseRealEstateBlog.com)

[www.Linkedin.com/in/stoilas](http://www.Linkedin.com/in/stoilas)

On Feb 3, 2015, at 5:58 AM, "Nelson, Patricia A" <[Patricia.Nelson@flhealth.gov](mailto:Patricia.Nelson@flhealth.gov)> wrote:

I don't know what draft you are looking at. That language does not appear in either the Notice of Proposed Rule published July 7, 2014, or the Notice of Change published August 1, 2014.

On Feb 2, 2015, at 9:04 PM, Kostas Stoilas <[stoilas@yahoo.com](mailto:stoilas@yahoo.com)> wrote:

Patty - to make it easier, please find towards the top of page 3, the definition under (16) for Nursery Block Number. It's right above the definition for Owner, which was revised from 5% to 7%. Who updated the chapter, such that this removal wasn't noted? The administrative law judge didn't have a problem with Nursery Block Number, so I'm concerned that other things might have been left out.

Thanks,

Kostas Stoilas  
239-822-7816 cell  
[stoilas@yahoo.com](mailto:stoilas@yahoo.com)

On Feb 2, 2015, at 11:24 AM, Nelson, Patricia A <[Patricia.Nelson@flhealth.gov](mailto:Patricia.Nelson@flhealth.gov)> wrote:

Mr. Stoilas,

Thank you for your comments. I am unclear on some of your questions. I cannot find the term "nursery block number" in any of the previous draft rules. Can you please identify for me the part of the rules that addressed that topic? Regarding your process question, the remainder of the rulemaking will proceed according to the requirements of section 120.54, F.S. The Legislature is normally not involved in the rulemaking process. Its only involvement is to ratify rules that exceed certain regulatory cost thresholds.

Patty

From: Kostas Stoilas [<mailto:stoilas@yahoo.com>]  
Sent: Sunday, February 01, 2015 5:29 PM  
To: Nelson, Patricia A  
Cc: Cowie, Tiffany C; Dunn, Nathan P  
Subject: Re: Updated Draft Text for 64-4, F.A.C.

Patty - thanks for the email. I have a couple questions, just to understand if this is a new point we're starting from for Rule 64 or if this picks up somewhere from where we left off in the Fall of 2014. In previous drafts/revisions, it was noted whether subsequent drafts changed language in the prior draft or simply added to existing language. For example, I don't see any mention of the "nursery block number" that would allow cultivation to happen at multiple facilities as long as they fell under the nursery's control and their Dept of Agr block number. Does this mean the block number carries over from the last rule draft from Fall 2014, or has it been struck off and now we start over with new rule-making?

In addition, I've attached an update to my written comments from early January, due to added input from others and personal research. I've highlighted the added comments in yellow, and you'll see most of page 4 is input from a nursery we are working with. Consider this "food for thought" since we are not able to participate in verbal testimony this week in Tallahassee.

One final question, based on process. Will the results of the Feb 4-5 workshop go into some planning material for committee review at the Legislative level, or is Legislature no longer involved in this rule making process?

**Bist, Kevin**

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**From:** Kostas Stoilas <stoilas@yahoo.com>  
**Sent:** Tuesday, February 03, 2015 6:56 AM  
**To:** Nelson, Patricia A  
**Subject:** Re: Updated Draft Text for 64-4, F.A.C.  
**Attachments:** 64-4.001.doc; ATT00001.htm

This draft was issued prior to the September 5th hearing, as noted at the bottom 1/3rd of page 1 in the "64-4.001.doc" attached. The following definition was noted on page 3:

(16) Nursery block number – Subpart of a nursery certificate of registration that identifies where plants or grown or produced.

It was then referenced at the bottom of page 3 under the Initial Application Requirements:

Each nursery that meets the requirements of Section 381.986(5)(b)1., F.S., may have an ownership interest in only one application per qualifying nursery registration. The qualifying nursery certificate of registration or nursery block thereof must be located within the dispensing region applied for.

Hope this helps... Thanks,

Kostas Stoilas  
239-822-7816 cell  
[stoilas@yahoo.com](mailto:stoilas@yahoo.com)

## NOTICE OF PROPOSED RULE

### DEPARTMENT OF HEALTH

#### Office of Compassionate Use

#### RULE NOS.:RULE TITLES:

- 64-4.001 Definitions
- 64-4.002 Initial Application Requirements for Dispensing Organizations
- 64-4.003 Biennial Renewal Requirements for Dispensing Organizations
- 64-4.004 Denial or Revocation for Dispensing Organization Approval
- 64-4.005 Inspection Procedures
- 64-4.006 Identification, Labeling and Testing Low-THC Cannabis Plants and Products
- 64-4.007 Recordkeeping and Reporting Requirements
- 64-4.008 Procedural Requirements
- 64-4.009 Compassionate Use Registry

**PURPOSE AND EFFECT:** This rulemaking establishes a comprehensive regulatory framework for implementing the Compassionate Medical Cannabis Act of 2014. It establishes the requirements for persons who cultivate and produce the medical cannabis as well as the requirements for dispensing and use of the cannabis.

**SUMMARY:** The rulemaking establishes, licensure and biennial licensure renewal requirements for dispensing organizations, reasons for denial or revocation of dispensing organization approval, inspection procedures for dispensing organization facilities, medical direction for dispensing organizations, requirements for pre-dispensing identification, testing and labelling of low THC cannabis and derivative products, inventory control, recordkeeping and reporting requirements, procedural requirements including dispensing facility hours, policies and procedures for inventory control and patient records, facility security, staffing, facility cleanliness, and refuse removal, requirements for accessing and inputting information as well as maintenance of the compassionate use registry.

#### SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS AND LEGISLATIVE

**RATIFICATION:** The agency has determined that seven of the nine rules associated with the regulatory framework will not have an adverse impact on small business or likely increase directly or indirectly regulatory costs in excess of \$200,000 in the aggregate within one year after the implementation of the rule. The agency has determined that two of the nine rules associated with the regulatory framework, Rules 64-4.002 and 64-4.003, F.A.C., will have an adverse impact on small business or likely increase directly or indirectly regulatory costs in excess of \$200,000 in the aggregate within one year after the implementation of the rule. A SERC has been prepared by the agency for Rules 64-4.002 and 64-4.003, F.A.C. The Agency has determined that proposed Rule 64-4.003, F.A.C., is expected to require legislative ratification based on the statement of estimated regulatory costs. Based on the SERC checklist, this rulemaking, except for proposed Rule 64-4.003, F.A.C., will not have an adverse impact or regulatory costs in excess of \$1 million within five years as established in Section 120.541(2)(a), F.S. Proposed section 64-4.003 will have an adverse impact or regulatory costs in excess of \$1 million within five years as established in Section 120.541(2)(a), F.S.

Any person who wishes to provide information regarding the statement of estimated regulatory costs, or to provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

**RULEMAKING AUTHORITY:** 381.986(5)(d) FS.

**LAW IMPLEMENTED:** 381.986(5)(b) FS.

**A HEARING WILL BE HELD AT THE DATE, TIME AND PLACE SHOWN BELOW:**

**DATE AND TIME:** September 5, 2014, 9:00 a.m. – 5:00 p.m., Eastern Time or until the hearing is concluded

**PLACE:** Room 152, Betty Easley Conference Center, Esplanade Way, Tallahassee, Florida 32399

Any person wanting to request a hearing regarding the proposed rule must do so within 21 days of the date of publication of this notice by contacting the agency's designated contact, as described herein.

**THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS:** Linda N. McMullen, Director of Office of Compassionate Use, 4052 Bald Cypress Way, Bin A-02, Tallahassee, Florida 32399-1703, E-mail: linda.mcmullen@flhealth.gov

**THE FULL TEXT OF THE PROPOSED RULE IS:**

64-4.001 Definitions.

For the purposes of this chapter, the following words and phrases shall have the meanings indicated:

(1) Applicant – An entity with at least 25% ownership by a nursery that meets the requirements of Section 381.986(5)(b)1., F.S., that applies for approval as a dispensing organization.

(2) Approval – Written notification from the department to an applicant that its application for dispensing organization approval has been found to be in compliance with the provisions of this chapter and that the department is awaiting notification from the applicant that it is prepared to be inspected and authorized to begin cultivation and other operations.

(3) Authorization – Written notification by the department to a dispensing organization that it may begin specific phases of operation including cultivation, harvesting, processing, dispensing and other activities authorized by this chapter involving the possession of low-THC cannabis and the manufacturing of low-THC cannabis derivative products. Authorization may be requested and given in stages as the infrastructure and staffing requirements of the operation are completed.

(4) Batch – means a specific lot of low-THC cannabis derivative product produced from one or more harvests of low-THC cannabis plants that are processed or blended into a uniform mixture before portioning such that all products bearing the same batch number would be expected to be representative of the entire batch for the purpose of laboratory testing.

(5) Batch number – means a unique numeric or alphanumeric identifier assigned to a batch by a dispensing organization when the batch is portioned and packaged for dispensing.

(6) Cultivation – means the reproduction of source plant or tissue culture material.

(7) Derivative product – means forms of low-THC cannabis suitable for routes of medical administration, including but not limited to vapor, resins, salts, extracts, capsules, oral sprays and any compound, mixture or preparation derived from low-THC cannabis plants that is dispensed only from a dispensing organization.

(8) Dispensing Region – A geographical area where the growing, production and dispensing of Low-THC cannabis under the control of a dispensing organization shall occur. The five dispensing regions shall be identified as follows:

(a) Northwest Florida Region consisting of Bay, Calhoun, Escambia, Franklin, Gadsden, Gulf, Holmes, Jackson, Jefferson, Leon, Liberty, Madison, Santa Rosa, Okaloosa, Taylor, Wakulla, Walton, and Washington counties.

(b) Northeast Florida Region consisting of Alachua, Baker, Bradford, Clay, Columbia, Dixie, Duval, Flagler, Gilchrist, Hamilton, Lafayette, Levy, Marion, Nassau, Putnam, St. Johns, Suwannee, and Union counties.

(c) Central Florida Region consisting of Brevard, Citrus, Hardee, Hernando, Indian River, Lake, Martin, Orange, Osceola, Pasco, Pinellas, Polk, Seminole, St. Lucie, Sumter, and Volusia counties.

(d) Southwest Florida Region consisting of Charlotte, Collier, DeSoto, Glades, Hendry, Highlands, Hillsborough, Lee, Manatee, Okeechobee, and Sarasota counties.

(e) Southeast Florida Region consisting of Broward, Dade, Monroe, and Palm Beach counties.

(9) Dispensing Organization – an entity which has been approved by the department to cultivate, process and dispense organically grown low-THC cannabis.

(10) Dispensing Organization Facility – One or multiple structures within the same contiguous property that are used by the dispensing organization for the preparation, cultivation, storage, processing, dispensing, or any other action in the presence of or involving low-THC cannabis.

(11) Edible food product – Food products made with low-THC cannabis such as cakes, cookies, candies, brownies and other food items intended to be taken into the mouth, chewed and swallowed. Low-THC cannabis derivative products such as pills or ingestible substances used as delivery agents for low-THC cannabis such as olive oil are not considered edible food products.

(12) Harvest – A specific lot of low-THC cannabis plants grown from one or more seeds, cuttings or tissue cultures, that are planted, cloned or cultured and harvested at the same time such that any plant in the harvest is expected to be representative of the entire harvest for the purposes of laboratory testing.

(13) Harvest number – means a unique numeric or alphanumeric identifier assigned to a harvest by a dispensing organization when the harvest is planted.

(14) Inventory Agent – An employee of the dispensing organization who has been designated in writing to have oversight of the inventory control system.

(15) Manager – Any person with the authority to exercise operational direction or management of the dispensing organization or the authority to supervise any employee of the dispensing authority, including but not limited to the following:

(a) All directors, officers, board members and managers identified in the most recent annual report filed with the Florida Division of Corporations;

(b) The inventory agent;

(c) The security director;

(d) The medical director; and

(e) If the dispensing organization is a joint venture, all persons associated with each joint venture partner who have the authority to exercise operational direction or management of the dispensing organization or have the authority to supervise any employee of the dispensing organization.

(16) Nursery block number – Subpart of a nursery certificate of registration that identifies where plants or grown or produced.

(17) Owner – Any person, including any individual or other legal entity, with a direct or indirect ownership interest of 5% or more in the applicant, including the possession of stock, equity in capital, or any interest in the profits of the applicant.

(18) Permanent resident – A person has his or her true, fixed and permanent home and principal establishment in Florida to which, whenever absent, he or she has the intention of returning. Once a permanent residence is established in Florida it is presumed to continue until the resident shows that a change has occurred. Any person who has established a residence in this state may manifest and evidence the same by filing a sworn statement pursuant to Section 222.17, F.S.

(19) Routes of administration – means the path by which a low-THC cannabis derivative product is taken into the body, and includes oral, topical, transdermal, and nasal administration.

(20) Tissue culture – Technique of cultivating low-THC cannabis plant tissue in a prepared medium and the low-THC cannabis plant tissue so cultivated.

(21) Transportation plan – Method of transporting up to a 90-day supply of low-THC cannabis derivative product for each qualified registered patient served on the trip from the dispensing organization to qualified registered patients in the state which documents, at a minimum, confirmation of the order from the registry, confirmation from the qualified registered patient that he or she requests delivery, place of delivery, date and time of trip, route of transportation, security of the low-THC cannabis product or products being transported, signature of the qualified registered patient or the qualified registered patient’s legal guardian receiving the order, and creation and maintenance of a log of all low-THC derivative products transported on an annual basis.

Rulemaking Authority 381.986(5)(d) FS. Law Implemented 381.986(5)(b) FS. History–New \_\_\_\_\_.

#### 64-4.002 Initial Application Requirements for Dispensing Organizations.

(1) An entity desiring to be authorized as a dispensing organization shall make application to the department using Form DH8006-OCU-06/2014, “Application for Low-THC Cannabis Dispensing Organization Approval” herein incorporated by reference and available at <https://flrules.com/gateway/reference.asp?No=Ref-#####>. Each nursery that meets the requirements of Section 381.986(5)(b)1., F.S., may have an ownership interest in only one application per qualifying nursery registration. The qualifying nursery certificate of registration or nursery block thereof must be located within the dispensing region applied for.

(2) In addition to the completed application form, applicants shall provide the following exhibits:

(a) Written documentation demonstrating that the applicant meets the requirements of Section 381.986(5)(b)1., F.S.;

(b) Written documentation of the applicant’s plan for cultivating low-THC cannabis, and processing and dispensing low-THC cannabis derivative products, including a business plan showing applicant’s expected production.

(c) Written documentation of a detailed security and safety plan to include, but not be limited to:

1. Locking options, alarm systems, and video surveillance;

2. Diversion and trafficking prevention procedures;
3. A facility emergency management plan;
4. Proof of compliance or the ability to comply with the current local and state building codes, fire codes and electric codes.

(d) Written documentation of the applicant's quality assurance plan to ensure the quality and consistency of low-THC cannabis grown, processed and dispensed.

(e) Written documentation demonstrating the applicant's ability to obtain and maintain the premises, facilities, resources, and personnel necessary to operate as a dispensing organization. At a minimum, documentation shall include:

1. A map showing the location of the applicant's dispensing organization facility;
2. A site plan drawn to scale of the actual or proposed cultivation, processing and dispensing location showing streets, property lines, buildings, parking areas, outdoor areas if applicable, fences, security features, fire hydrants if applicable, and access to water mains; and
3. A floor plan drawn to scale of the actual or proposed building or buildings where the cultivation, processing, and dispensing activities will occur showing the:

- a. Layout and dimensions of each room;
- b. Name and function of each room;
- c. Location of each hand-washing sink;
- d. Location of each toilet room;
- e. Means of ingress and egress; and
- f. Location of natural and artificial lighting sources;

4. A list of current and proposed staffing including:

- a. Position, duties and responsibilities;
- b. The age in years of each current employee; and
- c. Written documentation that each employee has successfully completed Level-2 background screening within the last year;

(f) Written documentation that the applicant has the ability to maintain accountability of all raw materials, finished products, and any byproducts by submission of an inventory control plan that meets the requirements of this chapter;

(g) Written documentation that the applicant possesses an infrastructure reasonably located to dispense low-THC cannabis derivative products to registered patients in the state. At a minimum, such documentation shall include the physical address of the dispensing organization's dispensing facility and photographs showing the public access, driveway, parking and public access to the dispensary location and a transportation plan, if applicable, for delivery to qualified registered patients;

(h) Written documentation that the applicant has the experience, equipment, training, ability and personnel necessary to safely manufacture or produce low-THC cannabis derivative products that will be ingested by qualified registered patients.

