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THE FLORIDA LEGISLATURE

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COMMITTEE MEETING AGENDA

December 7, 2017

301 Senate Office Building

3:45 p.m. – 5:45 p.m.

CALL TO ORDER AND ROLL CALL

INTRODUCTORY REMARKS

TAB 1 **Presentation by staff of proposed legislation amending Chapter 120, Florida Statutes.**

TAB 2 **Presentation by the Department of Business and Professional Regulation, Division of Pari-mutuel Wagering, on the Settlement Agreement and Stipulation in *Seminole Tribe of Florida v. State of Florida*, and the status of litigation on rulemaking and the operation of cardrooms.**

TAB 3 **Presentation by the Department of Health, Office of Medical Marijuana Use, on the status of the implementation of section 381.986, Florida Statutes, and Article X, Section 29 of the Florida Constitution ("Amendment 2").**

REPORTS AND APPEARANCES

TAB 1

2018 PROPOSED LEGISLATION

Division of Administrative Hearings (Sections 1 and 8)

The requirement for electronic filing before the Division of Administrative Hearings is currently addressed in the definition of "Division" found in section 120.52, F.S. Since the filing requirement is not located under section 120.569, F.S., which sets forth the procedural requirements for filing challenges to decisions which affect substantial interests, a number of parties have refused to file documents electronically with the Division. The proposed amendments will clarify any perceived ambiguity with respect to the electronic filing by relocating the requirement in section 120.52, F.S., to section 120.569. F.S.

Committee review of existing rules (Sections 2 and 6)

Section 120.545, F.S., and Joint Rule 4 authorize the Committee to review existing rules to ensure, in part, that the rule is not an invalid exercise of delegated legislative authority, and that the rule's statutory authority and laws implemented have not been repealed or otherwise amended.

Section 120.74(1)(d)2., F.S., requires that, with the filing of the agency's annual regulatory plan, the agency head and legal counsel, "Verify that the agency regularly reviews all of its rules and identify the period during which all rules have most recently been reviewed to determine if the rules remain consistent with the agency's rulemaking authority and the laws implemented." There is no requirement, however, that the agency take any affirmative action to resolve any discrepancies that may be noted. Neither the agency's review nor the Committee's review of existing rules that do not require any changes is reflected in the history notes of the rules published in the Florida Administrative Code. As a result, 13% of administrative rules show no evidence of any agency review after 1990, with 5% of the rules having been last addressed in the 1960s and 1970s, and two-thirds of all rules show the latest effective date of the rule to be prior to 2010. The resulting perception is that many rules have not been reviewed by an agency in thirty or forty years. (See Attached Chart.)

The purpose of the amendment is to give greater structure to the existing rule review process by requiring existing rules to be "repromulgated" as they are reviewed, regardless of whether any changes are made – a procedure currently recognized by the Department of State rules, and noted in the history notes of some agency rules. The proposed procedure would place the public on notice that rules have actually been reviewed to be consistent with both statutory requirements and agency policy, but does not require (or incur the cost associated with) full republication of the rule in the Florida Administrative Register or open the rule to an administrative challenge.

Notice of filing regulatory alternatives with the Committee (Sections 4 and 5)

Sections 120.54(3)(b) and 120.541(1)(a), F.S., provide for the submission of regulatory alternatives to agencies for consideration. The submission of a regulatory alternative results in a 21-day extension to the rulemaking procedure timeframe, and in some cases will require an agency

to prepare a revised statement of estimated regulatory costs (SERC). There is currently no requirement that the Committee be provided with copies of the suggested regulatory alternative. The proposed amendments would require that the agency forward a copy of any regulatory alternative to the Committee, thereby enabling the Committee staff to keep an accurate record of any changes in the rulemaking timeframe.

Incorporation by reference (Sections 4 and 7)

1) In keeping with the effort to reduce the overall number of rules, many agencies are repealing numerically identified rules and consolidating several "repealed" rules into a single, larger rule, or reformatting or recharacterizing the rules as forms, manuals or guidelines. The forms, manuals, and guidelines remain "rules" as that term is defined in section 120.52(16), F.S., and are incorporated by reference into the agency's rules. The incorporated documents are available via a hyperlink, but do not add, per se, to the overall number of numerically identified rules promulgated.

Rules are amended by means of a strike-through and underline process, similar to that used by the Legislature in drafting bills. However, when rule text is moved to an incorporated manual or guideline, such coding is not required. The purpose of this proposed amendment is to require all documents created by an agency that meet the definition of a rule and that are incorporated by reference into a rule to have the same transparency in any proposed changes as a rule identified by a number assigned by the Department of State and be amended by strike-through and underlining.

2) Currently, material incorporated by reference need not be made available via hyperlink at the time that the rule is proposed. As such, the public's only notice of changes to an incorporated document is often a change to the document's effective date in the notice of proposed rulemaking. In keeping with the added transparency for incorporated material, where permitted by federal copyright law, the proposed amendment would require the proposed rule text to include hyperlinks to materials incorporated by reference to allow the public to review the material without having to request the material from the agency.

Section 120.54(1), F.S., requires that materials incorporated by reference be made available via hyperlink for all rules adopted after December 31, 2010. Since noted, two-thirds of all rules were adopted or amended prior to 2010, access to the material is not always straightforward. The proposed amendment would require that all rules, when repromulgated, include hyperlinks to any materials initially incorporated by reference.

Finally, the proposed amendment requires the Department of State to include the date of any technical changes are made to the rule. Currently, since technical changes are not substantive in nature, and there is no requirement that they be formally documented in the rule history.

Housekeeping (Section 3)

Section 120.536, F.S., authorizes the Committee to petition an agency to repeal any rule or portion thereof because it exceeds the agency's rulemaking authority. This provision has never been utilized by the Committee. The objection procedure provided by section 120.545, F.S., has been the remedy of choice of the Committee and is an effective and efficient manner to address rules that are an invalid exercise of delegated legislative authority. The proposed amendment would delete the authorization for the Committee to file an administrative challenge to a rule.

Notice to Committee (Section 9)

Section 120.54(7), F.S., allows any person regulated by an agency or having substantial interest in an agency rule to petition the agency to adopt, amend, or repeal a rule. Petitions are not filed with the Committee. The proposed amendment would require that a copy of the petition be filed with the Committee in order to allow the Committee to track the rulemaking proceedings.

EXISTING RULES (By decade of most recent effective date as of June 2017)

FAC Ch #	AGENCY	1960	1970	1980	1990	2000	2010	TOTAL
1	State		2		25	5	59	91
2	Legal Affiars				11	8	37	56
5	Agriculture	9	14	35	164	195	390	807
6	Education		16	151	68	208	266	709
11	Law Enforcement		1	3	5	42	86	137
12	Revenue		36	22	119	158	273	608
14	Transportation				1	78	127	206
15	Highway Safety		28	29	127	51	57	292
18	Board of Trustees			21	18	30	17	86
19	State Board of Administration			20	24	4	55	103
20	Citrus		87	27	115	83	77	389
23	FL Commission on Offender Review				7	6	37	50
25	Public Service Commission	13	56	98	123	93	95	478
27	Executive Office of the Governor			2	18	28	32	80
28	Administration Commission		45	33	59	21	33	191
29	Regional Planning Councils		58	84	183	45	4	374
32	Florida State Fair Authority				2			2

FAC Ch #	AGENCY	1960	1970	1980	1990	2000	2010	TOTAL
33	Corrections			5	24	71	107	207
34	Commission on Ethics		3	17	65	11	80	176
40	Water Management Districts							
40A	Northwest Florida Water Management			23	57	5	40	125
40B	Suwannee River Water Management			4	25	38	50	117
40C	St. Johns Water Management			21	46	48	59	174
40D	Southwest Florida Water Management			1	4	45	87	137
40E	South Florida Water Management			40	57	106	176	379
41	Commission for Transportation Disadv.							0
42	FL Land & Water Adjudicatory			24	49	92	13	178
49	Regional Utility Authorities			11	10	4	2	27
53	FL Lottery						2	2
54	Interlocal Agencies			28			1	29
55	Veterans' Affairs			6	9	24	16	55
57	Space Florida					18		18
58	Elder Affairs				10	51	45	106
59	Agency for Health Care Admin.			6	66	99	272	443
60	Management Services		20	70	87	190	209	576

FAC Ch #	AGENCY	1960	1970	1980	1990	2000	2010	TOTAL
61	Business & Professional Regulation		16	75	321	600	700	1712
62	Environmental Protection		3	70	386	407	629	1495
63	Juvenile Justice				2	62	187	251
64	Health		5	105	405	719	886	2120
65	Children & Families		7	17	83	165	279	551
66	Navigation Districts				32	2	22	56
67	FL Housing Finance Corporation			2	15	109	82	208
68	FL Fish & Wildlife		22	27	86	160	354	649
69	Financial Services		138	232	678	757	546	2351
70	Military Affairs					3		3
72	Board of Governors						2	2
73	Economic Opportunity			16	32	94	83	225
74	Agency for State Technology						18	18
	GRAND TOTAL	22	557	1325	3618	4935	6592	**17,049**
	Percentage by decade	0.05%	3%	7.08%	21.02%	28.09%	39.04%	

2018 PROPOSED LEGISLATION

Section 1: Subsection 120.52(5), F.S., is amended to read:

120.52 Definitions.—As used in this act:
(5) "Division" means the Division of Administrative Hearings. ~~Any document filed with the division by a party represented by an attorney shall be filed by electronic means through the division's website. Any document filed with the division by a party not represented by an attorney shall, whenever possible, be filed by electronic means through the division's website.~~

Section 2: Subsection 120.52(16), F.S., is created to read:

120.52 Definitions.—As used in this act:
(16) "Repromulgate" or "repromulgation" means the publication and adoption of an existing rule following an agency's review of the rule for consistency with the powers and duties granted by its enabling statutes.

Section 3: Subsection 120.536(3), F.S., is amended to read:

120.536 Rulemaking authority; repeal; challenge
(3) ~~The Administrative Procedures Committee or~~ Aany substantially affected person may petition an agency to repeal any rule, or portion thereof, because it exceeds the rulemaking authority permitted by this section. Not later than 30 days after the date of filing the petition if the agency is headed by an individual, or not later than 45 days if the agency is headed by a collegial body, the agency shall initiate rulemaking proceedings to repeal the rule, or portion thereof, or deny the petition, giving a written statement of its reasons for the denial.

Section 4: Subsections 120.54(1) and (3), F.S., are amended to read:

120.54 Rulemaking.—
(1) GENERAL PROVISIONS APPLICABLE TO ALL RULES OTHER THAN EMERGENCY RULES.—
(a) Rulemaking is not a matter of agency discretion. Each agency statement defined as a rule by s. 120.52 shall be adopted by the rulemaking procedure provided by this section as soon as feasible and practicable.
1. Rulemaking shall be presumed feasible unless the agency proves that:
a. The agency has not had sufficient time to acquire the knowledge and experience reasonably necessary to address a statement by rulemaking; or
b. Related matters are not sufficiently resolved to enable the agency to address a statement by rulemaking.
2. Rulemaking shall be presumed practicable to the extent necessary to provide fair notice to affected persons of relevant agency procedures and applicable principles, criteria, or standards for agency decisions unless the agency proves that:
a. Detail or precision in the establishment of principles, criteria, or standards for agency decisions is not reasonable under the circumstances; or

b. The particular questions addressed are of such a narrow scope that more specific resolution of the matter is impractical outside of an adjudication to determine the substantial interests of a party based on individual circumstances.

(b) Whenever an act of the Legislature is enacted which requires implementation of the act by rules of an agency within the executive branch of state government, such rules shall be drafted and formally proposed as provided in this section within the times provided in s. 120.74(4) and (5).

(c) No statutory provision shall be delayed in its implementation pending an agency's adoption of implementing rules unless there is an express statutory provision prohibiting its application until the adoption of implementing rules.

(d) In adopting rules, all agencies must, among the alternative approaches to any regulatory objective and to the extent allowed by law, choose the alternative that does not impose regulatory costs on the regulated person, county, or city which could be reduced by the adoption of less costly alternatives that substantially accomplish the statutory objectives.

(e) No agency has inherent rulemaking authority, nor has any agency authority to establish penalties for violation of a rule unless the Legislature, when establishing a penalty, specifically provides that the penalty applies to rules.

(f) An agency may adopt rules authorized by law and necessary to the proper implementation of a statute prior to the effective date of the statute, but the rules may not be effective until the statute upon which they are based is effective. An agency may not adopt retroactive rules, including retroactive rules intended to clarify existing law, unless that power is expressly authorized by statute.

(g) Each rule adopted shall contain only one subject.

(h) In rulemaking proceedings, the agency may recognize any material which may be judicially noticed, and it may provide that materials so recognized be incorporated into the record of the proceeding. Before the record of any proceeding is completed, all parties shall be provided a list of these materials and given a reasonable opportunity to examine them and offer written comments or written rebuttal.

(i)1. A rule may incorporate material by reference but only as the material exists on the date the rule is adopted. For purposes of the rule, changes in the material are not effective unless the rule is amended to incorporate the changes.

2. An agency rule that incorporates by specific reference another rule of that agency automatically incorporates subsequent amendments to the referenced rule unless a contrary intent is clearly indicated in the referencing rule. A notice of amendments to a rule that has been incorporated by specific reference in other rules of that agency must explain the effect of those amendments on the referencing rules.

3. In rules adopted after December 31, 2010, and rules repromulgated after December 31, 2018, material may not be incorporated by reference unless:

a. The material has been submitted in the prescribed electronic format to the Department of State and the full text of the material can be made available for free public access through an electronic hyperlink from the rule making the reference in the Florida Administrative Code; or

b. The agency has determined that posting the material on the Internet for purposes of public examination and inspection would constitute a violation of federal copyright law, in which case a statement to that effect, along with the address of locations at the Department of State and the agency at which the material is available for public inspection and examination, must be included in the notice required by subparagraph (3)(a)1.

4. A rule may not be amended by reference only. Amendments must set out the amended rule in full in the same manner as required by the State Constitution for laws.
5. Notwithstanding any contrary provision in this section, when an adopted rule of the Department of Environmental Protection or a water management district is incorporated by reference in the other agency's rule to implement a provision of part IV of chapter 373, subsequent amendments to the rule are not effective as to the incorporating rule unless the agency incorporating by reference notifies the committee and the Department of State of its intent to adopt the subsequent amendment, publishes notice of such intent in the Florida Administrative Register, and files with the Department of State a copy of the amended rule incorporated by reference. Changes in the rule incorporated by reference are effective as to the other agency 20 days after the date of the published notice and filing with the Department of State. The Department of State shall amend the history note of the incorporating rule to show the effective date of such change. Any substantially affected person may, within 14 days after the date of publication of the notice of intent in the Florida Administrative Register, file an objection to rulemaking with the agency. The objection shall specify the portions of the rule incorporated by reference to which the person objects and the reasons for the objection. The agency shall not have the authority under this subparagraph to adopt those portions of the rule specified in such objection. The agency shall publish notice of the objection and of its action in response in the next available issue of the Florida Administrative Register.
6. The Department of State may adopt by rule requirements for incorporating materials pursuant to this paragraph.
(j) A rule published in the Florida Administrative Code must be indexed by the Department of State within 90 days after the rule is filed. The Department of State shall by rule establish procedures for indexing rules.
(k) An agency head may delegate the authority to initiate rule development under subsection (2); however, rulemaking responsibilities of an agency head under subparagraph (3)(a)1., subparagraph (3)(e)1., or subparagraph (3)(e)6. may not be delegated or transferred.
(2) No change.
(3) ADOPTION PROCEDURES.—
(a) Notices.—
1. Prior to the adoption, amendment, or repeal of any rule other than an emergency rule, an agency, upon approval of the agency head, shall give notice of its intended action, setting forth a short, plain explanation of the purpose and effect of the proposed action; the full text of the proposed rule or amendment and a summary thereof; a reference to the grant of rulemaking authority pursuant to which the rule is adopted; and a reference to the section or subsection of the Florida Statutes or the Laws of Florida being implemented or interpreted. The notice must include a summary of the agency's statement of the estimated regulatory costs, if one has been prepared, based on the factors set forth in s. 120.541(2); a statement that any person who wishes to provide the agency with information regarding the statement of estimated regulatory costs, or to provide a proposal for a lower cost regulatory alternative as provided by s. 120.541(1), must do so in writing within 21 days after publication of the notice; and a statement as to whether, based on the statement of the estimated regulatory costs or other information expressly relied upon and described by the agency if no statement of regulatory costs is required, the proposed rule is expected to require legislative ratification pursuant to s. 120.541(3). The notice must state the procedure for requesting a public hearing on the proposed rule. Except when the intended

action is the repeal of a rule, the notice must include a reference both to the date on which and to the place where the notice of rule development that is required by subsection (2) appeared.
2. The notice shall be published in the Florida Administrative Register not less than 28 days prior to the intended action. The proposed rule, including all material proposed to be incorporated by reference, shall be available for inspection and copying by the public at the time of the publication of notice. After December 31, 2018, material to be incorporated by reference in the notice required by this paragraph shall be made available in the manner prescribed by s. 120.54(1)(i)3.a. or b.
3. The notice shall be mailed to all persons named in the proposed rule and to all persons who, at least 14 days prior to such mailing, have made requests of the agency for advance notice of its proceedings. The agency shall also give such notice as is prescribed by rule to those particular classes of persons to whom the intended action is directed.
4. The adopting agency shall file with the committee, at least 21 days prior to the proposed adoption date, a copy of each rule it proposes to adopt; a copy of any material incorporated by reference in the rule; a detailed written statement of the facts and circumstances justifying the proposed rule; a copy of any statement of estimated regulatory costs that has been prepared pursuant to s. 120.541; a statement of the extent to which the proposed rule relates to federal standards or rules on the same subject; and the notice required by subparagraph 1.
(b) Special matters to be considered in rule adoption.—
1. Statement of estimated regulatory costs.—Before the adoption, amendment, or repeal of any rule other than an emergency rule, an agency is encouraged to prepare a statement of estimated regulatory costs of the proposed rule, as provided by s. 120.541. However, an agency must prepare a statement of estimated regulatory costs of the proposed rule, as provided by s. 120.541, if:
a. The proposed rule will have an adverse impact on small business; or
b. The proposed rule is likely to directly or indirectly increase regulatory costs in excess of $200,000 in the aggregate in this state within 1 year after the implementation of the rule.
2. Small businesses, small counties, and small cities.—
a. Each agency, before the adoption, amendment, or repeal of a rule, shall consider the impact of the rule on small businesses as defined by s. 288.703 and the impact of the rule on small counties or small cities as defined by s. 120.52. Whenever practicable, an agency shall tier its rules to reduce disproportionate impacts on small businesses, small counties, or small cities to avoid regulating small businesses, small counties, or small cities that do not contribute significantly to the problem the rule is designed to address. An agency may define "small business" to include businesses employing more than 200 persons, may define "small county" to include those with populations of more than 75,000, and may define "small city" to include those with populations of more than 10,000, if it finds that such a definition is necessary to adapt a rule to the needs and problems of small businesses, small counties, or small cities. The agency shall consider each of the following methods for reducing the impact of the proposed rule on small businesses, small counties, and small cities, or any combination of these entities:
(I) Establishing less stringent compliance or reporting requirements in the rule.
(II) Establishing less stringent schedules or deadlines in the rule for compliance or reporting requirements.
(III) Consolidating or simplifying the rule's compliance or reporting requirements.
(IV) Establishing performance standards or best management practices to replace design or operational standards in the rule.

(V) Exempting small businesses, small counties, or small cities from any or all requirements of the rule.
b.(I) If the agency determines that the proposed action will affect small businesses as defined by the agency as provided in sub-subparagraph a., the agency shall send written notice of the rule to the rules ombudsman in the Executive Office of the Governor at least 28 days before the intended action.
(II) Each agency shall adopt those regulatory alternatives offered by the rules ombudsman in the Executive Office of the Governor and provided to the agency no later than 21 days after the rules ombudsman's receipt of the written notice of the rule which it finds are feasible and consistent with the stated objectives of the proposed rule and which would reduce the impact on small businesses. When regulatory alternatives are offered by the rules ombudsman in the Executive Office of the Governor, the 90-day period for filing the rule in subparagraph (e)2. is extended for a period of 21 days. The agency shall provide notice to the committee of any regulatory alternative offered to the agency pursuant to this sub-subparagraph at least 21 days prior to filing the rule for adoption.
(III) If an agency does not adopt all alternatives offered pursuant to this sub-subparagraph, it shall, before rule adoption or amendment and pursuant to subparagraph (d)1., file a detailed written statement with the committee explaining the reasons for failure to adopt such alternatives. Within 3 working days after the filing of such notice, the agency shall send a copy of such notice to the rules ombudsman in the Executive Office of the Governor.
(c) Hearings.—
1. If the intended action concerns any rule other than one relating exclusively to procedure or practice, the agency shall, on the request of any affected person received within 21 days after the date of publication of the notice of intended agency action, give affected persons an opportunity to present evidence and argument on all issues under consideration. The agency may schedule a public hearing on the rule and, if requested by any affected person, shall schedule a public hearing on the rule. When a public hearing is held, the agency must ensure that staff are available to explain the agency's proposal and to respond to questions or comments regarding the rule. If the agency head is a board or other collegial body created under s. 20.165(4) or s. 20.43(3)(g), and one or more requested public hearings is scheduled, the board or other collegial body shall conduct at least one of the public hearings itself and may not delegate this responsibility without the consent of those persons requesting the public hearing. Any material pertinent to the issues under consideration submitted to the agency within 21 days after the date of publication of the notice or submitted to the agency between the date of publication of the notice and the end of the final public hearing shall be considered by the agency and made a part of the record of the rulemaking proceeding.
2. Rulemaking proceedings shall be governed solely by the provisions of this section unless a person timely asserts that the person's substantial interests will be affected in the proceeding and affirmatively demonstrates to the agency that the proceeding does not provide adequate opportunity to protect those interests. If the agency determines that the rulemaking proceeding is not adequate to protect the person's interests, it shall suspend the rulemaking proceeding and convene a separate proceeding under the provisions of ss. 120.569 and 120.57. Similarly situated persons may be requested to join and participate in the separate proceeding. Upon conclusion of the separate proceeding, the rulemaking proceeding shall be resumed.
(d) Modification or withdrawal of proposed rules.—

1. After the final public hearing on the proposed rule, or after the time for requesting a hearing has expired, if the rule has not been changed from the rule as previously filed with the committee, or contains only technical changes, the adopting agency shall file a notice to that effect with the committee at least 7 days prior to filing the rule for adoption. Any change, other than a technical change that does not affect the substance of the rule, must be supported by the record of public hearings held on the rule, must be in response to written material submitted to the agency within 21 days after the date of publication of the notice of intended agency action or submitted to the agency between the date of publication of the notice and the end of the final public hearing, or must be in response to a proposed objection by the committee. In addition, when any change is made in the ~~a~~ proposed rule text or any material incorporated by reference, other than a technical change, the adopting agency shall provide a copy of a notice of change by certified mail or actual delivery to any person who requests it in writing no later than 21 days after the notice required in paragraph (a). The agency shall file the notice of change with the committee, along with the reasons for the change, and provide the notice of change to persons requesting it, at least 21 days prior to filing the rule for adoption. The notice of change shall be published in the Florida Administrative Register at least 21 days prior to filing the rule for adoption. This subparagraph does not apply to emergency rules adopted pursuant to subsection (4). After December 31, 2018, material proposed to be incorporated by reference in the notice required by this paragraph shall be made available in the manner prescribed by s. 120.54(1)(i)3.a. or b.

2. After the notice required by paragraph (a) and prior to adoption, the agency may withdraw the rule in whole or in part.

3. After adoption and before the rule becomes effective, a rule may be modified or withdrawn only in the following circumstances:

a. When the committee objects to the rule;

b. When a final order, which is not subject to further appeal, is entered in a rule challenge brought pursuant to s. 120.56 after the date of adoption but before the rule becomes effective pursuant to subparagraph (e)6.;

c. If the rule requires ratification, when more than 90 days have passed since the rule was filed for adoption without the Legislature ratifying the rule, in which case the rule may be withdrawn but may not be modified; or

d. When the committee notifies the agency that an objection to the rule is being considered, in which case the rule may be modified to extend the effective date by not more than 60 days.

4. The agency shall give notice of its decision to withdraw or modify a rule in the first available issue of the publication in which the original notice of rulemaking was published, shall notify those persons described in subparagraph (a)3. in accordance with the requirements of that subparagraph, and shall notify the Department of State if the rule is required to be filed with the Department of State.

5. After a rule has become effective, it may be repealed or amended only through the rulemaking procedures specified in this chapter.

(e) Filing for final adoption; effective date.—

1. If the adopting agency is required to publish its rules in the Florida Administrative Code, the agency, upon approval of the agency head, shall file with the Department of State three certified copies of the rule it proposes to adopt; one copy of any material incorporated by reference in the rule, certified by the agency; a summary of the rule; a summary of any hearings held on the rule; and a detailed written statement of the facts and circumstances justifying the rule. Agencies not

required to publish their rules in the Florida Administrative Code shall file one certified copy of the proposed rule, and the other material required by this subparagraph, in the office of the agency head, and such rules shall be open to the public.

2. A rule may not be filed for adoption less than 28 days or more than 90 days after the notice required by paragraph (a), until 21 days after the notice of change required by paragraph (d), until 14 days after the final public hearing, until 21 days after a statement of estimated regulatory costs required under s. 120.541 has been provided to all persons who submitted a lower cost regulatory alternative and made available to the public, or until the administrative law judge has rendered a decision under s. 120.56(2), whichever applies. When a required notice of change is published prior to the expiration of the time to file the rule for adoption, the period during which a rule must be filed for adoption is extended to 45 days after the date of publication. If notice of a public hearing is published prior to the expiration of the time to file the rule for adoption, the period during which a rule must be filed for adoption is extended to 45 days after adjournment of the final hearing on the rule, 21 days after receipt of all material authorized to be submitted at the hearing, or 21 days after receipt of the transcript, if one is made, whichever is latest. The term "public hearing" includes any public meeting held by any agency at which the rule is considered. If a petition for an administrative determination under s. 120.56(2) is filed, the period during which a rule must be filed for adoption is extended to 60 days after the administrative law judge files the final order with the clerk or until 60 days after subsequent judicial review is complete.

3. At the time a rule is filed, the agency shall certify that the time limitations prescribed by this paragraph have been complied with, that all statutory rulemaking requirements have been met, and that there is no administrative determination pending on the rule.

4. At the time a rule is filed, the committee shall certify whether the agency has responded in writing to all material and timely written comments or written inquiries made on behalf of the committee. The department shall reject any rule that is not filed within the prescribed time limits; that does not comply with all statutory rulemaking requirements and rules of the department; upon which an agency has not responded in writing to all material and timely written inquiries or written comments; upon which an administrative determination is pending; or which does not include a statement of estimated regulatory costs, if required.

5. If a rule has not been adopted within the time limits imposed by this paragraph or has not been adopted in compliance with all statutory rulemaking requirements, the agency proposing the rule shall withdraw the rule and give notice of its action in the next available issue of the Florida Administrative Register.