(i) Written documentation of the applicant's financial strength as required by Section 381.986(5)(b)5., F.S., including a financial statement prepared in accordance with generally accepted auditing standards by a Certified Public Accountant licensed pursuant to Chapter 473, F.S.

(j) Written documentation of the ability to post a \$5 million performance bond for the biennial approval period. The 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, or a portion thereof, 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.

(k) Written documentation that all owners and managers of the dispensing organization have successfully completed Level-2 background screening pursuant to Section 435.04, F.S., within the last year, to include:

1. An organizational chart illustrating the supervisory structure of the dispensing organization; and
2. A list of all owners and managers indicating the date and status of each individual's most recent Level-2 background screening.

3. For the purposes of this chapter, the following individuals are considered owners or managers:

- a. If an individual is applying to become a dispensing organization, the individual;
- b. The dispensing organization's inventory agent;
- c. The dispensing organization's security director; and
- d. The dispensing organization's medical director.

(1) Written documentation that the organization employs a medical director who is a physician licensed pursuant to Chapter 458 or 459, F.S., who does not register qualified patients or place orders for low-THC cannabis derivative products in the Compassionate Use Registry. For the purposes of this chapter, employment means a relationship evidenced by an independent contract or where compensation can be documented by the regular deduction of FICA and federal withholding tax as required by law.

(3) If the applicant intends to claim any exemption from public records disclosure under Section 119.07, F.S., or any other exemption from public records disclosure provided by law for any part of its application, it shall indicate on the application the specific sections for which it claims an exemption and the basis for the exemption.

(4) Any completed "Application for Low-THC Cannabis Dispensing Organization Approval" and all required exhibits and supporting documents shall be delivered to the Agency Clerk of the Department of Health physically located at 2585 Merchants Row Boulevard in Tallahassee, Florida, no earlier than 10:00 AM, Eastern Time, on the effective date of this rule and no later than 5:00 PM, Eastern Time, 15 calendar days after the effective date of this rule. A courtesy copy of the completed application shall also be delivered to the Sheriff of the county in which the dispensing organization facility is located.

(a) The Department will substantively review and evaluate all timely received applications to determine if the applicant is qualified by meeting the requirements of Section 381.986(5)(b), F.S., and this Chapter. 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 random lottery-type selection by public drawing to designate the approved applicant and the rank order of other applications within each dispensing region.

(b) Upon notification that it has been selected as a region's dispensing organization, the applicant shall have ten calendar days to pay a non-refundable \$150,000 application fee to the department and post a \$5 million performance bond.

(c) If the selected applicant fails to pay the application fee and post the bond within the required timeframes, the applicant next in rank order and located in the applicable dispensing region shall be selected and the selected applicant notified.

Rulemaking Authority 381.986(5)(d) FS. Law Implemented 381.986(5)(b) FS. History--New \_\_\_\_\_.

#### 64-4.003 Biennial Renewal Requirements for Dispensing Organizations.

(1) No less than 60 calendar days prior to the expiration of an existing dispensing organization's authorization to dispense low-THC cannabis derivative products, the dispensing organization shall make application for renewal of the dispensing organization approval using Form DH8006-OCU-06/2014, "Application for Low-THC Cannabis Dispensing Organization Approval" herein incorporated by reference and available at <https://flrules.com/gateway/reference.asp?No=Ref-#####>, indicating that the application is a renewal application.

(2) In addition to the completed application form, dispensing organization renewal applicants shall:

(a) Demonstrate that they continue to meet the requirements of Section 381.986(5)(b)1.-7., F.S., by updating the documentation submitted with the original application or providing a notarized statement that there have been no changes;

(b) Provide written documentation that any violations noted during any inspections or investigations by the department, Department of Agriculture and Consumer Services or law enforcement officials have been corrected; and

(c) Provide written documentation of compliance with the financial requirements of Section 381.986(5)(b)5., F.S., including a financial report of an audit by a Florida Certified Public Accountant of the financial statement for the previous two years.

(3) If the dispensing organization meets the requirements of Section 381.986(5)(b), F.S., and this chapter, the department shall notify the dispensing organization that it intends to renew the approval.

(4) Upon notification that its renewal will be approved, the dispensing organization shall have 30 calendar days to pay a nonrefundable \$300,000 renewal fee to the department and to provide proof that its \$5 million performance bond remains in effect.

(5) If the applicant fails to renew within the required timeframes, the department shall seek new applications for a dispensing organization in the applicable dispensing region.

(6) A dispensing organization that fails to renew its approval shall not dispense low-THC cannabis products after midnight local time on the date that its authorization expires and shall destroy all low-THC cannabis in its possession within 24 hours of the last dispensing day. Any undestroyed low-THC cannabis remaining under the control of the dispensing organization more than 24 hours after the last dispensing day shall be seized and destroyed by the Department.

PROPOSED EFFECTIVE DATE: Upon Legislative ratification.

Rulemaking Authority 381.986(5)(d) FS. Law Implemented 381.986(5)(b) FS. History--New \_\_\_\_\_.

#### 64-4.004 Denial or Revocation of Dispensing Organization Approval.

(1) The department shall deny an application for a dispensing organization approval or renewal if:

(a) Any dispensing organization facility is within 1000 feet, as measured from the primary dispensing organization structure to the nearest property line of an elementary, middle or secondary school, day care facility as defined in Section 402.302, F.S., county or municipal park, or place of worship that existed before the date the dispensing organization submitted its initial application for approval;

(b) Any owner or manager:

1. Has been convicted of a felony offense;

2. Has served as an owner or manager for any entity or organization in any state that has had its authority to cultivate, harvest, process or dispense low-THC cannabis or low-THC cannabis derivative product revoked;

3. Is under 21 years of age;

4. Is a physician currently ordering low-THC cannabis derivative products for use by qualified registered patients;

5. Is a law enforcement official; or

6. Is an employee or contractor of the department;

(c) The application of the dispensing organization does not comply with the requirements Section 381.986, F.S., or this chapter;

(d) The dispensing organization has failed to correct any violation noted during an inspection in accordance with its corrective action plan; or

(e) The applicant provides false or misleading information to the department.

(2) The department shall revoke its approval of the dispensing organization if:

(a) The dispensing organization:

1. Cultivates low-THC cannabis before obtaining department authorization; or

2. Knowingly dispenses, delivers, or otherwise transfers low-THC cannabis derivative product to an individual or entity other than a qualified registered patient or a qualified registered patient's legal guardian; or

(b) An owner or manager has been convicted of a felony offense; or

(3) The department may revoke a dispensing organization's approval or authorization if the dispensing organization does not:

(a) Comply with the requirements in Section 381.986, F.S., or this chapter;

(b) Implement the policies and procedures or comply with the statements provided to the department with the dispensing organization's application;

(c) Seek authorization to begin cultivation within 75 calendar days of application approval; or

(d) Begin dispensing within 150 calendar days of the authorization granted pursuant to subsection 64-4.005(2),

F.A.C.

Rulemaking Authority 381.986(5)(d) FS. Law Implemented 381.986(5)(b) FS. History--New \_\_\_\_\_.

#### 64-4.005 Inspection Procedures.

(1) Submission of an application for dispensing organization approval constitutes permission for entry by the department, the Department of Agriculture and Consumer Services or law enforcement officials and agents into any dispensing organization facility to inspect any portion of the facility, review the records required pursuant to Section 381.986, F.S., or this chapter, and collect samples of any low-THC cannabis for laboratory examination at any reasonable time. All inspectors shall follow the dispensing organization's sanitation protocol when conducting any inspection.

(2) No less than 30 calendar days prior to the initial cultivation of low-THC cannabis, the dispensing organization shall notify the department and the sheriff of the county in which the dispensing organization facility is located that the dispensing organization facility is complete, the dispensing organization is in compliance with Section 381.986, F.S., and this chapter and is seeking authorization to begin operation. No low-THC cannabis, including seeds, tissue culture, and cuttings, may be present in any dispensing organization facility prior to authorization by the department.

(3) If the department identifies a violation of Section 381.986, F.S., or this chapter during an inspection of a dispensing organization facility, the dispensing organization shall notify the department in writing, with a postmark date within 20 working days after the date of receipt of the written notice of violations, identifying the corrective actions taken and the date of the correction.

Rulemaking Authority 381.986(5)(d) FS. Law Implemented 381.986(5)(b) FS. History--New \_\_\_\_\_.

#### 64-4.006 Identification, Labeling and Testing Low-THC Cannabis Seeds, Dried Flowers and Derivative Products.

(1) A dispensing organization shall ensure that the low-THC cannabis derivative product provided to a qualified patient is in medical grade, childproof containers labeled with:

(a) The dispensing organization name and location;

(b) The amount, harvest number, and batch number of the low-THC cannabis derivative product being dispensed;

(c) The date of product processing or manufacture;

(d) A list of all additives, including pesticides, herbicides, and fertilizers, used in the cultivation and production of the low-THC Cannabis;

(e) The percent by weight of tetrahydrocannabinol and cannabidiol; and

(f) The registry identification number of the qualified registered patient.

(2) Prior to dispensing any low-THC derivative product, a dispensing organization shall sample and have tested by a department approved testing laboratory each batch of each product to be distributed. The testing laboratory shall file with the department an electronic copy of each laboratory test result for any batch that does not pass the microbial, mycotoxin, heavy metal, pesticide, chemical residue or residual solvents levels test or meet the composition requirements required by s. 381.986(1)(b), F.S. Dispensing shall not occur until the test results have been received by the dispensing organization. Testing shall include, but is not limited to:

(a) Tetrahydrocannabinol concentration reported as a percentage by weight;

(b) Cannabidiol concentration reported as percentage by weight; and

(c) Bacteria and molds, including aerobic bacteria, e coli, enterobacteria, powdery mildew, penicillium, yeast, aspergillus, cladosporin, fusarium, botrytis, aureobasidium and acremonium.

(d) Heavy metals;

(e) All chemical additives, including nonorganic pesticides, herbicides, and fertilizers, and solvents used in the cultivation and production of the low-THC Cannabis reported as parts per billion.

(3) The dispensing organization shall provide copies of any test results to the department upon request.

(4) If any batch sample test result shows the presence of a chemical additive over the Health Advisory Level (HAL) as provided in the department's Environmental Chemistry Analyte List, the entire batch from which the sample was derived shall be identified and segregated to prevent further processing or distribution. The entire batch and harvest shall be destroyed.

(5) Any batch sample or any other sample that exceeds 0.8% tetrahydrocannabinol by weight or 10% or less of cannabidiol by weight shall be reported immediately to law enforcement officials. The entire batch or other material from which the sample was derived shall be identified and segregated to prevent further processing or dispensing. If

the batch cannot be made to conform in a reasonable period of time, any further handling and destruction of the material shall be conducted with the consent of law enforcement officials.

(6) Upon request from the department, a dispensing organization shall submit a sample of any specific seed, dried flower or derivative product from the low-THC cannabis inventory to a laboratory selected by the department for analysis and reporting to the department.

(7) Laboratories shall immediately destroy any untested low-THC cannabis or low-THC cannabis derivative product upon the completion of the testing. Laboratories shall retain the tested sample for 30 calendar days to allow for retesting before destroying the sample. If the low-THC cannabis or low-THC cannabis derivative product is destroyed, the time and method of destruction or disposal shall be documented.

(8) Compliance with the testing requirements constitutes the legal authority to possess and transmit low-THC cannabis and low-THC cannabis derivative products under Florida law.

(9) All low-THC derivative products shall be maintained in a climate-controlled and appropriate environment.

Rulemaking Authority 381.986(5)(d) FS. Law Implemented 381.986(5)(b) FS. History—New \_\_\_\_\_.

#### 64-4.007 Recordkeeping and Reporting Requirements.

(1) A dispensing organization shall designate in writing an inventory agent who has oversight of the inventory control system.

(2) A dispensing organization shall establish and implement an inventory control system for the low-THC cannabis plants and derivative products that documents:

(a) Each day's beginning and ending inventory of, seeds, tissue culture, cuttings, harvests, processed low-THC cannabis derivative products, sales, disbursements, and disposal of unusable plants or low-THC cannabis derivative products;

(b) For each harvest of low-THC cannabis cultivated:

1. The harvest number;

2. Whether the harvest originated from seeds, tissue culture or cuttings;

3. The strain of the seeds, tissue culture or cuttings planted;

4. The number of seeds, tissue culture or cuttings planted;

5. The date the seeds, tissue culture or cuttings were planted;

6. A list of all chemical additives, including organic pesticides, herbicides, and fertilizers used in the cultivation;

7. The number of low-THC plants grown to maturity;

8. Date of harvest;

9. Final harvest yield weight;

10. Name of the inventory agent responsible for the harvest, and

11. The disposal of low-THC plants or plant parts not used for the production of dispensable products including

the:

a. Description of and reason for disposal including, if applicable, the number of failed or other unusable plants;

b. Date of disposal;

c. Method of disposal; and

d. Name of the inventory agent responsible for the disposal.

(c) For each batch of low-THC cannabis produced:

1. The batch number;

2. The harvest number(s) of the low-THC plants incorporated into the batch;

3. The name (if applicable) of the low-THC cannabis derivative product produced;

4. Form and quantity of low-THC cannabis derivative product produced;

5. Date sampled for laboratory analysis;

6. Laboratory sample results; and

7. Date laboratory results were received.

(d) For low-THC cannabis derivative products dispensed:

1. Name (if applicable) of the low-THC cannabis derivative product;

2. Form of the low-THC cannabis derivative product;

3. Batch number;

4. Amount of each low-THC cannabis derivative product dispensed; and

5. Price of the low-THC cannabis derivative product dispensed

(e) For low-THC cannabis derivative products disposed:

1. Name (if applicable) of the low-THC cannabis derivative product, form, batch number and amount;

2. Reason for disposal; and

3. Method of disposal.

(3) The inventory agent shall conduct and document an audit of the dispensing organization's inventory at least once every 30 days. If the audit identifies a discrepancy in the amount of low-THC cannabis or low-THC cannabis derivative product, the dispensing organization shall determine where the discrepancy has occurred and take and document immediate corrective action. The dispensing organization shall notify the department of any identified discrepancy and the corrective action taken within 5 working days of the identification of the discrepancy. If criminal activity is suspected, the dispensing organization shall immediately report the suspicion to law enforcement officials.

(4) The dispensing organization shall maintain the required documentation for a minimum of five years from the date of the document and provide the documentation to the department upon request.

Rulemaking Authority 381.986(5)(d) FS. Law Implemented 381.986(5)(b) FS. History--New \_\_\_\_\_.

#### 64-4.008 Procedural Requirements.

(1) A dispensing organization shall:

(a) Ensure that dispensing hours of operation, at a minimum, adhere to the dispensing availability proposed in the approved application, and that its dispensary is operating and available to dispense low-THC cannabis derivative product to any qualified registered patient on a regular schedule which shall be prominently displayed in the dispensary, posted online and available upon request to qualified registered patients, their legal guardians and ordering physicians;

(b) Develop, document, and implement policies and procedures regarding:

1. Training and adherence to confidentiality requirements;

2. Inventory control; and

3. Patient records;

(c) Maintain policies and procedures and provide copies to the department upon request;

(d) Post the following information in a place that can be viewed by individuals entering the dispensary:

1. Name of the dispensing organization;

2. Name of the medical director and the medical director's license number; and

3. Hours of operation;

(e) Limit access to the dispensing organization to owners, agents, managers, designated employees and qualified registered patients, their legal guardians, authorized inspectors and authorized visitors. Authorized visitors must wear an identifying badge and be escorted and monitored at all times by an owner, manager, agent or employee. The dispensing organization shall create and maintain a visitor log and the name of any visitor and the date and duration of the visit shall be entered the log. All authorized visitors must comply with the sanitary protocol of the dispensing organization; and

(f) Advise the department within seven calendar days of any change in medical director. A dispensing organization cannot operate in the absence of a contracted or employed medical director.