6. The proposed rule shall be adopted on being filed with the Department of State and become effective 20 days after being filed, on a later date specified in the notice required by subparagraph (a)1., on a date required by statute, or upon ratification by the Legislature pursuant to s. 120.541(3). Rules not required to be filed with the Department of State shall become effective when adopted by the agency head, on a later date specified by rule or statute, or upon ratification by the Legislature pursuant to s. 120.541(3). If the committee notifies an agency that an objection to a rule is being considered, the agency may postpone the adoption of the rule to accommodate review of the rule by the committee. When an agency postpones adoption of a rule to accommodate review by the committee, the 90-day period for filing the rule is tolled until the committee notifies the agency that it has completed its review of the rule.

Section 5: Paragraph (a) of Subsection 120.541(1), F.S., is amended to read:

120.541 Statement of estimated regulatory costs.—
(1)(a) Within 21 days after publication of the notice required under s. 120.54(3)(a), a substantially affected person may submit to an agency a good faith written proposal for a lower cost regulatory alternative to a proposed rule which substantially accomplishes the objectives of the law being implemented. The agency shall provide a copy of any proposal for a lower cost regulatory alternative to the committee at least 21 days prior to filing the rule for adoption. The proposal may include the alternative of not adopting any rule if the proposal explains how the lower costs and objectives of the law will be achieved by not adopting any rule. If such a proposal is submitted, the 90-day period for filing the rule is extended 21 days. Upon the submission of the lower cost regulatory alternative, the agency shall prepare a statement of estimated regulatory costs as provided in subsection (2), or shall revise its prior statement of estimated regulatory costs, and either adopt the alternative or provide a statement of the reasons for rejecting the alternative in favor of the proposed rule.

Section 6: Section 120.543, F.S., is created to read:

120.543 Repromulgation of rules –
(1) It is the intent of the Legislature that each agency shall periodically review its rules for consistency with the powers and duties granted by its enabling statutes. If, after review, no substantive changes are required to update a rule, an agency shall repromulgate the rule to reflect the date of such review.
(2) Prior to repromulgation of the rule, an agency, shall, upon approval by the agency head:
(a) publish a notice of repromulgation in the Florida Administrative Register, which shall not be required to include the text of the rule being promulgated; and
(b) file the rule for repromulgation with the Department of State. A rule may not be filed for repromulgation less than 28 days or more than 90 days after the publication of the notice required by paragraph (a).
(3) The agency shall file notice with the committee at least 14 days prior to filing the rule for repromulgation. At the time the rule is filed for repromulgation, the committee shall certify whether the agency has responded in writing to all material and timely written comments or written inquiries made on behalf of the committee.
(4) If the rule is not filed for repromulgation within the time limits imposed by subsection (2), the agency shall withdraw the rule for repromulgation and give notice of the withdrawal in the next available issue of the Florida Administrative Register.
(5) A repromulgated rule shall not be subject to challenge as a proposed rule pursuant to s. 120.56(2).
(6) The hearing requirements of section 120.54 shall not apply to subsection (2).
(7) Adoption of repromulgated rules; effective date. –
(a) The agency, upon approval of the agency head or designee, shall file with the Department of State three certified copies of the repromulgated rule it proposes to adopt and one certified copy of any material incorporated by reference in the rule.
(b) The repromulgated rule shall be adopted upon filing with the Department of State and repromulgation becomes effective 20 days after being filed.

(c) The Department of State shall update the history note of the rule in the Florida Administrative Code to reflect the effective date of repromulgation.
(8) The Department of State shall adopt rules to implement this section no later than December 31, 2018.

Section 7: Subsection 120.55(1), F.S., is amended to read:

120.55 Publication.—
(1) The Department of State shall:
(a)1. Through a continuous revision and publication system, compile and publish electronically, on a website managed by the department, the "Florida Administrative Code." The Florida Administrative Code shall contain all rules adopted by each agency, citing the grant of rulemaking authority and the specific law implemented pursuant to which each rule was adopted, all history notes as authorized in s. 120.545(7), complete indexes to all rules contained in the code, and any other material required or authorized by law or deemed useful by the department. The electronic code shall display each rule chapter currently in effect in browse mode and allow full text search of the code and each rule chapter. The department may contract with a publishing firm for a printed publication; however, the department shall retain responsibility for the code as provided in this section. The electronic publication shall be the official compilation of the administrative rules of this state. The Department of State shall retain the copyright over the Florida Administrative Code.
2. Rules general in form but applicable to only one school district, community college district, or county, or a part thereof, or state university rules relating to internal personnel or business and finance shall not be published in the Florida Administrative Code. Exclusion from publication in the Florida Administrative Code shall not affect the validity or effectiveness of such rules.
3. At the beginning of the section of the code dealing with an agency that files copies of its rules with the department, the department shall publish the address and telephone number of the executive offices of each agency, the manner by which the agency indexes its rules, a listing of all rules of that agency excluded from publication in the code, and a statement as to where those rules may be inspected.
4. Forms shall not be published in the Florida Administrative Code; but any form which an agency uses in its dealings with the public, along with any accompanying instructions, shall be filed with the committee before it is used. Any form or instruction which meets the definition of "rule" provided in s. 120.52 shall be incorporated by reference into the appropriate rule. The reference shall specifically state that the form is being incorporated by reference and shall include the number, title, and effective date of the form and an explanation of how the form may be obtained. Each form created by an agency which is incorporated by reference in a rule notice of which is given under s. 120.54(3)(a) after December 31, 2007, must clearly display the number, title, and effective date of the form and the number of the rule in which the form is incorporated.
5. After December 31, 2018, t~~T~~he department shall require all material incorporated by reference in any part of an adopted rule~~s~~, and in any part of a repromulgated rule, to be filed in the manner prescribed by s. 120.54(1)(i)3.a. or b. When a rule is filed for adoption or repromulgation with incorporated material in electronic form, the department's publication of the Florida Administrative Code on its website must contain a hyperlink from the incorporating reference in the rule directly to that material. The department may not allow hyperlinks from

rules in the Florida Administrative Code to any material other than that filed with and maintained by the department, but may allow hyperlinks to incorporated material maintained by the department from the adopting agency's website or other sites.
6. The Department of State shall include the date of any technical changes in the history note of a rule. A technical change shall not change the effective date of the rule.
(b) Electronically publish on a website managed by the department a continuous revision and publication entitled the "Florida Administrative Register," which shall serve as the official publication and must contain:
1. All notices required by s. 120.54(2) and (3)(a), showing the text of all rules proposed for consideration.
2. All notices of public meetings, hearings, and workshops conducted in accordance with s. 120.525, including a statement of the manner in which a copy of the agenda may be obtained.
3. A notice of each request for authorization to amend or repeal an existing uniform rule or for the adoption of new uniform rules.
4. Notice of petitions for declaratory statements or administrative determinations.
5. A summary of each objection to any rule filed by the Administrative Procedures Committee.
6. A list of rules filed for adoption in the previous 7 days.
7. A list of all rules filed for adoption pending legislative ratification under s. 120.541(3). A rule shall be removed from the list once notice of ratification or withdrawal of the rule is received.
8. Any other material required or authorized by law or deemed useful by the department.

The department may contract with a publishing firm for a printed publication of the Florida Administrative Register and make copies available on an annual subscription basis.

(c) Prescribe by rule the style and form required for rules, notices, and other materials submitted for filing, including a rule requiring documents created by an agency that are proposed to be incorporated by reference in notices published pursuant to s. 120.54(3)(a) and (d) to be coded in the same manner as notices published pursuant to s. 120.54(3)(a)1.
(d) Charge each agency using the Florida Administrative Register a space rate to cover the costs related to the Florida Administrative Register and the Florida Administrative Code.
(e) Maintain a permanent record of all notices published in the Florida Administrative Register.

Section 8: Paragraph (b) of Subsection 120.569(1), F.S., is created to read:

120.569 Decisions which affect substantial interests.—
(1)(a) The provisions of this section apply in all proceedings in which the substantial interests of a party are determined by an agency, unless the parties are proceeding under s. 120.573 or s. 120.574. Unless waived by all parties, s. 120.57(1) applies whenever the proceeding involves a disputed issue of material fact. Unless otherwise agreed, s. 120.57(2) applies in all other cases. If a disputed issue of material fact arises during a proceeding under s. 120.57(2), then, unless waived by all parties, the proceeding under s. 120.57(2) shall be terminated and a proceeding under s. 120.57(1) shall be conducted. Parties shall be notified of any order, including a final order. Unless waived, a copy of the order shall be delivered or mailed to each party or the party's attorney of record at the address of record. Each notice shall inform the recipient of any administrative hearing or judicial review that is available under this section, s. 120.57, or s.

120.68; shall indicate the procedure which must be followed to obtain the hearing or judicial review; and shall state the time limits which apply.
(b) In all proceedings pursuant to this chapter being conducted before the division, any document filed with the division by a party represented by an attorney shall be filed by electronic means through the division's website. Any document filed with the division by a party not represented by an attorney shall, whenever possible, be filed by electronic means through the division's website. The division shall serve all such documents on all parties of record by electronic means through the division's website. The parties are relieved of any requirement to serve the other parties who are registered e-filers when they e-file documents with the division.

Section 9: Paragraph (a) of subsection 120.54(7), is amended to read:

(7) PETITION TO INITIATE RULEMAKING.—
(a) Any person regulated by an agency or having substantial interest in an agency rule may petition an agency to adopt, amend, or repeal a rule or to provide the minimum public information required by this chapter. The petition shall specify the proposed rule and action requested. A copy of the petition shall be filed with the committee. Not later than 30 calendar days following the date of filing a petition, the agency shall initiate rulemaking proceedings under this chapter, otherwise comply with the requested action, or deny the petition with a written statement of its reasons for the denial.

TAB 2

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

Case No. 17-10304-CC

SEMINOLE TRIBE OF FLORIDA,
Plaintiff/Appellee

v.

STATE OF FLORIDA,
Defendant/Appellant.

APPEAL FROM THE UNITED STATES DISTRICT
COURT FOR THE NORTHERN DISTRICT OF FLORIDA
Case No. 4:15-cv-516-RH-CAS

STATE OF FLORIDA, and
FLORIDA DEPARTMENT OF BUSINESS
AND PROFESSIONAL REGULATION,
Plaintiffs/Appellants

v.

SEMINOLE TRIBE OF FLORIDA,
Defendant/Appellee.

APPEAL FROM THE UNITED STATES DISTRICT
COURT FOR THE NORTHERN DISTRICT OF FLORIDA
Case No. 4:15-cv-588-RH-CAS

SETTLEMENT AGREEMENT AND STIPULATION

THIS SETTLEMENT AGREEMENT AND STIPULATION ("Settlement") is entered into by and between the Appellants, STATE OF FLORIDA and FLORIDA DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION (collectively "the State"), and the Appellee, SEMINOLE TRIBE OF FLORIDA ("the Tribe").

WHEREAS, the State and the Tribe entered into a tribal-state compact pursuant to the Indian Gaming Regulatory Act on April 7, 2010, which became effective on July 6, 2010, 75 Fed. Reg. 38,833 ("2010 Compact").

WHEREAS, this Settlement is not intended to amend Florida law, as interpreted by the opinion on the merits entered in the consolidated cases, or modify any of the provisions of the 2010Compact.

WHEREAS, the Florida Legislature designated the Division of Pari-Mutuel Wagering of the Department of Business and Professional Regulation as the State Compliance Agency having the authority to carry out the State's oversight responsibilities under the 2010 Compact on behalf of the State. § 285.710(7), Fla. Stat.

WHEREAS, Part XVI, Section B, of the 2010 Compact provided that " . . . the authorization for the Tribe to conduct banking or banked card games as defined in Part III, Section F(2) shall terminate on the last day of the sixtieth (60th) month

after this Compact becomes effective unless the authorization to conduct such games is renewed by the parties or the State permits any other person, organization or entity, except for any other federally recognized tribe pursuant to Indian Gaming Regulatory Act, provided that the tribe has land in federal trust in the State as of February 1, 2010, to conduct such games. In the event that the Tribe's authorization to conduct banking or banked card games terminates, the Payments due the State pursuant to Part XI, Sections B.1.(b) and D of this Compact shall becalculated by excluding the Net Win from the Tribe's Facilities in Broward County."

WHEREAS, after July 31, 2015, the Tribe continued making Revenue Share Payments to the State based on calculations that did not exclude the Net Win from the Tribe's Facilities in Broward County. The State deposited each Revenue Share Payment into the General Revenue Fund pursuant to § 285.710(9), Florida Statutes, and then administratively segregated out the portion that was based on the Net Win from the Tribe's Facilities in Broward County (the "Administratively Segregated Funds"). The State has not allocated the Administratively Segregated Funds to any portion of the State's budget.

WHEREAS, on October 26, 2015, in the United States District Court for the Northern District of Florida, the Tribe sued the State in case number 4:15-cv-

588. On October 30, 2015, in the United States District Court for the Middle District of Florida, the State sued the Tribe in case number 8:15-cv-2568. Case No: 17-10304-CC. Thereafter, the State's suit against the Tribe was transferred from the Middle District of Florida to the Northern District of Florida and consolidated with the Tribe's suit against the State. The consolidated cases include a dispute regarding the rights and obligations under the 2010Compact.

WHEREAS, in the consolidated cases, the Tribe and the State filed a pretrial stipulation that the Tribe's obligation to make periodic "Revenue Share Payments" (as such term is defined in the 2010 Compact) was not at issue for determination in the consolidated cases.

WHEREAS, during a bench trial of the consolidated cases, the Tribe presented evidence of pari-mutuel facilities' operation of (a) player-banked card games which use a designated player ("Designated Player Games"), and electronic table games ("Electronic Table Games").

WHEREAS, after the bench trial, the district court entered an opinion on the merits in which the district court concluded that regulation permitting Designated Player Games triggered an exception, in Part XVI, Section B, of the 2010 Compact, to the five-year limitation on the Tribe's right to conduct banking or banked card games.

WHEREAS, pursuant to the opinion on the merits, the district clerk entered a judgment in case number 4:15-cv-588 declaring that "the Seminole Tribe of Florida has the right under the 2010 Compact to provide banked card games for the Compact's entire 20-year term at the seven locations listed in Part IV.B. of the Compact."

WHEREAS, pursuant to the opinion on the merits, the district clerk entered a judgment in case number 8:15-cv-2568 dismissing the State's claim for declaratory and injunctive relief.

WHEREAS, on January 19, 2017, the State appealed to the United States Court of Appeals for the Eleventh Circuit from the judgments entered in case number 4:15-cv-588 and case number 8:15-cv-2568.

WHEREAS, the Tribe has informed the State that it claims the right to suspend payments or pay into an escrow account, under Part XII of the 2010 Compact, its Revenue Share Payments.

WHEREAS, the Tribe and the State affirm that it is in the best interests of the Tribe and the State for the Tribe to forbear, until after the Florida Legislature's 2018 session, any action to suspend payments or pay into an escrow account, under Part XII of the 2010 Compact, its Revenue Share Payments.

NOW THEREFORE, the Tribe and the State enter this Settlement and agree to the following terms:

1. On the date of the execution of this Settlement (the "Effective Date"), the State will file a motion with the Eleventh Circuit Court of Appeals to dismiss this Appeal, and upon issuance of a final order dismissing the Appeal, the Tribe will release the State from any and all claims that under Part XII of the 2010 Compact the Tribe is entitled, based on the operation of Designated Player Games or Electronic Table Games in the State of Florida, to recover past Revenue Share Payments.

2. After the Appeal is dismissed, the State is entitled to the unencumbered use of the Administratively Segregated Funds, and the Tribe will not seek the return of the Administratively Segregated Funds.

3. During the time period beginning on the Effective Date through and including the last day of the month in which the Florida Legislature adjourns its 2018 session (the "Forbearance Period"), the Tribe will not suspend Revenue Share Payments or begin making Revenue Share Payments into an escrow account pursuant to the procedures set forth in Part XII of the 2010 Compact; nor will the Tribe initiate an action asserting that it is entitled, based on the continued operation

of Designated Player Games or Electronic Table Games in the State of Florida, to begin making Revenue Share Payments into an escrow account pursuant to the procedures set forth in Part XII of the 2010 Compact, provided that the State takes aggressive enforcement action against the continued operation of banked card games, including Designated Player Games that are operated in a banked game manner, as described in the opinion on the merits entered in the consolidated cases, and no other violations of the Tribe's exclusivity occur during the Forbearance Period. If a new violation of the Tribe's exclusivity occurs during the Forbearance Period due to a court decision or administrative agency ruling or decision, the Tribe will follow the process set forth in Part XII.A of the Compact.

4. The Tribe will continue to make, and the State may continue to deposit into the General Revenue Fund, pursuant to § 285.710(9), Florida Statutes, all of the Revenue Share Payments for the Forbearance Period, provided that the State takes aggressive enforcement action against the continued operation of banked card games, including Designated Player Games that are operated in a banked game manner, as described in the opinion on the merits entered in the consolidated cases, and no other violations of the Tribe's exclusivity occur during the Forbearance Period. The State will be entitled to the unencumbered use of such payments, and the Tribe will not seek the return of such payments.

5. The Tribe and the State agree that the findings of fact and conclusions of law in the opinion on the merits entered in the consolidated cases are binding on the parties.

6. The Tribe and the State agree that this Settlement shall not amend Florida law, as interpreted by the opinion on the merits entered in the consolidated cases, or modify any of the provisions of the 2010 Compact. Specifically, this Settlement shall not modify Part XII, Section A of the 2010 Compact, which provides that: "If, after February 1, 2010, Florida law is amended by action of the Florida Legislature or an amendment to the Florida Constitution to allow (1) the operation of Class III gaming or other casino-style gaming at any location under the jurisdiction of the State that was not in operation as of February 1, 2010, or (2) new forms of Class III gaming or other casino-style gaming that were not in operation as of February 1, 2010, the Payments due to the State pursuant to Part XI, Sections B. and D. of this Compact shall cease when the newly authorized gaming begins to be offered for public or private use. The cessation of payments due to the State pursuant to Part XI, Sections B. and D. of this Compact shall continue until such gaming is no longer operated, in which event the Payments shall resume. . . . ."

7. The Director of the Division of Pari-Mutuel Wagering affirms that (a) the Division of Pari-Mutuel Wagering has authority to act as the State Compliance Agency under the 2010 Compact, (b) the Director of the Division of Pari-Mutuel Wagering is duly authorized and has the authority to execute this Settlement on behalf of the State of Florida and the Department of Business and Professional Regulation, (c) the Division of Pari-Mutuel Wagering will take all appropriate steps to defend its authority to execute this Settlement on behalf of the State and the Department of Business and Professional Regulation and to defend the validity of this Settlement, and (d) the Division of Pari-Mutuel Wagering will take all appropriate steps to effectuate this Settlement's purposes and intent.

8. The Chairman of the Tribal Council of the Seminole Tribe of Florida affirms that (a) he is duly authorized and has authority to execute this Settlement on behalf of the Tribe, (b) the Seminole Tribe of Florida will take all appropriate steps to defend the validity of this Settlement, and (c) he will take all appropriate steps to effectuate this Settlement's purposes and intent.

Seminole Tribe of Florida v. State of Florida
Case No. 17-10304-CC

APPROVED:

Appellants, STATE OF FLORIDA and FLORIDA DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

Date: 7/5, 2017
Anthony J. Glover
Director of the Florida Division of Pari-Mutuel Wagering

Date: 7/5, 2017
Jason Maine
Counsel for Florida Department of Business and Professional Regulation

Appellee, SEMINOLE TRIBE OF FLORIDA

Date: 7/3, 2017
Marcellus W. Osceola Jr.
Chairman of the Tribal Council

Date: 7/5, 2017
Barry Richard
Counsel for Seminole Tribe of Florida

TAL 452125943v2

TAB 3

INDEX OF DOCUMENTS

MANDATORY RULEMAKING REQUIREMENTS
SECTIONS 381.986 AND 381.988, FLORIDA STATUTES

Section	Requirement	Completed
381.986(4)(c)	Quantify a daily dose amount with equivalent dose amounts for each allowable form of marijuana dispensed by a marijuana treatment center.	
381.986(7)(c)	Establish procedures for the issuance, renewal, suspension, replacement, surrender, and revocation of medical marijuana use registry identification cards.	
381.986(8)(b)	Adopt an application form for licensure as a MMTC.	√
	Establish a procedure for the issuance and biennial renewal of licenses, including initial application and biennial renewal fees.	√[1]
381.986(8)(e)6.a.	Identify pesticides to be safely applied to plants intended for human consumption.	√[2]
381.986(8)(e)8.	Determine shapes, forms, and ingredients allowed and prohibited for edibles.	
381.986(8)(e)8.	Adopt sanitation rules providing the standards and requirements for the storage, display, or dispensing of edibles.	
381.986(8)(e)10.b.	Determine requirements for MMTCs to use solvents or gases exhibiting potential toxicity to humans.	
381.986(8)(e)10.c.	Determine procedures for the storage, handling, transportation, management, and disposal of solid and liquid waste generated during marijuana production and processing.	
381.986(8)(e)10.d.	Determine which contaminants must be tested for, and the maximum levels of each contaminant which are safe for human consumption.	

[1] Rule 64ER17-2 adopted only the initial application fee.
[2] Notice of Proposed Rule 64-4.013, Pesticide Use on Marijuana, published on November 22, 2017, with a proposed effective date of March 1, 2018.

381.986(8)(e)10.d.	Develop testing requirements for contaminants that are unsafe for human consumption in edibles.
381.986(8)(e)10.d.	Determine procedures for the treatment of marijuana that fails to meet the testing requirements of section 381.988, Florida Statutes, or department rules.
381.986(8)(e)(10)f.(IX)	Develop a marijuana universal symbol.
381.986(8)(h)1.	Develop standards for approving trade names and logos.
381.986(8)(h)2.a.	Develop standards for approval of all MMTC advertisements.
381.988(1)(b)	Develop an application and application fee for certification of medical marijuana testing laboratories.
381.988(1)(c)	Adopt a list of laboratory accreditations or certifications and accreditation or certification organizations.
381.988(2)	Establish a procedure for certification and biennial review.
381.988(3)	Establish standards for certification of marijuana testing laboratories.

MEDICAL MARIJUANA USE IMPLEMENTATION TIMELINE

2014 ----------

June 16[1] Section 381.986, Florida Statutes, Compassionate Medical Cannabis Act of 2014, created by Chapter 2014-157, Laws of Florida.

2015 ----------

June 17 Effective date of rules adopted by the Department of Health:
64-4.001, Definitions
64-4.002, Initial Application Requirements for Dispensing Organizations
64-4.004, Revocation of Dispensing Organization Approval
64-4.005, Inspection and Authorization Procedures
64-4.009, Compassionate Use Registry

Nov. 23 Dispensing licenses issued to:
Aphria (Chestnut Hill)
Knox Medical
Curaleaf (Costa)
Surterra Therapeutics (Alpha)
Trulieve (Hackney)

[Total number of licenses issued to date: 5]

2016 ----------

March 25 Section 381.986, Florida Statutes, substantially amended by section 1, Chapter 2016-123, Laws of Florida.

April 4 Dispensing license issued to The Green Solution (San Felasco).

[Total number of licenses issued to date: 6]

Dec. 21 Dispensing license issued to GrowHealthy (McCrory's).

[Total number of licenses issued to date: 7]

2017 ----------

Jan. 3 Effective date of Section 29, Article X of the Florida Constitution (Amendment 2).

Feb. 19 Effective date of rule 64-4.011, Compassionate Use Registry Identification Cards.

March 15 Notice of Rule Development for Rule 64-4.013, Pesticide Use on Cannabis.

[1] Dates in bold represent constitutional and statutory requirements.

June 23	Effective date of SB 8-A, Chapter 2017-232, Laws of Florida, substantially amending section 381.986, Florida Statutes, implementing Amendment 2.
July 3	Adoption of regulation 1-1.01, Medical Marijuana for Debilitating Medical Conditions.
July 3	Date set by Amendment 2 for promulgation of implementing regulations.
	Date set by SB 8-A for issuing Medical Marijuana Treatment Center (MMTC) licenses for all entities holding licenses previously issued under section 381.986, Florida Statutes (2016).
July 31	MMTC licenses issued to 3 Boys Farm and Plants of Ruskin, Inc.
	[Total number of licenses issued to date: 9]
Aug. 1	Date set (no later than) by SB 8-A for issuing MMTC licenses for applicants whose application was reviewed, evaluated, and scored by the Department and which was denied a dispensing organization license under former section 381.986, Florida Statutes (2014), which had one or more administrative or judicial challenges pending as of January 1, 2017, or had a final ranking within one point of the highest final ranking in its region under section 381.986, Florida Statutes (2014).
Aug. 9	MMTC licenses issued to Sunbulb Company, Inc. and Treadwell Nursery.
	[Total number of licenses issued to date: 11]
Aug. 23	MMTC license issued to Loop's Nursery & Greenhouses, Inc.
	[Total number of licenses issued to date: 12]
Sept. 19	Adoption of emergency rules 64ER17-1, Definitions, and 64ER17-2, Application for Registration of Medical Marijuana Treatment Centers.
Sept. 22	Complaint filed in *Columbus Smith v. Florida Department of Health* (Circuit Court, Leon County), alleging unconstitutionality of section 381.986(8)(a)2.b., Florida Statutes, and seeking injunction from issuing MMTC license to a black farmer.
Sept. 29	Letter from Christian Bax, Director, Office of Medical Marijuana Use, to the Florida Legislature advising that the Office of Medical Marijuana Use will not be issuing five additional licenses by October 3, 2017.
Oct. 3	Letter from JAPC to Christian Bax regarding emergency rules 64ER17- 1, Definitions, and 64ER17-2, Application for Registration of Medical Marijuana Treatment Centers, advising Mr. Bax of the mandatory rulemaking requirements of section 381.986, Florida Statutes, and requesting an explanation of the interaction between the adopted rules and regulations

Oct. 3 Date (as soon as practicable, but no later than) set by SB 8-A for issuing MMTC licenses to:

1) an applicant who is a recognized class member of *Pigford v. Glickman* or *In re Black Farmers Litig.*; and
2) applicants that meet the requirements of section 381.986, Florida Statutes (2017), in sufficient numbers to result in 10 total licenses issued. Preference for up to two licenses to applicants who own citrus processing facilities that will use or convert the facilities for the processing of marijuana.

Date set by SB 8-A for issuing "qualified patient" identification cards. (Amendment 2 addresses "qualifying patient" and caregiver identification cards.)

Oct. 9 Comment letters from JAPC to the Department of Health regarding emergency rules 64ER17-2, Application Requirements for Medical Marijuana Treatment Centers, and 64ER17-2, Application Requirements for Medical Marijuana Treatment Centers.

Oct. 24 Adoption of emergency rule 64ER17-6, Disciplinary Guidelines and Fines.

Oct. 30 MMTC license issued to Keith St. Germain Nursery Farms.

[Total number of licenses issued to date: 13]

Notice of Development of Rulemaking for rule 64-4.014, Standards for Production of Edibles.

Comment letter from JAPC to the Department of Health, regarding rule 64-4.011, Compassionate Use Registry Identification Cards.

Complaint filed in *Tropiflora, LLC. v. Florida Department of Health, Office of Compassionate Use* (Circuit Court, Leon County), alleging unconstitutionality of the provision in section 381.986, Florida Statutes, giving preference to applicants with citrus fruit processing facilities. The suit seeks to enjoin the Department from issuing any further licenses.

Nov. 3 Notice of adoption of regulations 1-1.02 and 2-1.01 governing MMTC applications.

Nov. 17 Letter from JAPC to Christian Bax regarding of Notice of Development of Rulemaking for rule 64-4.014, Standards for Production of Edibles, advising Mr. Bax of the requirement under section 381.986, Florida Statutes, to adopt emergency rules.

Nov. 20 Letter from JAPC to Christian Bax requesting a timeframe for adoption of rules mandated under section 381.986, Florida Statutes, and again requesting an explanation of the interplay between the rules and regulations adopted by the Department.

Notice of adoption of regulation 2-1.02, Disciplinary Guidelines and Fines.

Nov. 21 Complaint filed in *Bill's Nursery, Inc. and Michael Bowen* v. *Department of Health* (Circuit Court, Leon County), requesting that the court direct the Department to issue licenses as required under section 381.986, Florida Statutes.

Nov. 22 Notice of Proposed Rule for rule 64-4.013, Pesticide Use on Marijuana, with a proposed effective date of March 1, 2018.

Nov. 27 Letter from JAPC to Christian Bax regarding proposed rule 64-4.013, Pesticide Use on Marijuana, again advising Mr. Bax of the emergency rulemaking requirements of section 381.986, Florida Statutes.

Nov. 28 Comment letter from JAPC to the Department of Health, regarding emergency rule 64ER17-6, Disciplinary Guidelines and Fees.

[Number of licenses remaining to be issued: 4]

SECTION 29. Medical marijuana production, possession and use.—
(a) PUBLIC POLICY.
(1) The medical use of marijuana by a qualifying patient or caregiver in compliance with this section is not subject to criminal or civil liability or sanctions under Florida law.
(2) A physician shall not be subject to criminal or civil liability or sanctions under Florida law solely for issuing a physician certification with reasonable care to a person diagnosed with a debilitating medical condition in compliance with this section.
(3) Actions and conduct by a Medical Marijuana Treatment Center registered with the Department, or its agents or employees, and in compliance with this section and Department regulations, shall not be subject to criminal or civil liability or sanctions under Florida law.
(b) DEFINITIONS. For purposes of this section, the following words and terms shall have the following meanings:
(1) "Debilitating Medical Condition" means cancer, epilepsy, glaucoma, positive status for human immunodeficiency virus (HIV), acquired immune deficiency syndrome (AIDS), post-traumatic stress disorder (PTSD), amyotrophic lateral sclerosis (ALS), Crohn's disease, Parkinson's disease, multiple sclerosis, or other debilitating medical conditions of the same kind or class as or comparable to those enumerated, and for which a physician believes that the medical use of marijuana would likely outweigh the potential health risks for a patient.
(2) "Department" means the Department of Health or its successor agency.
(3) "Identification card" means a document issued by the Department that identifies a qualifying patient or a caregiver.
(4) "Marijuana" has the meaning given cannabis in Section 893.02(3), Florida Statutes (2014), and, in addition, "Low-THC cannabis" as defined in Section 381.986(1)(b), Florida Statutes (2014), shall also be included in the meaning of the term "marijuana."
(5) "Medical Marijuana Treatment Center" (MMTC) means an entity that acquires, cultivates, possesses, processes (including development of related products such as food, tinctures, aerosols, oils, or ointments), transfers, transports, sells, distributes, dispenses, or administers marijuana, products containing marijuana, related supplies, or educational materials to qualifying patients or their caregivers and is registered by the Department.
(6) "Medical use" means the acquisition, possession, use, delivery, transfer, or administration of an amount of marijuana not in conflict with Department rules, or of related supplies by a qualifying patient or caregiver for use by the caregiver's designated qualifying patient for the treatment of a debilitating medical condition.
(7) "Caregiver" means a person who is at least twenty-one (21) years old who has agreed to assist with a qualifying patient's medical use of marijuana and has qualified for and obtained a caregiver identification card issued by the Department. The Department may limit the number of qualifying patients a caregiver may assist at one time and the number of caregivers that a qualifying patient may have at one time. Caregivers are prohibited from consuming marijuana obtained for medical use by the qualifying patient.
(8) "Physician" means a person who is licensed to practice medicine in Florida.
(9) "Physician certification" means a written document signed by a physician, stating that in the physician's professional opinion, the patient suffers from a debilitating medical condition, that the medical use of marijuana would likely outweigh the potential health risks for the patient, and for how long the physician recommends the medical use of marijuana for the patient. A physician certification may only be provided after the physician has conducted a physical examination and a full assessment of the medical history of the patient. In order for a physician

certification to be issued to a minor, a parent or legal guardian of the minor must consent in writing.
(10) "Qualifying patient" means a person who has been diagnosed to have a debilitating medical condition, who has a physician certification and a valid qualifying patient identification card. If the Department does not begin issuing identification cards within nine (9) months after the effective date of this section, then a valid physician certification will serve as a patient identification card in order to allow a person to become a "qualifying patient" until the Department begins issuing identification cards.
(c) LIMITATIONS.
(1) Nothing in this section allows for a violation of any law other than for conduct in compliance with the provisions of this section.
(2) Nothing in this section shall affect or repeal laws relating to non-medical use, possession, production, or sale of marijuana.
(3) Nothing in this section authorizes the use of medical marijuana by anyone other than a qualifying patient.
(4) Nothing in this section shall permit the operation of any vehicle, aircraft, train or boat while under the influence of marijuana.
(5) Nothing in this section requires the violation of federal law or purports to give immunity under federal law.
(6) Nothing in this section shall require any accommodation of any on-site medical use of marijuana in any correctional institution or detention facility or place of education or employment, or of smoking medical marijuana in any public place.
(7) Nothing in this section shall require any health insurance provider or any government agency or authority to reimburse any person for expenses related to the medical use of marijuana.
(8) Nothing in this section shall affect or repeal laws relating to negligence or professional malpractice on the part of a qualified patient, caregiver, physician, MMTC, or its agents or employees.
(d) DUTIES OF THE DEPARTMENT. The Department shall issue reasonable regulations necessary for the implementation and enforcement of this section. The purpose of the regulations is to ensure the availability and safe use of medical marijuana by qualifying patients. It is the duty of the Department to promulgate regulations in a timely fashion.
(1) Implementing Regulations. In order to allow the Department sufficient time after passage of this section, the following regulations shall be promulgated no later than six (6) months after the effective date of this section:
a. Procedures for the issuance and annual renewal of qualifying patient identification cards to people with physician certifications and standards for renewal of such identification cards. Before issuing an identification card to a minor, the Department must receive written consent from the minor's parent or legal guardian, in addition to the physician certification.
b. Procedures establishing qualifications and standards for caregivers, including conducting appropriate background checks, and procedures for the issuance and annual renewal of caregiver identification cards.
c. Procedures for the registration of MMTCs that include procedures for the issuance, renewal, suspension and revocation of registration, and standards to ensure proper security, record keeping, testing, labeling, inspection, and safety.
d. A regulation that defines the amount of marijuana that could reasonably be presumed to be an adequate supply for qualifying patients' medical use, based on the best available evidence.

This presumption as to quantity may be overcome with evidence of a particular qualifying patient's appropriate medical use.
(2) Identification cards and registrations. The Department shall begin issuing qualifying patient and caregiver identification cards, and registering MMTCs no later than nine (9) months after the effective date of this section.
(3) If the Department does not issue regulations, or if the Department does not begin issuing identification cards and registering MMTCs within the time limits set in this section, any Florida citizen shall have standing to seek judicial relief to compel compliance with the Department's constitutional duties.
(4) The Department shall protect the confidentiality of all qualifying patients. All records containing the identity of qualifying patients shall be confidential and kept from public disclosure other than for valid medical or law enforcement purposes.
(e) LEGISLATION. Nothing in this section shall limit the legislature from enacting laws consistent with this section.
(f) SEVERABILITY. The provisions of this section are severable and if any clause, sentence, paragraph or section of this measure, or an application thereof, is adjudged invalid by a court of competent jurisdiction other provisions shall continue to be in effect to the fullest extent possible.
History.—Proposed by Initiative Petition filed with the Secretary of State January 9, 2015; adopted 2016.

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[1]381.986 Medical use of marijuana.—

(1) DEFINITIONS.—As used in this section, the term:

(a) "Caregiver" means a resident of this state who has agreed to assist with a qualified patient's medical use of marijuana, has a caregiver identification card, and meets the requirements of subsection (6).

(b) "Chronic nonmalignant pain" means pain that is caused by a qualifying medical condition or that originates from a qualifying medical condition and persists beyond the usual course of that qualifying medical condition.

(c) "Close relative" means a spouse, parent, sibling, grandparent, child, or grandchild, whether related by whole or half blood, by marriage, or by adoption.

(d) "Edibles" means commercially produced food items made with marijuana oil, but no other form of marijuana, that are produced and dispensed by a medical marijuana treatment center.

(e) "Low-THC cannabis" means a plant of the genus *Cannabis*, the dried flowers of which contain 0.8 percent or less of tetrahydrocannabinol and more than 10 percent of cannabidiol weight for weight; the seeds thereof; the resin extracted from any part of such plant; or any compound, manufacture, salt, derivative, mixture, or preparation of such plant or its seeds or resin that is dispensed from a medical marijuana treatment center.

(f) "Marijuana" means all parts of any plant of the genus *Cannabis*, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant or its seeds or resin, including low-THC cannabis, which are dispensed from a medical marijuana treatment center for medical use by a qualified patient.

(g) "Marijuana delivery device" means an object used, intended for use, or designed for use in preparing, storing, ingesting, inhaling, or otherwise introducing marijuana into the human body, and which is dispensed from a medical marijuana treatment center for medical use by a qualified patient.

(h) "Marijuana testing laboratory" means a facility that collects and analyzes marijuana samples from a medical marijuana treatment center and has been certified by the department pursuant to s. 381.988.

(i) "Medical director" means a person who holds an active, unrestricted license as an allopathic physician under chapter 458 or osteopathic physician under chapter 459 and is in compliance with the requirements of paragraph (3)(c).

(j) "Medical use" means the acquisition, possession, use, delivery, transfer, or administration of marijuana authorized by a physician certification. The term does not include:

1. Possession, use, or administration of marijuana that was not purchased or acquired from a medical marijuana treatment center.

2. Possession, use, or administration of marijuana in a form for smoking, in the form of commercially produced food items other than edibles, or of marijuana seeds or flower, except for flower in a sealed, tamper-proof receptacle for vaping.

3. Use or administration of any form or amount of marijuana in a manner that is inconsistent with the qualified physician's directions or physician certification.

4. Transfer of marijuana to a person other than the qualified patient for whom it was authorized or the qualified patient's caregiver on behalf of the qualified patient.

5. Use or administration of marijuana in the following locations:

a. On any form of public transportation, except for low-THC cannabis.

b. In any public place, except for low-THC cannabis.

c. In a qualified patient's place of employment, except when permitted by his or her employer.

d. In a state correctional institution, as defined in s. 944.02, or a correctional institution, as defined in s. 944.241.

e. On the grounds of a preschool, primary school, or secondary school, except as provided in s. 1006.062.

f. In a school bus, a vehicle, an aircraft, or a motorboat, except for low-THC cannabis.

(k) "Physician certification" means a qualified physician's authorization for a qualified patient to receive marijuana and a marijuana delivery device from a medical marijuana treatment center.

(l) "Qualified patient" means a resident of this state who has been added to the medical marijuana use registry by a qualified physician to receive marijuana or a marijuana delivery device for a medical use and who has a qualified patient identification card.

(m) "Qualified physician" means a person who holds an active, unrestricted license as an allopathic physician under chapter 458 or as an osteopathic physician under chapter 459 and is in compliance with the physician education requirements of subsection (3).

(n) "Smoking" means burning or igniting a substance and inhaling the smoke.

(o) "Terminal condition" means a progressive disease or medical or surgical condition that causes significant functional impairment, is not considered by a treating physician to be reversible without the administration of life-sustaining procedures, and will result in death within 1 year after diagnosis if the condition runs its normal course.

(2) QUALIFYING MEDICAL CONDITIONS.—A patient must be diagnosed with at least one of the following conditions to qualify to receive marijuana or a marijuana delivery device:

(a) Cancer.

(b) Epilepsy.

(c) Glaucoma.

(d) Positive status for human immunodeficiency virus.

(e) Acquired immune deficiency syndrome.

(f) Post-traumatic stress disorder.

(g) Amyotrophic lateral sclerosis.

(h) Crohn's disease.

(i) Parkinson's disease.

(j) Multiple sclerosis.

(k) Medical conditions of the same kind or class as or comparable to those enumerated in paragraphs (a)-(j).

(l) A terminal condition diagnosed by a physician other than the qualified physician issuing the physician certification.

(m) Chronic nonmalignant pain.

(3) QUALIFIED PHYSICIANS AND MEDICAL DIRECTORS.—

(a) Before being approved as a qualified physician, as defined in paragraph (1)(m), and before each license renewal, a physician must successfully complete a 2-hour course and subsequent examination offered by the Florida Medical Association or the Florida Osteopathic Medical Association which encompass the requirements of this section and any rules adopted hereunder. The course and examination shall be administered at least annually and may be offered in a distance learning format, including an electronic, online format that is available upon request. The price of the course may not exceed $500. A physician who has met the physician education requirements of former s. 381.986(4), Florida Statutes 2016, before June 23, 2017, shall be deemed to be in compliance with this paragraph from June 23, 2017, until 90 days after the course and examination required by this paragraph become available.

(b) A qualified physician may not be employed by, or have any direct or indirect economic interest in, a medical marijuana treatment center or marijuana testing laboratory.

(c) Before being employed as a medical director, as defined in paragraph (1)(i), and before each license renewal, a medical director must successfully complete a 2-hour course and subsequent examination offered by the Florida Medical Association or the Florida Osteopathic Medical Association which encompass the requirements of this section and any rules adopted hereunder. The course and examination shall be administered at least annually and may be offered in a distance learning format, including an electronic, online format that is available upon request. The price of the course may not exceed $500.

(4) PHYSICIAN CERTIFICATION.—

(a) A qualified physician may issue a physician certification only if the qualified physician:

1. Conducted a physical examination while physically present in the same room as the patient and a full assessment of the medical history of the patient.

2. Diagnosed the patient with at least one qualifying medical condition.

3. Determined that the medical use of marijuana would likely outweigh the potential health risks for the patient, and such determination must be documented in the patient's medical record. If a patient is younger than 18 years of age, a second physician must concur with this determination, and such concurrence must be documented in the patient's medical record.

4. Determined whether the patient is pregnant and documented such determination in the patient's medical record. A physician may not issue a physician certification, except for low-THC cannabis, to a patient who is pregnant.

5. Reviewed the patient's controlled drug prescription history in the prescription drug monitoring program database established pursuant to s. 893.055.

6. Reviews the medical marijuana use registry and confirmed that the patient does not have an active physician certification from another qualified physician.

7. Registers as the issuer of the physician certification for the named qualified patient on the medical marijuana use registry in an electronic manner determined by the department, and:

a. Enters into the registry the contents of the physician certification, including the patient's qualifying condition and the dosage not to exceed the daily dose amount determined by the department, the amount and forms of marijuana authorized for the patient, and any types of marijuana delivery devices needed by the patient for the medical use of marijuana.

b. Updates the registry within 7 days after any change is made to the original physician certification to reflect such change.

c. Deactivates the registration of the qualified patient and the patient's caregiver when the physician no longer recommends the medical use of marijuana for the patient.

8. Obtains the voluntary and informed written consent of the patient for medical use of marijuana each time the qualified physician issues a physician certification for the patient, which shall be maintained in the patient's medical record. The patient, or the patient's parent or legal guardian if the patient is a minor, must sign the informed consent acknowledging that the qualified physician has sufficiently explained its content. The qualified physician must use a standardized informed consent form adopted in rule by the Board of Medicine and the Board of Osteopathic Medicine, which must include, at a minimum, information related to:

a. The Federal Government's classification of marijuana as a Schedule I controlled substance.

b. The approval and oversight status of marijuana by the Food and Drug Administration.

c. The current state of research on the efficacy of marijuana to treat the qualifying conditions set forth in this section.

d. The potential for addiction.

e. The potential effect that marijuana may have on a patient's coordination, motor skills, and cognition, including a warning against operating heavy machinery, operating a motor vehicle, or engaging in activities that require a person to be alert or respond quickly.

f. The potential side effects of marijuana use.

g. The risks, benefits, and drug interactions of marijuana.

h. That the patient's de-identified health information contained in the physician certification and medical marijuana use registry may be used for research purposes.

(b) If a qualified physician issues a physician certification for a qualified patient diagnosed with a qualifying medical condition pursuant to paragraph (2)(k), the physician must submit the following to the applicable board within 14 days after issuing the physician certification:

1. Documentation supporting the qualified physician's opinion that the medical condition is of the same kind or class as the conditions in paragraphs (2)(a)-(j).

2. Documentation that establishes the efficacy of marijuana as treatment for the condition.

3. Documentation supporting the qualified physician's opinion that the benefits of medical use of marijuana would likely outweigh the potential health risks for the patient.

4. Any other documentation as required by board rule.

The department must submit such documentation to the Coalition for Medical Marijuana Research and Education established pursuant to s. 1004.4351.

(c) A qualified physician may not issue a physician certification for more than three 70-day supply limits of marijuana. The department shall quantify by rule a daily dose amount with equivalent dose amounts for each allowable form of marijuana dispensed by a medical marijuana treatment center. The department shall use the daily dose amount to calculate a 70-day supply.

1. A qualified physician may request an exception to the daily dose amount limit. The request shall be made electronically on a form adopted by the department in rule and must include, at a minimum:

a. The qualified patient's qualifying medical condition.

b. The dosage and route of administration that was insufficient to provide relief to the qualified patient.

c. A description of how the patient will benefit from an increased amount.

d. The minimum daily dose amount of marijuana that would be sufficient for the treatment of the qualified patient's qualifying medical condition.

2. A qualified physician must provide the qualified patient's records upon the request of the department.

3. The department shall approve or disapprove the request within 14 days after receipt of the complete documentation required by this paragraph. The request shall be deemed approved if the department fails to act within this time period.

(d) A qualified physician must evaluate an existing qualified patient at least once every 30 weeks before issuing a new physician certification. A physician must:

1. Determine if the patient still meets the requirements to be issued a physician certification under paragraph (a).

2. Identify and document in the qualified patient's medical records whether the qualified patient experienced either of the following related to the medical use of marijuana:

a. An adverse drug interaction with any prescription or nonprescription medication; or

b. A reduction in the use of, or dependence on, other types of controlled substances as defined in s. 893.02.

3. Submit a report with the findings required pursuant to subparagraph 2. to the department. The department shall submit such reports to the Coalition for Medical Marijuana Research and Education established pursuant to s. 1004.4351.

(e) An active order for low-THC cannabis or medical cannabis issued pursuant to former s. 381.986, Florida Statutes 2016, and registered with the compassionate use registry before June 23, 2017, is deemed a physician certification, and all patients possessing such orders are deemed qualified patients until the department begins issuing medical marijuana use registry identification cards.

(f) The department shall monitor physician registration in the medical marijuana use registry and the issuance of physician certifications for practices that could facilitate unlawful diversion or misuse of marijuana or a marijuana delivery device and shall take disciplinary action as appropriate.

(g) The Board of Medicine and the Board of Osteopathic Medicine shall jointly create a physician certification pattern review panel that shall review all physician certifications submitted to the medical marijuana use registry. The panel shall track and report the number of physician certifications and the qualifying medical conditions, dosage, supply amount, and form of marijuana certified. The panel shall report the data both by individual qualified physician and in the aggregate, by county, and statewide. The physician certification pattern review panel shall, beginning January 1, 2018, submit an annual report of its findings and recommendations to the Governor, the President of the Senate, and the Speaker of the House of Representatives.

(h) The department, the Board of Medicine, and the Board of Osteopathic Medicine may adopt rules pursuant to ss. 120.536(1) and 120.54 to implement this subsection.

(5) MEDICAL MARIJUANA USE REGISTRY.—

(a) The department shall create and maintain a secure, electronic, and online medical marijuana use registry for physicians, patients, and caregivers as provided under this section. The medical marijuana use registry must be accessible to law enforcement agencies, qualified physicians, and medical marijuana treatment centers to verify the authorization of a qualified patient or a caregiver to possess marijuana or a marijuana delivery device and record the marijuana or marijuana delivery device dispensed. The medical marijuana use registry must also be accessible to practitioners licensed to prescribe prescription drugs to ensure proper care for patients before medications that may interact with the medical use of marijuana are prescribed. The medical marijuana use registry must prevent an active registration of a qualified patient by multiple physicians.

(b) The department shall determine whether an individual is a resident of this state for the purpose of registration of qualified patients and caregivers in the medical marijuana use registry. To prove residency:

1. An adult resident must provide the department with a copy of his or her valid Florida driver license issued under s. 322.18 or a copy of a valid Florida identification card issued under s. 322.051.

2. An adult seasonal resident who cannot meet the requirements of subparagraph 1. may provide the department with a copy of two of the following that show proof of residential address:

a. A deed, mortgage, monthly mortgage statement, mortgage payment booklet or residential rental or lease agreement.

b. One proof of residential address from the seasonal resident's parent, step-parent, legal guardian or other person with whom the seasonal resident resides and a statement from the person with whom the seasonal resident resides stating that the seasonal resident does reside with him or her.

c. A utility hookup or work order dated within 60 days before registration in the medical use registry.

d. A utility bill, not more than 2 months old.

e. Mail from a financial institution, including checking, savings, or investment account statements, not more than 2 months old.

f. Mail from a federal, state, county, or municipal government agency, not more than 2 months old.

g. Any other documentation that provides proof of residential address as determined by department rule.

3. A minor must provide the department with a certified copy of a birth certificate or a current record of registration from a Florida K-12 school and must have a parent or legal guardian who meets the requirements of subparagraph 1.

For the purposes of this paragraph, the term "seasonal resident" means any person who temporarily resides in this state for a period of at least 31 consecutive days in each calendar year, maintains a temporary residence in this state, returns to the state or jurisdiction of his or her residence at least one time during each calendar year, and is registered to vote or pays income tax in another state or jurisdiction.

(c) The department may suspend or revoke the registration of a qualified patient or caregiver if the qualified patient or caregiver:

1. Provides misleading, incorrect, false, or fraudulent information to the department;

2. Obtains a supply of marijuana in an amount greater than the amount authorized by the physician certification;

3. Falsifies, alters, or otherwise modifies an identification card;

4. Fails to timely notify the department of any changes to his or her qualified patient status; or

5. Violates the requirements of this section or any rule adopted under this section.

(d) The department shall immediately suspend the registration of a qualified patient charged with a violation of chapter 893 until final disposition of any alleged offense. Thereafter, the department may extend the suspension, revoke the registration, or reinstate the registration.

(e) The department shall immediately suspend the registration of any caregiver charged with a violation of chapter 893 until final disposition of any alleged offense. The department shall revoke a caregiver registration if the caregiver does not meet the requirements of subparagraph (6)(b)6.

(f) The department may revoke the registration of a qualified patient or caregiver who cultivates marijuana or who acquires, possesses, or delivers marijuana from any person or entity other than a medical marijuana treatment center.

(g) The department shall revoke the registration of a qualified patient, and the patient's associated caregiver, upon notification that the patient no longer meets the criteria of a qualified patient.

(h) The department may adopt rules pursuant to ss. 120.536(1) and 120.54 to implement this subsection.

(6) CAREGIVERS.—

(a) The department must register an individual as a caregiver on the medical marijuana use registry and issue a caregiver identification card if an individual designated by a qualified patient meets all of the requirements of this subsection and department rule.

(b) A caregiver must:

1. Not be a qualified physician and not be employed by or have an economic interest in a medical marijuana treatment center or a marijuana testing laboratory.

2. Be 21 years of age or older and a resident of this state.

3. Agree in writing to assist with the qualified patient's medical use of marijuana.

4. Be registered in the medical marijuana use registry as a caregiver for no more than one qualified patient, except as provided in this paragraph.

5. Successfully complete a caregiver certification course developed and administered by the department or its designee, which must be renewed biennially. The price of the course may not exceed $100.

6. Pass a background screening pursuant to subsection (9), unless the patient is a close relative of the caregiver.

(c) A qualified patient may designate no more than one caregiver to assist with the qualified patient's medical use of marijuana, unless:

1. *The qualified patient is a minor and the designated caregivers are parents or legal guardians of* the qualified patient;

2. The qualified patient is an adult who has an intellectual or developmental disability that prevents the patient from being able to protect or care for himself or herself without assistance or supervision and the designated caregivers are the parents or legal guardians of the qualified patient; or

3. The qualified patient is admitted to a hospice program.

(d) A caregiver may be registered in the medical marijuana use registry as a designated caregiver for no more than one qualified patient, unless:

1. The caregiver is a parent or legal guardian of more than one minor who is a qualified patient;

2. The caregiver is a parent or legal guardian of more than one adult who is a qualified patient and who has an intellectual or developmental disability that prevents the patient from being able to protect or care for himself or herself without assistance or supervision; or

3. All qualified patients the caregiver has agreed to assist are admitted to a hospice program and have requested the assistance of that caregiver with the medical use of marijuana; the caregiver is an employee of the hospice; and the caregiver provides personal care or other services directly to clients of the hospice in the scope of that employment.

(e) A caregiver may not receive compensation, other than actual expenses incurred, for any services provided to the qualified patient.

(f) If a qualified patient is younger than 18 years of age, only a caregiver may purchase or administer marijuana for medical use by the qualified patient. The qualified patient may not purchase marijuana.

(g) A caregiver must be in immediate possession of his or her medical marijuana use registry identification card at all times when in possession of marijuana or a marijuana delivery device and must present his or her medical marijuana use registry identification card upon the request of a law enforcement officer.

(h) The department may adopt rules pursuant to ss. 120.536(1) and 120.54 to implement this subsection.

(7) IDENTIFICATION CARDS.—

(a) The department shall issue medical marijuana use registry identification cards for qualified patients and caregivers who are residents of this state, which must be renewed annually. The identification cards must be resistant to counterfeiting and tampering and must include, at a minimum, the following:

1. The name, address, and date of birth of the qualified patient or caregiver.

2. A full-face, passport-type, color photograph of the qualified patient or caregiver taken within the 90 days immediately preceding registration or the Florida driver license or Florida identification card photograph of the qualified patient or caregiver obtained directly from the Department of Highway Safety and Motor Vehicles.

3. Identification as a qualified patient or a caregiver.

4. The unique numeric identifier used for the qualified patient in the medical marijuana use registry.

5. For a caregiver, the name and unique numeric identifier of the caregiver and the qualified patient or patients that the caregiver is assisting.

6. The expiration date of the identification card.

(b) The department must receive written consent from a qualified patient's parent or legal guardian before it may issue an identification card to a qualified patient who is a minor.

[2](c) The department shall adopt rules pursuant to ss. 120.536(1) and 120.54 establishing procedures for the issuance, renewal, suspension, replacement, surrender, and revocation of medical marijuana use registry identification cards pursuant to this section and shall begin issuing qualified patient identification cards by October 3, 2017.