(2) The dispensing organization shall cultivate, process, store, dispense, and perform any other activity involving low-THC cannabis in an enclosed and locked facility that protects the growing and processing operations from view.

(3) The dispensing organization shall make reasonable efforts to mitigate odors.

(4) Dispensing organizations shall not produce or provide low-THC cannabis that is part of, mixed with, or added to an edible food product.

(5) The dispensing organization shall ensure that all buildings and equipment used for the cultivation, harvest, preparation, packaging, storage, or sale of low-THC cannabis and low-THC cannabis derivative products are maintained in a clean and sanitary condition.

(a) Low-THC cannabis in the process of preparation, production, packing, storage, sale or dispensing shall be protected from insects, dust, dirt and other contamination in fully enclosed rooms.

(b) Refuse or waste products incident to the manufacture, preparation, packing, selling, or distribution of low-THC cannabis and low-THC cannabis derivative products shall be destroyed on-site at least once every 24 hours.

(c) All trucks, trays, buckets, other receptacles, platforms, racks, tables, shelves, knives, saws, cleavers, other utensils, or the machinery used in moving, handling, cutting, chopping, mixing, canning, packaging, or other processes shall be cleaned at least once every 24 hours.

(6) The medical director must be onsite or available by telephone, pager or other electronic communication and must designate a back-up medical director when not so available. The medical director shall provide for standards and protocols that ensure proper testing of low-THC medical cannabis derivative products for potency and contamination. The medical director shall assist with the development and implementation of policies and procedures regarding, at a minimum, emergency responses, sanitary practices, compliance with state and federal regulations regarding confidentiality of personally identifiable health information, quality assurance, and disease prevention. The medical director shall also respond to the Department of Health and local municipalities regarding compliance with rules and regulations and community health and public safety concerns. If the medical director determines that any employee of the dispensing organization has a health condition that may adversely affect the safety or quality of the low-THC cannabis or derivative products, the employee shall be prohibited from direct contact with any product or equipment or materials for processing low-THC cannabis until the medical director determines that the employee's health condition will not adversely affect the safety and quality of the low-THC cannabis.

(7) Dispensing organizations shall ensure that all owners, managers and employees are at least 21 years of age and have successfully completed Level-2 background screening within the last year before commencing employment. Any owner, manager or employee arrested for a disqualifying felony shall be immediately suspended. Any owner, manager or employee shall be immediately terminated upon conviction of a disqualifying felony.

(8) With approval from the Department, dispensing organizations may alter, expand or consolidate their infrastructure, operations or staffing structure in order to better serve patients, provided the changes comply with the requirements of Section 381.986(5)(b), F.S., and this chapter. Dispensing organizations shall request approval using Form DH8007-OCU-06/2014, "Request to Alter, Expand or Consolidate Dispensing Organization" herein incorporated by reference and available at <https://flrules.com/gateway/reference.asp?No=Ref-####>.

Rulemaking Authority 381.986(5)(d) FS. Law Implemented 381.986(5)(b) FS. History—New \_\_\_\_\_.

#### 64-4.009 Compassionate Use Registry.

(1) Ordering physicians licensed under Chapter 458 or 459, F.S., meeting the educational requirements of Section 381.986(4), F.S., may access the Compassionate Use Registry using their existing MOA Services credentials.

(2) Designated persons may request access to the Compassionate Use Registry by completing form DH8008-OCU-06/2014, "Request for Access to the Compassionate Use Registry", herein incorporated by reference and available at <https://flrules.com/gateway/reference.asp?No=Ref-####>. Those requesting access must meet one of the following criteria:

(a) Authorized employee of a dispensing organization - Each dispensing organization may designate up to five employees for access to the Compassionate Use Registry;

(b) Law enforcement official;

(c) Authorized employee of the University of Florida, College of Pharmacy Program – The University of Florida College of Pharmacy may designate up to five employees for access to the Compassionate Use Registry;

(d) Authorized employee of the department; or

(e) A person authorized by the department to conduct research pursuant to Section 381.987(3)(f), F.S.

(3) Persons seeking to access to the registry shall have successfully completed a department-approved course in their responsibilities related to patient confidentiality and shall make documentation of completion available to the department upon request.

(4) Before dispensing any low-THC cannabis derivative product to a qualified registered patient or the patient's legal guardian, the dispensing organization must verify that the patient has an active registration, the order presented matches the order contents as recorded by the physician in the registry and the order has not already been filled.

(5) The dispensing organization shall enter a dispensing action into the registry immediately upon dispensing the low-THC cannabis to the qualified registered patient or the patient's legal guardian.

Rulemaking Authority 381.986(5)(d) FS. Law Implemented 381.986(5)(a) FS. History--New \_\_\_\_\_.

NAME OF PERSON ORIGINATING PROPOSED RULE: Linda N. McMullen

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: John H. Armstrong, MD, FACS,  
Surgeon General and Secretary

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: August 13, 2014

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: June 18, 2014

## **Bist, Kevin**

---

**From:** Kostas Stoilas <stoilas@yahoo.com>  
**Sent:** Tuesday, February 03, 2015 6:58 AM  
**To:** Nelson, Patricia A  
**Subject:** Fwd: FL hearing in February  
**Attachments:** Department of Health.Florida.2015.docx; ATT00001.htm

Also, just received these inputs last night from the President of a relevant Nurses Association.

Thanks,

Kostas Stoilas  
239-822-7816 cell  
[stoilas@yahoo.com](mailto:stoilas@yahoo.com)

Begin forwarded message:

**From:** Eileen Konieczny <[olivemmj@gmail.com](mailto:olivemmj@gmail.com)>  
**Subject:** FL hearing in February  
**Date:** February 2, 2015 at 10:40:14 PM EST  
**To:** Kostas Stoilas <[stoilas@yahoo.com](mailto:stoilas@yahoo.com)>

Kostas,  
I have attached my comments for submission to the committee. I hope they are acceptable to you and your group. Thank you so much for this opportunity.

*Namaste,*

*eileen*

*Everything is possible. The impossible just takes longer.*

*This message contains information which may be privileged and confidential unless you are the addressee (or authorized to receive correspondence for the addressee), you may not use, copy or disclose to anyone the message or any information contained in the message (including attachments). If you have received the message in error, please advise me by reply e-main and delete the message. Thank you.*

Department of Health  
4052 Bald Cypress Way, Bin A-02  
Tallahassee, FL 32399

Although I was not selected to participate on the Rulemaking Committee, I respectfully submit some input for your consideration.

My background in advocacy and policy making as well as experience being a clinician in medicinal cannabis, makes me uniquely qualified to submit these suggestions on behalf of patients in Florida.

As a nurse and human, my experiences and expertise know no state boundary or zip code. I am concerned about the health and safety of communities, families and individual patients. The laws Florida is creating focuses on providing medical cannabis to patients; it is my hope that Florida will learn the lessons from other states that have come before them and also patient caregivers. I ask that my experience in medical cannabis policy and advocacy be considered a valuable resource for your committee in developing practical regulations for the dispensing of medical cannabis in Florida.

Sincerely,

*Eileen Konieczny*

Eileen Konieczny RN

President elect of American Cannabis Nurses Association



eileen konieczny RN

Nurses have a unique opportunity to affect the lives of the people they touch every day. It is not the easiest of professions, yet it is one that shows true human compassion. eileen konieczny has over 20 years of nursing experience specializing in oncology.

As a healthcare provider, eileen has witnessed her patients struggle with a host of side effects associated with their treatment protocols which “greatly reduce their quality of life”. Because of cannabis’s safety profile and few side effects, eileen strongly believes that medical cannabis should be available as a treatment option to many.

Since 2008 eileen has been an outspoken advocate for the use of medical cannabis as a complimentary medicine to combat disease and illnesses. She is President-elect of the American Cannabis Nurses Association. She played an integral role in the passage of medical cannabis legislation in Connecticut (2012) and New York (2014), securing safe access of medical cannabis for over 23 million people. She worked as Executive Director of the Connecticut Cannabis Business Alliance, a trade association created for the industry by the industry to promote Education, Best Practices and Industry Standards as well as founding a company that successfully won a license for the cultivation and production of medical cannabis in Connecticut.

## Points of interest

- If you are treating this as medicine, then regulation should call for the oversight or the inclusion of a pharmacist in the dispensary. This is necessary not only for compliance issues but for patient interactions.
  - There is a growing body of literature that validates that pharmacist-provided medication management can improve health outcomes across a number of settings.
  - Their inclusion in the dispensary setting can improve medication adherence and clinical outcomes as well as maintain lines of communication with the patient's physician.
- There is no mention of product standardization
  - Patients deserve to have a standardized product
  - Level of integrity to the industry brings about more willingness of physicians to utilize it.
    - In CT they required a pharmaceutical grade standard of 3% in regards to label claim and compliance ie. If you state there is 50 mg of cannabinoid in product X, there has to be 50mg +/- 3%
    - In NY they are proposing a medical grade standard of 5%
- While the effects of each individual compound are not yet understood, one thing is clear: The whole is more than the sum of its parts.
  - With 66 unique cannabinoids and an even longer list of other plant compounds found in cannabis, legislation limiting one specific compound is irresponsible.
  - We already have a clear understanding that isolating and synthesizing a single compound appears to be less effective and often causes serious adverse side effect.
  - Each cannabis plant contains any number of cannabinoids, THC, CBD, CBG, CBN, CBC and THCV in various ratios and percentages as well as other compounds like terpenes, flavonoids, amino acids, proteins, sugars, fatty acids and esters.
  - While the effects of each individual compound are not yet understood, one thing is clear: The whole is more than the sum of its parts.
  - Until more research is done on the other constituents of whole plant cannabis, eliminating or preventing the inclusion of even one could have dire effects for patients in need
  - No single cannabinoid demonstrates the level of efficacy as do whole plant extracts.
  - According to the NIH website, our federal government notes that the components of cannabis may prove to be useful for treating a range of illness or symptoms.
  - Research funded by the NIH is actively investigating the possible therapeutic uses of THC, CBD, and other cannabinoids to treat autoimmune diseases, cancer, inflammation, pain, seizures, substance use disorders, and other psychiatric disorders.
  - One of the reasons that it is believed that cannabis is effective in the treatment of multiple disorders can be attributed to the entourage or ensemble effect.
    - (1)This is defined by Wagner and Ulrich-Merzenich, as the mechanisms of whole plant extract synergy:
      - Ability to affect multiple targets within the body
      - Ability to improve the absorption of active ingredients

- Ability to overcome bacterial defense mechanisms
- Ability to minimize adverse side effects.

(1) <http://www.medicaljane.com/2014/05/14/thc-cbd-and-more-the-entourage-effect-of-whole-plant-cannabis-medicine/>

**Bist, Kevin**

---

**From:** julio lopez <fcd1910@gmail.com>  
**Sent:** Tuesday, February 03, 2015 9:10 AM  
**To:** Nelson, Patricia A  
**Subject:** Re: Updated Draft Text for 64-4, F.A.C.

Ms. Nelson,

These proposed rules still do not comply with the administrative's judge ruling. I would like to know why the FLDOH is refusing to follow compliance to the ruling.

Julio A. Lopez, PhD  
President/CEO  
Florida Cannabis Dispensaries, Inc.



Facebook

On Fri, Jan 30, 2015 at 5:43 PM, Nelson, Patricia A <[Patricia.Nelson@flhealth.gov](mailto:Patricia.Nelson@flhealth.gov)> wrote:

Please see the attached updated draft text.

Have a great weekend!

Patricia Nelson

Director

Office of Compassionate Use

Florida Department of Health



**Bist, Kevin**

---

**From:** howard.l@ironlaboratories.com  
**Sent:** Tuesday, February 03, 2015 9:17 AM  
**To:** Nelson, Patricia A  
**Subject:** RE: Questions from Florida

**Ms. Nelson,**

**Thank you the email and specific questions inherent. I will review with my chief scientist and reply accordingly.**

**Best Regards,**

**Howard J Lutz, CEO Iron Laboratories LLC**

----- Original Message -----

Subject: Questions from Florida  
From: "Nelson, Patricia A"  
Date: 2/2/15 6:42 pm  
To: "howard.l@ironlaboratories.com"

Mr. Lutz,

Thank you very much for taking the time to talk to me today. I understand your concerns, and hopefully, you can answer some of my questions without revealing any proprietary, or otherwise sensitive, information.

I will offer a little more background on my office for you. We have been tasked with implementation of a low-THC cannabis regulatory structure. The main statute is attached for your reference. The Department's first attempt was invalidated by an administrative law judge, and we are on our second attempt using the guidance we received from the ALJ. I have some data gaps in my own understanding of the industry you operate in. Although I am currently a lawyer, I have some experience in analytical chemistry from my pre-law school days. Most of that experience is in the area of environmental analysis. I have been trying to determine whether parallels can be drawn from that experience to testing cannabis and products derived from cannabis. For example:

1. In the environmental laboratory, we were accredited by various entities, including a state agency. I do not think an accreditation system exists for cannabis testing beyond having an ISO 17025 certification. If you can confirm that, it would be helpful.
2. Also, in the environmental laboratory, we operated under SOPs that were derived from methods approved by the EPA, e.g., Method 8270 for the analysis of semivolatile organic compounds by GC/MS (I performed extraction and analysis under this method as well as several others). Are there any standard methods used in connection with cannabis analysis, or do individual labs develop their own SOPs and methods?
3. Finally, each EPA method had an analyte list. It is my understanding that no such list exists for cannabis testing. Right now, the only viable lists I have seen are USP 1111 for microbiology (and maybe 61 and 62, embarrassingly, I'm still figuring out how they fit together), the pesticides listed in the AHP, *Cannabis Inflorescence*, residual solvent(s), and the big four heavy metals (I have seen conflicting

views on these with some saying it's unnecessary and others saying it is necessary). Is there a better resource I can use, including lists put together by other states?

Any help you can offer would be appreciated, either answering these questions or explaining why those are all the wrong questions to ask – I'm getting used to that, too. Thank you in advance.

Sincerely,

Patty

Direct (850) 245-4657

Cell (850) 510-7915

Patricia Nelson

Director

Office of Compassionate Use

Florida Department of Health



## Bist, Kevin

---

**From:** Berry, Michael S  
**Sent:** Tuesday, February 03, 2015 11:31 AM  
**To:** Nelson, Patricia A  
**Cc:** Reich, Andy; Donahue, Charles R; Higginbotham, Joseph M  
**Subject:** 64-4 Query referred by DACS

Ms Nelson

Yesterday, we received an email from Davis Daiker over at FDACS regarding the draft version of 64-4, particularly 64-4.005(4), where it specifies testing against the Health Advisory Levels (HAL) from our Environmental Chemistry lab.

“(4) If any batch sample test result shows the presence of any bacteria, mold, heavy metal, or chemical additive over the Health Advisory Level (HAL) as provided in the department’s Environmental Chemistry Analyte List [use *U.S. Pharmacopeia Herbal Medicines Compendium?*], dated July 31, 2014, herein incorporated by reference...”

The HALs are drinking water standards that assume 2L per day consumption over a lifetime. Dr Daiker wondered if standards created for drinking water would be the correct ones to use for the purposes outlined in 64-4. I understand that a public hearing is set for tomorrow, and although not on the agenda, he wanted someone over here to know about his concerns in case they came up so that they didn’t throw anyone for a loop.

We deal with drinking water over here, but I promised to forward this on to the correct people. Please let me know if you’re not the right person to contact on this.

Thanks,  
Mike

=====  
Michael Berry, OMC Manager  
Florida Department of Health  
Division of Disease Control and Health Protection  
Bureau of Environmental Health  
4052 Bald Cypress Way, Bin A08 Tallahassee, FL 32399-1710  
(850) 245-4444 ext \*2074  
Fax (850) 487-0864

[Michael.Berry@flhealth.gov](mailto:Michael.Berry@flhealth.gov)

How are we doing? Take our survey:  
<http://adminapps.doh35.doh.state.fl.us/ContactUs/DOHFeedback.aspx?Email=EnvironmentalHealth@doh.state.fl.us&Office=BureauOfEnvironmentalHealth>

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

**PLEASE NOTE:** Florida has a very broad public records law. Most written communications to or from state officials regarding state business are public records available to the public and media upon request. Your e-mail communications may be subject to public disclosure.