(d) Applications for identification cards must be submitted on a form prescribed by the department. The department may charge a reasonable fee associated with the issuance, replacement, and renewal of identification cards. The department shall allocate $10 of the identification card fee to the Division of Research at Florida Agricultural and Mechanical University for the purpose of educating minorities about marijuana for medical use and the impact of the unlawful use of marijuana on minority communities. The department shall contract with a third-party vendor to issue identification cards. The vendor selected by the department must have experience performing similar functions for other state agencies.

(e) A qualified patient or caregiver shall return his or her identification card to the department within 5 business days after revocation.

[2](8) MEDICAL MARIJUANA TREATMENT CENTERS.—

(a) The department shall license medical marijuana treatment centers to ensure reasonable statewide accessibility and availability as necessary for qualified patients registered in the medical marijuana use registry and who are issued a physician certification under this section.

1. As soon as practicable, but no later than July 3, 2017, the department shall license as a medical marijuana treatment center any entity that holds an active, unrestricted license to cultivate, process, transport, and dispense low-THC cannabis, medical cannabis, and cannabis delivery devices, under former s. 381.986, Florida Statutes 2016, before July 1, 2017, and which meets the requirements of this section. In addition to the authority granted under this section, these entities are authorized to dispense low-THC cannabis, medical cannabis, and cannabis delivery devices ordered pursuant to former s. 381.986, Florida Statutes 2016, which were entered into the compassionate use registry before July 1, 2017, and are authorized to begin dispensing marijuana under this section on July 3, 2017. The department may grant variances from the representations made in such an entity's original application for approval under former s. 381.986, Florida Statutes 2014, pursuant to paragraph (e).

2. The department shall license as medical marijuana treatment centers 10 applicants that meet the requirements of this section, under the following parameters:

a. As soon as practicable, but no later than August 1, 2017, the department shall license any applicant whose application was reviewed, evaluated, and scored by the department and which was denied a dispensing organization license by the department under former s. 381.986, Florida Statutes 2014; which had one or more administrative or judicial challenges pending as of January 1, 2017, or had a final ranking within one point of the highest final ranking in its region under former s. 381.986, Florida Statutes 2014; which meets the requirements of this section; and which provides documentation to the department that it has the existing infrastructure and technical and technological ability to begin cultivating marijuana within 30 days after registration as a medical marijuana treatment center.

b. As soon as practicable, but no later than October 3, 2017, the department shall license one applicant that is a recognized class member of *Pigford v. Glickman*, 185 F.R.D. 82 (D.D.C. 1999), or *In Re Black Farmers Litig.*, 856 F. Supp. 2d 1 (D.D.C. 2011) and is a member of the Black Farmers and Agriculturalists Association-Florida Chapter. An applicant licensed under this sub-subparagraph is exempt from the requirements of subparagraphs (b)1. and 2.

c. As soon as practicable, but no later than October 3, 2017, the department shall license applicants that meet the requirements of this section in sufficient numbers to result in 10 total licenses issued under this subparagraph, while accounting for the number of licenses issued under sub-subparagraphs a. and b.

3. For up to two of the licenses issued under subparagraph 2., the department shall give preference to applicants that demonstrate in their applications that they own one or more facilities that are, or were, used for the canning, concentrating, or otherwise processing of citrus fruit or citrus molasses and will use or convert the facility or facilities for the processing of marijuana.

4. Within 6 months after the registration of 100,000 active qualified patients in the medical marijuana use registry, the department shall license four additional medical marijuana treatment centers that meet the requirements of this section. Thereafter, the department shall license four medical marijuana treatment centers within 6 months after the registration of each additional 100,000 active qualified patients in the medical marijuana use registry that meet the requirements of this section.

5. Dispensing facilities are subject to the following requirements:

a. A medical marijuana treatment center may not establish or operate more than a statewide maximum of 25 dispensing facilities, unless the medical marijuana use registry reaches a total of 100,000 active registered qualified patients. When the medical marijuana use registry reaches 100,000 active registered qualified patients, and then upon each further instance of the total active registered

qualified patients increasing by 100,000, the statewide maximum number of dispensing facilities that each licensed medical marijuana treatment center may establish and operate increases by five.

b. A medical marijuana treatment center may not establish more than the maximum number of dispensing facilities allowed in each of the Northwest, Northeast, Central, Southwest, and Southeast Regions. The department shall determine a medical marijuana treatment center's maximum number of dispensing facilities allowed in each region by calculating the percentage of the total statewide population contained within that region and multiplying that percentage by the medical marijuana treatment center's statewide maximum number of dispensing facilities established under sub-subparagraph a., rounded to the nearest whole number. The department shall ensure that such rounding does not cause a medical marijuana treatment center's total number of statewide dispensing facilities to exceed its statewide maximum. The department shall initially calculate the maximum number of dispensing facilities allowed in each region for each medical marijuana treatment center using county population estimates from the Florida Estimates of Population 2016, as published by the Office of Economic and Demographic Research, and shall perform recalculations following the official release of county population data resulting from each United States Decennial Census. For the purposes of this subparagraph:

(I) The Northwest Region consists of Bay, Calhoun, Escambia, Franklin, Gadsden, Gulf, Holmes, Jackson, Jefferson, Leon, Liberty, Madison, Okaloosa, Santa Rosa, Taylor, Wakulla, Walton, and Washington Counties.

(II) The Northeast Region consists of Alachua, Baker, Bradford, Clay, Columbia, Dixie, Duval, Flagler, Gilchrist, Hamilton, Lafayette, Levy, Marion, Nassau, Putnam, St. Johns, Suwannee, and Union Counties.

(III) The Central Region consists of Brevard, Citrus, Hardee, Hernando, Indian River, Lake, Orange, Osceola, Pasco, Pinellas, Polk, Seminole, St. Lucie, Sumter, and Volusia Counties.

(IV) The Southwest Region consists of Charlotte, Collier, DeSoto, Glades, Hendry, Highlands, Hillsborough, Lee, Manatee, Okeechobee, and Sarasota Counties.

(V) The Southeast Region consists of Broward, Miami-Dade, Martin, Monroe, and Palm Beach Counties.

c. If a medical marijuana treatment center establishes a number of dispensing facilities within a region that is less than the number allowed for that region under sub-subparagraph b., the medical marijuana treatment center may sell one or more of its unused dispensing facility slots to other licensed medical marijuana treatment centers. For each dispensing facility slot that a medical marijuana treatment center sells, that medical marijuana treatment center's statewide maximum number of dispensing facilities, as determined under sub-subparagraph a., is reduced by one. The statewide maximum number of dispensing facilities for a medical marijuana treatment center that purchases an unused dispensing facility slot is increased by one per slot purchased. Additionally, the sale of a dispensing facility slot shall reduce the seller's regional maximum and increase the purchaser's regional maximum number of dispensing facilities, as determined in sub-subparagraph b., by one for that region. For any slot purchased under this sub-subparagraph, the regional restriction applied to that slot's location under sub-subparagraph b. before the purchase shall remain in effect following the purchase. A medical marijuana treatment center that sells or purchases a dispensing facility slot must notify the department within 3 days of sale.

d. This subparagraph shall expire on April 1, 2020.

If this subparagraph or its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of this act which can be given effect without the invalid provision or application, and to this end, the provisions of this subparagraph are severable.

(b) An applicant for licensure as a medical marijuana treatment center shall apply to the department on a form prescribed by the department and adopted in rule. The department shall adopt rules pursuant to ss. 120.536(1) and 120.54 establishing a procedure for the issuance and biennial renewal of licenses, including initial application and biennial renewal fees sufficient to cover the costs of implementing and administering this section, and establishing supplemental licensure fees for payment beginning May 1, 2018, sufficient to cover the costs of administering ss. 381.989 and 1004.4351. The department shall identify applicants with strong diversity plans reflecting this state's commitment to diversity and implement training programs and other educational programs to enable minority persons and minority business enterprises, as defined in s. 288.703, and veteran business enterprises, as defined in s. 295.187, to compete for medical marijuana treatment center licensure and contracts. Subject to the requirements in subparagraphs (a)2.-4., the department shall issue a license to an applicant if the applicant meets the requirements of this section and pays the initial application fee. The department shall renew the licensure of a medical marijuana treatment center biennially if the licensee meets the requirements of this section and pays the biennial renewal fee. An individual may not be an applicant, owner, officer, board member, or manager on more than one application for licensure as a medical marijuana treatment center. An individual or entity may not be awarded more than one license as a medical marijuana treatment center. An applicant for licensure as a medical marijuana treatment center must demonstrate:

1. That, for the 5 consecutive years before submitting the application, the applicant has been registered to do business in the state.

2. Possession of a valid certificate of registration issued by the Department of Agriculture and Consumer Services pursuant to s. 581.131.

3. The technical and technological ability to cultivate and produce marijuana, including, but not limited to, low-THC cannabis.

4. The ability to secure the premises, resources, and personnel necessary to operate as a medical marijuana treatment center.

5. 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.

6. An infrastructure reasonably located to dispense marijuana to registered qualified patients statewide or regionally as determined by the department.

7. The financial ability to maintain operations for the duration of the 2-year approval cycle, including the provision of certified financial statements to the department.

a. Upon approval, the applicant must post a $5 million performance bond issued by an authorized surety insurance company rated in one of the three highest rating categories by a nationally recognized rating service. However, a medical marijuana treatment center serving at least 1,000 qualified patients is only required to maintain a $2 million performance bond.

b. In lieu of the performance bond required under sub-subparagraph a., the applicant may provide an irrevocable letter of credit payable to the department or provide cash to the department. If provided with cash under this sub-subparagraph, the department shall deposit the cash in the Grants and Donations Trust Fund within the Department of Health, subject to the same conditions as the bond regarding requirements for the applicant to forfeit ownership of the funds. If the funds deposited under

this sub-subparagraph generate interest, the amount of that interest shall be used by the department for the administration of this section.

8. That all owners, officers, board members, and managers have passed a background screening pursuant to subsection (9).

9. The employment of a medical director to supervise the activities of the medical marijuana treatment center.

10. A diversity plan that promotes and ensures the involvement of minority persons and minority business enterprises, as defined in s. 288.703, or veteran business enterprises, as defined in s. 295.187, in ownership, management, and employment. An applicant for licensure renewal must show the effectiveness of the diversity plan by including the following with his or her application for renewal:

a. Representation of minority persons and veterans in the medical marijuana treatment center's workforce;

b. Efforts to recruit minority persons and veterans for employment; and

c. A record of contracts for services with minority business enterprises and veteran business enterprises.

(c) A medical marijuana treatment center may not make a wholesale purchase of marijuana from, or a distribution of marijuana to, another medical marijuana treatment center, unless the medical marijuana treatment center seeking to make a wholesale purchase of marijuana submits proof of harvest failure to the department.

(d) The department shall establish, maintain, and control a computer software tracking system that traces marijuana from seed to sale and allows real-time, 24-hour access by the department to data from all medical marijuana treatment centers and marijuana testing laboratories. The tracking system must allow for integration of other seed-to-sale systems and, at a minimum, include notification of when marijuana seeds are planted, when marijuana plants are harvested and destroyed, and when marijuana is transported, sold, stolen, diverted, or lost. Each medical marijuana treatment center shall use the seed-to-sale tracking system established by the department or integrate its own seed-to-sale tracking system with the seed-to-sale tracking system established by the department. Each medical marijuana treatment center may use its own seed-to-sale system until the department establishes a seed-to-sale tracking system. The department may contract with a vendor to establish the seed-to-sale tracking system. The vendor selected by the department may not have a contractual relationship with the department to perform any services pursuant to this section other than the seed-to-sale tracking system. The vendor may not have a direct or indirect financial interest in a medical marijuana treatment center or a marijuana testing laboratory.

(e) A licensed medical marijuana treatment center shall cultivate, process, transport, and dispense marijuana for medical use. A licensed medical marijuana treatment center may not contract for services directly related to the cultivation, processing, and dispensing of marijuana or marijuana delivery devices, except that a medical marijuana treatment center licensed pursuant to subparagraph (a)1. may contract with a single entity for the cultivation, processing, transporting, and dispensing of marijuana and marijuana delivery devices. A licensed medical marijuana treatment center must, at all times, maintain compliance with the criteria demonstrated and representations made in the initial application and the criteria established in this subsection. Upon request, the department may grant a medical marijuana treatment center a variance from the representations made in the initial application. Consideration of such a request shall be based upon the individual facts and circumstances surrounding the request. A variance may not be granted unless the requesting medical marijuana treatment center can demonstrate to the department that it has a proposed alternative to the specific representation

made in its application which fulfills the same or a similar purpose as the specific representation in a way that the department can reasonably determine will not be a lower standard than the specific representation in the application. A variance may not be granted from the requirements in subparagraph 2. and subparagraphs (b)1. and 2.

1. A licensed medical marijuana treatment center may transfer ownership to an individual or entity who meets the requirements of this section. A publicly traded corporation or publicly traded company that meets the requirements of this section is not precluded from ownership of a medical marijuana treatment center. To accommodate a change in ownership:

a. The licensed medical marijuana treatment center shall notify the department in writing at least 60 days before the anticipated date of the change of ownership.

b. The individual or entity applying for initial licensure due to a change of ownership must submit an application that must be received by the department at least 60 days before the date of change of ownership.

c. Upon receipt of an application for a license, the department shall examine the application and, within 30 days after receipt, notify the applicant in writing of any apparent errors or omissions and request any additional information required.

d. Requested information omitted from an application for licensure must be filed with the department within 21 days after the department's request for omitted information or the application shall be deemed incomplete and shall be withdrawn from further consideration and the fees shall be forfeited.

Within 30 days after the receipt of a complete application, the department shall approve or deny the application.

2. A medical marijuana treatment center, and any individual or entity who directly or indirectly owns, controls, or holds with power to vote 5 percent or more of the voting shares of a medical marijuana treatment center, may not acquire direct or indirect ownership or control of any voting shares or other form of ownership of any other medical marijuana treatment center.

3. A medical marijuana treatment center may not enter into any form of profit-sharing arrangement with the property owner or lessor of any of its facilities where cultivation, processing, storing, or dispensing of marijuana and marijuana delivery devices occurs.

4. All employees of a medical marijuana treatment center must be 21 years of age or older and have passed a background screening pursuant to subsection (9).

5. Each medical marijuana treatment center must adopt and enforce policies and procedures to ensure employees and volunteers receive training on the legal requirements to dispense marijuana to qualified patients.

6. When growing marijuana, a medical marijuana treatment center:

a. May use pesticides determined by the department, after consultation with the Department of Agriculture and Consumer Services, to be safely applied to plants intended for human consumption, but may not use pesticides designated as restricted-use pesticides pursuant to s. 487.042.

b. Must grow marijuana within an enclosed structure and in a room separate from any other plant.

c. Must inspect seeds and growing plants for plant pests that endanger or threaten the horticultural and agricultural interests of the state in accordance with chapter 581 and any rules adopted thereunder.

d. Must perform fumigation or treatment of plants, or remove and destroy infested or infected plants, in accordance with chapter 581 and any rules adopted thereunder.

7. Each medical marijuana treatment center must produce and make available for purchase at least one low-THC cannabis product.

8. A medical marijuana treatment center that produces edibles must hold a permit to operate as a food establishment pursuant to chapter 500, the Florida Food Safety Act, and must comply with all the requirements for food establishments pursuant to chapter 500 and any rules adopted thereunder. Edibles may not contain more than 200 milligrams of tetrahydrocannabinol, and a single serving portion of an edible may not exceed 10 milligrams of tetrahydrocannabinol. Edibles may have a potency variance of no greater than 15 percent. Edibles may not be attractive to children; be manufactured in the shape of humans, cartoons, or animals; be manufactured in a form that bears any reasonable resemblance to products available for consumption as commercially available candy; or contain any color additives. To discourage consumption of edibles by children, the department shall determine by rule any shapes, forms, and ingredients allowed and prohibited for edibles. Medical marijuana treatment centers may not begin processing or dispensing edibles until after the effective date of the rule. The department shall also adopt sanitation rules providing the standards and requirements for the storage, display, or dispensing of edibles.

9. Within 12 months after licensure, a medical marijuana treatment center must demonstrate to the department that all of its processing facilities have passed a Food Safety Good Manufacturing Practices, such as Global Food Safety Initiative or equivalent, inspection by a nationally accredited certifying body. A medical marijuana treatment center must immediately stop processing at any facility which fails to pass this inspection until it demonstrates to the department that such facility has met this requirement.

10. When processing marijuana, a medical marijuana treatment center must:

a. Process the marijuana within an enclosed structure and in a room separate from other plants or products.

b. Comply with department rules when processing marijuana with hydrocarbon solvents or other solvents or gases exhibiting potential toxicity to humans. The department shall determine by rule the requirements for medical marijuana treatment centers to use such solvents or gases exhibiting potential toxicity to humans.

c. Comply with federal and state laws and regulations and department rules for solid and liquid wastes. The department shall determine by rule procedures for the storage, handling, transportation, management, and disposal of solid and liquid waste generated during marijuana production and processing. The Department of Environmental Protection shall assist the department in developing such rules.

d. Test the processed marijuana using a medical marijuana testing laboratory before it is dispensed. Results must be verified and signed by two medical marijuana treatment center employees. Before dispensing, the medical marijuana treatment center must determine that the test results indicate that low-THC cannabis meets the definition of low-THC cannabis, the concentration of tetrahydrocannabinol meets the potency requirements of this section, the labeling of the concentration of tetrahydrocannabinol and cannabidiol is accurate, and all marijuana is safe for human consumption and free from contaminants that are unsafe for human consumption. The department shall determine by rule which contaminants must be tested for and the maximum levels of each contaminant which are safe for human consumption. The Department of Agriculture and Consumer Services shall assist the department in developing the testing requirements for contaminants that are unsafe for human consumption in edibles. The department shall also determine by rule the procedures for the treatment of marijuana that fails to meet the testing requirements of this section, s. 381.988, or department rule. The department may select a random sample from edibles available for purchase in a dispensing facility

which shall be tested by the department to determine that the edible meets the potency requirements of this section, is safe for human consumption, and the labeling of the tetrahydrocannabinol and cannabidiol concentration is accurate. A medical marijuana treatment center may not require payment from the department for the sample. A medical marijuana treatment center must recall edibles, including all edibles made from the same batch of marijuana, which fail to meet the potency requirements of this section, which are unsafe for human consumption, or for which the labeling of the tetrahydrocannabinol and cannabidiol concentration is inaccurate. The medical marijuana treatment center must retain records of all testing and samples of each homogenous batch of marijuana for at least 9 months. The medical marijuana treatment center must contract with a marijuana testing laboratory to perform audits on the medical marijuana treatment center's standard operating procedures, testing records, and samples and provide the results to the department to confirm that the marijuana or low-THC cannabis meets the requirements of this section and that the marijuana or low-THC cannabis is safe for human consumption. A medical marijuana treatment center shall reserve two processed samples from each batch and retain such samples for at least 9 months for the purpose of such audits. A medical marijuana treatment center may use a laboratory that has not been certified by the department under s. 381.988 until such time as at least one laboratory holds the required certification, but in no event later than July 1, 2018.

e. Package the marijuana in compliance with the United States Poison Prevention Packaging Act of 1970, 15 U.S.C. ss. 1471 et seq.

f. Package the marijuana in a receptacle that has a firmly affixed and legible label stating the following information:

(I) The marijuana or low-THC cannabis meets the requirements of sub-subparagraph d.

(II) The name of the medical marijuana treatment center from which the marijuana originates.

(III) The batch number and harvest number from which the marijuana originates and the date dispensed.

(IV) The name of the physician who issued the physician certification.

(V) The name of the patient.

(VI) The product name, if applicable, and dosage form, including concentration of tetrahydrocannabinol and cannabidiol. The product name may not contain wording commonly associated with products marketed by or to children.

(VII) The recommended dose.

(VIII) A warning that it is illegal to transfer medical marijuana to another person.

(IX) A marijuana universal symbol developed by the department.

11. The medical marijuana treatment center shall include in each package a patient package insert with information on the specific product dispensed related to:

a. Clinical pharmacology.

b. Indications and use.

c. Dosage and administration.

d. Dosage forms and strengths.

e. Contraindications.

f. Warnings and precautions.

g. Adverse reactions.

12. Each edible shall be individually sealed in plain, opaque wrapping marked only with the marijuana universal symbol. Where practical, each edible shall be marked with the marijuana universal symbol. In addition to the packaging and labeling requirements in subparagraphs 10. and 11., edible

receptacles must be plain, opaque, and white without depictions of the product or images other than the medical marijuana treatment center's department-approved logo and the marijuana universal symbol. The receptacle must also include a list all of the edible's ingredients, storage instructions, an expiration date, a legible and prominent warning to keep away from children and pets, and a warning that the edible has not been produced or inspected pursuant to federal food safety laws.

13. When dispensing marijuana or a marijuana delivery device, a medical marijuana treatment center:

a. May dispense any active, valid order for low-THC cannabis, medical cannabis and cannabis delivery devices issued pursuant to former s. 381.986, Florida Statutes 2016, which was entered into the medical marijuana use registry before July 1, 2017.

b. May not dispense more than a 70-day supply of marijuana to a qualified patient or caregiver.

c. Must have the medical marijuana treatment center's employee who dispenses the marijuana or a marijuana delivery device enter into the medical marijuana use registry his or her name or unique employee identifier.

d. Must verify that the qualified patient and the caregiver, if applicable, each have an active registration in the medical marijuana use registry and an active and valid medical marijuana use registry identification card, the amount and type of marijuana dispensed matches the physician certification in the medical marijuana use registry for that qualified patient, and the physician certification has not already been filled.

e. May not dispense marijuana to a qualified patient who is younger than 18 years of age. If the qualified patient is younger than 18 years of age, marijuana may only be dispensed to the qualified patient's caregiver.

f. May not dispense or sell any other type of cannabis, alcohol, or illicit drug-related product, including pipes, bongs, or wrapping papers, other than a marijuana delivery device required for the medical use of marijuana and which is specified in a physician certification.

g. Must, upon dispensing the marijuana or marijuana delivery device, record in the registry the date, time, quantity, and form of marijuana dispensed; the type of marijuana delivery device dispensed; and the name and medical marijuana use registry identification number of the qualified patient or caregiver to whom the marijuana delivery device was dispensed.

h. Must ensure that patient records are not visible to anyone other than the qualified patient, his or her caregiver, and authorized medical marijuana treatment center employees.

(f) To ensure the safety and security of premises where the cultivation, processing, storing, or dispensing of marijuana occurs, and to maintain adequate controls against the diversion, theft, and loss of marijuana or marijuana delivery devices, a medical marijuana treatment center shall:

1.a. Maintain a fully operational security alarm system that secures all entry points and perimeter windows and is equipped with motion detectors; pressure switches; and duress, panic, and hold-up alarms; and

b. Maintain a video surveillance system that records continuously 24 hours a day and meets the following criteria:

(I) Cameras are fixed in a place that allows for the clear identification of persons and activities in controlled areas of the premises. Controlled areas include grow rooms, processing rooms, storage rooms, disposal rooms or areas, and point-of-sale rooms.

(II) Cameras are fixed in entrances and exits to the premises, which shall record from both indoor and outdoor, or ingress and egress, vantage points.

(III) Recorded images must clearly and accurately display the time and date.

(IV) Retain video surveillance recordings for at least 45 days or longer upon the request of a law enforcement agency.

2. Ensure that the medical marijuana treatment center's outdoor premises have sufficient lighting from dusk until dawn.

3. Ensure that the indoor premises where dispensing occurs includes a waiting area with sufficient space and seating to accommodate qualified patients and caregivers and at least one private consultation area that is isolated from the waiting area and area where dispensing occurs. A medical marijuana treatment center may not display products or dispense marijuana or marijuana delivery devices in the waiting area.

4. Not dispense from its premises marijuana or a marijuana delivery device between the hours of 9 p.m. and 7 a.m., but may perform all other operations and deliver marijuana to qualified patients 24 hours a day.

5. Store marijuana in a secured, locked room or a vault.

6. Require at least two of its employees, or two employees of a security agency with whom it contracts, to be on the premises at all times where cultivation, processing, or storing of marijuana occurs.

7. Require each employee or contractor to wear a photo identification badge at all times while on the premises.

8. Require each visitor to wear a visitor pass at all times while on the premises.

9. Implement an alcohol and drug-free workplace policy.

10. Report to local law enforcement within 24 hours after the medical marijuana treatment center is notified or becomes aware of the theft, diversion, or loss of marijuana.

(g) To ensure the safe transport of marijuana and marijuana delivery devices to medical marijuana treatment centers, marijuana testing laboratories, or qualified patients, a medical marijuana treatment center must:

1. Maintain a marijuana transportation manifest in any vehicle transporting marijuana. The marijuana transportation manifest must be generated from a medical marijuana treatment center's seed-to-sale tracking system and include the:

a. Departure date and approximate time of departure.

b. Name, location address, and license number of the originating medical marijuana treatment center.

c. Name and address of the recipient of the delivery.

d. Quantity and form of any marijuana or marijuana delivery device being transported.

e. Arrival date and estimated time of arrival.

f. Delivery vehicle make and model and license plate number.

g. Name and signature of the medical marijuana treatment center employees delivering the product.

(I) A copy of the marijuana transportation manifest must be provided to each individual, medical marijuana treatment center, or marijuana testing laboratory that receives a delivery. The individual, or a representative of the center or laboratory, must sign a copy of the marijuana transportation manifest acknowledging receipt.

(II) An individual transporting marijuana or a marijuana delivery device must present a copy of the relevant marijuana transportation manifest and his or her employee identification card to a law enforcement officer upon request.

(III) Medical marijuana treatment centers and marijuana testing laboratories must retain copies of all marijuana transportation manifests for at least 3 years.

2. Ensure only vehicles in good working order are used to transport marijuana.

3. Lock marijuana and marijuana delivery devices in a separate compartment or container within the vehicle.

4. Require employees to have possession of their employee identification card at all times when transporting marijuana or marijuana delivery devices.

5. Require at least two persons to be in a vehicle transporting marijuana or marijuana delivery devices, and require at least one person to remain in the vehicle while the marijuana or marijuana delivery device is being delivered.

6. Provide specific safety and security training to employees transporting or delivering marijuana and marijuana delivery devices.

(h) A medical marijuana treatment center may not engage in advertising that is visible to members of the public from any street, sidewalk, park, or other public place, except:

1. The dispensing location of a medical marijuana treatment center may have a sign that is affixed to the outside or hanging in the window of the premises which identifies the dispensary by the licensee's business name, a department-approved trade name, or a department-approved logo. A medical marijuana treatment center's trade name and logo may not contain wording or images commonly associated with marketing targeted toward children or which promote recreational use of marijuana.

2. A medical marijuana treatment center may engage in Internet advertising and marketing under the following conditions:

a. All advertisements must be approved by the department.

b. An advertisement may not have any content that specifically targets individuals under the age of 18, including cartoon characters or similar images.

c. An advertisement may not be an unsolicited pop-up advertisement.

d. Opt-in marketing must include an easy and permanent opt-out feature.

(i) Each medical marijuana treatment center that dispenses marijuana and marijuana delivery devices shall make available to the public on its website:

1. Each marijuana and low-THC product available for purchase, including the form, strain of marijuana from which it was extracted, cannabidiol content, tetrahydrocannabinol content, dose unit, total number of doses available, and the ratio of cannabidiol to tetrahydrocannabinol for each product.

2. The price for a 30-day, 50-day, and 70-day supply at a standard dose for each marijuana and low-THC product available for purchase.

3. The price for each marijuana delivery device available for purchase.

4. If applicable, any discount policies and eligibility criteria for such discounts.

(j) Medical marijuana treatment centers are the sole source from which a qualified patient may legally obtain marijuana.

(k) The department may adopt rules pursuant to ss. 120.536(1) and 120.54 to implement this subsection.

(9) BACKGROUND SCREENING.—An individual required to undergo a background screening pursuant to this section must pass a level 2 background screening as provided under chapter 435, which, in addition to the disqualifying offenses provided in s. 435.04, shall exclude an individual who has an arrest awaiting final disposition for, has been found guilty of, regardless of adjudication, or has entered a plea of nolo contendere or guilty to an offense under chapter 837, chapter 895, or chapter 896 or similar law of another jurisdiction.

(a) Such individual must submit a full set of fingerprints to the department or to a vendor, entity, or agency authorized by s. 943.053(13). The department, vendor, entity, or agency shall forward the fingerprints to the Department of Law Enforcement for state processing, and the Department of Law Enforcement shall forward the fingerprints to the Federal Bureau of Investigation for national processing.

(b) Fees for state and federal fingerprint processing and retention shall be borne by the individual. The state cost for fingerprint processing shall be as provided in s. 943.053(3)(e) for records provided to persons or entities other than those specified as exceptions therein.

(c) Fingerprints submitted to the Department of Law Enforcement pursuant to this subsection shall be retained by the Department of Law Enforcement as provided in s. 943.05(2)(g) and (h) and, when the Department of Law Enforcement begins participation in the program, enrolled in the Federal Bureau of Investigation's national retained print arrest notification program. Any arrest record identified shall be reported to the department.

(10) MEDICAL MARIJUANA TREATMENT CENTER INSPECTIONS; ADMINISTRATIVE ACTIONS.—

(a) The department shall conduct announced or unannounced inspections of medical marijuana treatment centers to determine compliance with this section or rules adopted pursuant to this section.

(b) The department shall inspect a medical marijuana treatment center upon receiving a complaint or notice that the medical marijuana treatment center has dispensed marijuana containing mold, bacteria, or other contaminant that may cause or has caused an adverse effect to human health or the environment.

(c) The department shall conduct at least a biennial inspection of each medical marijuana treatment center to evaluate the medical marijuana treatment center's records, personnel, equipment, processes, security measures, sanitation practices, and quality assurance practices.

(d) The Department of Agriculture and Consumer Services and the department shall enter into an interagency agreement to ensure cooperation and coordination in the performance of their obligations under this section and their respective regulatory and authorizing laws. The department, the Department of Highway Safety and Motor Vehicles, and the Department of Law Enforcement may enter into interagency agreements for the purposes specified in this subsection or subsection (7).

(e) The department shall publish a list of all approved medical marijuana treatment centers, medical directors, and qualified physicians on its website.

(f) The department may impose reasonable fines not to exceed $10,000 on a medical marijuana treatment center for any of the following violations:

1. Violating this section or department rule.
2. Failing to maintain qualifications for approval.
3. Endangering the health, safety, or security of a qualified patient.
4. Improperly disclosing personal and confidential information of the qualified patient.
5. Attempting to procure medical marijuana treatment center approval by bribery, fraudulent misrepresentation, or extortion.
6. Being convicted or found guilty of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which directly relates to the business of a medical marijuana treatment center.
7. Making or filing a report or record that the medical marijuana treatment center knows to be false.
8. Willfully failing to maintain a record required by this section or department rule.

9. Willfully impeding or obstructing an employee or agent of the department in the furtherance of his or her official duties.

10. Engaging in fraud or deceit, negligence, incompetence, or misconduct in the business practices of a medical marijuana treatment center.

11. Making misleading, deceptive, or fraudulent representations in or related to the business practices of a medical marijuana treatment center.

12. Having a license or the authority to engage in any regulated profession, occupation, or business that is related to the business practices of a medical marijuana treatment center suspended, revoked, or otherwise acted against by the licensing authority of any jurisdiction, including its agencies or subdivisions, for a violation that would constitute a violation under Florida law.

13. Violating a lawful order of the department or an agency of the state, or failing to comply with a lawfully issued subpoena of the department or an agency of the state.

(g) The department may suspend, revoke, or refuse to renew a medical marijuana treatment center license if the medical marijuana treatment center commits any of the violations in paragraph (f).

(h) The department may adopt rules pursuant to ss. 120.536(1) and 120.54 to implement this subsection.

(11) PREEMPTION.—Regulation of cultivation, processing, and delivery of marijuana by medical marijuana treatment centers is preempted to the state except as provided in this subsection.

(a) A medical marijuana treatment center cultivating or processing facility may not be located within 500 feet of the real property that comprises a public or private elementary school, middle school, or secondary school.

(b)1. A county or municipality may, by ordinance, ban medical marijuana treatment center dispensing facilities from being located within the boundaries of that county or municipality. A county or municipality that does not ban dispensing facilities under this subparagraph may not place specific limits, by ordinance, on the number of dispensing facilities that may locate within that county or municipality.

2. A municipality may determine by ordinance the criteria for the location of, and other permitting requirements that do not conflict with state law or department rule for, medical marijuana treatment center dispensing facilities located within the boundaries of that municipality. A county may determine by ordinance the criteria for the location of, and other permitting requirements that do not conflict with state law or department rule for, all such dispensing facilities located within the unincorporated areas of that county. Except as provided in paragraph (c), a county or municipality may not enact ordinances for permitting or for determining the location of dispensing facilities which are more restrictive than its ordinances permitting or determining the locations for pharmacies licensed under chapter 465. A municipality or county may not charge a medical marijuana treatment center a license or permit fee in an amount greater than the fee charged by such municipality or county to pharmacies. A dispensing facility location approved by a municipality or county pursuant to former s. 381.986(8)(b), Florida Statutes 2016, is not subject to the location requirements of this subsection.

(c) A medical marijuana treatment center dispensing facility may not be located within 500 feet of the real property that comprises a public or private elementary school, middle school, or secondary school unless the county or municipality approves the location through a formal proceeding open to the public at which the county or municipality determines that the location promotes the public health, safety, and general welfare of the community.

(d) This subsection does not prohibit any local jurisdiction from ensuring medical marijuana treatment center facilities comply with the Florida Building Code, the Florida Fire Prevention Code, or any local amendments to the Florida Building Code or the Florida Fire Prevention Code.

(12) PENALTIES.—

(a) A qualified physician commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083, if the qualified physician issues a physician certification for the medical use of marijuana for a patient without a reasonable belief that the patient is suffering from a qualifying medical condition.

(b) A person who fraudulently represents that he or she has a qualifying medical condition to a qualified physician for the purpose of being issued a physician certification commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(c) A qualified patient who uses marijuana, not including low-THC cannabis, or a caregiver who administers marijuana, not including low-THC cannabis, in plain view of or in a place open to the general public; in a school bus, a vehicle, an aircraft, or a boat; or on the grounds of a school except as provided in s. 1006.062, commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(d) A qualified patient or caregiver who cultivates marijuana or who purchases or acquires marijuana from any person or entity other than a medical marijuana treatment center violates s. 893.13 and is subject to the penalties provided therein.

(e)1. A qualified patient or caregiver in possession of marijuana or a marijuana delivery device who fails or refuses to present his or her marijuana use registry identification card upon the request of a law enforcement officer commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083, unless it can be determined through the medical marijuana use registry that the person is authorized to be in possession of that marijuana or marijuana delivery device.

2. A person charged with a violation of this paragraph may not be convicted if, before or at the time of his or her court or hearing appearance, the person produces in court or to the clerk of the court in which the charge is pending a medical marijuana use registry identification card issued to him or her which is valid at the time of his or her arrest. The clerk of the court is authorized to dismiss such case at any time before the defendant's appearance in court. The clerk of the court may assess a fee of $5 for dismissing the case under this paragraph.

(f) A caregiver who violates any of the applicable provisions of this section or applicable department rules, for the first offense, commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083 and, for a second or subsequent offense, commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(g) A qualified physician who issues a physician certification for marijuana or a marijuana delivery device and receives compensation from a medical marijuana treatment center related to the issuance of a physician certification for marijuana or a marijuana delivery device is subject to disciplinary action under the applicable practice act and s. 456.072(1)(n).

(h) A person transporting marijuana or marijuana delivery devices on behalf of a medical marijuana treatment center or marijuana testing laboratory who fails or refuses to present a transportation manifest upon the request of a law enforcement officer commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083.

(i) Persons and entities conducting activities authorized and governed by this section and s. 381.988 are subject to ss. 456.053, 456.054, and 817.505, as applicable.

(j) A person or entity that cultivates, processes, distributes, sells, or dispenses marijuana, as defined in s. 29(b)(4), Art. X of the State Constitution, and is not licensed as a medical marijuana treatment center violates s. 893.13 and is subject to the penalties provided therein.

(k) A person who manufactures, distributes, sells, gives, or possesses with the intent to manufacture, distribute, sell, or give marijuana or a marijuana delivery device that he or she holds out to have originated from a licensed medical marijuana treatment center but that is counterfeit commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. For the purposes of this paragraph, the term "counterfeit" means marijuana; a marijuana delivery device; or a marijuana or marijuana delivery device container, seal, or label which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a licensed medical marijuana treatment center and which thereby falsely purports or is represented to be the product of, or to have been distributed by, that licensed medical marijuana treatment facility.

(l) Any person who possesses or manufactures a blank, forged, stolen, fictitious, fraudulent, counterfeit, or otherwise unlawfully issued medical marijuana use registry identification card commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(13) UNLICENSED ACTIVITY.—

(a) If the department has probable cause to believe that a person or entity that is not registered or licensed with the department has violated this section, s. 381.988, or any rule adopted pursuant to this section, the department may issue and deliver to such person or entity a notice to cease and desist from such violation. The department also may issue and deliver a notice to cease and desist to any person or entity who aids and abets such unlicensed activity. The issuance of a notice to cease and desist does not constitute agency action for which a hearing under s. 120.569 or s. 120.57 may be sought. For the purpose of enforcing a cease and desist order, the department may file a proceeding in the name of the state seeking issuance of an injunction or a writ of mandamus against any person or entity who violates any provisions of such order.

(b) In addition to the remedies under paragraph (a), the department may impose by citation an administrative penalty not to exceed $5,000 per incident. The citation shall be issued to the subject and must contain the subject's name and any other information the department determines to be necessary to identify the subject, a brief factual statement, the sections of the law allegedly violated, and the penalty imposed. If the subject does not dispute the matter in the citation with the department within 30 days after the citation is served, the citation shall become a final order of the department. The department may adopt rules pursuant to ss. 120.536(1) and 120.54 to implement this section. Each day that the unlicensed activity continues after issuance of a notice to cease and desist constitutes a separate violation. The department shall be entitled to recover the costs of investigation and prosecution in addition to the fine levied pursuant to the citation. Service of a citation may be made by personal service or by mail to the subject at the subject's last known address or place of practice. If the department is required to seek enforcement of the cease and desist or agency order, it shall be entitled to collect attorney fees and costs.

(c) In addition to or in lieu of any other administrative remedy, the department may seek the imposition of a civil penalty through the circuit court for any violation for which the department may issue a notice to cease and desist. The civil penalty shall be no less than $5,000 and no more than $10,000 for each offense. The court may also award to the prevailing party court costs and reasonable attorney fees and, in the event the department prevails, may also award reasonable costs of investigation and prosecution.

(d) In addition to the other remedies provided in this section, the department or any state attorney may bring an action for an injunction to restrain any unlicensed activity or to enjoin the future operation or maintenance of the unlicensed activity or the performance of any service in violation of this section.

(e) The department must notify local law enforcement of such unlicensed activity for a determination of any criminal violation of chapter 893.

(14) EXCEPTIONS TO OTHER LAWS.—

(a) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or any other provision of law, but subject to the requirements of this section, a qualified patient and the qualified patient's caregiver may purchase from a medical marijuana treatment center for the patient's medical use a marijuana delivery device and up to the amount of marijuana authorized in the physician certification, but may not possess more than a 70-day supply of marijuana at any given time and all marijuana purchased must remain in its original packaging.

(b) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or any other provision of law, but subject to the requirements of this section, an approved medical marijuana treatment center and its owners, managers, and employees may manufacture, possess, sell, deliver, distribute, dispense, and lawfully dispose of marijuana or a marijuana delivery device as provided in this section, s. 381.988, and by department rule. For the purposes of this subsection, the terms "manufacture," "possession," "deliver," "distribute," and "dispense" have the same meanings as provided in s. 893.02.

(c) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or any other provision of law, but subject to the requirements of this section, a certified marijuana testing laboratory, including an employee of a certified marijuana testing laboratory acting within the scope of his or her employment, may acquire, possess, test, transport, and lawfully dispose of marijuana as provided in this section, in s. 381.988, and by department rule.

(d) A licensed medical marijuana treatment center and its owners, managers, and employees are not subject to licensure or regulation under chapter 465 or chapter 499 for manufacturing, possessing, selling, delivering, distributing, dispensing, or lawfully disposing of marijuana or a marijuana delivery device, as provided in this section, [3]in s. 381.988, and by department rule.

(e) This subsection does not exempt a person from prosecution for a criminal offense related to impairment or intoxication resulting from the medical use of marijuana or relieve a person from any requirement under law to submit to a breath, blood, urine, or other test to detect the presence of a controlled substance.

(f) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or any other provision of law, but subject to the requirements of this section and pursuant to policies and procedures established pursuant to s. 1006.62(8), school personnel may possess marijuana that is obtained for medical use pursuant to this section by a student who is a qualified patient.

(g) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or any other provision of law, but subject to the requirements of this section, a research institute established by a public postsecondary educational institution, such as the H. Lee Moffitt Cancer Center and Research Institute, Inc., established under s. 1004.43, or a state university that has achieved the preeminent state research university designation under s. 1001.7065 may possess, test, transport, and lawfully dispose of marijuana for research purposes as provided by this section.

(15) APPLICABILITY.—This section does not limit the ability of an employer to establish, continue, or enforce a drug-free workplace program or policy. This section does not require an employer to accommodate the medical use of marijuana in any workplace or any employee working while under the

influence of marijuana. This section does not create a cause of action against an employer for wrongful discharge or discrimination. Marijuana, as defined in this section, is not reimbursable under chapter 440.

(16) FINES AND FEES.—Fines and fees collected by the department under this section shall be deposited in the Grants and Donations Trust Fund within the Department of Health.

History.—s. 2, ch. 2014-157; s. 1, ch. 2016-123; s. 24, ch. 2016-145; ss. 1, 3, 18, ch. 2017-232.

[1]**Note.**—

A. Section 1, ch. 2017-232, provides that "[i]t is the intent of the Legislature to implement s. 29, Article X of the State Constitution by creating a unified regulatory structure. If s. 29, Article X of the State Constitution is amended or a constitutional amendment related to cannabis or marijuana is adopted, this act shall expire 6 months after the effective date of such amendment." If such amendment or adoption takes place, s. 381.986, as amended by s. 1, ch. 2017-232, will read:

381.986 Compassionate use of low-THC and medical cannabis.—

(1) DEFINITIONS.—As used in this section, the term:

(a) "Cannabis delivery device" means an object used, intended for use, or designed for use in preparing, storing, ingesting, inhaling, or otherwise introducing low-THC cannabis or medical cannabis into the human body.

(b) "Dispensing organization" means an organization approved by the department to cultivate, process, transport, and dispense low-THC cannabis or medical cannabis pursuant to this section.

(c) "Independent testing laboratory" means a laboratory, including the managers, employees, or contractors of the laboratory, which has no direct or indirect interest in a dispensing organization.

(d) "Legal representative" means the qualified patient's parent, legal guardian acting pursuant to a court's authorization as required under s. 744.3215(4), health care surrogate acting pursuant to the qualified patient's written consent or a court's authorization as required under s. 765.113, or an individual who is authorized under a power of attorney to make health care decisions on behalf of the qualified patient.

(e) "Low-THC cannabis" means a plant of the genus *Cannabis*, the dried flowers of which contain 0.8 percent or less of tetrahydrocannabinol and more than 10 percent of cannabidiol weight for weight; the seeds thereof; the resin extracted from any part of such plant; or any compound, manufacture, salt, derivative, mixture, or preparation of such plant or its seeds or resin that is dispensed only from a dispensing organization.

(f) "Medical cannabis" means all parts of any plant of the genus *Cannabis*, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, sale, derivative, mixture, or preparation of the plant or its seeds or resin that is dispensed only from a dispensing organization for medical use by an eligible patient as defined in s. 499.0295.

(g) "Medical use" means administration of the ordered amount of low-THC cannabis or medical cannabis. The term does not include the:

1. Possession, use, or administration of low-THC cannabis or medical cannabis by smoking.

2. Transfer of low-THC cannabis or medical cannabis to a person other than the qualified patient for whom it was ordered or the qualified patient's legal representative on behalf of the qualified patient.

3. Use or administration of low-THC cannabis or medical cannabis:

a. On any form of public transportation.

b. In any public place.

c. In a qualified patient's place of employment, if restricted by his or her employer.

d. In a state correctional institution as defined in s. 944.02 or a correctional institution as defined in s. 944.241.

e. On the grounds of a preschool, primary school, or secondary school.

f. On a school bus or in a vehicle, aircraft, or motorboat.

(h) "Qualified patient" means a resident of this state who has been added to the compassionate use registry by a physician licensed under chapter 458 or chapter 459 to receive low-THC cannabis or medical cannabis from a dispensing organization.

(i) "Smoking" means burning or igniting a substance and inhaling the smoke. Smoking does not include the use of a vaporizer.

(2) PHYSICIAN ORDERING.—A physician is authorized to order low-THC cannabis to treat a qualified patient suffering from cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms; order low-THC cannabis to alleviate symptoms of such disease, disorder, or condition, if no other satisfactory alternative treatment options exist for the qualified patient; order medical cannabis to treat an eligible patient as defined in

s. 499.0295; or order a cannabis delivery device for the medical use of low-THC cannabis or medical cannabis, only if the physician:

(a) Holds an active, unrestricted license as a physician under chapter 458 or an osteopathic physician under chapter 459;

(b) Has treated the patient for at least 3 months immediately preceding the patient's registration in the compassionate use registry;

(c) Has successfully completed the course and examination required under paragraph (4)(a);

(d) Has determined that the risks of treating the patient with low-THC cannabis or medical cannabis are reasonable in light of the potential benefit to the patient. If a patient is younger than 18 years of age, a second physician must concur with this determination, and such determination must be documented in the patient's medical record;

(e) Registers as the orderer of low-THC cannabis or medical cannabis for the named patient on the compassionate use registry maintained by the department and updates the registry to reflect the contents of the order, including the amount of low-THC cannabis or medical cannabis that will provide the patient with not more than a 45-day supply and a cannabis delivery device needed by the patient for the medical use of low-THC cannabis or medical cannabis. The physician must also update the registry within 7 days after any change is made to the original order to reflect the change. The physician shall deactivate the registration of the patient and the patient's legal representative when treatment is discontinued;

(f) Maintains a patient treatment plan that includes the dose, route of administration, planned duration, and monitoring of the patient's symptoms and other indicators of tolerance or reaction to the low-THC cannabis or medical cannabis;

(g) Submits the patient treatment plan quarterly to the University of Florida College of Pharmacy for research on the safety and efficacy of low-THC cannabis and medical cannabis on patients;

(h) Obtains the voluntary written informed consent of the patient or the patient's legal representative to treatment with low-THC cannabis after sufficiently explaining the current state of knowledge in the medical community of the effectiveness of treatment of the patient's condition with low-THC cannabis, the medically acceptable alternatives, and the potential risks and side effects;

(i) Obtains written informed consent as defined in and required under s. 499.0295, if the physician is ordering medical cannabis for an eligible patient pursuant to that section; and

(j) Is not a medical director employed by a dispensing organization.

(3) PENALTIES.—

(a) A physician commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083, if the physician orders low-THC cannabis for a patient without a reasonable belief that the patient is suffering from:

1. Cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms that can be treated with low-THC cannabis; or

2. Symptoms of cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms that can be alleviated with low-THC cannabis.

(b) A physician commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083, if the physician orders medical cannabis for a patient without a reasonable belief that the patient has a terminal condition as defined in s. 499.0295.

(c) A person who fraudulently represents that he or she has cancer, a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms, or a terminal condition to a physician for the purpose of being ordered low-THC cannabis, medical cannabis, or a cannabis delivery device by such physician commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(d) An eligible patient as defined in s. 499.0295 who uses medical cannabis, and such patient's legal representative who administers medical cannabis, in plain view of or in a place open to the general public, on the grounds of a school, or in a school bus, vehicle, aircraft, or motorboat, commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(e) A physician who orders low-THC cannabis, medical cannabis, or a cannabis delivery device and receives compensation from a dispensing organization related to the ordering of low-THC cannabis, medical cannabis, or a cannabis delivery device is subject to disciplinary action under the applicable practice act and s. 456.072(1)(n).

(4) PHYSICIAN EDUCATION.—

(a) Before ordering low-THC cannabis, medical cannabis, or a cannabis delivery device for medical use by a patient in this state, the appropriate board shall require the ordering physician to successfully complete an 8-hour course and subsequent examination offered by the Florida Medical Association or the Florida Osteopathic Medical Association that encompasses the clinical indications for the appropriate use of low-THC cannabis and medical cannabis, the appropriate cannabis delivery devices, the contraindications for such use, and the relevant state and federal laws governing the ordering, dispensing, and possessing of these substances and devices. The course and examination shall be administered at least annually. Successful

completion of the course may be used by a physician to satisfy 8 hours of the continuing medical education requirements required by his or her respective board for licensure renewal. This course may be offered in a distance learning format.

(b) The appropriate board shall require the medical director of each dispensing organization to hold an active, unrestricted license as a physician under chapter 458 or as an osteopathic physician under chapter 459 and successfully complete a 2-hour course and subsequent examination offered by the Florida Medical Association or the Florida Osteopathic Medical Association that encompasses appropriate safety procedures and knowledge of low-THC cannabis, medical cannabis, and cannabis delivery devices.

(c) Successful completion of the course and examination specified in paragraph (a) is required for every physician who orders low-THC cannabis, medical cannabis, or a cannabis delivery device each time such physician renews his or her license. In addition, successful completion of the course and examination specified in paragraph (b) is required for the medical director of each dispensing organization each time such physician renews his or her license.

(d) A physician who fails to comply with this subsection and who orders low-THC cannabis, medical cannabis, or a cannabis delivery device may be subject to disciplinary action under the applicable practice act and under s. 456.072(1)(k).

(5) DUTIES OF THE DEPARTMENT.—The department shall:

(a) Create and maintain a secure, electronic, and online compassionate use registry for the registration of physicians, patients, and the legal representatives of patients as provided under this section. The registry must be accessible to law enforcement agencies and to a dispensing organization to verify the authorization of a patient or a patient's legal representative to possess low-THC cannabis, medical cannabis, or a cannabis delivery device and record the low-THC cannabis, medical cannabis, or cannabis delivery device dispensed. The registry must prevent an active registration of a patient by multiple physicians.

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

1. The technical and technological ability to cultivate and produce low-THC cannabis. The applicant must possess a valid certificate of registration issued by the Department of Agriculture and Consumer Services pursuant to s. 581.131 that is issued for the cultivation of more than 400,000 plants, be operated by a nurseryman as defined in s. 581.011, and have been operated as a registered nursery in this state for at least 30 continuous years.

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

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

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

5. The financial ability to maintain operations for the duration of the 2-year approval cycle, including the provision of certified financials to the department. Upon approval, the applicant must post a $5 million performance bond. However, upon a dispensing organization's serving at least 1,000 qualified patients, the dispensing organization is only required to maintain a $2 million performance bond.

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

7. The employment of a medical director to supervise the activities of the dispensing organization.

(c) Upon the registration of 250,000 active qualified patients in the compassionate use registry, approve three dispensing organizations, including, but not limited to, an applicant that is a recognized class member of *Pigford v. Glickman*, 185 F.R.D. 82 (D.D.C. 1999), or *In Re Black Farmers Litig.*, 856 F. Supp. 2d 1 (D.D.C. 2011), and a member of the Black Farmers and Agriculturalists Association, which must meet the requirements of subparagraphs (b)2.-7. and demonstrate the technical and technological ability to cultivate and produce low-THC cannabis.

(d) Allow a dispensing organization to make a wholesale purchase of low-THC cannabis or medical cannabis from, or a distribution of low-THC cannabis or medical cannabis to, another dispensing organization.

(e) Monitor physician registration and ordering of low-THC cannabis, medical cannabis, or a cannabis delivery device for ordering practices that could facilitate unlawful diversion or misuse of low-THC cannabis, medical cannabis, or a cannabis delivery device and take disciplinary action as indicated.

(6) DISPENSING ORGANIZATION.—An approved dispensing organization must, at all times, maintain compliance with the criteria demonstrated for selection and approval as a dispensing organization under subsection (5) and the criteria required in this subsection.

(a) When growing low-THC cannabis or medical cannabis, a dispensing organization:

1. May use pesticides determined by the department, after consultation with the Department of Agriculture and Consumer Services, to be safely applied to plants intended for human consumption, but may not use pesticides designated as restricted-use pesticides pursuant to s. 487.042.

2. Must grow low-THC cannabis or medical cannabis within an enclosed structure and in a room separate from any other plant.

3. Must inspect seeds and growing plants for plant pests that endanger or threaten the horticultural and agricultural interests of the state, notify the Department of Agriculture and Consumer Services within 10 calendar days after a determination that a plant is infested or infected by such plant pest, and implement and maintain phytosanitary policies and procedures.

4. Must perform fumigation or treatment of plants, or the removal and destruction of infested or infected plants, in accordance with chapter 581 and any rules adopted thereunder.

(b) When processing low-THC cannabis or medical cannabis, a dispensing organization must:

1. Process the low-THC cannabis or medical cannabis within an enclosed structure and in a room separate from other plants or products.

2. Test the processed low-THC cannabis and medical cannabis before they are dispensed. Results must be verified and signed by two dispensing organization employees. Before dispensing low-THC cannabis, the dispensing organization must determine that the test results indicate that the low-THC cannabis meets the definition of low-THC cannabis and, for medical cannabis and low-THC cannabis, that all medical cannabis and low-THC cannabis is safe for human consumption and free from contaminants that are unsafe for human consumption. The dispensing organization must retain records of all testing and samples of each homogenous batch of cannabis and low-THC cannabis for at least 9 months. The dispensing organization must contract with an independent testing laboratory to perform audits on the dispensing organization's standard operating procedures, testing records, and samples and provide the results to the department to confirm that the low-THC cannabis or medical cannabis meets the requirements of this section and that the medical cannabis and low-THC cannabis is safe for human consumption.