## Bist, Kevin

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**From:** Nelson, Patricia A  
**Sent:** Tuesday, February 03, 2015 11:55 AM  
**To:** Berry, Michael S  
**Subject:** RE: 64-4 Query referred by DACS

Thank you, Michael. This issue is still in flux, and his point is a good one. It will most likely be discussed at length. I will make sure that his concern is included on the rulemaking comments considered in the negotiation.

Patty

Patricia Nelson  
Director  
Office of Compassionate Use  
Florida Department of Health



---

**From:** Berry, Michael S  
**Sent:** Tuesday, February 03, 2015 11:31 AM  
**To:** Nelson, Patricia A  
**Cc:** Reich, Andy; Donahue, Charles R; Higginbotham, Joseph M  
**Subject:** 64-4 Query referred by DACS

Ms Nelson

Yesterday, we received an email from Davis Daiker over at FDACS regarding the draft version of 64-4, particularly 64-4.005(4), where it specifies testing against the Health Advisory Levels (HAL) from our Environmental Chemistry lab.

"(4) If any batch sample test result shows the presence of any bacteria, mold, heavy metal, or chemical additive over the Health Advisory Level (HAL) as provided in the department's Environmental Chemistry Analyte List [use *U.S. Pharmacopeia Herbal Medicines Compendium?*], dated July 31, 2014, herein incorporated by reference..."

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We deal with drinking water over here, but I promised to forward this on to the correct people. Please let me know if you're not the right person to contact on this.

Thanks,  
Mike

=====

Michael Berry, OMC Manager  
Florida Department of Health  
Division of Disease Control and Health Protection  
Bureau of Environmental Health  
4052 Bald Cypress Way, Bin A08 Tallahassee, FL 32399-1710  
(850) 245-4444 ext \*2074  
Fax (850) 487-0864

[Michael.Berry@flhealth.gov](mailto:Michael.Berry@flhealth.gov)

How are we doing? Take our survey:

<http://adminappsdo35.doh.state.fl.us/ContactUs/DOHFeedback.aspx?Email=EnvironmentalHealth@doh.state.fl.us&Office=BureauOfEnvironmentalHealth>

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**Bist, Kevin**

---

**From:** Chris Hansen <chansen@ballardfl.com>  
**Sent:** Tuesday, February 03, 2015 12:05 PM  
**To:** Nelson, Patricia A  
**Cc:** Tschetter, Jennifer  
**Subject:** FW:  
**Attachments:** 64\_4\_FAC\_Ballard Partners Memo.doc

One final thought / comments regarding the scoring of applications. Good luck tomorrow.

Chris Hansen

---

**From:** Shanna Crawley  
**Sent:** Tuesday, February 3, 2015 11:57 AM  
**To:** Chris Hansen  
**Subject:**

## MEMORANDUM

To: Patricia Nelson, Director, Office of Compassionate Use

From: Chris Hansen, Ballard Partners

Date: February 2, 2015

Re: 64-4, F.A.C. Comments from Keith St. Germain Nursery and Good Chemistry

---

Thank you for sending our office a draft copy of 64-4, F.A.C. Keith St. Germain Nursery and Good Chemistry reviewed the document and continue to be highly supportive and complementary of your work. We believe this is a very well-thought-out and comprehensive set of criteria and program requirements.

We understand that the approach to the scoring of the applications will be a significant topic of discussion during the upcoming February 4<sup>th</sup> and 5<sup>th</sup> workgroup. We believe that the medical marijuana-specific experience of the actual operating partner is critical as a focus on real world success will mitigate the risk of selecting inexperienced consultants and operators who are not truly qualified to service Florida's patient base.

We believe that the following criteria should carry significant weight in the scoring process:

- A senior management team with proven medical marijuana industry experience (3+ years);
- Successful medical marijuana operations in other states outside of Florida;
- History of successful medical marijuana regulatory compliance;
- Medical marijuana cultivation experience;
- Medical marijuana product development experience;
- Medical marijuana dispensary management experience;
- Medical marijuana inventory tracking and security experience; and
- Proven track record of working with patients using marijuana-related medications.

The State of Florida and Office of Compassionate Use have a unique opportunity to select only the most knowledgeable and experienced applicants. A strong focus on the successful track records of the operating partners will ultimately ensure the success of the Compassionate Use program and the health and safety of its patients.

#### TALLAHASSEE

403 East Park Ave.  
Tallahassee, FL 32301  
850.577.0444  
850.577.0022 fax

#### WEST PALM BEACH

1400 Centre Park Blvd.  
Suite 1010  
West Palm Beach, FL 33401  
561.253.3232

#### JACKSONVILLE

818 A1A North  
Suite 101, The Veranda  
Ponte Vedra Beach, FL 32082  
904.834.2679

#### MIAMI

2 Alhambra Plaza  
Suite 102  
Coral Gables, FL 33134  
305.906.0155

#### TAMPA

2202 N. West Shore Blvd.  
Suite 200  
Tampa, FL 33607  
813.294.7024

#### ORLANDO

250 International Pkwy.  
Suite 250  
Lake Mary, FL 32746  
407.803.3878

**Bist, Kevin**

---

**From:** Nelson, Patricia A  
**Sent:** Tuesday, February 03, 2015 2:25 PM  
**To:** Genester Wilson-King  
**Subject:** Re: Question about the meeting tomorrow

The only people participating in the negotiation are the members of the committee. There is no public comment period.

On Feb 3, 2015, at 2:22 PM, Genester Wilson-King <[drwilsonking@drwilsonking.com](mailto:drwilsonking@drwilsonking.com)> wrote:

Are you allowing any public comment tomorrow and Thursday?  
There seems to be lots of confusion about this. People are going to your meeting thinking they will have say.

Please respond to me as soon as possible.

--Genester Wilson-King MD, FACOG

**Victory Rejuvenation Center**  
**1540 International Pkwy**  
**Lake Mary, FL 32746**  
Website: [www.victoryrejuvenationcenter.com](http://www.victoryrejuvenationcenter.com)  
Email: [drwilsonking@drwilsonking.com](mailto:drwilsonking@drwilsonking.com)  
Phone: 407-536-5125  
Fax: 321-280-6977

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**Bist, Kevin**

---

**From:** Nelson, Patricia A  
**Sent:** Tuesday, February 03, 2015 2:50 PM  
**To:** 'Genester Wilson-King'  
**Subject:** RE: Question about the meeting tomorrow

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---

**From:** Genester Wilson-King [<mailto:drwilsonking@drwilsonking.com>]  
**Sent:** Tuesday, February 03, 2015 2:28 PM  
**To:** Nelson, Patricia A  
**Subject:** Re: Question about the meeting tomorrow

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Genester Wilson-King MD, FACOG

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**Bist, Kevin**

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**From:** Genester Wilson-King <drwilsonking@drwilsonking.com>  
**Sent:** Tuesday, February 03, 2015 3:21 PM  
**To:** Nelson, Patricia A  
**Subject:** Re: Question about the meeting tomorrow

Thank you. :-)

Genester Wilson-King MD, FACOG

**Victory Rejuvenation Center**  
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**Lake Mary, FL 32746**  
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## **Bist, Kevin**

---

**From:** Jammie Treadwell <jammietreadwell@yahoo.com>  
**Sent:** Tuesday, February 03, 2015 4:29 PM  
**To:** Nelson, Patricia A  
**Cc:** Glen Treadwell; jeffreysark@gmail.com; Jenny Treadwell  
**Subject:** Questions/Comments for Rule Negotiation Meeting

Patti -

Following are some questions/comments for consideration in the HB 1030 negotiated sessions. Dr. Sharkey advised us that we should share them with you. I have noted the applicable section in hopes that this is helpful as you go through the discussion.

### **Section 64-4.001**

1. Applicant – There is no reference to an ownership requirement and percentage by the nursery. Please clarify any requirements.

11. Dispensing Organization Facility – We assume contiguous property means that the dispensary is co- located with the full operation. Please confirm.

Removal of Transportation Plan - Transport and delivery were specifically addressed in the previous rules and then left out of the latest draft. Does that mean transport and delivery across the state will no longer be allowed?

### **Section 64-4.002**

H Medical Director 2.f

There are now very specific and detailed requirements for the medical director which is very much welcomed. How will you assess the adequacy of the experience or the knowledge? This is clearly not addressed in the low THC-high CBD physician certification course.

5.b.1

What criteria will be used to determine an “uninterrupted supply of Low THC cannabis qualified patients...sufficient enough to supply qualified patients with an adequate supply of Low THC cannabis?”

Does uninterrupted supply refer to continuous cultivation? What does sufficient enough mean and what is an adequate supply? What happens if qualified patient projections exceed DOH projections, physician utilization is higher than expected etc.? What reasonableness test will be used to exercise revocation of bond if triggered?

### **64-4.006**

1.h

There aren't very many labs in the entire US that test for terpenes. In fact, there is no lab in the state of Florida that does this. It is also a federal violation for cannabis to cross state line. Will you require the testing labs that set up here to test for terpenes?

Thanks for adding them to your list. Please let me know if you have any questions.

Regards,

Jammie Treadwell  
Treadwell Nursery  
352.409.0952

## **Bist, Kevin**

---

**From:** Robert Tornello <tornellobamboo@gmail.com>  
**Sent:** Tuesday, February 03, 2015 4:52 PM  
**To:** Nelson, Patricia A  
**Subject:** Comments on Rule 64.docx  
**Attachments:** Comments on Rule 64.docx; ATT00001.txt

Patty please see attached.

Thank you.

Look forward to seeing you tomorrow.

Robert

## **Comments on Rule 64-4.001 – 64-4.009**

### **Relating to the Compassionate Use of Medical Marijuana Dispensary**

To: Patti Nelson, Director, Office of Compassionate Use

From: Robert Tornello, 3 Boys Farms

We would like to provide comments on the following items in the January 27, 2015 version of the Draft Rule

**1. 64-4.0001 ((9) – Dispensing Region – Keep as is**

We believe there has been more than adequate discussion about the 5 Dispensing regions and the counties that are included in each. We strongly recommend that the DOH keep the county profiles in each region as they have been designated in this rule. The county distribution makes sense from a distribution system framework and ensures that there is adequate population base for each dispensary. Changing any at this time would cause a great deal of resistance and potential challenges, which we do not support.

**2. 64-4.0001 ((11) – Dispensing Organization Facility – Allow retail outlets**

In order to provide medical cannabis effectively, affordably and efficiently to patients, we strongly believe that the dispensing organization should be allowed to operate retail dispensing outlets that are located separately from the nursery and grow facility. The prospect of requiring patients to travel to the nursery/grow facility to purchase the medicine, or alternatively, to have the medicine delivered to the patient through a very extensive transportation program seems to place an unusual burden on patients and the dispensary. We would urge a change in the rule language

“one of multiple structures on contiguous properties that are used by the dispensing organization for the preparation, cultivation, storage, and production of the low-THC cannabis and retail outlets that may be separately located from the nursery location for dispensing the medicine”

**3. 64-4.0001 (17) – Owner – Reduce ownership percentage to 5%**

The standard percentage ownership threshold for determining a meaningful financial beneficiary in most other state laws is 5%. Since the current statute does not subdivide or create classes of owners who do not have to disclose their ownership, a better course of action might be to require the disclosure of all the owners of a dispensing organization until such time as the law is clarified in this regard. Until that time the 7% threshold seems arbitrary since in the Legislature has used a 5% threshold in housing and healthcare. The Florida Housing Finance

Corporation uses the 5% figure to determine financial beneficiary as well as ownership threshold requirements in Hospitals and Medical Clinics.

Thank you for your consideration. We appreciate your efforts to finalize the rule and expedite this process.

**Bist, Kevin**

---

**From:** Desiree Mufson <desireemufson@gmail.com>  
**Sent:** Tuesday, February 03, 2015 7:09 PM  
**To:** Nelson, Patricia A  
**Subject:** Lab testing regs in CALIF, CO and Washington  
**Attachments:** Med Marijuana Florida.docx

Hi Patty;  
It was so nice to speak with you earlier today.  
My apologies if I sounded distracted..  
Anyway...I got the information you requested...

See attached for a summarized brief that I created with a simplified overview of the laboratory testing requirements in Colorado, California and Washington.

I hope that it helps.  
I am also including the links to the various state's regulations..

Washington State (recommended by Botek) see [here](#)

California regs see [here](#)

Colorado Regs see [here](#)  
look up 700 series for lab testing although I copied it in my brief.

an additional read is this from the Boulder Journal see [here](#)

let me know if you need any additional info..  
or if you need me to contact anyone from the list of names or agencies that I have given you..it would be my pleasure.

Best,

--  
*Desiree Ardito Mufson*  
*Coastal Cannalabs*  
772-260-8636

Hi Patty;

I researched the information you wanted in development of state lab regs for Medical Marijuana.

The information was obtained from conferences and information through the internet.

I also just spoke directly with Jeannine Machon from CMT laboratories out in Denver who just came from a laboratory conference out in California, so the information she gave me is current as well.

### **Overall:**

Currently, No U.S. state has an accreditation requirement for marijuana testing labs, and there exist no generally accepted standards for such labs. The lab may have their own standards, but they are not industry-sanctioned standards.

### **Proficiency Testing**

Regardless of the design of an accreditation program, Proficiency Testing is a vital component. Proficiency testing is a way to check the performance of a laboratory on a specific sample. It does not check the overall laboratory performance nor does it ensure that all standards of quality assurance are being met. It simply provides a grade of performance on a specific sample. If a laboratory consistently fails the Proficiency Tests, there is an obvious problem with the performance of that laboratory. However, a proficiency test cannot spot all deficiencies of a laboratory.

There are no nationally recognized proficiency testing systems for cannabis testing laboratories. What is done in most locations is voluntary ring testing. A laboratory sends samples to other laboratories and results are compared. This type of testing is all that the labs can do at the present and they arrange and administer these systems on a voluntary basis. An official system of ring testing has the advantages of a "light handed" regulatory approach including cost but gives the state less transparency and control over such things as sample collection and the reporting and qualification of results.

Laboratories are certified by each state and are adopting proficiency testing procedures through interlab dialog. In Colorado, Cannlabs sends a sample to CMT lab and vice versa.

In California, the laboratories formed an Association of Commercial Cannabis Laboratories which offer interlab proficiency (ring style) testing.

## **Accreditation Programs by State**

States are developing meaningful accreditation programs comprised of several elements: a standard to determine acceptable testing procedures, quality assurance and quality control criteria, and standard operating procedure (SOP) requirements. An inspection process is necessary to ensure that the laboratories are in routine compliance with the prescribed criteria. In addition, an acceptable proficiency testing program must be implemented (either within each testing lab or by use of blind sample from an outside source)

There is an upcoming cannabis monograph (Cannabis Inflorescence and Leaf) from the American Herbal Pharmacopoeia which is expected to provide detailed testing recommendations for key cannabis attributes and will standardize the industry.

## **Standard Operating Procedure Manual and General Compliance**

Apparently, there are no guidelines regulating Marijuana testing laboratories with general standardized best practices for laboratories testing Medical Marijuana in any state. The quality control and quality assurance measures were up to the individual laboratory. There appears to be a good faith effort by the laboratories to comply with what they believe to be valid quality assurance measures. They seem to want to embrace any quality assurance guidelines that are developed. Quality assurance concerns begin with a comprehensive standard operating procedure manual (SOP) that describes every aspect of the quality assurance system as well as defining analytical and administrative procedures. At a minimum an SOP should contain sections that address:

- Security of the facility, encompassing:
  - the type of security in place, lock and key or security cards
  - who has access to the facility
  - security cameras or alarm systems in place
- Organizational Chart
- Credentials requirements for the senior scientist and laboratory staff
- Training records for the staff, including competency statements for each procedure
- Administrative procedures for sample acceptance or rejection
- Sampling protocols
  
- Analytical procedures for each test that is performed
- Validation data for each procedure be maintained and available for inspection
- Quality control procedures
- Proficiency testing results, if available.