3. Package the low-THC cannabis or medical cannabis in compliance with the United States Poison Prevention Packaging Act of 1970, 15 U.S.C. ss. 1471 et seq.

4. Package the low-THC cannabis or medical cannabis in a receptacle that has a firmly affixed and legible label stating the following information:

a. A statement that the low-THC cannabis or medical cannabis meets the requirements of subparagraph 2.;

b. The name of the dispensing organization from which the medical cannabis or low-THC cannabis originates; and

c. The batch number and harvest number from which the medical cannabis or low-THC cannabis originates.

5. Reserve two processed samples from each batch and retain such samples for at least 9 months for the purpose of testing pursuant to the audit required under subparagraph 2.

(c) When dispensing low-THC cannabis, medical cannabis, or a cannabis delivery device, a dispensing organization:

1. May not dispense more than a 45-day supply of low-THC cannabis or medical cannabis to a patient or the patient's legal representative.

2. Must have the dispensing organization's employee who dispenses the low-THC cannabis, medical cannabis, or a cannabis delivery device enter into the compassionate use registry his or her name or unique employee identifier.

3. Must verify in the compassionate use registry that a physician has ordered the low-THC cannabis, medical cannabis, or a specific type of a cannabis delivery device for the patient.

4. May not dispense or sell any other type of cannabis, alcohol, or illicit drug-related product, including pipes, bongs, or wrapping papers, other than a physician-ordered cannabis delivery device required for the medical use of low-THC cannabis or medical cannabis, while dispensing low-THC cannabis or medical cannabis.

5. Must verify that the patient has an active registration in the compassionate use registry, the patient or patient's legal representative holds a valid and active registration card, the order presented matches the order contents as recorded in the registry, and the order has not already been filled.

6. Must, upon dispensing the low-THC cannabis, medical cannabis, or cannabis delivery device, record in the registry the date, time, quantity, and form of low-THC cannabis or medical cannabis dispensed and the type of cannabis delivery device dispensed.

(d) To ensure the safety and security of its premises and any off-site storage facilities, and to maintain adequate controls against the diversion, theft, and loss of low-THC cannabis, medical cannabis, or cannabis delivery devices, a dispensing organization shall:

1.a. Maintain a fully operational security alarm system that secures all entry points and perimeter windows and is equipped with motion detectors; pressure switches; and duress, panic, and hold-up alarms; or

b. Maintain a video surveillance system that records continuously 24 hours each day and meets at least one of the following criteria:

(I) Cameras are fixed in a place that allows for the clear identification of persons and activities in controlled areas of the premises. Controlled areas include grow rooms, processing rooms, storage rooms, disposal rooms or areas, and point-of-sale rooms;

(II) Cameras are fixed in entrances and exits to the premises, which shall record from both indoor and outdoor, or ingress and egress, vantage points;

(III) Recorded images must clearly and accurately display the time and date; or

(IV) Retain video surveillance recordings for a minimum of 45 days or longer upon the request of a law enforcement agency.

2. Ensure that the organization's outdoor premises have sufficient lighting from dusk until dawn.

3. Establish and maintain a tracking system approved by the department that traces the low-THC cannabis or medical cannabis from seed to sale. The tracking system shall include notification of key events as determined by the department, including when cannabis seeds are planted, when cannabis plants are harvested and destroyed, and when low-THC cannabis or medical cannabis is transported, sold, stolen, diverted, or lost.

4. Not dispense from its premises low-THC cannabis, medical cannabis, or a cannabis delivery device between the hours of 9 p.m. and 7 a.m., but may perform all other operations and deliver low-THC cannabis and medical cannabis to qualified patients 24 hours each day.

5. Store low-THC cannabis or medical cannabis in a secured, locked room or a vault.

6. Require at least two of its employees, or two employees of a security agency with whom it contracts, to be on the premises at all times.

7. Require each employee to wear a photo identification badge at all times while on the premises.

8. Require each visitor to wear a visitor's pass at all times while on the premises.

9. Implement an alcohol and drug-free workplace policy.

10. Report to local law enforcement within 24 hours after it is notified or becomes aware of the theft, diversion, or loss of low-THC cannabis or medical cannabis.

(e) To ensure the safe transport of low-THC cannabis or medical cannabis to dispensing organization facilities, independent testing laboratories, or patients, the dispensing organization must:

1. Maintain a transportation manifest, which must be retained for at least 1 year.

2. Ensure only vehicles in good working order are used to transport low-THC cannabis or medical cannabis.

3. Lock low-THC cannabis or medical cannabis in a separate compartment or container within the vehicle.

4. Require at least two persons to be in a vehicle transporting low-THC cannabis or medical cannabis, and require at least one person to remain in the vehicle while the low-THC cannabis or medical cannabis is being delivered.

5. Provide specific safety and security training to employees transporting or delivering low-THC cannabis or medical cannabis.

(7) DEPARTMENT AUTHORITY AND RESPONSIBILITIES.–

(a) The department may conduct announced or unannounced inspections of dispensing organizations to determine compliance with this section or rules adopted pursuant to this section.

(b) The department shall inspect a dispensing organization upon complaint or notice provided to the department that the dispensing organization has dispensed low-THC cannabis or medical cannabis containing any mold, bacteria, or other contaminant that may cause or has caused an adverse effect to human health or the environment.

(c) The department shall conduct at least a biennial inspection of each dispensing organization to evaluate the dispensing organization's records, personnel, equipment, processes, security measures, sanitation practices, and quality assurance practices.

(d) The department may enter into interagency agreements with the Department of Agriculture and Consumer Services, the Department of Business and Professional Regulation, the Department of Transportation, the Department of Highway Safety and Motor Vehicles, and the Agency for Health Care Administration, and such agencies are authorized to enter into an interagency agreement with the department, to conduct inspections or perform other responsibilities assigned to the department under this section.

(e) The department must make a list of all approved dispensing organizations and qualified ordering physicians and medical directors publicly available on its website.

(f) The department may establish a system for issuing and renewing registration cards for patients and their legal representatives, establish the circumstances under which the cards may be revoked by or must be returned to the department, and establish fees to implement such system. The department must require, at a minimum, the registration cards to:

1. Provide the name, address, and date of birth of the patient or legal representative.
2. Have a full-face, passport-type, color photograph of the patient or legal representative taken within the 90 days immediately preceding registration.
3. Identify whether the cardholder is a patient or legal representative.
4. List a unique numeric identifier for the patient or legal representative that is matched to the identifier used for such person in the department's compassionate use registry.
5. Provide the expiration date, which shall be 1 year after the date of the physician's initial order of low-THC cannabis or medical cannabis.
6. For the legal representative, provide the name and unique numeric identifier of the patient that the legal representative is assisting.
7. Be resistant to counterfeiting or tampering.

(g) The department may impose reasonable fines not to exceed $10,000 on a dispensing organization for any of the following violations:

1. Violating this section, s. 499.0295, or department rule.
2. Failing to maintain qualifications for approval.
3. Endangering the health, safety, or security of a qualified patient.
4. Improperly disclosing personal and confidential information of the qualified patient.
5. Attempting to procure dispensing organization approval by bribery, fraudulent misrepresentation, or extortion.
6. Being convicted or found guilty of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which directly relates to the business of a dispensing organization.
7. Making or filing a report or record that the dispensing organization knows to be false.
8. Willfully failing to maintain a record required by this section or department rule.
9. Willfully impeding or obstructing an employee or agent of the department in the furtherance of his or her official duties.
10. Engaging in fraud or deceit, negligence, incompetence, or misconduct in the business practices of a dispensing organization.
11. Making misleading, deceptive, or fraudulent representations in or related to the business practices of a dispensing organization.
12. Having a license or the authority to engage in any regulated profession, occupation, or business that is related to the business practices of a dispensing organization suspended, revoked, or otherwise acted against by the licensing authority of any jurisdiction, including its agencies or subdivisions, for a violation that would constitute a violation under Florida law.
13. Violating a lawful order of the department or an agency of the state, or failing to comply with a lawfully issued subpoena of the department or an agency of the state.

(h) The department may suspend, revoke, or refuse to renew a dispensing organization's approval if a dispensing organization commits any of the violations in paragraph (g).

(i) The department shall renew the approval of a dispensing organization biennially if the dispensing organization meets the requirements of this section and pays the biennial renewal fee.

(j) The department may adopt rules necessary to implement this section.

(8) PREEMPTION.–

(a) All matters regarding the regulation of the cultivation and processing of medical cannabis or low-THC cannabis by dispensing organizations are preempted to the state.

(b) A municipality may determine by ordinance the criteria for the number and location of, and other permitting requirements that do not conflict with state law or department rule for, dispensing facilities of dispensing organizations located within its municipal boundaries. A county may determine by ordinance the criteria for the number, location, and other permitting requirements that do not conflict with state law or department rule for all dispensing facilities of dispensing organizations located within the unincorporated areas of that county.

(9) EXCEPTIONS TO OTHER LAWS.–

(a) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or any other provision of law, but subject to the requirements of this section, a qualified patient and the qualified patient's legal representative may purchase and possess for the patient's medical use up to the amount of low-THC cannabis or medical cannabis ordered for the patient, but not more than a 45-day supply, and a cannabis delivery device ordered for the patient.

(b) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or any other provision of law, but subject to the requirements of this section, an approved dispensing organization and its owners, managers, and employees may manufacture, possess, sell, deliver, distribute, dispense, and lawfully dispose of reasonable quantities, as established by department rule, of low-THC cannabis, medical cannabis, or a cannabis delivery device. For purposes of this subsection, the terms "manufacture," "possession," "deliver," "distribute," and "dispense" have the same meanings as provided in s. 893.02.

(c) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or any other provision of law, but subject to the requirements of this section, an approved independent testing laboratory may possess, test, transport, and lawfully dispose of low-THC cannabis or medical cannabis as provided by department rule.

(d) An approved dispensing organization and its owners, managers, and employees are not subject to licensure or regulation under chapter 465 or chapter 499 for manufacturing, possessing, selling, delivering, distributing, dispensing, or lawfully disposing of reasonable quantities, as established by department rule, of low-THC cannabis, medical cannabis, or a cannabis delivery device.

(e) An approved dispensing organization that continues to meet the requirements for approval is presumed to be registered with the department and to meet the regulations adopted by the department or its successor agency for the purpose of dispensing medical cannabis or low-THC cannabis under Florida law. Additionally, the authority provided to a dispensing organization in s. 499.0295 does not impair the approval of a dispensing organization.

(f) This subsection does not exempt a person from prosecution for a criminal offense related to impairment or intoxication resulting from the medical use of low-THC cannabis or medical cannabis or relieve a person from any requirement under law to submit to a breath, blood, urine, or other test to detect the presence of a controlled substance.

B. Section 14(1), ch. 2017-232, provides that:

"(1) EMERGENCY RULEMAKING.—

"(a) The Department of Health and the applicable boards shall adopt emergency rules pursuant to s. 120.54(4), Florida Statutes, and this section necessary to implement ss. 381.986 and 381.988, Florida Statutes. If an emergency rule adopted under this section is held to be unconstitutional or an invalid exercise of delegated legislative authority, and becomes void, the department or the applicable boards may adopt an emergency rule pursuant to this section to replace the rule that has become void. If the emergency rule adopted to replace the void emergency rule is also held to be unconstitutional or an invalid exercise of delegated legislative authority and becomes void, the department and the applicable boards must follow the nonemergency rulemaking procedures of the Administrative Procedures Act to replace the rule that has become void.

"(b) For emergency rules adopted under this section, the department and the applicable boards need not make the findings required by s. 120.54(4)(a), Florida Statutes. Emergency rules adopted under this section are exempt from ss. 120.54 (3)(b) and 120.541, Florida Statutes. The department and the applicable boards shall meet the procedural requirements in s. 120.54(a), Florida Statutes, if the department or the applicable boards have, before [June 23, 2017], held any public workshops or hearings on the subject matter of the emergency rules adopted under this subsection. Challenges to emergency rules adopted under this subsection are subject to the time schedules provided in s. 120.56(5), Florida Statutes.

"(c) Emergency rules adopted under this section are exempt from s. 120.54(4)(c), Florida Statutes, and shall remain in effect until replaced by rules adopted under the nonemergency rulemaking procedures of the Administrative Procedures Act. By January 1, 2018, the department and the applicable boards shall initiate nonemergency rulemaking pursuant to the Administrative Procedures Act to replace all emergency rules adopted under this section by publishing a notice of rule development in the Florida Administrative Register. Except as provided in paragraph (a), after January 1, 2018, the department and applicable boards may not adopt rules pursuant to the emergency rulemaking procedures provided in this section."

[2]**Note.**—Section 14(2), ch. 2017-232, provides that:

"(2) CAUSE OF ACTION.—

"(a) As used in s. 29(d)(3), Article X of the State Constitution, the term:

"1. 'Issue regulations' means the filing by the department of a rule or emergency rule for adoption with the Department of State.

"2. 'Judicial relief' means an action for declaratory judgment pursuant to chapter 86, Florida Statutes.

"(b) The venue for actions brought against the department pursuant to s. 29(d)(3), Article X of the State Constitution shall be in the circuit court in and for Leon County.

"(c) If the department is not issuing patient and caregiver identification cards or licensing medical marijuana treatment centers by October 3, 2017, the following shall be a defense to a cause of action brought under s. 29(d)(3), Article X of the State Constitution:

"1. The department is unable to issue patient and caregiver identification cards or license medical marijuana treatment centers due to litigation challenging a rule as an invalid exercise of delegated legislative authority or unconstitutional.

"2. The department is unable to issue patient or caregiver identification cards or license medical marijuana treatment centers due to a rule being held as an invalid exercise of delegated legislative authority or unconstitutional."

[3]**Note.**—The word "in" was inserted by the editors.

Notice of Emergency Rule

DEPARTMENT OF HEALTH

RULE NO.: RULE TITLE:

64ER17-1 Definitions

SPECIFIC REASONS FOR FINDING AN IMMEDIATE DANGER TO THE PUBLIC, HEALTH, SAFETY, OR WELFARE: Pursuant to Chapter 2017-232, § 14, at 45, Laws of Florida, the Department is not required to make findings of an immediate danger to the public, health, safety, or welfare.

REASONS FOR CONCLUDING THAT THE PROCEDURE USED IS FAIR UNDER THE CIRCUMSTANCES: The Department of Health is directed by Chapter 2017-232, § 14, at 45, Laws of Florida, to adopt emergency rules to implement section 381.986, Florida Statutes.

SUMMARY: Emergency rule 64ER17-1 (64-4.001) provides the definitions necessary to implement the statutory changes creating medical marijuana treatment centers in Florida.

THE PERSON TO BE CONTACTED REGARDING THE EMERGENCY RULE IS: Courtney Coppola at Courtney.Coppola@flhealth.gov.

THE FULL TEXT OF THE EMERGENCY RULE IS:

(Substantial rewording of Rule 64-4.001 follows. See Florida Administrative Code for present text.)

64ER17-1 (64-4.001) Definitions.

For the purposes of Department of Health (the "department") medical marijuana treatment center rules and regulations, the following words and phrases shall have the meanings indicated:

(1) Applicant – An individual or entity that meets the requirements of section 381.986(8)(b), F.S., and applies for registration as a medical marijuana treatment center pursuant to section 381.986(8)(a)2.b. and c., F.S.

(2) Approval – Written notification from the department to an applicant that its application for registration as a medical marijuana treatment center has been found to be in compliance with the provisions of department rules and regulations and that the department is awaiting notification that the medical marijuana treatment center is prepared to be inspected and authorized to begin cultivation, processing, and dispensing.

(3) Certified financials – Financial statements that have been audited in accordance with Generally Accepted Auditing Standards (GAAS) by a Certified Public Accountant, licensed pursuant to Chapter 473, F.S.

(4) Contingent licensee – An applicant that has been granted approval contingent upon the initial registration of 100,000 active patients in the Medical Marijuana Use Registry in accordance with section 381.986(8)(a)4., F.S.

(5) Cultivation – Growth of marijuana plant source material.

(6) Cultivation authorization – Written notification by the department to a medical marijuana treatment center that it may begin cultivating marijuana.

(7) Cultivation facility – Any area designated in the application to be used for cultivation of marijuana

(8) Derivative product – Forms of marijuana suitable for routes of administration.

(9) Dispensing authorization – Written notification by the department to a medical marijuana treatment center that it may begin dispensing derivative product.

(10) Dispensing facility – Any area designated in the application where derivative product and marijuana delivery devices are dispensed at retail.

(11) Employee – Any person whose duties involve any aspect of the cultivation, processing, or dispensing of marijuana whether or not compensated for the performance of such duties.

(12) Financial Statements – A presentation of financial data, including accompanying notes, derived from accounting records that purports to show actual or anticipated financial position and intended to communicate an entity's economic resources or obligations at a point in time, and the results of operations and cash flows for a period of time, in accordance with generally accepted accounting principles or a comprehensive basis of accounting other than generally accepted accounting principles. Financial presentations included in tax returns are not financial statements. The method of preparation (for example, manual or computer preparation) is not relevant to the definition of a financial statement.

(13) Interests – Any form of ownership in or control of an applicant or a medical marijuana treatment center, including, but not limited to ownership of stock, membership interests, partnership interests, a sole proprietorship or otherwise and which convey to the holder thereof, an ownership right or an interest in or right to the profits, capital, or voting with respect to such applicant or medical marijuana treatment center.

(14) Majority ownership –Ownership of more than 50% of the interests of an applicant or registered medical marijuana treatment center, such ownership being determined by application of the requirements in subsection (16) below.

(15) Manager – Any person with the authority, directly or indirectly, to exercise or contribute to the operational control, direction or management of an applicant or a medical marijuana treatment center or who has direct or indirect authority to supervise any employee of an applicant or a medical marijuana treatment center. The term shall be interpreted broadly and shall include, but not be limited to, all officers, managers, and members of board of directors as well as any other person engaged to undertake management or control of the applicant or a medical marijuana treatment center or any person or persons in control of an entity engaged to undertake management or control of the applicant or medical marijuana treatment center.

(16) Owner – Any person who, directly or indirectly, owns (actually or beneficially) or controls, a 5% or greater share of interests of the applicant or a medical marijuana treatment center. In the event that one person owns a beneficial right to interests and another person holds the voting rights with respect to such interests, then in such case, both shall be considered the owner of such interests. In determining the owners of the applicant or a medical marijuana treatment center, the attribution of ownership rules set forth in the Treasury Regulations cited as 26 CFR 1.414(c)-4 (b) and (c) (4-1-17 edition),as incorporated by reference, shall apply, but with the following exceptions and additions:

(a) The use of the term "option" in 26 CFR 1.414(c)-4(b) shall be interpreted broadly to include, but not be limited to, any and all options, warrants, calls, rights of first refusal and any other right to acquire an interest (as defined herein), whether such right is vested or unvested and regardless of whether such right is then exercisable or becomes exercisable at a future date or upon the occurrence of a future event.

(b) The exception for attribution of a spouse's interest, as defined in subsection (13), as set forth in 26 CFR 1.414(c)-4(b)(5)(ii) is eliminated and shall not apply.

(c) The age limitation contained in 26 CFR 1.414(c)-4(b)(6) is amended to 18 years. The term interest as used in 26 CFR 1.414(c)-4(b)(6) shall have the meaning as set forth in subsection (13).

(d) In the event that a person under the age of 18 owns or is deemed an owner of an interest, such person must be disclosed to the department. Persons under the age of 18 shall only be required to submit to a background screening in the event that the interest or ownership was not imputed to another family member or guardian as outlined in paragraph (c) above.

(e) To the extent that the above alterations to the provisions of 26 CFR 1.414(c)-4 alter the outcome of any of the examples set forth therein, then, in such case, such example is deemed eliminated.

(f) As used in 26 CFR 1.414(c)-4(b)(3), the term "actuarial interest" shall be interpreted broadly and shall include, but not be limited to the right of a beneficiary of a trust or an estate to receive either income or principal distributions with respect to an interest held by such trust or estate.

(g) With regard to publicly traded companies with ownership interests in the applicant, any person who holds 10% or more interest in the publicly traded company shall be considered an owner.

(17) Processing authorization – Written notification by the department to a medical marijuana treatment center that it may begin processing marijuana to derivative product.

(18) Processing facility – Any area designated in the application to be used for processing of derivative product.

(19) Registration – Approval and licensure as a medical marijuana treatment center pursuant to section 381.986(8), F.S.

(20) Resident – A person who meets the requirements of section 381.986(5)(b), F.S.

(21) Routes of administration – means the path by which a derivative product is ordered by a physician to be taken into the body of the qualified patient, but does not include smoking.

Rulemaking Authority 381.986(8)(b) FS. Law Implemented 381.986 FS. History–New 6-17-15, Amended 9-19-17.

THIS RULE TAKES EFFECT UPON BEING FILED WITH THE DEPARTMENT OF STATE UNLESS A LATER TIME AND DATE IS SPECIFIED IN THE RULE.
EFFECTIVE DATE: September 19, 2017

Notice of Emergency Rule

DEPARTMENT OF HEALTH

RULE NO.: RULE TITLE:

64ER17-2 Application Requirements for Medical Marijuana Treatment Centers

SPECIFIC REASONS FOR FINDING AN IMMEDIATE DANGER TO THE PUBLIC, HEALTH, SAFETY, OR WELFARE: Pursuant to Chapter 2017-232, § 14, at 45, Laws of Florida, the Department is not required to make findings of an immediate danger to the public, health, safety, or welfare.

REASONS FOR CONCLUDING THAT THE PROCEDURE USED IS FAIR UNDER THE CIRCUMSTANCES: The Department of Health is directed by Chapter 2017-232, § 14, at 45, Laws of Florida, to adopt emergency rules to implement section 381.986, Florida Statutes.

SUMMARY: Emergency rule 64ER17-2 (64-4.002) provides the application requirements and process necessary to apply and be approved for registration as a medical marijuana treatment center.

THE PERSON TO BE CONTACTED REGARDING THE EMERGENCY RULE IS: Courtney Coppola at Courtney.Coppola@flhealth.gov.

THE FULL TEXT OF THE EMERGENCY RULE IS:

(Substantial rewording of Rule 64-4.002 follows. See Florida Administrative Code for present text.)

64ER17-2 (64-4.002) Application for Registration of Medical Marijuana Treatment Centers.

Pursuant to section 381.986, F.S., all applicants seeking registration with the department as a medical marijuana treatment center shall comply with the registration process detailed below. The registration process set forth in this regulation does not apply to individuals requesting registration pursuant to section 381.986(8)(a)2.a., F.S.

(1) Each individual or entity that meets the requirements of section 381.986(8)(b), F.S., desiring to be registered as a medical marijuana treatment center pursuant to section 381.986, F.S., shall submit an application to the department using Form DH8013-OMMU-08/2017, "Application for Medical Marijuana Treatment Center Registration" herein incorporated by reference. The application must comply with the page limits, blind grading, format, and organization instructions detailed in the application. The application, once submitted to the department, shall be considered final. The department will not accept any amendments or supplements to the initial application. The applicant must include with the application at the time of submission, the following:

(a) A non-refundable application fee of $60,830.00.

(b) Written documentation from the Department of State or the Department of Revenue, as applicable under Florida law, demonstrating that the applicant has been registered to do business in Florida for the prior five consecutive years and that the applicant possesses a valid certificate of registration issued by the Department of Agriculture and Consumer Services pursuant to section 581.131, F.S. The name of the applicant as submitted to the department must match the name on any documents provided in accordance with this paragraph.

(c) A list of all owners, officers, board members, and managers indicating the date of each individual's most recent Level-2 background screening pursuant to section 381.986(9), F,S, within the calendar year prior to application. Each owner, officer, board member, and manager shall go to the Florida Department of Law Enforcement (FDLE) or one of its approved vendors for fingerprinting and, at such time, shall give to FDLE or the FDLE approved vendor the entity ORI number FL924890Z (DOH – OFFICE OF MEDICAL MARIJUANA USE). The report will be sent directly to the Office of Medical Marijuana Use. To be eligible for registration, all of the applicant's owners, officers, board members, and managers must have successfully passed a Level-2 background screening.

(d) For applicants seeking registration pursuant to section 381.986(8)(a)2.b., F.S., the applicant must provide evidence that it is majority-owned by (an) African-American farmer(s) who:

1. Is a recognized class member of *Pigford v. Glickman*, 185 F.R.D. 82 (D.D.C. 1999) *(Pigford*) or *In re Black Farmers Discrimination Litigation*, 856 F. Supp. 2d 1 (D.D.C. 2011) (*BFDL*). Examples of acceptable evidence include:

a. Documentation from Poorman-Douglass Corporation (now Epiq Systems Inc.) that the applicant received a consent decree case number in *Pigford*;

b. Documentation that the applicant was granted class status by the *Pigford* adjudicator;

c. Court documents or United States Department of Agriculture (USDA) documents showing that the applicant received judgment discharging debt, providing a cash payment, or providing injunctive relief in *Pigford*;

d. Documentation that the applicant was determined to be a class member by Epiq Systems Inc. in *BFDL*;

e. Documentation that the applicant received a settlement award in *BFDL*; or

f. Other court documents or USDA documents demonstrating that the applicant was granted class member status in either *Pigford* or *BFDL*.

2. Is currently a member of the Black Farmers and Agriculturists Association – Florida Chapter.

3. A letter from the Black Farmers and Agriculturists Association – Florida Chapter certifying that the applicant meets subparagraph 1. and 2. will be accepted as sufficient evidence that the applicant qualifies for registration pursuant to section 381.986(8)(a)2.b., F.S.

4. Applicants seeking registration pursuant to section 381.986(8)(a)2.b., F.S., are exempt from the evidentiary requirements of paragraph (1)(b) above and therefore, are also exempt from the provisions of paragraph (3)(b) below. However, if an applicant wishes to be considered under both sections 381.986(8)(a)2.b. and 381.986(8)(a)2.c., F.S., the applicant must provide the documentation required in paragraph (1)(b).

(e) For applicants seeking preference for registration pursuant to section 381.986(8)(a)3., F.S., the applicant must provide evidence that:

1. The property at issue currently is or was previously used for the canning, concentrating, or otherwise processing of citrus fruit or citrus molasses. In order to demonstrate the property meets this criteria the applicant may provide documentation that the applicant currently holds or has held a registration certificate or a citrus fruit dealer license pursuant to sections 601.40 and 601.55, F.S, respectively. A letter from the Department of Citrus certifying that the property currently is or was previously used for the canning, concentrating, or otherwise processing of citrus fruit or citrus molasses will be accepted as sufficient evidence;

2. The applicant as an individual holds, in his or her name, or the applicant as an entity holds, in the legal name of the entity the deed to property meeting the criteria set forth in subparagraph 1. above; and

3. A brief explanation of how the property will be used for purposes of growing, processing or dispensing medical marijuana if the applicant is awarded a license.

(2) 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 statutory basis for the exemption. The applicant shall submit a redacted copy of the application redacting those items identified as exempt concurrent with the submission of the application for approval under subsection (4) below. Failure to provide a redacted copy of the application at the time of submission, or failure to identify and redact information claimed as trade secret will result in the release of all application information in response to a public records request unless the information falls under another public records exemption. All identified trade secrets are subject to the department review in accordance with section 381.83, F.S.