- Calibration and maintenance data for equipment that is used
- How and to whom results are reported.
- Disposition of excess sample
- Record retention

### **ISO/IEC: (as per State of Washington, August 2013)**

ISO 17025 is an international standard recognized around the world. ISO/IEC 17025:2005 specifies the general requirements for the competence to carry out tests and/or calibrations, including sampling. It covers testing and calibration performed using standard methods, non-standard methods, and laboratory-developed methods. It does not specify methods or techniques.

The standards required by ISO 17025 are for all testing laboratories, irrespective of what is being tested, i.e., they are not cannabis specific. For a method to be accepted, it must meet defined criteria for accuracy and precision. Accreditation by ISO 17025 standards or some other published and recognized standards offers several advantages to the State. Requirements for testing methods, validations, quality assurance and record keeping requirements are published and do not have to be developed. Since these are international standards, their acceptance is essentially universal.

ISO certification requires an inspection by an organization or company that has been recognized to perform the inspection by the international group. As of July 2013, there is only one ISO 17025 certified marijuana testing laboratory in the US at the moment. At least one other laboratory states on its website that it is pursuing ISO 17025. Neither of these laboratories is in the State of Washington.

It should be noted that there will be a considerable financial burden to the laboratories if ISO 17025 is required. It would also take a period of time for the laboratories to meet all the requirements of this accreditation. A period of two years, no more than three years, should be adequate to attain ISO 17025 accreditation. (The author has personal experience with accreditation via ISO 17025 standards.) It is a bit of work to transform a laboratory to meet all the requirements in these standards, but once that is accomplished, all it takes to stay in compliance is diligence on the part of the laboratory and the will to do so, rather than extraordinary expertise or economic cost.

**Colorado:** The Regulation for Laboratory Testing in Colorado was just updated in December 2014 by:

**Colorado Marijuana Enforcement Division** which hails from the **Department of Revenue.**

Colorado medical and retail marijuana laboratories are only allowed to test marijuana from state-licensed marijuana facilities.

Their certification includes a day long inspection and review of lab procedures and credentials of scientists who work there.

**Washington: The laboratory is regulated by the Washington Liquor Control Board Certified –I-502**

**California: Department of Consumer Affairs a Bureau of Medical marijuana Regulation**

## TESTING

In Colorado, the new State Potency and Safety Testing Rules state that plants, tinctures, edibles, oils etc must be tested for the following:

**Potency:** Concentration on all products includes the identification and quantification of 5 compounds:

THC, THCA, CBD, CBDA, CBN and can also identify and quantify Terpenes.

Homogeneity: consistent, even distribution of THC through an edible product.

**Contaminants:** testing for residual solvents such as: Butane, Propane, hexane, acetone and ethanol. The US Pharmacopeia sets the guidelines as to what amount of solvents a person can be exposed to on a daily basis without developing complication due to overexposure.

**Microbial and Yeast:** flowers, edibles, topical, extracts

Identification of presences of:

Salmonella, E. coli, Aspergillus, Shigella

## **Pesticides:** Identification of pesticides

**Heavy Metals:** heavy metals pollutants such as lead, chromium, arsenic, cadmium, mercury and uranium are found in cannabis plants through soil and the environment and are considered dangerous.

## **Definitions:** I thought it would be helpful.

Accreditation- a process whereby a professional organization or nongovernmental agency grants recognition of a demonstrated ability to meet predetermined criteria for established quality and performance standards. Accreditation differs from “license” in that license is not voluntary. A license requirement can include a specific accreditation requirement, as a prerequisite to obtaining a license. In the context of this report, laboratories are accredited and individuals are certified by an appropriate organization.

AHP – the American Herbal Pharmacopoeia, a non-profit organization that formed in 1995. Their mission is to produce the responsible use of herbal products and herbal medicines.

AHPS — the American Herbal Products Association, a non-profit organization founded in 1982. Their mission is to promote the responsible commerce of herbal products.

AOAC International — the Association of Analytical Communities, an international organization committed to being a proactive, worldwide provider and facilitator in the development, use, and harmonization of validated analytical methods and laboratory quality assurance programs and services.

CBGA – Cannabigerol- Acid CBDA – Cannabidiol Acid CBC – Cannabichromene CBD – Cannabidiol

CBG – Cannabigerol

CBN - Cannabinol

Certification—a written assurance by a third party of the conformity of a product, process,

person, or service to specified requirements.

Δ- 8 THC – Delta 8 Tetrahydrocannabinol

$\Delta$ - 9 THC – Delta 9 Tetrahydrocannabinol Department—the Department of Health.

ELISA– Enzyme linked immunosorbent assay. A screening technique that relies upon an antigen/antibody reaction. This test is not a confirmatory test and positive results should be confirmed by a more specific technique.

GC/MS – Gas Chromatography/Mass Spectrometry, a laboratory method that uses sophisticated instrumentation to identify and quantitatively measure compounds. In the Marijuana Testing industry this method can be applied to potency testing, residual solvent testing, and pesticide testing.

HPLC/DAD– High Performance Liquid Chromatography/Diode Array Detector (used by some laboratories to quantitatively measure the concentrations of Cannabinoid Compounds in Marijuana and Marijuana Edibles)

GLP – Good Laboratory Practices. GLP, a quality system concerned with the organizational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported.

LC/MS/MS – Liquid chromatography/mass spectrometry/mass spectrometry or tandem

LC/MS, a very sophisticated technique that uses liquid chromatography coupled with two mass filters. It is capable of very good sensitivity and signal to noise. It is applicable to measuring a small concentration of analyte in a complex matrix.

ISO — the International Organization for Standardization; it is the world's largest developer of voluntary International Standards

ISO 17025 – 17025— the unique number assigned by ISO for standards specific for a Management System for Testing and Calibration Laboratories

ISO 9000 – 9000 —the unique number assigned by ISO for standards specific to Quality Management Systems

License — a non-voluntary process by which an agency of government regulates the activities of an institution, profession or individual

Marijuana or "marihuana" — all parts of the plant Cannabis, whether growing or not, with a THC concentration greater than 0.3 percent on a dry weight basis; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin. The term does not include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt, derivative, mixture, or preparation of the mature stalks (except

the resin extracted there from), fiber, oil, or cake, or the sterilized seed of the plant which is incapable of germination.

PCR - polymerase chain reaction, laboratory method that amplifies DNA to generate millions of “copies” of the original DNA sequence. One of the applications of this method is the identification of Fungus, or Bacteria by their unique DNA

Potency Testing - the analytical testing of Marijuana to measure compounds that are considered psychotropic

Proficiency Testing - the Quality Assurance component of laboratory testing that involves the laboratory testing of a Reference or Standard material, intended to represent the materials that the laboratory will routinely be testing and resulting to their clients. The accurate assessment of the material by the laboratory assures independent assessment of the proficiency of the laboratory to delivery accurate results to their clients

Quality - the totality of characteristics of an entity that bare on its ability to satisfy stated and implied needs.

Quality Assurance - all the planned and systematic activities implemented within the quality system and demonstrated as needed, to provide adequate confidence that an entity will full fill requirements for quality

Quality System - organizational structure, procedures, processes, and resources needed to implement quality management

Quality Management - means all activities of the overall management function that determine the quality policy, objectives and responsibilities, and implement them by means such as quality planning, quality control, quality assurance, and quality improvement within a quality system.

Quality Control - operational techniques and activities that are used to fulfill requirements for quality. The terms internal “quality control” and “external quality control” are commonly used. The former refers to activities conducted within a laboratory to monitor performance and the later refers to activities leading to comparison with other reference laboratories or consensus results amongst several laboratories.

THC – Tetrahydrocannabinol

THCA – Tetrahydrocannabinol Acid THCV - Tetrahydrocannabivarin

THC concentration in product - percent of delta-9 tetrahydrocannabinol content per dry weight of any part of the plant *Cannabis*, or per volume or weight of marijuana product.

Traceability - that all steps in a procedure can be checked by reference to documented results, calibrations, standards or calculations.

Useable marijuana - dried marijuana flowers. The term "useable marijuana" does not include marijuana-infused products.

#### Misc NOTES:

The standards being used are from: Resteck, Caman and Sigma..but there is great discrepancy on the standards from laboratory to laboratory.

Emerald Scientific hosted a laboratory conference just last month in Calif to update labs on current standards in each state. I have just signed up for future conferences so that I can be current on all regs.

## **Colorado Updated Regulations for Testing Laboratories**

### **(copied from their regulations)**

#### **R 700 Series – Retail Marijuana Testing Facilities**

##### **Basis and Purpose – R 712**

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b), 12-43.4-202(3)(a)(IV), 12-43.4-202(3)(a)(VII), 12-43.4-202(3)(a)(X), 12-43.4-202(3)(a)(XI), 12-43.4-202(3)(b)(III), 12-43.4-202(3)(b)(IX), 12-43.4-202(3)(c)(V), 12-43.4-202(3)(c)(VI), 12-43.4-202(3)(c)(VII), and 12-43.4-405, C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VII). The purpose of this rule is to establish the portion of the Division's Mandatory Testing and Random Sampling program that is applicable to Retail Marijuana Testing Facilities.

##### **R 712 – Retail Marijuana Testing Facility: Mandatory Sampling and Testing Program**

1. Division Authority. The Division may elect to require that a Test Batch be submitted to a specific Retail Marijuana Testing Facility for testing to verify compliance, perform investigations, compile data or address a public health and safety concern.
2. Test Batches
  1. Retail Marijuana and Retail Marijuana Concentrate. A Retail Marijuana Testing Facility must establish a standard minimum weight of Retail Marijuana and Retail Marijuana Concentrate that must be included in a Test Batch for every type of test that it conducts.

2. Retail Marijuana Product. A Retail Marijuana Testing Facility must establish a standard number of finished product(s) it requires to be included in each Test Batch of Retail Marijuana Product for every type of test that it conducts.
3. Rejection of Test Batches and Samples
  1. A Retail Marijuana Testing Facility may not accept a Test Batch that is smaller than its standard minimum amount.
  2. Beginning on July 1, 2014, a Retail Marijuana Testing Facility may not accept a Test Batch or Sample that it knows was not taken in accordance these rules or any additional Division sampling procedures or was not collected by Division personnel or a Division Approved Sampler.
4. Notification of Retail Marijuana Establishment. If Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product failed a contaminant test, then the Retail Marijuana Testing Facility must immediately notify the Retail Marijuana Establishment that submitted the sample for testing and report the failure in accordance with all Inventory Tracking System procedures.
5. Permissible Levels of Contaminants. If Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product is found to have a contaminant in levels exceeding those established as permissible under this rule, then it shall be considered to have failed contaminant testing. Notwithstanding the permissible levels established in this rule, the

26

Division reserves the right to determine, upon good cause and reasonable grounds, that a particular Test Batch presents a risk to the public health or safety and therefore shall be considered to have failed a contaminant test.

1. Microbials (Bacteria, Fungus)

\*Testing facilities should contact the Colorado Department of Public Health and Environment when STEC and Salmonella are detected beyond the acceptable limits.

2. Residual Solvents and Metals

Substance	Acceptable Limits Per Gram	Product to be Tested
-Shiga-toxin producing Escherichia coli (STEC)*- Bacteria	< 1 Colony Forming Unit (CFU)	Flower; Retail Marijuana Products; Water- and Food-Based Concentrates
Salmonella species* – Bacteria	< 1 Colony Forming Unit (CFU)	
Aspergillus fumigatus, Aspergillus flavus, Aspergillus niger - Fungus	< 1 Colony Forming Unit (CFU)	
Substance	Acceptable Limits Per Gram	Product to be Tested
Butanes	< 800 Parts Per Million (PPM)	Solvent-Based Concentrates
Heptanes	< 500 Parts Per Million (PPM)	
Benzene**	< 1 Parts Per Million (PPM)	
Toluene**	< 1 Parts Per Million (PPM)	
Hexane**	< 10 Parts Per Million	

	(PPM)	
Total Xylenes (m,p, o-xylenes)**	< 1 Parts Per Million (PPM)	
Any solvent not permitted for use pursuant to Rule R 605.	None Detected	

\*\* Note: These solvents are not approved for use. Due to their possible presence in the solvents approved for use per Rule R 605, limits have been listed here accordingly.

3. Metals
4. Other Contaminants

Substance	Acceptable Limits Per Gram	Product to be Tested
Metals (Arsenic, Cadmium, Lead and Mercury)	Lead – Max Limit: < 10 ppm Arsenic – Max Limit: < 10 ppm Cadmium – Max Limit: < 4.1 ppm Mercury – Max Limit: < 2.0 ppm	Flower; Water-, Food-, and Solvent-Based Concentrates; and Retail Marijuana Products
Pesticide	If testing identifies the use of a banned Pesticide or the improper application of a permitted Pesticide, then that Test Batch shall be considered to have failed contaminant testing.	
Chemicals	If Test Batch is found to contain levels of any chemical that could be toxic if consumed, then the Division may determine that the Test Batch has failed contaminant testing.	
Microbials	If Test Batch is found to contain levels of any microbial that could be toxic if consumed, then the Division may determine that the Test Batch has failed contaminant testing.	
Molds, Mildew, and Filth	If a Test Batch is found to contain levels of any mold, mildew, or filth that could be toxic if consumed, then that Test Batch shall be considered to have failed contaminant testing.	

4. Division Notification. A Retail Marijuana Testing Facility must notify the Division if a Test Batch is found to contain levels of a contaminant not listed within this rule that could be injurious to human health if consumed.

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#### F. Potency Testing

1. Cannabinoids Potency Profiles. A Retail Marijuana Testing Facility may test and report results for any cannabinoid provided the test is conducted in accordance with the Division's Retail Marijuana Testing Facility Certification Policy Statement.
2. Reporting of Results
  1. For potency tests on Retail Marijuana and Retail Marijuana Concentrate, results must be reported by listing a single percentage concentration for each cannabinoid that represents an average of all samples within the Test Batch.
  2. For potency tests conducted on Retail Marijuana Product, whether conducted on each individual production batch or via Process Validation per rule R 1503, results must be reported by listing the total number of milligrams contained within a single Retail Marijuana Product unit for sale for each cannabinoid and affirming the THC content is homogenous.
3. Dried Flower. All potency tests conducted on Retail Marijuana must occur on dried and cured Retail Marijuana that is ready for sale.

4. Failed Potency Tests for Retail Marijuana Products

1. If an individually packaged Edible Retail Marijuana Product contained within a Test Batch is determined to have more than 100 mgs of THC within it, then the Test Batch shall be considered to have failed potency testing.
2. If the THC content of a Marijuana Product is determined through testing to not be homogenous, then it shall be considered to have failed potency testing. A Retail Marijuana Product shall be considered to not be homogenous if 10% of the infused portion of the Retail Marijuana Product contains more than 20% of the total THC contained within entire Retail Marijuana Product.

**Bist, Kevin**

---

**From:** Mary Thomas <MThomas@flmedical.org>  
**Sent:** Tuesday, February 03, 2015 8:29 PM  
**To:** Nelson, Patricia A  
**Cc:** hmiller@flmedical.org; Jeff Scott; Nobo MD, Ralph; Pillersdorf MD, Alan B.; jasonpirozzolo@yahoo.com  
**Subject:** FMA Proposed Revisions R. 64-4.002

Dear Patricia Nelson,

On behalf of the Florida Medical Association, I write to submit our proposed revision to Rule 64-4.002(2)(h)5, Initial Application Requirements for Dispensing Organizations, for review at the Negotiated Rulemaking Committee Session on February 4 and 5, 2015. I sincerely apologize for this late notice and greatly appreciate your help.