(3) Failure to provide the following at the time of submission of the application shall result in the application being denied prior to any scoring as contemplated in subsection (5) of this regulation:

(a) The $60,830.00 application fee;

(b) Documentation required under paragraph (1)(b); or

(c) The list of owners, officers, board members, and managers required under paragraph (1)(c).

(4) The department shall publish in the Florida Administrative Register and on its website the date upon which the department will begin accepting applications and the deadline to receive all applications. Applications and all required exhibits and supporting documents shall be hand delivered to the Department of Health at 4052 Bald Cypress Way in Tallahassee, Florida, during normal business hours, but no earlier than 10:00 a.m. (Eastern Time), on the date the department begins accepting applications and no later than 5:00 p.m. (Eastern Time) on the last date upon which the applications are accepted. Applications submitted after 5:00 p.m. Eastern Time on the final day of the application period will be denied.

(5) Subject matter experts will substantively and comparatively review, evaluate, and score applications using Form DH8014-OMMU-08/2017, "Scorecard for Medical Marijuana Treatment Center Selection" herein incorporated by reference.

(a) The subject matter experts shall have the following qualifications:

1. Subject matter experts reviewing Sections 1-3 of the application, the cultivation components, shall have at least 2 years of professional experience or advanced degree in one of the following areas: agriculture, horticulture, or agronomy, or comparable field.

2. Subject matter experts reviewing Sections 4-5 of the application, the processing components, shall have at least 2 years of professional experience or advanced degree in chemistry, biology, or biochemistry.

3. Subject matter experts reviewing Sections 6-8 of the application, the dispensing components, shall have at least 2 years of professional experience or advanced degree in industrial engineering, supply chain management, or strategic management.

4. Subject matter experts reviewing Sections 9, 10, 12, and 16 of the application, the compliance components, shall have at least 2 years of professional experience or advanced degree related to operating a business in a highly regulated environment.

5. Subject matter experts reviewing Section 13 of the application shall have at least 2 years of management experience within a business operating in a regulated industry or at least 2 years of experience working in human resources.

6. Subject matter experts reviewing Section 11 of the application shall have at least 2 years of management experience within a business operating in the health care industry or an active, unrestricted license as a medical doctor or doctor of osteopathic medicine.

7. Subject matter experts reviewing Sections 14-15 of the application, the legal and financial components, shall have an active CPA license or an active license to practice law and experience in business structuring.

Subject matter experts will certify that they do not have a conflict of interest and will evaluate and score each section of the application according to the rubric set forth in DH8014-OMMU-08/2017.

(b) Scores for each Section of the application will be combined to create an applicant's total score. The department shall generate a final ranking of the applicants in order of highest to lowest scores. Any application which demonstrates a failure to comply with the minimum statutory requirements for cultivation, processing, dispensing, security, or general operations, as identified in DH8014-OMMU-08/2017, shall be denied and will not be considered in the final ranking of applications.

(c) In accordance with section 381.986(8)(a)3., F.S., the two highest scoring applicants that own one or more facilities that are, or were, used for the canning, concentrating, or otherwise processing of citrus fruit or citrus molasses and will use or convert the facility or facilities for the processing or marijuana will receive an additional 35 points to their respective total score.

(6) Licenses will be awarded, subject to availability, as set forth in s. 381.986(8)(a)2., F.S., based on the highest total score in the following manner:

(a) The highest scoring applicant that is a recognized member of *Pigford* or *BFDL* and a member of the Black Farmers and Agriculturalists Association-Florida Chapter, will receive a license

(b) The remaining highest scoring applicants, after the addition of the preference for applicants that own citrus and molasses facilities, will receive licenses up to the statutory cap set forth in section 381.986(8)(a)2., F.S.

(c) The next four highest scoring applicants, after removing any preference points for citrus applicants provided under paragraph (5)(c) above, will receive notification of approval as contingent licensees. The contingent license will not become active until such time as the department provides notification of the registration of 100,000 active patients in the Medical Marijuana Use Registry. The department will provide notification to the contingent licensee of the activation of its license within 30 days of the registration of the first 100,000 active patients.

(d) In the event of a tie, the following tiebreakers will be applied:

1. The first tiebreaker shall be the score for Section 14 – Financials: Certified Financial Documents. The applicant with the highest score in Section 14 shall be awarded a license. In the event that this does not resolve the tie:

2. The second tiebreaker shall be the score for Section 15 – Financials: Business Structure. The applicant with the highest score in Section 15 shall be awarded a license. In the event that this does not resolve the tie:

3. The third tiebreaker shall be the score for Section 13 – Diversity Plan. The applicant with the highest score in Section 13 shall be awarded a license. In the event that this does not resolve the tie:

4. The final tiebreaker shall be the score for Section 10 – Accountability: Operations.

(7) Upon notification that it has been approved as a medical marijuana treatment center as an active license, the applicant shall have 10 business days to:

(a) Post a performance bond, provide an irrevocable letter of credit payable to the department or provide cash to the department in the amount of $5 million (collectively "financial assurance") pursuant to section 381.986(8)(b)7., F.S. If a bond is provided, the bond shall:

1. Be payable to the department in the event the medical marijuana treatment center's approval is revoked;

2. Be written by an authorized surety company rated in one of the three highest rating categories by a nationally recognized rating service; and

3. Be written so that the individual or entity name on the bond corresponds exactly with the applicant name.

4. The surety company can use any form it prefers for the performance bond as long as it complies with this regulation. For convenience, the surety company can use Form DH8015-OMMU-08/2017, "Florida Medical Marijuana Performance Bond" herein incorporated by reference.

(b) Provide documentation supporting representations related to property ownership and/or leases made in the application.

(8) If a financial assurance is canceled or revoked in any manner and the medical marijuana treatment center fails to provide new financial assurance to the department in the required amount on or before the effective date of cancellation or revocation, the medical marijuana treatment center's approval shall be revoked.

(9) If a selected applicant fails to post the financial assurance or supporting property ownership and/or use documents within the required timeframe, the applicant with the next highest score shall be selected and notified.

Rulemaking Authority 381.986(8)(b) FS. Law Implemented 381.986 FS. History–New 6-17-15, Amended 9-19-17.

THIS RULE TAKES EFFECT UPON BEING FILED WITH THE DEPARTMENT OF STATE UNLESS A LATER TIME AND DATE IS SPECIFIED IN THE RULE.

EFFECTIVE DATE: September 19, 2017

DEPARTMENT OF HEALTH

Office of Medical Marijuana Use Notice of Adoption

The Department of Health, Office of Medical Marijuana Use hereby provides notice that Regulations 1-1.02 and 2-1.01 below have been filed for adoption with the Department Agency Clerk and are effective as of November 1, 2017, pursuant to the Department's authority under Article X, Section 29, of the Florida Constitution. The Department previously provided notice of the proposed regulation in Vol. 43 No. 182, September 20, 2017 issue of the Florida Administrative Register.

1-1.02 Definitions.

For the purposes of Department of Health (the "department") medical marijuana treatment center rules and regulations, the following words and phrases shall have the meanings indicated:

(1) Applicant – An individual or entity that meets the requirements of section 381.986(8)(b), F.S., and applies for registration as a medical marijuana treatment center pursuant to Article X, Section 29 of the Florida Constitution and consistent with section 381.986(8)(a)2.b. and c., F.S.

(2) Approval – Written notification from the department to an applicant that its application for registration as a medical marijuana treatment center has been found to be in compliance with the provisions of department rules and regulations and that the department is awaiting notification that the medical marijuana treatment center is prepared to be inspected and authorized to begin cultivation, processing, and dispensing.

(3) Certified financials – Financial statements that have been audited in accordance with Generally Accepted Auditing Standards (GAAS) by a Certified Public Accountant, licensed pursuant to Chapter 473, F.S.

(4) Contingent licensee – An applicant that has been granted approval contingent upon the initial registration of 100,000 active patients in the Medical Marijuana Use Registry in accordance with section 381.986(8)(a)4., F.S.

(5) Cultivation – Growth of marijuana plant source material.

(6) Cultivation authorization – Written notification by the department to a medical marijuana treatment center that it may begin cultivating marijuana.

(7) Cultivation facility – Any area designated in the application to be used for cultivation of marijuana

(8) Derivative product – Forms of marijuana suitable for routes of administration.

(9) Dispensing authorization – Written notification by the department to a medical marijuana treatment center that it may begin dispensing derivative product.

(10) Dispensing facility – Any area designated in the application where derivative product and marijuana delivery devices are dispensed at retail.

(11) Employee – Any person whose duties involve any aspect of the cultivation, processing, or dispensing of marijuana whether or not compensated for the performance of such duties.

(12) Financial Statements – A presentation of financial data, including accompanying notes, derived from accounting records that purports to show actual or anticipated financial position and intended to communicate an entity's economic resources or obligations at a point in time, and the results of operations and cash flows for a period of time, in accordance with generally accepted accounting principles or a comprehensive basis of accounting other than generally accepted accounting principles. Financial presentations included in tax returns are not financial statements. The method of preparation (for example, manual or computer preparation) is not relevant to the definition of a financial statement.

(13) Interests – Any form of ownership in or control of an applicant or a medical marijuana treatment center, including, but not limited to ownership of stock, membership interests, partnership interests, a sole proprietorship or otherwise and which convey to the holder thereof, an ownership right or an interest in or right to the profits, capital, or voting with respect to such applicant or medical marijuana treatment center.

(14) Majority ownership –Ownership of more than 50% of the interests of an applicant or registered medical marijuana treatment center, such ownership being determined by application of the requirements in subsection (16) below.

(15) Manager – Any person with the authority, directly or indirectly, to exercise or contribute to the operational control, direction or management of an applicant or a medical marijuana treatment center or who has direct or indirect authority to supervise any employee of an applicant or a medical marijuana treatment center. The term shall

be interpreted broadly and shall include, but not be limited to, all officers, managers, and members of board of directors as well as any other person engaged to undertake management or control of the applicant or a medical marijuana treatment center or any person or persons in control of an entity engaged to undertake management or control of the applicant or medical marijuana treatment center.

(16) Owner – Any person who, directly or indirectly, owns (actually or beneficially) or controls, a 5% or greater share of interests of the applicant or a medical marijuana treatment center. In the event that one person owns a beneficial right to interests and another person holds the voting rights with respect to such interests, then in such case, both shall be considered the owner of such interests. In determining the owners of the applicant or a medical marijuana treatment center, the attribution of ownership rules set forth in the Treasury Regulations cited as 26 CFR 1.414(c)-4 (b) and (c) (4-1-17 edition) shall apply, but with the following exceptions and additions:

(a) The use of the term "option" in 26 CFR 1.414(c)-4(b) shall be interpreted broadly to include, but not be limited to, any and all options, warrants, calls, rights of first refusal and any other right to acquire an interest (as defined herein), whether such right is vested or unvested and regardless of whether such right is then exercisable or becomes exercisable at a future date or upon the occurrence of a future event.

(b) The exception for attribution of a spouse's interest, as defined in subsection (13), as set forth in 26 CFR 1.414(c)-4(b)(5)(ii) is eliminated and shall not apply.

(c) The age limitation contained in 26 CFR 1.414(c)-4(b)(6) is amended to 18 years. The term interest as used in 26 CFR 1.414(c)-4(b)(6) shall have the meaning as set forth in subsection (13).

(d) In the event that a person under the age of 18 owns or is deemed an owner of an interest, such person must be disclosed to the department. Persons under the age of 18 shall only be required to submit to a background screening in the event that the interest or ownership was not imputed to another family member or guardian as outlined in paragraph (c) above.

(e) To the extent that the above alterations to the provisions of 26 CFR 1.414(c)-4 alter the outcome of any of the examples set forth therein, then, in such case, such example is deemed eliminated.

(f) As used in 26 CFR 1.414(c)-4(b)(3), the term "actuarial interest" shall be interpreted broadly and shall include, but not be limited to the right of a beneficiary of a trust or an estate to receive either income or principal distributions with respect to an interest held by such trust or estate.

(g) With regard to publicly traded companies with ownership interests in the applicant, any person who holds 10% or more interest in the publicly traded company shall be considered an owner.

(17) Processing authorization – Written notification by the department to a medical marijuana treatment center that it may begin processing marijuana to derivative product.

(18) Processing facility – Any area designated in the application to be used for processing of derivative product.

(19) Registration – Approval and licensure as a medical marijuana treatment center pursuant to Article X, Section 29 of the Florida Constitution and consistent with section 381.986(8), F.S.

(20) Resident – A person who meets the requirements of section 381.986(5)(b), F.S.

(21) Routes of administration – means the path by which a derivative product is ordered by a physician to be taken into the body of the qualified patient, but does not include smoking.

Regulation Authority Art. X, § 29(d), Fla. Const. History–New 11-1-17.

2-1.01 Application for Registration of Medical Marijuana Treatment Centers.

Pursuant to Article X, Section 29 of the Florida Constitution and consistent with section 381.986, F.S., all applicants seeking registration with the department as a medical marijuana treatment center shall comply with the registration process detailed below. The registration process set forth in this regulation does not apply to individuals requesting registration pursuant to section 381.986(8)(a)2.a., F.S.

(1) Each individual or entity that meets the requirements of section 381.986(8)(b), F.S., desiring to be registered as a medical marijuana treatment center pursuant to Article X, Section 29 of the Florida Constitution and section 381.986, F.S., shall submit an application to the department using Form DH8013-OMMU-08/2017, "Application for Medical Marijuana Treatment Center Registration" herein incorporated by reference and available at http://www.floridahealth.gov/programs-and-services/office-of-medical-marijuana-use/mmtc-applicants/index.html. The application must comply with the page limits, blind grading, format, and organization instructions detailed in the application. The application, once submitted to the department, shall be considered final. The department will

not accept any amendments or supplements to the initial application. The applicant must include with the application at the time of submission, the following:

(a) A non-refundable application fee of $60,830.00.

(b) Written documentation from the Department of State or the Department of Revenue, as applicable under Florida law, demonstrating that the applicant has been registered to do business in Florida for the prior five consecutive years and that the applicant possesses a valid certificate of registration issued by the Department of Agriculture and Consumer Services pursuant to section 581.131, F.S. The name of the applicant as submitted to the department must match the name on any documents provided in accordance with this paragraph.

(c) A list of all owners, officers, board members, and managers indicating the date of each individual's most recent Level-2 background screening consistent with section 381.986(9), F,S, within the calendar year prior to application. Each owner, officer, board member, and manager shall go to the Florida Department of Law Enforcement (FDLE) or one of its approved vendors for fingerprinting and, at such time, shall give to FDLE or the FDLE approved vendor the entity ORI number FL924890Z (DOH – OFFICE OF MEDICAL MARIJUANA USE). The report will be sent directly to the Office of Medical Marijuana Use. To be eligible for registration, all of the applicant's owners, officers, board members, and managers must have successfully passed a Level-2 background screening.

(d) For applicants seeking registration consistent with section 381.986(8)(a)2.b., F.S., the applicant must provide evidence that it is majority-owned by (an) African-American farmer(s) who:

1. Is a recognized class member of *Pigford v. Glickman*, 185 F.R.D. 82 (D.D.C. 1999) *(Pigford*) or *In re Black Farmers Discrimination Litigation*, 856 F. Supp. 2d 1 (D.D.C. 2011) (*BFDL*). Examples of acceptable evidence include:

a. Documentation from Poorman-Douglass Corporation (now Epiq Systems Inc.) that the applicant received a consent decree case number in *Pigford*;

b. Documentation that the applicant was granted class status by the *Pigford* adjudicator;

c. Court documents or United States Department of Agriculture (USDA) documents showing that the applicant received judgment discharging debt, providing a cash payment, or providing injunctive relief in *Pigford*;

d. Documentation that the applicant was determined to be a class member by Epiq Systems Inc. in *BFDL*;

e. Documentation that the applicant received a settlement award in *BFDL*; or

f. Other court documents or USDA documents demonstrating that the applicant was granted class member status in either *Pigford* or *BFDL*.

2. Is currently a member of the Black Farmers and Agriculturists Association – Florida Chapter.

3. A letter from the Black Farmers and Agriculturists Association – Florida Chapter certifying that the applicant meets subparagraph 1. and 2. will be accepted as sufficient evidence that the applicant qualifies for registration consistent with section 381.986(8)(a)2.b., F.S.

4. Applicants seeking registration consistent with section 381.986(8)(a)2.b., F.S., are exempt from the evidentiary requirements of paragraph (1)(b) above and therefore, are also exempt from the provisions of paragraph (3)(b) below. However, if an applicant wishes to be considered under both sections 381.986(8)(a)2.b. and 381.986(8)(a)2.c., F.S., the applicant must provide the documentation required in paragraph (1)(b).

(e) For applicants seeking preference for registration consistent with section 381.986(8)(a)3., F.S., the applicant must provide evidence that:

1. The property at issue currently is or was previously used for the canning, concentrating, or otherwise processing of citrus fruit or citrus molasses. In order to demonstrate the property meets this criteria the applicant may provide documentation that the applicant currently holds or has held a registration certificate or a citrus fruit dealer license pursuant to sections 601.40 and 601.55, F.S, respectively. A letter from the Department of Citrus certifying that the property currently is or was previously used for the canning, concentrating, or otherwise processing of citrus fruit or citrus molasses will be accepted as sufficient evidence;

2. The applicant as an individual holds, in his or her name, or the applicant as an entity holds, in the legal name of the entity the deed to property meeting the criteria set forth in subparagraph 1. above; and

3. A brief explanation of how the property will be used for purposes of growing, processing or dispensing medical marijuana if the applicant is awarded a license.

(2) 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 statutory basis for the exemption. The applicant shall submit a redacted copy of the application redacting those items identified as exempt concurrent with the submission of the application for approval under subsection (4) below. Failure to provide a redacted copy of the application at the time of submission, or failure to identify and redact information claimed as trade secret will result in the release of all application information in response to a public records request unless the information falls under another public records exemption. All identified trade secrets are subject to the department review in accordance with section 381.83, F.S.

(3) Failure to provide the following at the time of submission of the application shall result in the application being denied prior to any scoring as contemplated in subsection (5) of this regulation:

(a) The $60,830.00 application fee;

(b) Documentation required under paragraph (1)(b); or

(c) The list of owners, officers, board members, and managers required under paragraph (1)(c).

(4) The department shall publish in the Florida Administrative Register and on its website the date upon which the department will begin accepting applications and the deadline to receive all applications. Applications and all required exhibits and supporting documents shall be hand delivered to the Department of Health at 4052 Bald Cypress Way in Tallahassee, Florida, during normal business hours, but no earlier than 10:00 a.m. (Eastern Time), on the date the department begins accepting applications and no later than 5:00 p.m. (Eastern Time) on the last date upon which the applications are accepted. Applications submitted after 5:00 p.m. Eastern Time on the final day of the application period will be denied.

(5) Subject matter experts will substantively and comparatively review, evaluate, and score applications using Form DH8014-OMMU-08/2017, "Scorecard for Medical Marijuana Treatment Center Selection" herein incorporated by reference and available at http://www.floridahealth.gov/programs-and-services/office-of-medical-marijuana-use/mmtc-applicants/index.html.

(a) The subject matter experts shall have the following qualifications:

1. Subject matter experts reviewing Sections 1-3 of the application, the cultivation components, shall have at least 2 years of professional experience or advanced degree in one of the following areas: agriculture, horticulture, or agronomy, or comparable field.

2. Subject matter experts reviewing Sections 4-5 of the application, the processing components, shall have at least 2 years of professional experience or advanced degree in chemistry, biology, or biochemistry.

3. Subject matter experts reviewing Sections 6-8 of the application, the dispensing components, shall have at least 2 years of professional experience or advanced degree in industrial engineering, supply chain management, or strategic management.

4. Subject matter experts reviewing Sections 9, 10, 12, and 16 of the application, the compliance components, shall have at least 2 years of professional experience or advanced degree related to operating a business in a highly regulated environment.

5. Subject matter experts reviewing Section 13 of the application shall have at least 2 years of management experience within a business operating in a regulated industry or at least 2 years of experience working in human resources.

6. Subject matter experts reviewing Section 11 of the application shall have at least 2 years of management experience within a business operating in the health care industry or an active, unrestricted license as a medical doctor or doctor of osteopathic medicine.

7. Subject matter experts reviewing Sections 14-15 of the application, the legal and financial components, shall have an active CPA license or an active license to practice law and experience in business structuring.

Subject matter experts will certify that they do not have a conflict of interest and will evaluate and score each section of the application according to the rubric set forth in DH8014-OMMU-08/2017.

(b) Scores for each Section of the application will be combined to create an applicant's total score. The department shall generate a final ranking of the applicants in order of highest to lowest scores. Any application which demonstrates a failure to comply with the minimum statutory requirements for cultivation, processing,

dispensing, security, or general operations, as identified in DH8014-OMMU-08/2017, shall be denied and will not be considered in the final ranking of applications.

(c) Consistent with section 381.986(8)(a)3., F.S., the two highest scoring applicants that own one or more facilities that are, or were, used for the canning, concentrating, or otherwise processing of citrus fruit or citrus molasses and will use or convert the facility or facilities for the processing or marijuana will receive an additional 35 points to their respective total score.

(6) Licenses will be awarded, subject to availability, consistent with s. 381.986(8)(a)2., F.S., based on the highest total score in the following manner:

(a) The highest scoring applicant that is a recognized member of *Pigford* or *BFDL* and a member of the Black Farmers and Agriculturalists Association-Florida Chapter, will receive a license.

(b) The remaining highest scoring applicants, after the addition of the preference for applicants that own citrus and molasses facilities, will receive licenses up to the statutory cap set forth in section 381.986(8)(a)2., F.S.

(c) The next four highest scoring applicants, after removing any preference points for citrus applicants provided under paragraph (5)(c) above, will receive notification of approval as contingent licensees. The contingent license will not become active until such time as the department provides notification of the registration of 100,000 active patients in the Medical Marijuana Use Registry. The department will provide notification to the contingent licensee of the activation of its license within 30 days of the registration of the first 100,000 active patients.

(d) In the event of a tie, the following tiebreakers will be applied:

1. The first tiebreaker shall be the score for Section 14 – Financials: Certified Financial Documents. The applicant with the highest score in Section 14 shall be awarded a license. In the event that this does not resolve the tie:

2. The second tiebreaker shall be the score for Section 15 – Financials: Business Structure. The applicant with the highest score in Section 15 shall be awarded a license. In the event that this does not resolve the tie:

3. The third tiebreaker shall be the score for Section 13 – Diversity Plan. The applicant with the highest score in Section 13 shall be awarded a license. In the event that this does not resolve the tie:

4. The final tiebreaker shall be the score for Section 10 – Accountability: Operations.

(7) Upon notification that it has been approved as a medical marijuana treatment center as an active license, the applicant shall have 10 business days to:

(a) Post a performance bond, provide an irrevocable letter of credit payable to the department or provide cash to the department in the amount of $5 million (collectively "financial assurance") consistent with section 381.986(8)(b)7., F.S. If a bond is provided, the bond shall:

1. Be payable to the department in the event the medical marijuana treatment center's approval is revoked;

2. Be written by an authorized surety company rated in one of the three highest rating categories by a nationally recognized rating service; and

3. Be written so that the individual or entity name on the bond corresponds exactly with the applicant name.

4. The surety company can use any form it prefers for the performance bond as long as it complies with this regulation. For convenience, the surety company can use Form DH8015-OMMU-08/2017, "Florida Medical Marijuana Performance Bond" herein incorporated by reference and available at http://www.floridahealth.gov/programs-and-services/office-of-medical-marijuana-use/mmtc-applicants/index.html.

(b) Provide documentation supporting representations related to property ownership and/or leases made in the application.

(8) If a financial assurance is canceled or revoked in any manner and the medical marijuana treatment center fails to provide new financial assurance to the department in the required amount on or before the effective date of cancellation or revocation, the medical marijuana treatment center's approval shall be revoked.

(9) If a selected applicant fails to post the financial assurance or supporting property ownership and/or use documents within the required timeframe, the applicant with the next highest score shall be selected and notified.

Regulation Authority Art. X, § 29(d), Fla. Const. History- New 11-1-17.

September 29, 2017

The Honorable Travis Cummings
Chair, House Health and Human Services Committee
214 House Office Building
402 South Monroe Street
Tallahassee, Florida 32399-1100

Dear Chair Cummings:

During a special session called earlier this year, the Florida Legislature passed Senate Bill 8-A (2017). SB 8-A went into effect on June 23, 2017, and represents a significant step forward in implementing Article X Section 29 of the Florida Constitution. It includes several requirements that the Office of Medical Marijuana Use (OMMU) has diligently worked to implement.

One key objective the OMMU continues to work toward completing is the issuance of five additional licenses through a competitive licensure process. The issuance of five, merit-based Medical Marijuana Treatment Center (MMTC) licenses by October 3, 2017, was an extraordinarily challenging timeline.

This is especially true considering the Department of Health has recently been served with a lawsuit challenging the constitutionality of the statutory requirement to reserve a license for a Pigford class litigant who is also a member of the Florida Chapter of the Black Farmers and Agriculturalists Association. In addition, response and recovery efforts related to Hurricane Irma necessitated the mobilization of all available Department assets for almost two weeks.

In light of the above, the OMMU will not be issuing five additional MMTC licenses by October 3, 2017. The OMMU is aware of its important role in continuing to move this process forward to provide patient access as quickly and safely as possible. However, recent history has emphasized the importance of getting the MMTC licensure process right the first time. The low-THC marijuana licensing selection in 2015 resulted in 13 administrative challenges, two of which the Department continues to litigate.

The OMMU has issued rules for the MMTC license application process. We believe the current process, which includes the use of blind grading, subject matter expert evaluators, and more efficient calls for information, will allow for an open and straightforward process. Even without any regulatory challenges, the OMMU must afford sufficient time for respondents to complete applications, for staff to assess each application for sufficiency, and for reviewers to read, evaluate, and score all completed applications.

The lawsuit filed last week, *Smith v. Department of Health,* Case No. 2017-CA 001972, includes a claim for injunctive relief, asking the court to stop the OMMU from issuing a license to a Pigford class litigant during the challenge. As the application process for the Pigford class litigant license is intertwined with the application process for general licensure, the Department is obligated to let the court rule on the claim for injunctive relief prior to accepting and scoring any applications. To move forward under these

circumstances would potentially disenfranchise other Pigford class litigant applicants and deplete state resources dedicated to the careful and thoughtful expert evaluation of all MMTC applications. The Department is working with the Plaintiff in the *Smith* suit to expedite the process and bring resolution to this issue as quickly as possible.

During the past 13 weeks, the OMMU has worked diligently to implement Senate Bill 8-A (2017). The OMMU has:

- Granted seven Medical Marijuana Treatment Center (MMTC) licenses to existing Dispensing Organizations.
- Approved five new MMTCs and commenced cultivation authorization inspections.
- Issued a Request for Quotes (RFQ) related to MMTC application grading.
- Established an OMMU organizational structure for 28 initial FTEs as well as the 27 FTEs held in reserve by SB-8A.
- Developed position descriptions, class codes and pay bands for each new OMMU position.
- Assembled screening and interview teams that have begun establishing positions and hiring candidates.
- Developed a Request for Proposal (RFP) for Statewide Seed-to-Sale Tracking.
- Developed and issued an Invitation to Negotiate (ITN) for Medical Marijuana Identification Card outsourcing and commenced negotiations with vendors.
- Engaged Moffitt Cancer Center regarding their requirements under SB 8-A and is currently working toward finalizing an agreement with the organization.
- Established a contract with the University of Florida to fulfill the research requirement for the education component of SB 8-A.