\*Changes are underlined

#### **64-4.002 Initial Application Requirements for Dispensing Organizations**

(h) The employment of a medical director who is a physician licensed pursuant to chapter 458 or chapter 459, F.S., to supervise the activities of the proposed dispensing organization. Please address the following items for the physician chosen as medical director:

1. Specialty area, if any;
2. Experience with epileptic patients;
3. Experience with cancer patients;
4. Experience with patients with severe seizures or muscle spasms;
5. Experience recommending THC/CBD products to patients;
6. Knowledge of the use of low-THC cannabis for treatment of cancer or physical medical conditions that chronically produce symptoms of seizures or severe and persistent muscle spasms;
7. Knowledge of good manufacturing practices;
8. Knowledge of analytical and organic chemistry;
9. Knowledge of analytical laboratory methods;
10. Knowledge of analytical laboratory quality control, including maintaining a chain of custody;

11. Knowledge of and experience with CBD/low-THC extraction techniques;

12. Knowledge of CBD/low-THC routes of administration;

13. Experience in or knowledge of clinical trials or observational studies;

18. Knowledge of and experience with producing CBD/low-THC products;

Please do not hesitate to contact me if you have any further questions.

Thank you,

Mary Thomas  
Assistant General Counsel  
Florida Medical Association

**Bist, Kevin**

---

**From:** Scott Habraken - Florida Medical Growers <scotth@fmgrowers.com>  
**Sent:** Wednesday, February 04, 2015 8:51 AM  
**To:** Nelson, Patricia A  
**Subject:** Compasionate Medical Cannabis Meeting

Ms. Nelson,

My name is Scott Habraken representing Florida Medical Growers in the Central Florida Region. I would like to ask how I could obtain an electronic version of the Binder you just referred to with comments and observations that you have received since the December meeting.

Thank you for your assistance in this and I look forward to working with you as we move forward in this process.

Scott Habraken

No virus found in this message.

Checked by AVG - [www.avg.com](http://www.avg.com)

Version: 2015.0.5646 / Virus Database: 4281/9056 - Release Date: 02/04/15

## **Bist, Kevin**

---

**From:** Joe Sansonetti <jsansonetti@earthlink.net>  
**Sent:** Wednesday, February 04, 2015 9:33 AM  
**To:** Nelson, Patricia A  
**Cc:** 'Joe Sansonetti'  
**Subject:** Negotiated Rule  
**Attachments:** DOH Rule committee feedback.docx

Negotiated Rule February 4, 2015

Patricia Nelson  
Director  
Compassionate Use Registry  
Department of Health  
4052 Bald Cypress Way, Bin A-02  
Tallahassee, FL 32399

Director Nelson:

Below are two suggestions for consideration by the negotiated rule committee.

### **DISTRIBUTION OF DERIVATIVE PRODUCT:**

Florida law requires in s. 381.986 (5) (b) 4, F.S., that a dispensing organization be able to demonstrate "an infrastructure reasonably located to dispense low-THC cannabis to registered patients statewide or regionally as determined by the department".

The latest version of the proposed rule as noticed January 30, 2015, removes the definition of "transportation plan" which would have enabled a dispensing organization to transport an ordered derivative product to a qualified patient in his home.

We suggest that in the alternative to a transportation plan to distribute ordered medicine, additional dispensing locations be permitted and regulated to accommodate patient population. Each location must be considered part of the authorized dispensing organization and subject to all the laws, rules, and regulations of the authorized dispensing organization.

Negotiated Rule February 4, 2015

### **INVENTORY CONTROL:**

Florida law requires accountability of raw material from seed through to distribution of the derivative product to the qualified patient.

Unless the dispensing organization is required to report all inventory activity to the Department of Health, there is no guarantee that illegal possession or diversion will be prevented. Diversion is not a one-way event. Diversion of plants or raw materials can go out the door without strict accountability and reporting...that is an obvious problem that must be addressed. What is less obvious, perhaps, is the problem of "inbound" raw material.

Unless each dispensing organization is required to report all inventory control information to the Department each day, there is no way to determine the raw material located at a Dispensing Organization is within the parameters of Florida law. Each Dispensing Organization should be required to generate a tracking manifest and report the results to Medical Quality Assurance.

The Department of Health has a strong reputation for protecting the public through the compliance requirements of the MQA. The Legislature has entrusted the Department to sufficiently regulate this form of medicine through the rulemaking process.

We suggest required reporting of all inventory control information to the Department of Health, Medical Quality Assurance.

Thank you in advance for your consideration.

Respectfully,

Joseph Sansonetti

Joseph Sansonetti

[jsansonetti@earthlink.net](mailto:jsansonetti@earthlink.net)

Cell: 678-576-0479

February 4, 2015

Negotiated Rule

Patricia Nelson

Director  
Compassionate Use Registry  
Department of Health  
4052 Bald Cypress Way, Bin A-02  
Tallahassee, FL 32399

Director Nelson:

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February 4, 2015

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Thank you in advance for your consideration.

Respectfully,

*Joseph Sansonetti*

Joseph Sansonetti  
jsansonetti@earthlink.net  
Cell: 678-576-0479

February 4, 2015

**Bist, Kevin**

---

**From:** kherndon@kerrys.com  
**Sent:** Wednesday, February 04, 2015 12:52 PM  
**To:** Nelson, Patricia A  
**Subject:** Mets on first day of rules

USDA good agricultural practices and good handling processes are independent audit based standards and processes for maximizing product safety for end consumers. Nurseries that have that certification operate at a high level of safety. Organic by federal law is defined as USDA certified organic. If a grower has USDA organic certification it is proof that they currently produce crops that conform to strict standards that are independently audited.

Sent from my iPhone

## Bist, Kevin

---

**From:** Domingo Moya <diamoyand@gmail.com>  
**Sent:** Wednesday, February 04, 2015 4:23 PM  
**To:** Nelson, Patricia A  
**Subject:** Fwd: Criminal History Record Check ORI Number

This was the ORI# that the dept gave interested parties.

Domingo Moya

Sent from my iPhone

Begin forwarded message:

**From:** "McMullen, Linda N" <Linda.McMullen@flhealth.gov>  
**Date:** September 15, 2014 at 9:42:14 AM EDT  
**To:** DL 64-4 Interested Parties <DL64-4InterestedParties@flhealth.gov>  
**Cc:** "Bist, Kevin" <Kevin.Bist@flhealth.gov>, "Sachs, Taylor" <Taylor.Sachs@flhealth.gov>  
**Subject:** Criminal History Record Check ORI Number

Dear Compassionate Use Interested Party,

The Office of Compassionate Use (OCU) has been assigned an ORI number. The number, **FL924890Z (DOH – OFFICE OF COMPASSIONATE USE)**, has been entered into the Florida Department of Law Enforcement (FDLE) production system and is ready for use.

Those needing a Level 2 criminal history record check for purposes of submitting an application for approval as a dispensing organization pursuant to the Compassionate Medical Cannabis Act of 2014 should present this number to the FDLE or one of its approved vendors for fingerprinting. Payment for the background check will be made directly to FDLE or the approved vendor. (Please note that if a person chooses to make electronic submissions via a Livescan service provider, the service provider may assess a fee in addition to the record check fee.) Results of the criminal history check will be provided to the OCU and not to the person being checked. The OCU will notify any person who does not successfully pass the criminal history record check.

For more information and answers to Frequently Asked Questions regarding criminal history background checks, please visit the FDLE website at <http://www.fdle.state.fl.us/Content/getdoc/1acc7c3e-dac7-45d4-8739-0d221749d8ce/FAQ.aspx>

A list of Livescan service providers can be found at <http://www.fdle.state.fl.us/content/criminal-history/livescan-service-providers-and-device-vendors.aspx>

Best regards,

Linda McMullen, Director  
Office of Compassionate Use  
Florida Department of Health  
4052 Bald Cypress Way, Bin #A-06  
Tallahassee, Florida 32399-1708  
850-245-4657  
850-245-4662 (Fax)

Please note: Florida has a very broad public records law. Most written communications to or from state officials regarding state business are public records available to the public and media upon request. Your

e-mail communications may therefore be subject to public disclosure. If this e-mail concerns anticipated or current litigation or adversarial administrative proceeding to which the Florida Department of Health is a party, this email is an attorney-client communication, and is, therefore, a limited access public document exempt from the provisions of Chapter 119, Florida Statutes. See Section 119.071(d)1, Florida Statutes (2010).

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I nnovation: We search for creative solutions and manage resources wisely.

C ollaboration: We use teamwork to achieve common goals & solve problems.

A ccountability: We perform with integrity & respect.

R esponsiveness: We achieve our mission by serving our customers & engaging our partners.

E xcellence: We promote quality outcomes through learning and continuous performance improvement.

**Bist, Kevin**

---

**From:** Desiree Mufson <desireemufson@gmail.com>  
**Sent:** Wednesday, February 04, 2015 4:50 PM  
**To:** Nelson, Patricia A  
**Subject:** Lab info

hi Patty,  
I hope your meeting went well.  
Just checking to see if you received my information.  
Best,  
Desiree

--  
*Desiree Ardito Mufson*  
*New Vision Productions, Inc.*  
Stuart, Fl  
772-219-0140

**Bist, Kevin**

---

**From:** Buford, Rivers <BufordR@ficpa.org>  
**Sent:** Wednesday, February 04, 2015 5:27 PM  
**To:** Nelson, Patricia A  
**Subject:** CPA language

Can you call me please. My direct number is 521-5954

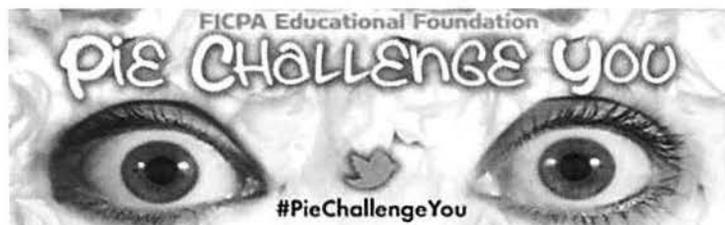
Thank you

Rivers Buford

**Rivers H. Buford III, DPL | Director of Governmental Affairs**  
**Florida Institute of CPAs | 325 W. College Ave. | Tallahassee, FL 32301**  
800.342.3197, | 850.224.2727, x203 | Fax : 850.222.8190 | [www.ficpa.org](http://www.ficpa.org)  
Cell 850-528-8815 (text enabled)



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**Bist, Kevin**

---

**From:** Nelson, Patricia A  
**Sent:** Wednesday, February 04, 2015 7:36 PM  
**To:** desireemufson@gmail.com  
**Subject:** Re: Lab info

I got it!

On Feb 4, 2015, at 4:50 PM, Desiree Mufson <[desireemufson@gmail.com](mailto:desireemufson@gmail.com)> wrote:

hi Patty,  
I hope your meeting went well.  
Just checking to see if you received my information.  
Best,  
Desiree

--

*Desiree Ardito Mufson*  
*New Vision Productions, Inc.*  
Stuart, FL  
772-219-0140

**Bist, Kevin**

---

**From:** anthonyardizzone <anthonyardizzone@comcast.net>  
**Sent:** Wednesday, February 04, 2015 10:45 PM  
**To:** Nelson, Patricia A  
**Subject:** Notes from meeting

Patty,

64-4.001 #10. Dispensing organization

Must remain the nursery it can not be moved to something else or it can't meet the requirements of sb1030

Not worried about banking and personally know 10 others that feel the same

219 (6) DISPENSING ORGANIZATION.—An approved dispensing  
220 organization shall maintain compliance with the criteria  
221 demonstrated for selection and approval as a dispensing  
222 organization under subsection (5) at all times.

64-4.001 #17 Owner

The percentage of an owner should go as low as 1% organizations can hide with anything less  
example 5 family members own only 4% each but together they would own 20% 10 organization  
members could own 4% each but together they would control 40% and would be unchecked major  
stakeholders

If a company were to go public you would have to be a major shareholder to have a controlling  
interest and would than need to be reported you do not own any part of the company just owning  
a small amount of shares

EXPERIENCE

I think experience being asked for alone on a lot of items leaves room for. challenges just  
list it as you did in a lot of others  
knowledge and experience on all and give the extra points for the attached. experience we list  
no one will be able to say they had knowledge but you just wanted. experiance

Dispensing Regions Dispensaries

I don't know what the plan is but I have a thought each regional dispensing organization may have  
up to 5 in their own region but only 1 in other regions I am sure the north east north west and  
south west will look to set up in the most populated regions their cost will be less and be more  
profitable but the most populated regions have nothing to gain in the less populated ones their  
costs will be more just because of location Or just allow dispensing regionally only. I  
hope you get my point  
You all did a great job tonight  
Should of did this 7 months ago

Sorry for the type couldn't figure how to get it off to tired

Thank you  
Anthony Ardizzone  
Ed Miller & SON  
772-201-3065

Sent from my Verizon Wireless 4G LTE Tablet

## Bist, Kevin

---

**From:** Nelson, Patricia A  
**Sent:** Thursday, February 05, 2015 9:55 PM  
**To:** diamoyand@gmail.com  
**Subject:** RE: Criminal History Record Check ORI Number

Thank you!

---

**From:** Domingo Moya [mailto:diamoyand@gmail.com]  
**Sent:** Wednesday, February 04, 2015 4:23 PM  
**To:** Nelson, Patricia A  
**Subject:** Fwd: Criminal History Record Check ORI Number

This was the ORI# that the dept gave interested parties.

Domingo Moya

Sent from my iPhone

Begin forwarded message:

**From:** "McMullen, Linda N" <Linda.McMullen@flhealth.gov>  
**Date:** September 15, 2014 at 9:42:14 AM EDT  
**To:** DL 64-4 Interested Parties <DL64-4InterestedParties@flhealth.gov>  
**Cc:** "Bist, Kevin" <Kevin.Bist@flhealth.gov>, "Sachs, Taylor" <Taylor.Sachs@flhealth.gov>  
**Subject:** Criminal History Record Check ORI Number

Dear Compassionate Use Interested Party,

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For more information and answers to Frequently Asked Questions regarding criminal history background checks, please visit the FDLE website at <http://www.fdle.state.fl.us/Content/getdoc/1acc7c3e-dac7-45d4-8739-0d221749d8ce/FAQ.aspx>

A list of Livescan service providers can be found at <http://www.fdle.state.fl.us/content/criminal-history/livescan-service-providers-and-device-vendors.aspx>

Best regards,

Linda McMullen, Director  
Office of Compassionate Use  
Florida Department of Health  
4052 Bald Cypress Way, Bin #A-06  
Tallahassee, Florida 32399-1708  
850-245-4657  
850-245-4662 (Fax)

Please note: Florida has a very broad public records law. Most written communications to or from state officials regarding state business are public records available to the public and media upon request. Your e-mail communications may therefore be subject to public disclosure. If this e-mail concerns anticipated or current litigation or adversarial administrative proceeding to which the Florida Department of Health is a party, this email is an attorney-client communication, and is, therefore, a limited access public document exempt from the provisions of Chapter 119, Florida Statutes. See Section 119.071(d)1, Florida Statutes (2010).

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C ollaboration: We use teamwork to achieve common goals & solve problems.

A ccountability: We perform with integrity & respect.

R esponsiveness: We achieve our mission by serving our customers & engaging our partners.

E xcellence: We promote quality outcomes through learning and continuous performance improvement.

## Bist, Kevin

---

**From:** Domingo Moya <diamoyand@gmail.com>  
**Sent:** Thursday, February 05, 2015 10:05 PM  
**To:** Nelson, Patricia A  
**Subject:** Re: Criminal History Record Check ORI Number

You are welcome. I had to pop in and out today. Did you give an anticipated timeline for publishing and challenges and ratification if required?

Thanks

Domingo Moya

Ps good job

Sent from my iPhone

On Feb 5, 2015, at 9:55 PM, Nelson, Patricia A <[Patricia.Nelson@flhealth.gov](mailto:Patricia.Nelson@flhealth.gov)> wrote:

Thank you!

---

**From:** Domingo Moya [<mailto:diamoyand@gmail.com>]  
**Sent:** Wednesday, February 04, 2015 4:23 PM  
**To:** Nelson, Patricia A  
**Subject:** Fwd: Criminal History Record Check ORI Number  
This was the ORI# that the dept gave interested parties.  
Domingo Moya

Sent from my iPhone

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**From:** "McMullen, Linda N" <[Linda.McMullen@flhealth.gov](mailto:Linda.McMullen@flhealth.gov)>  
**Date:** September 15, 2014 at 9:42:14 AM EDT  
**To:** DL 64-4 Interested Parties <[DL64-4InterestedParties@flhealth.gov](mailto:DL64-4InterestedParties@flhealth.gov)>  
**Cc:** "Bist, Kevin" <[Kevin.Bist@flhealth.gov](mailto:Kevin.Bist@flhealth.gov)>, "Sachs, Taylor" <[Taylor.Sachs@flhealth.gov](mailto:Taylor.Sachs@flhealth.gov)>  
**Subject:** Criminal History Record Check ORI Number

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Best regards,

Linda McMullen, Director  
Office of Compassionate Use  
Florida Department of Health  
4052 Bald Cypress Way, Bin #A-06  
Tallahassee, Florida 32399-1708  
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850-245-4662 (Fax)

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Accountability: We perform with integrity & respect.

Responsiveness: We achieve our mission by serving our customers & engaging our partners.

Excellence: We promote quality outcomes through learning and continuous performance improvement.

**Bist, Kevin**

---

**From:** anthonyardizzone <anthonyardizzone@comcast.net>  
**Sent:** Thursday, February 05, 2015 10:47 PM  
**To:** Nelson, Patricia A

Patty,

Just a thought while I was driving home, I believe dispensing organizations were given state wide dispensaries. I don't know if FDOH has the authority to add to the new rule, thinking something like. A dispensing organization must provide infrastructure that ensures reasonable accessibility regionally to dispense low THC cannabis derivative product to registered patients in their region of licensure, before it places a dispensary in any other regions

I hope you understand what I am getting at

And again great job it nice to see a professional at work, and that you did!

Anthony Ardizzone

Ed Miller & Son  
772- 201- 3065

Sent from my Verizon Wireless 4G LTE Tablet

**Bist, Kevin**

---

**From:** Jeffrey Sharkey <jeffreysark@gmail.com>  
**Sent:** Friday, February 06, 2015 11:47 AM  
**To:** Nelson, Patricia A  
**Subject:** sharkey

Patti

I know you are super exhausted. Very thorough and productive rule meetings.

I have a few comments which I will send in writing, but one that you might want to explore is the scoring tie issue. Florida Housing deals with this all the time and because of the subjectivity of scoring, they have several tie breakers that are clearly defined that provide a quantitative decision which will eliminate some of the challenge options.

I would urge you to talk with Steve Auger or Wellington to discuss to give yourself some cover.

Rescoring or having reviewers review tied applications opens you up to the perception of politics.

Just trying to be helpful

Jeff

**Dr. Jeffrey Sharkey**  
**Managing Partner**  
**Capitol Alliance Group, Inc**  
**106 E. College Avenue, Suite 640**  
**Tallahassee, FL 32301**  
**850.224.1660 office**  
**850.224.6785 fax**  
**850.443.3355 cell**  
**[jeffreysark@gmail.com](mailto:jeffreysark@gmail.com)**

**[www.capitolalliancegroup.com](http://www.capitolalliancegroup.com)**

## **Bist, Kevin**

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**From:** Gary Abrahams <garyabrahams@comcast.net>  
**Sent:** Friday, February 06, 2015 6:02 PM  
**To:** Nelson, Patricia A  
**Subject:** Compassionate Care rules and regulations discussed during two day meeting Feb 4&5, 2015

Dear Ms. Nelson,

I attended the past 2 day meeting, as well as previous sessions. I have generally sat quietly just to absorb knowledge that would help us put together the best presentation in the application process. I currently work with a smaller nursery in the central district.

I applaud the effort the department has put into this process, and how you have quickly pushed this process forward. There has been a great deal of progress over the past two days, but in some areas where this committee lacked expertise important technical decisions were made that gave me great concern. Although these comments are late to be heard in the process, many did not come to light until the past two days and no one in the audience was given a chance to speak to the committee. I understand that the committee was under a time constraint but I believe that not taking any feedback from the audience did a disservice to the people and the process. There was a great deal of knowledge and expertise in the audience.

I was concerned that after seeing the committee that it appears that the Department selected the "biggest" growers in each district. It would be naive to think that these nurseries would be the "best" candidates to move forward with. or that they would not form the rules to favor themselves. It gave an unfair advantage to the large nurseries to be able to vote on rules or definitions that would best serve themselves. I was disappointed that the Department did not select a cross section of growers that would qualify under the statute, so that a fair playing field was represented. Backgrounds and expertise of "non-growers" at times had members speaking on topics that they were under qualified to speak to. For example a lab expert discussing financial statements, or bonding.

There will be much to judge in selecting best applicants, most important have been highlighted in the scorecard. Financing by the inclusion of investors and the expertise they bring to a venture could well have the smallest of nurseries having the most to offer. We all have the ability to purchase and use current technology, but who might bring to the table the ability to move this forward and move Florida to the forefront on the application of cannabis medicine? The groups with the best researchers and pharmaceutical backgrounds. There is much to consider.

In our case and many of the nurseries, the banking issue, is a non-issue, as we will replace the bank credit the nursery currently uses, with personal funds. This might be a problem for other nurseries with large loans from traditional banks, but rules cannot bend the intentions of the statute, which was to give all qualifying nurseries a fair chance to obtain a license if they could provide the patients with the best medicine and, a promise of financial stability which, in turn, assures access.

I think the Department and most of the committee missed the legislative intent in the financial statement requirement and the words of the ALJ. The only statement that a nursery without a prior audit can be attested to as true is the actual present financial ability. While we will take whatever actions that are necessary to meet the criteria, I believe that this requirement is improper. As a CPA with past experience with Big Eight accounting firms I will inform you that the purpose of a successful "audit" is to get an unqualified opinion. This states the financials represent a fair and accurate presentation of financial information conforming to "Generally Accepted

Accounting Principles". Those that have not had audited statements in the past, almost everyone, will only be able to obtain a qualified opinion on a twelve month statement as beginning balances on inventory cannot be verified in addition to other short comings. These applicants could get a clean audited opinion on a current statement of position (balance sheet). This is all the department should be concerned with as it represents the current position upon which future pro-formas will be constructed. At every single meeting Costa farms has been demanding, begging and pleading for this past auditing requirement. This is because they already had to have one to support their large bank loans. It is not something the others have and it weighted the process in their favor. What is important to the patients is that the dispensary organization have the verified resources to meet the commitments of their business plans. This is the audited and or attested financials that most nurseries that have not had audits in the past year will be able to present, and therefore they should not be penalized by a biased scoring system

The "performance bond" has been changed into a penalty bond for a licensed being revoked. This is onerous, and cannot be rated for risk by the insurance company.

There are many items that a license could be revoked for if a waiver was not obtained or leniency provided by the Department. An insurance company could not rely upon future positions the department may take in an appeals process in assessing risk. For example, a disgruntled employee sabotaging a water filter system, or destroying a crop, could cause non delivery or product not meeting standards etc. An employee doing something outside the guidelines when making delivery, which would have the firm dismiss the employee, but could allow the Department to revoke the license triggering the bond. Although it seems that the department would take those actions into account, the fact that the department or the general revenue fund will receive a windfall of \$5,000,000.00 can cause the bonding company to rate the cost of the bond to a prohibitive number. The bond should be revised as a performance bond that would decrease as the work was completed. I do not believe the legislative intent was to give the bonding companies and the state of Florida a windfall and increase the cost of the medicine. I believe it was to assure performance. The state's budget for the two years is approximately \$900,000.00, one fifth of that is attributable to the applicant. The cost of getting a replacement applicant would be less as the infrastructure in the department will already be in place and paid for. Therefore this \$5,000,000.00 cannot be for the purpose of protecting the state. If it is a performance bond, set it up as one. If you are worried about the renewal bond It also will be a \$5,000,000.00 performance bond with the condition that all new work has to be bonded and lowered as work is being done or if no work is being done that the \$5,000,000.00 bond will be immediately stepped down upon notification from your office of performance or lesser need requirements.

Can you imagine if a medical director knew a bond of \$5,000,000 was at risk, and if he was unhappy with his arrangement, he could blackmail by threatening to leave and shut down the business, calling for the state to cause the bond to be called. Even with a backup director, this is a very disturbing condition. One that doing prudent business would not be acceptable.

The high bar that the state wants to set is realized when the applicant spends the large sums necessary to set up this operation. The financial risk of losing the investment, which is a real possibility and which is dependent upon political whims make this a very precarious investment. Therefore the five million dollar penalty bond is not only unreasonable, it raises the cost of the medicine to such a degree that the business may be completely unsustainable. Qualified nursery men that are good businessmen know that they cannot risk everything on the dubious conditions , some out of their control, as presently set forth in this penalty bond.

I do look forward to being able to provide a quality and quantity of medicine at a reasonable price that the compassionate care act envisions. Please review the regulations and revise them in such a manner as to allow the best and the most capable to apply for the licenses. We believe that it is morally reprehensible for these patients to have to continue to suffer and look forward to working with you in bringing this endeavor to fruition.

The language I suggest for the bond is:

1. The Applicant must provide a \$5,000,000.00 performance bond within 10 business days of being notified that he has been chosen as the dispensing organization for his district. The conditions of this bond are:

\$2,000,000.00 shall be released upon completion of the Grow Facility. If the business plan has more than 1 grow facility the release shall be pro rata based upon the number of facilities to be built.

\$1,000,000.00 shall be released upon the completion of the laboratory facilities. If the business plan has more than 1 laboratory the release shall be pro rata based upon the number of facilities to be built.

\$1,000,000.00 shall be released upon the completion of the dispensing facilities. If the business plan has more than 1 dispensary the release shall be pro rata based upon the number of facilities to be built.

\$250,000.00 shall be released upon completion of the delivery plan as specified in business plan.

\$750,000 shall remain in the bond to secure business performance. The conditions of this part of the bond cover:

- a. If a dispensary operation closes up to \$125,000.00 will be for the disposal and or destruction of any crop, product or hazardous materials.
- b. If any, officer or director or manager is found to knowingly have sold, gifted or transferred any Low THC product to anyone who does not have the proper documentation as required by the state of Florida must be fired upon and removed from any interest in the company when the company receives knowledge of such action. Failure to fire and remove the persons interest and to ban the person from the premise shall result in a partial bond forfeiture in the amount of \$250,000.00.
- c. Failure to sell any product prior to that product being batch tested shall result in a bond forfeiture in the amount of \$250,000.00.
- d. If any employee who has passed the required CBI background check is convicted of any felony, other than the federal crime of working at a state authorized dispensary operation and carrying out the normal operations of such job, he shall be terminated upon the dispensary organization learning of such conviction. Failure to terminate shall result in bond forfeiture in the amount of \$125,000.00

Last item I would like to comment on is the application fee. It should cover the costs of the Department to issue and review applications and the issue of initial licenses. Any unused funds should not be used to pay for expenses of those getting licenses into the future. I do believe you have the authority to use funds raised by those not receiving licenses to the future benefit of those who receive licenses. I think more should be done to investigate how the Department would raise revenue from those receiving licenses to cover future expenses if required by statute and not in the Department's budget.

Please feel free to contact me with any questions or if you believe I may be of assistance in any way.

Thank you for your consideration,

Gary Abrahams

Phone 301-674-4441

**Bist, Kevin**

---

**From:** zzzz Feedback, Health  
**Sent:** Monday, February 09, 2015 9:10 AM  
**To:** randsney@gmail.com  
**Subject:** FW: Pesticides and other chemicals in medical marijuana

Thank you for writing to the Florida Department of Health. Your email has been forwarded to our Office of Compassionate Use for follow up.

**Florida Department of Health**

*OUR MISSION*

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

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**From:** Ronald Ney [mailto:randsney@gmail.com]  
**Sent:** Friday, February 06, 2015 4:25 PM  
**To:** zzzz Feedback, Health; zzzz Feedback, Health; adam putnam; dblanton@radelylaw.com  
**Cc:** Ron & Sue McClure Ney  
**Subject:** Pesticides and other chemicals in medical marijuana

To: John H. Armstrong, MD, FACS, Surgeon General and Secretary of Health for the State of Florida [health@flhealth.gov](mailto:health@flhealth.gov)

To: Patricia Nelson Director of Health's Office of Compassionate, [Health@doh.state.fl.us](mailto:Health@doh.state.fl.us)

To: Adam H. Putnam, Commissioner, [adam.putnam@freshfromflorida.com](mailto:adam.putnam@freshfromflorida.com)

Florida Department of Agricultural and Consumers Service

To: Donna E. Blanton, Radey Law Firm, [dblanton@radelylaw.com](mailto:dblanton@radelylaw.com)

From: Ronald E. Ney, Jr., PhD, and Advocate for Valid Science

Subject: Marijuana

First let me state I am fully in favor of medical marijuana.

I have concerns I wish to bring to your attention about growing marijuana for medical use.

Marijuana grown for medical use in nurseries may be contaminated with pesticides used in the nursery or pesticides may even be applied to the marijuana.

I read in the newspaper that the pesticide Paclobutrazol (which is a suspected carcinogen) and Daminozide (also a suspected carcinogen) has been used on marijuana plants grown for medical use.

Any of these chemical structures can be predicted to be a carcinogen.

- Can Paclobutrazol form ortho-, meta- and/or para-chlorophenol which may cause damage to the liver and immune system and may have other toxic hazards.
  - 3-Amino-1,2,4-triazole (3-AT) is also a triazol like Paclobutrazol and 3-AT was known for its toxic problems. I remember 3-AT and the cranberry scare.
  - Tebuconazole which is very similar in chemical structure to Paclobutrazol is considered a possible carcinogen.
- To my knowledge there are no registered pesticides for use on marijuana grown for medical use so any use of a pesticide on medical marijuana would be illegal under FIFRA.

Questions;

1. What will prevent marijuana grown for medical use from being contaminated with pesticides used at the nursery on other plants?

- Pesticides can drift during spraying, can volatilize and can sublime thus contaminating marijuana plants with parent chemical and degradates.
- Degradates in this case may also be photodegradation products.

2. What chemicals are present in the soil that can be taken up by marijuana plants grown for medical purposes?

- This includes those residues (parent and degradation products) which are adsorbed (bound in soil organic matter) and absorbed in soil.
- This includes chemicals present that are not pesticides.

3. Will the marijuana plants and the extract used for medical purposes be analyzed for pesticides and other contaminants?

- This includes analysis for residues of parent chemical and its degradation products.

4. Will FDACS or FDOH protect children and adults from possible pesticides and toxic chemicals in marijuana plants grown for medical use and if not, why not?

Regards,

Dr. Ron Ney

➤ Certificate of Achievement and entered into the 16th edition of AMERICAN MEN AND WOMEN OF SCIENCE, January 1987.

➤ In 1994-1995, included in Marquis WHO'S WHO IN SCIENCE AND ENGINEERING, Marquis WHO'S WHO in America.

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- Retired Supervisory Chemist USEPA (USDA & FDA), and a former NREP & Registered Environmental Professional in the State of California.
- Science Advisor in the Office of Solid Waste Disposal, USEPA; Liaison to EPS's Office of Research and Development, and Universities Centers of Excellence Research.
- USEPA Office of Solid Waste and Emergency Response Environmental Remediation Technologies Student Manual (5201G) December 2011 refers to the book by Ronald E. Ney, Jr., Ph.D. *Where Did That Chemical Go?* to be used for clean-up of sites.
- Chief of Environmental Chemistry, USEPA; for Fate and Transport of Pesticides in Air, Water, Soil, Plants and Animals, and Modeling. I wrote the data requirements for 40CFR § 158.290 and § 158.1300 Subpart N.
- Department of Agriculture's Pesticide Registration Division, Supervisory Chemist for Pesticide Tolerance Review for Pesticides in or on food, meat, dairy, eggs, etc. and started the regulations on Fate and Transport of Pesticides in Air, Water, Soil, Plants and Animals.
- Food and Drug Administration, Analytical Chemist for analysis of phenoxy herbicides, aldrin, dieldrin and endrin, Laboratory Group Leader for Total Mercury Analysis.
- Assistant Referee for the Association of Official Analytical Chemist for Total Mercury determination in treated seed.
- Collegiate Professional Teaching Certificate for chemistry, science and biology.
- Adjunct Assistant Professor/Instructor for College Chemistry (general, organic and biochemistry), Topics in Environmental Issues, Topics in Environmental Risk in Real Estate Transactions and Real Estate Appraisal.
- Principal Real Estate Broker and Certified Real Estate Appraiser.
- Author of *Where Did That Chemical Go?*, *Fate and Transport of Organic Chemicals in the Environment* (third edition), *Your Guide to Safety and Chemicals: What you need to know*.
- Served as a member on the Dioxin Disposal Advisory Group in the USEPA in the early 1980's.

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- Appointed by Lake County Commissioners, Lake County, Florida to serve on Solid Waste Advisory Committee.
- Science Advisor to Lake County Solid Waste Alternative

#### Task Force (SWATF)

1. I have reviewed and/or supervised the review of data on plants, animals, air, soil and water to make regulatory decisions and enforcement decisions (actions) and other type reviews.
2. I have reviewed about 10,000 pesticides labels for chemical names, crop restrictions, etc.
3. I have reviewed about 3,000 reports for pesticide petitions for tolerance (chemical residues in crops), rotational crops, planting restrictions, etc. I wrote many data requirements for this under FIFRA, which were adopted by FFDC (pre-USEPA).
4. I have reviewed about 500 reports for environmental chemistry data on fate and transport of pesticides in air, water, soil, plants and animals. These data requirements were written and started by me.
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**Bist, Kevin**

---

**From:** Bist, Kevin  
**Sent:** Tuesday, February 10, 2015 9:54 AM  
**To:** Nelson, Patricia A  
**Subject:** FW: Pesticides and other chemicals in medical marijuana

FYI.

---

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7. I have reviewed many pesticide studies on fate and transport submitted by the USACOE to USDA and USEPA.

**Bist, Kevin**

---

**From:** Latresia Wilson <redbirdllc@gmail.com>  
**Sent:** Tuesday, February 10, 2015 10:58 AM  
**To:** Nelson, Patricia A  
**Subject:** Re: 64-4 Notice of Proposed Rule

Thanks. I did get an opportunity to see most of it and was impressed with the level of conversation. I think you all were able to get allot done in the marathon. If I had one comment and that would be that the medical directors role was greatly diminished to 5% compared to the role written in the law. Hopefully perhaps this can still be rectified.

Great job.

Dr Latresia Wilson

On Tuesday, February 10, 2015, Nelson, Patricia A <[Patricia.Nelson@flhealth.gov](mailto:Patricia.Nelson@flhealth.gov)> wrote:

Hello, Everyone!

I am so sorry for the delay. In all the excitement, I forgot to send an email to the Interested Parties. Below you will find the Department's official press release regarding the negotiation and its results. I really am very pleased with our product and optimistic about this rule. There is a link to the publication in the release.

Have a great day!

Patty

Patricia Nelson

Director

Office of Compassionate Use

Florida Department of Health



### **The Florida Department of Health Announces Successful Negotiated Rulemaking Session**

TALLAHASSEE—After two days of a marathon rulemaking workshop, the Office of Compassionate Use with the Florida Department of Health announced today the successful negotiation of a proposed rule to implement the Compassionate Medical Cannabis Act. This rulemaking negotiation is part of the department's commitment

to working with all stakeholders to deliver this product to children with intractable epilepsy and people with advanced cancer as safely and quickly as possible.

"We came in with an unprecedented opportunity to collaborate and create a complete set of rules in just two days, and we did so successfully," said Patricia Nelson, director of the Office of Compassionate Use. "This rule brings us much closer to providing this product safely and efficiently to children and families dealing with intractable epilepsy and patients dealing with advanced cancer."

The 12 committee members who successfully negotiated the rule included nurseries, patient advocates, out-of-state experts and other interested parties. Highlights of the rule include a scorecard to guide the selection of applicants, timeline requirements for product development and application fees.

A copy of the rule is available at [https://www.flrules.org/Gateway/View\\_notice.asp?id=15645147](https://www.flrules.org/Gateway/View_notice.asp?id=15645147). A public hearing, if requested, is scheduled for March 2, 2015, in Tallahassee.

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**Bist, Kevin**

---

**From:** Joel Ewusiak <joel@ewusiaklaw.com>  
**Sent:** Wednesday, February 11, 2015 4:08 PM  
**To:** Nelson, Patricia A  
**Subject:** RE: 64-4 Notice of Proposed Rule - Bond Requirement

Patty: Thanks for the email - and your efforts. With respect to the performance bond requirement, are you aware of any companies willing to provide the bond? If so, I'd greatly appreciate any contact information. —Joel

Joel Ewusiak

Ewusiak Law, P.A.

100 Main St., Suite 205

Safety Harbor, FL 34695

P: 727.286.3559 | F: 727.286.3219 | [www.ewusiaklaw.com](http://www.ewusiaklaw.com)

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---

**From:** Nelson, Patricia A [mailto:[Patricia.Nelson@flhealth.gov](mailto:Patricia.Nelson@flhealth.gov)]

**Sent:** Tuesday, February 10, 2015 10:48 AM

**To:** DL 64-4 Interested Parties; DL 64-4 Interested Parties 2

**Cc:** Cowie, Tiffany C; Dunn, Nathan P

**Subject:** 64-4 Notice of Proposed Rule

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Director

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Florida Department of Health



STATE & FEDERAL  
GOVERNMENT &  
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PRACTICE

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The department works to protect, promote and improve the health of all people in Florida through integrated state, county and community efforts. Follow us on Twitter at [@HealthyFla](#) and on [Facebook](#). For more information about the Florida Department of Health please visit [www.floridahealth.gov](http://www.floridahealth.gov).

## Bist, Kevin

---

**From:** Gary Abrahams <garyabrahams@comcast.net>  
**Sent:** Thursday, February 12, 2015 9:28 AM  
**To:** Nelson, Patricia A  
**Subject:** FW: Compassionate Care rules and regulations discussed during two day meeting Feb 4 &5, 2015

Some folks have told me they got a response to their emails you had received them. I just wanted to make sure my email of 2/6 reached you.

I will be at the next meeting and intend to speak to the issues below.

Thank you, and if you can respond that this email has been received I would appreciate it.

**From:** Gary Abrahams [mailto:garyabrahams@comcast.net]  
**Sent:** Friday, February 6, 2015 6:02 PM  
**To:** 'patricia.nelson@flhealth.gov'  
**Subject:** Compassionate Care rules and regulations discussed during two day meeting Feb 4&5, 2015

Dear Ms. Nelson,

I attended the past 2 day meeting, as well as previous sessions. I have generally sat quietly just to absorb knowledge that would help us put together the best presentation in the application process. I currently work with a smaller nursery in the central district.

I applaud the effort the department has put into this process, and how you have quickly pushed this process forward. There has been a great deal of progress over the past two days, but in some areas where this committee lacked expertise important technical decisions were made that gave me great concern. Although these comments are late to be heard in the process, many did not come to light until the past two days and no one in the audience was given a chance to speak to the committee. I understand that the committee was under a time constraint but I believe that not taking any feedback from the audience did a disservice to the people and the process. There was a great deal of knowledge and expertise in the audience.

I was concerned that after seeing the committee that it appears that the Department selected the "biggest" growers in each district. It would be naive to think that these nurseries would be the "best" candidates to move forward with. or that they would not form the rules to favor themselves. It gave an unfair advantage to the large nurseries to be able to vote on rules or definitions that would best serve themselves. I was disappointed that the Department did not select a cross section of growers that would qualify under the statute, so that a fair playing field was represented. Backgrounds and expertise of "non-growers" at times had members speaking on topics that they were under qualified to speak to. For example a lab expert discussing financial statements, or bonding.

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In our case and many of the nurseries, the banking issue, is a non-issue, as we will replace the bank credit the nursery currently uses, with personal funds. This might be a problem for other nurseries with large loans from traditional banks, but rules cannot bend the intentions of the statute, which was to give all qualifying nurseries a fair chance to obtain a license if they could provide the patients with the best medicine and, a promise of financial stability which, in turn, assures access.

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The "performance bond" has been changed into a penalty bond for a licensed being revoked. This is onerous, and cannot be rated for risk by the insurance company.

There are many items that a license could be revoked for if a waiver was not obtained or leniency provided by the Department. An insurance company could not rely upon future positions the department may take in an appeals process in assessing risk. For example, a disgruntled employee sabotaging a water filter system, or destroying a crop, could cause non delivery or product not meeting standards etc. An employee doing something outside the guidelines when making delivery, which would have the firm dismiss the employee, but could allow the Department to revoke the license triggering the bond. Although it seems that the department would take those actions into account, the fact that the department or the general revenue fund will receive a windfall of \$5,000,000.00 can cause the bonding company to rate the cost of the bond to a prohibitive number. The bond should be revised as a performance bond that would decrease as the work was completed. I do not believe the legislative intent was to give the bonding companies and the state of Florida a windfall and increase the cost of the medicine. I believe it was to assure performance. The state's budget for the two years is approximately \$900,000.00, one fifth of that is attributable to the applicant. The cost of getting a replacement applicant would be less as the infrastructure in the department will already be in place and paid for. Therefore this \$5,000,000.00 cannot be for the purpose of protecting the state. If it is a performance bond, set it up as one. If you are worried about the renewal bond It also will be a \$5,000,000.00 performance bond with the condition that all new work has to be bonded and lowered as work is being done or if no work is being done that the \$5,000,000.00 bond will be immediately stepped down upon notification from your office of performance or lesser need requirements.

Can you imagine if a medical director knew a bond of \$5,000,000 was at risk, and if he was unhappy with his arrangement, he could blackmail by threatening to leave and shut down the business, calling for the state to cause the bond to be called. Even with a backup director, this is a very disturbing condition. One that doing prudent business would not be acceptable.

The high bar that the state wants to set is realized when the applicant spends the large sums necessary to set up this operation. The financial risk of losing the investment, which is a real possibility and which is dependent upon political whims make this a very precarious investment. Therefore the five million dollar penalty bond is not only unreasonable, it raises the cost of the medicine to such a degree that the business may be completely unsustainable. Qualified nursery men that are good businessmen know that they cannot risk everything on the dubious conditions, some out of their control, as presently set forth in this penalty bond.

I do look forward to being able to provide a quality and quantity of medicine at a reasonable price that the compassionate care act envisions. Please review the regulations and revise them in such a manner as to allow the best and the most capable to apply for the licenses. We believe that it is morally reprehensible for these patients to have to continue to suffer and look forward to working with you in bringing this endeavor to fruition.

The language I suggest for the bond is:

1. The Applicant must provide a \$5,000,000.00 performance bond within 10 business days of being notified that he has been chosen as the dispensing organization for his district. The conditions of this bond are:

\$2,000,000.00 shall be released upon completion of the Grow Facility. If the business plan has more than 1 grow facility the release shall be pro rata based upon the number of facilities to be built.

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a. If a dispensary operation closes up to \$125,000.00 will be for the disposal and or destruction of any crop, product or hazardous materials.

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c. Failure to sell any product prior to that product being batch tested shall result in a bond forfeiture in the amount of \$250,000.00.

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Last item I would like to comment on is the application fee. It should cover the costs of the Department to issue and review applications and the issue of initial licenses. Any unused funds should not be used to pay for

expenses of those getting licenses into the future. I do believe you have the authority to use funds raised by those not receiving licenses to the future benefit of those who receive licenses. I think more should be done to investigate how the Department would raise revenue from those receiving licenses to cover future expenses if required by statute and not in the Department's budget.

Please feel free to contact me with any questions or if you believe I may be of assistance in any way.

Thank you for your consideration,

Gary Abrahams

Phone 301-674-4441

## Bist, Kevin

---

**From:** Nelson, Patricia A  
**Sent:** Thursday, February 12, 2015 9:55 AM  
**To:** 'Gary Abrahams'  
**Subject:** RE: Compassionate Care rules and regulations discussed during two day meeting Feb 4 &5, 2015

Gary,

I don't always get a chance to respond, but I do get comments and make sure they are reviewed.

Thank you for your participation!

Patty

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Thank you for your consideration,

Gary Abrahams

Phone 301-674-4441

## Nelson, Patricia A

---

**From:** Sherry Center <sherrycenter@gmail.com>  
**Sent:** Thursday, February 12, 2015 2:47 PM  
**To:** zzzz Feedback, Compassionate Use  
**Subject:** New Rules

Dear Patty,

I am Sherry Center, the nurse practitioner who spoke at the December 30th meeting re: the department of agriculture working with the doh to assist growers in QI. There was nothing mentioned in the new rules regarding reporting adverse reactions to the registry etc. Perhaps this does not need to be a rule at this time. However, I feel a format for this must exist so that all growers can benefit and the patients' needs can be best met.

I did not mention at the meeting that I intend to have a dispensary. My company name is Therapeutic Cannabis Inc. I ran into a snafu with the city of Orlando zoning this week. In determining where appropriate sites for zoning dispensaries the only certain bet (because they have not made a determination) was Industrial Commercial which is where Orlando mandates pain clinics. The city planner and zoning officials indicated that this zoning designation would be likely for the dispensaries. I have begun to search the maps for locations; however, I'm finding it all but impossible to meet your appropriate criteria (near population centers and near patient populations) in the industrial commercial zones. At the December 30th meeting it was mentioned the possibility of creating a rule stating it should be zone like a medical office. After all 3 doctors seeing 4-8 patients an hour would create more traffic than a dispensary in all likelihood.

Although, I want to have a dispensary, my first concern is now, and always has been the patient. I want to be able to have a business in an appropriate, convenient area for those who require our service. Is there anything the doh can do to help this?

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Lastly, I want to compliment you on all you have accomplished. I feel the rules over all are excellent. Your determination to move forward for the patients in need is admirable. One question, unless someone is willing to admit to breaking the law (which is certainly not who I would choose to be a legal grower), how is a grower to show experience growing cannabis if he has operated a business in Florida for 30 years? Doesn't this give international companies an unfair advantage? Will there be an area in the registry so that dispensaries can see who the doctors are in there area who are participating?

Thank you for all your diligent work on the behalf of some of Florida's most vulnerable citizens.

truly,

Sherry Center MSN, ARNP, FNP-C

## Nelson, Patricia A

---

**From:** zzzz Feedback, Compassionate Use  
**Sent:** Thursday, February 12, 2015 4:33 PM  
**To:** 'Sherry Center'  
**Subject:** RE: New Rules

Sherry,

The Notice of Negotiated Rulemaking was on our website. Perhaps the name of the meeting threw you a little.

I'm confused as to how you are going to have a dispensary. Are you joining an eligible nursery?

Regarding experience, the rule language has said this since the first draft on January 27:

(2) An explanation or written documentation, as applicable, showing how the Applicant meets the statutory criteria listed in section 381.986(5)(b), F.S. In any explanation, the Applicant must address each item listed for each criterion below. The Applicant must disclose the name, position, and resume of the employee(s) who provides the knowledge or experience explained for each item.

Everyone has assumed since the bill was written that nurseries would have to hire people with experience growing cannabis.

Patty

**From:** Sherry Center [<mailto:sherrycenter@gmail.com>]  
**Sent:** Thursday, February 12, 2015 2:47 PM  
**To:** zzzz Feedback, Compassionate Use  
**Subject:** New Rules

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## Nelson, Patricia A

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**From:** Sherry Center <sherrycenter@gmail.com>  
**Sent:** Thursday, February 12, 2015 4:49 PM  
**To:** zzzz Feedback, Compassionate Use  
**Subject:** Re: New Rules

Dear Patty,

Since a grower is only obligated to own 25% of a dispensary it has been our desire to partner to be in compliance with the law. We are having positive response to our inquiries to growers. It seems overwhelming for the state to expect a "nurseryman" to have expertise in growing, extracting, transporting, retail sales and most importantly patient care. I hope your ZZZZ was not in response to my email.

You didn't respond to the zoning difficulties we are having. Since we are, it would be a good guess that it will be a problem that could potentially delay delivery to patients.

Looking forward to working with the doh to care for patients effectively who our registered in the compassionate use registry. thanks.

Sherry Center

On Thu, Feb 12, 2015 at 4:32 PM, zzzz Feedback, Compassionate Use <[CompassionateUse@flhealth.gov](mailto:CompassionateUse@flhealth.gov)> wrote:

Sherry,

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