The Department and the OMMU will continue to faithfully implement SB 8-A and Article X Section 29 of the Florida Constitution. We remain committed to moving this process forward, and will do so in an expedient and thoughtful manner.

Sincerely,

Christian Bax
Director
Office of Medical Marijuana Use

cc: The Honorable Joe Negron
The Honorable Richard Corcoran
The Honorable Rob Bradley
The Honorable Ray Rodrigues
Ms. Sandra Stovall
Ms. Christa Calamas

October 3, 2017

Mr. Christian J. Bax, Director
Office of Medical Marijuana Use
Department of Health
4052 Bald Cypress Way
Tallahassee, Florida 32399

Re: Emergency Rules 64ER17-1 (64-4.001), Definitions, and 64ER17-2 (64-4.002), Application for Registration of Medical Marijuana Treatment Centers

Dear Mr. Bax:

Section 14(1), chapter 2017-232, Laws of Florida (section 381.986, Note 1B(1)(a), Florida Statutes), provides in part, that, "The Department of Health and the applicable boards shall adopt emergency rules pursuant to s. 120.54(4), Florida Statutes, and this section necessary to implement ss. 381.986 and 381.988, Florida Statutes." On September 19, 2017, the Department filed Emergency Rules 64ER17-1 (64-4.001) and 64ER17-2 (64-4.002), F.A.C., with the Department of State. Both rules were published in the September 21, 2017, issue of the Florida Administrative Register.

Section 381.986, Florida Statutes, sets forth a number of mandatory rulemaking requirements. In conducting a preliminary review of Emergency Rule 64ER17-2 (64-4.002) and Form DH8013-OMMU-08/2017, incorporated by reference therein (the "Application"), pursuant to the Committee's authority under section 120.545, and Joint Rule 4.6 of the Florida Legislature, it appears that several issues required to be addressed in the Application are dependent upon criteria which must be established by rules that have not yet been adopted by the Department. Specifically:

- Section 2 of the Application requires the applicant to, "Provide a list of the strains, additives, pesticides, fungicides, and herbicides the applicant will use for the cultivation of medical marijuana." Section 381.986(8)(e)6.a. states that when growing marijuana, a medical marijuana treatment center, "May use pesticides determined by the department, after consultation with the Department of Agriculture and Consumer Services, ..."

- Sections 3 and 5 of the Application require the applicant to submit, "A plan to ensure compliance with federal, state, and local regulations regarding sanitation and waste disposal." Section 381.986(8)(e)10.c. requires that the Department, "determine by rule procedures for the storage, handling, transportation, management, and disposal of solid and liquid waste generated during marijuana production and processing."

- Section 4 of the Application requires the applicant to submit, "A plan to ensure a sanitary and safe processing facility," and "A plan for utilizing extraction processes that ensure a safe work environment (e.g., methods of extraction, use of proper ventilation, implementation of a closed-loop system, and implementation of Occupational Safety and Health Administration standards)." Section 381.986(8)(e)10.b. requires that the Department, "determine by rule the requirements for medical marijuana treatment centers to use [hydrocarbon solvents or other] solvents or gases exhibiting potential toxicity to humans."

- Section 4 of the Application also requires that the applicant submit, "A plan for testing medical marijuana, including: . . . A list of contaminants, if any, for which the applicant will require testing." Section 381.986(8)(e)10.d. states, "The department shall determine by rule which contaminants must be tested for and the maximum levels of each contaminant which are safe for human consumption."

- Section 6 of the Application requires that the applicant submit: "A marketing plan, including proposed branding, signage, as well as sources the applicant plans to use for advertising including documentation that the plan is compliant with the signage and Internet marketing restrictions set forth in section 381.986(8)(h), Florida Statutes." Section 381.986(8)(h)1. provides in part, that a medical marijuana treatment center may display a sign that contains, "a department-approved trade name, or a department-approved logo." With respect to Internet advertising and marketing, section 381.986(8)(h)2.a. requires that, "All advertisements must be approved by the department." Although both statutory provisions set forth guidelines for signage and Internet marketing, the requirement to submit, "documentation that the plan is compliant with the signage and Internet marketing restrictions set forth in section 381.986(8)(h), Florida Statutes[,]" suggests that prior review or approval has been obtained from the Department. Although the statutory criteria regarding signage and Internet marketing are fairly specific, they do require a subjective review of the proposed trade name, logo and website. As such, it appears that rules should be adopted in order to ensure a consistent review by the Department and to avoid any suggestion of the Department's exercise of unbridled discretion. Rulemaking is authorized pursuant to section 381.986(8)(k).

It is unclear how Applications submitted to the Department can be reviewed and scored absent the Department's adoption of the rules establishing the criteria for the information requested.

In addition to the foregoing, section 381.986 also requires the Department to adopt rules relating to the following:

- Section 381.986(4)(a)7.a. - Daily dosage amounts of medical marijuana.

- Section 381.986(8)(e)8. – The shapes, forms, and ingredients allowed and prohibited for edibles.

- Section 381.986(8)(e)8. - Sanitation rules providing the standards and requirements for the storage, display, or dispensing of edibles.

- Section 381.986(8)(e)10.d. – Procedures for the treatment of marijuana that fail to meet the testing requirements of section 381.986, section 381.988, or Department rule.

Please advise the Committee of the timeframe for the promulgation of the required rules and, in the interim, how the Department intends to review and score applications for Registration of Medical Marijuana Treatment Centers without the benefit of the standards or criteria statutorily required to be set by the Department.

Pending further review of the emergency rules, I would like to bring to your attention two matters of immediate concern considering the imminent publication of the date upon which the Department will begin accepting applications. First, Emergency Rule 64ER17-2(1)(a) (64-4.002(1)(a)), requires the submission of a nonrefundable fee of $60,830.00 with the Application. This requirement appears to be inconsistent with an Attorney General opinion that states, absent specific statutory authority to the contrary, if an individual requests a refund of a fee prior to any action being taken concerning the applicant's qualifications, the fee should be refundable. *See* Op. Att'y Gen. Fla. 75-293 (1975). Second, Emergency Rule 64ER17-2(1) and the instructions set out on page 3 of the Application, state: "The application, once submitted to the Department shall be considered final. The Department will not accept any amendments or supplements to the initial application." This statement appears to contradict the requirements of section 120.60 regarding an agency's procedures in processing license applications, which require that applicants be given the opportunity to correct any deficiencies discovered by the agency in its initial review. It does not appear that section 381.986, provides an exemption to section 120.60 for the process of obtaining a license to become a medical marijuana treatment center.

Finally, there is some confusion regarding the relationship between the proposed regulations published in the September 20, 2017, issue of the Florida Administrative Register, and the emergency rules published in the September 21, 2017, issue of the Florida Administrative Register. The "Rulemaking Authority" cited for proposed regulations 1-1.02 and 2-1.01 is "Art. X, § 29(d), Fla. Const." Reference to Article X, Section 29 of the Florida Constitution is further cited in regulation 1-1.02(1) ("Applicant" – An individual or entity that meets the requirements of section 381.986(8)(b), F.S., and applies for registration as a medical marijuana treatment center pursuant to Article X, Section 29 of the Florida Constitution and consistent with section 381.986(8)(a)2.b., and c., F.S."), and regulation 2-1.01 ("Pursuant to Article X, Section 29 of the Florida Constitution and consistent with section 381.986, F.S. . . .").

Section 14(2), Chapter 2017-232, Laws of Florida (section 381.986, Note 2), states in pertinent part:

> (2) CAUSE OF ACTION
> (a) As used in s. 2(d)(3), Article X of the State Constitution, the term:
> 1. "Issue regulations" means the filing by the department of a rule or emergency rule for adoption with the Department of State.

Given the specific language of section 14(2), chapter 2017-232, Laws of Florida, it would appear that the Department's reliance on Article X, Section 29 of the Florida Constitution, as "rulemaking authority" for the regulations is misplaced. Any "regulations" promulgated under Article X, Section 29(d), of the Florida Constitution, should be adopted as rules or emergency rules pursuant to chapter 120, and not as a stand-alone set of regulations. The simultaneous publication of regulations and emergency rules setting forth virtually identical requirements appears to be inconsistent with the requirements of section 14(2), chapter 2017-232, Laws of Florida, and chapter 120. Please explain the Department's authority to promulgate both a set of regulations and emergency rules.

Please let me know if you have any questions. I look forward to your response.

Sincerely,

Kenneth J. Plante
Coordinator

KJP:tl

cc: Ms. Nichole Geary, General Counsel
Ms. Amanda Bush, Senior Attorney

October 9, 2017

Ms. Amanda G. Bush
Senior Attorney
Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin A-02
Tallahassee, Florida 32399-1703

Re: Emergency Rule 64ER17-1
(Substantial Rewording of Rule 64-4.001, Florida Administrative Code)

Dear Ms. Bush:

I have reviewed the above-referenced emergency rule, which was filed with the Department of State on September 19, 2017, and published in the Florida Administrative Register on September 21, 2017. I have the following comments. The designation of the comments is based on the numbering of the emergency rule.

64ER17-1: Please explain why the introductory paragraph to this emergency rule refers to "medical marijuana treatment center rules and regulations." It appears it should refer to "medical marijuana treatment center rules."

64ER17-1(4): This subsection defines "Contingent licensee" as, "An applicant that has been granted approval contingent upon the initial registration of 100,000 active patients in the Medical Marijuana Use Registry in accordance with section 381.986(8)(a)4., F.S." Please explain the department's statutory authority to award licenses contingent upon meeting the 100,000 active patient threshold set forth in section 381.986(8)(a)4. at some unknown date in the future. It appears that awarding such contingent licenses now could foreclose application by certain applicants who will meet the requirements of section 381.986(8)(b) at the time that threshold is met. It appears that such licenses, contingent or otherwise, should not be awarded until after the 100,000 active patient threshold is reached. *See* § 120.52(8)(c), Fla. Stat.

Please explain whether the provisions of section 120.60(3) apply to the award of these contingent licenses.

64ER17-1(16)(d): Please explain the department's statutory authority to exempt persons under the age of 18 years in this rule paragraph from submitting to background screening if their "interest or ownership [is] not imputed to another family member or guardian as outlined in paragraph [64ER-1(16)](c). *See* § 381.986(8)(b)8., Fla. Stat. (requiring all owners of an MMTC to have passed a background screening pursuant to section 381.986(9)); Fla. Admin. Code R. 64ER17-2(1)(c) ("To be eligible for registration, all of the applicant's owners, officers, board members, and managers must have successfully passed a Level-2 background screening."). It appears this rule may enlarge, modify, or contravene the specific provisions of law implemented. *See* § 120.52(8)(c), Fla. Stat.

64ER17-1(19): Please explain why this subsection defines "registration" as, "Approval and licensure as a medical marijuana treatment center pursuant to section 381.986(8), F.S." It appears that Emergency Rule 64ER17-2 refers to the "registration" of patients in the Medical Marijuana Use Registry, and that Emergency Rule 64ER17-2 and its incorporated material refer to certificates of registration from the Department of Agriculture and Consumer Services. Thus, it appears that "registration" in these rules is used in contexts other than for the approval and licensure as a medical marijuana treatment center.

64ER17-1(20): This subsection defines "Resident" as, "A person who meets the requirements of section 381.986(5)(b), F.S." Section 381.986(5)(b) sets forth the documentation that the department is to use to determine whether an individual is a resident of this state. Among the permitted documentation is "[a]ny other documentation that provides proof of residential address as determined by department rule." *See* § 381.986(5)(b)2.g., Fla. Stat. Pease explain whether the documentation used to establish residency to obtain in rule 64-4.011(2) and its incorporated documents continues to be valid.

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

Sincerely,

Marjorie C. Holladay
Chief Attorney

cc: Ms. Nichole C. Geary, General Counsel
Mr. Christian J. Bax, Director
Ms. Renee C. Harkins, Assistant General Counsel

MCH:SA WORD/MARJORIE/EMERGENCY RULE 17-01LS100917_#6890

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October 9, 2017

Ms. Amanda G. Bush
Senior Attorney
Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin A-02
Tallahassee, Florida 32399-1703

Re: Emergency Rule 64ER17-2
(Substantial Rewording of Rule 64-4.002, Florida Administrative Code)

Dear Ms. Bush:

I have reviewed the above-referenced emergency rule, which was filed with the Department of State on September 19, 2017, and published in the Florida Administrative Register on September 21, 2017. I have the following comments. The designation of the comments is based on the numbering of the emergency rule.

64ER17-2: The title of the rule in the notice of the emergency rule is different from the title of the rule above the rule text. Please explain which title is correct.

Please explain why the rule and material incorporated by reference in the rule text refer to "registration" instead of "licensure" of medical marijuana treatment centers. *See* § 381.986(8)(a), Fla. Stat. (stating specifically that medical marijuana treatment centers shall be licensed by the department); *see also* § 120.52(10), Fla. Stat. (defining a license to include a "registration").

Please explain why the introductory paragraph to this emergency rule refers to "this regulation." It appears it should refer to "this rule" or to "this emergency rule."

64ER17-2(1): This rule subsection states that, "the application [to become a medical marijuana treatment center], once submitted to the department, shall be considered final" and that the department will not accept any amendments or supplements to the initial application.

Please explain which statute exempts the department from complying with the requirements of section 120.60(1). That statute states in part:

> Upon receipt of a license application, an agency shall examine the application and, within 30 days after such receipt, notify the applicant of any apparent errors or omissions and request any additional information the agency is permitted by law to require. An agency may not deny a license for failure to correct an error or omission or to supply additional information unless the agency timely notified the applicant within this 30-day period. The agency may establish by rule the time period for submitting any additional information requested by the agency. For good cause shown, the agency shall grant a request for an extension of time for submitting the additional information. If the applicant believes the agency's request for additional information is not authorized by law or rule, the agency, at the applicant's request, shall proceed to process the application. An application is complete upon receipt of all requested information and correction of any error or omission for which the applicant was timely notified or when the time for such notification has expired.

Thus, it appears the department must provide an opportunity to correct an error or omission or supply additional information requested by the department. If a rule and statute conflict, the statute controls. *See One Beacon Ins. v. Agency for Health Care Admin.*, 958 So. 2d 1127, 1129 (Fla. 1st DCA 2007) ("In cases of conflict, a statute takes precedence over an administrative rule.").

This subsection incorporates by reference Form DH8013-OMMU-08/2017, Application for Medical Marijuana Treatment Center Registration.

DH8013-OMMU-08/2017:
The department is setting a page limitation for all but one section for the narrative responses required by the application. Additionally, page two of the application instructions states that, "Pages in excess of the page limit will be removed from the application prior to evaluation." Please explain how the page limitation and the removal of pages from the application is not arbitrary and capricious, especially when neither the rule text nor the application advises the applicant how each item listed in each section of the application will be weighted. *See* § 120.52(8)(e), Fla. Stat.

Page 2, Section 1: This section states that, "With the exception of Sections 11, 14 and 15, Part II of the application will be evaluated using a blind grading method and must be de-identified." Please explain why the headers on pages 14, 18, and 19 of Form DH8014-OMMU-08/2017, which are the scorecards for sections 11, 14, and 15, reflect that a "Blind Grading Number" will be assigned to those sections. It appears that this statement conflicts with those headers.

Page 3: The form states, "The application [to become a medical marijuana treatment center], once submitted to the department, shall be considered final" and that the department will not accept any amendments or supplements to the initial application. Please explain which statute exempts the department from complying with the requirements of section 120.60(1). See comment to 64ER17-2(1) regarding the applicability of section 120.60(1).

Page 5, A.: Please explain how documentation from the Florida Department of Revenue demonstrates that the applicant has been registered to do business in the state for the previous five consecutive years.

Page 5, D., second paragraph and *NOTE: Please explain why the two references to "Pigford Class Applicant" do not also include a reference to the class members of *In Re Black Farmers Litig*. *See* § 381.986(8)(a)2.b., Fla. Stat.

Page 6, Section 1: This section is worth a total of 50 points, and the applicant is limited to a four page narrative to address ten items. It appears the applicant should be advised of the relative weight, percentage, or specific number of points that the subject matter expert(s) reviewing the application will award each applicant for each specific item to be addressed. Also, please explain how each application is evaluated and scored if there are no minimum thresholds or standards required for demonstrating each item enumerated in this paragraph. *See* § 120.52(8)(d), Fla. Stat.

Page 6, Section 1, Number 2.: Please explain what the department means by "regional cultivation" and to what region the department is referring. *See* § 120.52(8)(d), Fla. Stat.

Page 6, Section 1, Number 3.e.: Please explain what the department means by "good agricultural practices." *See* §§ 120.52(8)(d), .54(2)(b)2., Fla. Stat.

Page 6, Section 1, Number 3.f.: Please explain what the department means by "good handling practices." *See* §§ 120.52(8)(d), .54(2)(b)2., Fla. Stat.

Page 6, Section 2: This section is worth 50 points, and the applicant is limited to a seven page narrative to address eight items. See comments regarding page 6, section 1.

Page 6, Section 2, Number 1.e.: This section asks the applicant to provide a cultivation plan that will ensure a consistent supply of safe medical marijuana that addresses, "Inspection processes for pests that endanger or threaten the horticulture or agriculture of the state in accordance with Chapter 581, Florida Statutes." It appears this question should specify which sections of chapter 581 the department wants addressed. *See* § 120.52(8)(d), Fla. Stat.

Page 6, Section 2, Number 1.e.: Please explain why this question does not ask whether the applicant's cultivation plan addresses the inspection processes for pests that endanger or threaten the horticulture or agriculture of the state in accordance with any rules adopted pursuant to chapter 581. *See* § 381.986(8)(e)6.c., Fla. Stat. Also, it appears such rules should be specifically identified. It appears this question may enlarge, modify, or contravene section 381.986. *See* § 120.52(8)(c), Fla. Stat.

Page 6, Section 2, Number 1.f.: This question asks the applicant to address, "Fumigation, treatment, and plant destruction plans for infested or infected plants in accordance with Chapter 581, Florida Statutes." It appears this question should specify which sections of chapter 581 the department wants addressed. *See* § 120.52(8)(d), Fla. Stat.

Page 6, Section 2, Number 1.f.: Please explain why this question does not ask whether the applicant's cultivation plan addresses fumigation, treatment, and plant destruction plans in accordance with any rules adopted pursuant to chapter 581. *See* § 381.986(8)(e)6.d., Fla. Stat. It appears the Department of Agriculture and Consumer Services has adopted rules pertaining to fumigation. *See, e.g.*, Fla. Admin. Code ch. 5E-2. Also, it appears such rules should be specifically identified. It

appears this question may enlarge, modify, or contravene section 381.986. *See* § 120.52(8)(c), Fla. Stat.

Page 6, Section 2, Number 2.: Please explain why the department is asking for a list of the pesticides the applicant will use for the cultivation of medical marijuana. Section 381.986(8)(e)6.a. states that, when growing marijuana, a medical marijuana treatment center, "[m]ay use pesticides determined by the department, after consultation with the Department of Agriculture and Consumer Services, to be safely applied to plants intended for human consumption, but may not use pesticides designated as restricted-use pesticides pursuant to s. 487.042." It does not appear that the department has proposed a rule stating which pesticides may be used as required by this statute. Please explain whether the applications will be graded on criteria that the department has not yet established by rule. *See* § 120.52(8)(d), Fla. Stat.

Page 6, Section 3: This section is worth 50 points, and the applicant is limited to a four page narrative to address ten items. See comments regarding page 6, section 1.

Page 7, Section 3, Number 4.: This section asks the applicant to address its plan to ensure compliance with federal, state, and local regulations regarding sanitation and waste disposal." It appears that this section should identify the specific federal and state regulations that should be complied with regarding solid and liquid waste disposal. Also, please explain the department's statutory authority to require compliance with local regulations. It appears that section 381.986(8)(e)10.c. only requires a medical marijuana treatment center to comply with such federal and state laws and regulations relating to waste disposal. It does not appear that section 381.986(11) provides an exemption to preemption to the state regarding the disposal of solid and liquid wastes. *See* § 120.52(8)(c), Fla. Stat.

Page 7, Section 3, Number 4.: Please explain why this question does not address compliance with department rules for disposal of solid and liquid wastes as required by section 381.986(8)(e)10.c. *See* § 120.52(8)(c), Fla. Stat.

Page 7, Section 3, Number 4.: Please explain why the application does not ask the applicant to address the "storage, handling, transportation, and management of solid and liquid waste generated during marijuana production and processing." *See* § 381.986(8)(e)10.c., Fla. Stat.

Page 7, Section 3, Number 4.: Section 381.986(8)(e)10.c. requires the department to "determine by rule procedures for the storage, handling,

transportation, management, and disposal of solid and liquid waste generated during marijuana production and processing" with the assistance of the Department of Environmental Protection. It does not appear that a rule has been proposed yet.

Page 7, Section 4: This section is worth 100 points, and the applicant is limited to a seven page narrative to address 13 items. See comments regarding page 6, section 1.

Page 7, Section 4, Number 4.a.: This section requests applicants to provide a list of proposed product offerings, and if edibles are included, requests applicants to address the applicant's ability or plan to obtain a permit to operate as a food establishment in accordance with Chapter 500, Florida Statutes. It appears that applicant should also be required to show compliance with rules adopted pursuant to chapter 500 pursuant to section 381.986(8)(e)8. *See* § 120.52(8)(c), Fla. Stat. Also, it appears such rules should be specifically identified.

Page 7, Section 4, Number 6.: Please explain why this question asks the applicant to submit, "A plan for utilizing extraction processes that ensure a safe work environment (e.g., methods of extraction, use of proper ventilation, implementation of a closed-loop system, and implementation of Occupational Safety and Health Administration standards)." Section 381.986(8)(e)10.b. requires the department to, "determine by rule the requirements for medical marijuana treatment centers to use [hydrocarbon solvents or other] solvents or gases exhibiting potential toxicity to humans." Please explain whether the applications will be graded on criteria that the department has not yet established by rule. *See* § 120.52(8)(d), Fla. Stat.

Page 7, Section 4, Number 7.b.: Please explain why this question requests the applicant to submit a plan for testing medical marijuana, including, "A list of contaminants, if any, for which the applicant will require testing." Section 381.986(8)(e)10.d. requires the department to, "determine by rule which contaminants must be tested for and the maximum levels of each contaminant which are safe for human consumption." That statute also requires the department, with the assistance of the Department of Agriculture and Consumer Services, to develop, "the testing requirements for contaminants that are unsafe for human consumption in edibles." Please explain whether the applications will be graded on criteria that the department has not yet established by rule. *See* § 120.52(8)(d), Fla. Stat.

Page 7, Section 4, Number 7.b.: Please explain why this section does not ask the applicant to address, "the treatment of marijuana that fails to meet the testing requirements of this section [381.986], s. 381.988, or

department rule," which is a requirement of section 381.986(8)(e)10.d. Furthermore, it appears that the department has not yet proposed the rule to implement this provision as mandated by this statute.

Pages 7 and 8, Section 5: This section is worth 50 points, and the applicant is limited to a four page narrative to address 12 items. See comments regarding page 6, section 1.

Page 8, Section 5, Number 3.: Please explain why this question does not address compliance with department rules for disposal of solid and liquid wastes as required by section 381.986(8)(e)10.c. *See* § 120.52(8)(c), Fla. Stat.

Page 8, Section 5, Number 3.: Please explain why the application does not ask the applicant to address, "the storage, handling, transportation, and management of solid and liquid waste generated during marijuana production and processing." *See* § 381.986(8)(e)10.c., Fla. Stat.

Page 8, Section 5, Number 3.: Additionally, section 381.986(8)(e)10.c. requires the department to, "determine by rule procedures for the storage, handling, transportation, management, and disposal of solid and liquid waste generated during marijuana production and processing" with the assistance of the Department of Environmental Protection. It does not appear that a rule has been proposed yet as mandated by this statute.

Page 8, Section 6: This section is worth 50 points, and the applicant is limited to a five page narrative to address seven items. See comments regarding page 6, section 1.

Page 8, Section 6, Number 2.: This question requires the applicant to submit proposed branding, signage, and advertising documentation that shows compliance with section 381.986(8)(h). Section 381.986(8)(h) requires the department to approve any trade name, logo, and advertising. Please explain whether the department will be approving any branding, signage, and advertising using this application. Also, it appears that rules should be adopted governing such advertising. Please explain whether the applications will be graded on criteria that the department has not yet established by rule. *See* § 120.52(8)(d), Fla. Stat.

Page 8, Section 7: This section is worth 50 points, and the applicant is limited to a seven page narrative to address 17 items. See comments regarding page 6, section 1.

Pages 8 and 9, Section 8: This section is worth 100 points, and the applicant is limited to an eight page narrative to address eight items. See comments regarding page 6, section 1.

Pages 8 and 9, Section 8: Please explain why the map requested in number 1.a. and the floor plan requested in number 1.b. will be counted against the eight page limitation for this section. It does not appear that that the floor plans submitted pursuant to section 9 apply to the four page limitation set for that section.

Page 9, Section 9: This section is worth 100 points, and the applicant is limited to a four page narrative, plus a four page addendum, to address 16 items. See comments regarding page 6, section 1.

Page 9, Section 9, Number 1.b.: Please explain whether more than one alarm system will be required. The scorecard refers to "alarm systems," for Section 9, while this section in Form DH8013-OMMU-08/2017 refers to "alarm system." It appears the requirement should be identical in both documents.

Page 9, Section 9, Number 1.c.v.: Section 381.986(8)(f)1.b.(IV) requires medical marijuana treatment centers to retain video surveillance recordings for at least 45 days or longer upon the request of a law enforcement agency. Please explain why this section only requires demonstration of a plan for retention of such recordings for at least 45 days without mention of retaining the recordings longer pursuant to this statutory requirement. *See* § 120.52(8)(c), Fla. Stat.

Page 9, Section 9, Number 1.d.: Section 381.986(8)(f)2. requires a medical marijuana treatment center to ensure that its outdoor premises have sufficient lighting from dusk until dawn. Please explain why this section only requires the applicant's floor plan to demonstrate that it has outdoor lighting. *See* § 120.52(8)(c), Fla. Stat.

Page 10, Section 10: This section is worth 100 points, and the applicant is limited to a seven page narrative to address 19 items. See comments regarding page 6, section 1.

Page 10, Section 10: Also, section 381.986(8)(g)6. requires medical marijuana treatment centers to provide specific safety and security training to employees transporting or delivering marijuana and marijuana delivery devices. Please explain why this section does not require applicants to demonstrate compliance with this statutory requirement. *See* § 120.52(8)(c), Fla. Stat.

Page 10, Section 10, Number 4.: This section differs from the language in the scorecard for this section in DH8014-OMMU-08/2017, in omitting the "or" preceding "other reasons." It appears the language should be identical.

Pages 10 and 11, Section 11: This section is worth 50 points, and the applicant is limited to a six page narrative to address 21 items. See comments regarding page 6, section 1.

Page 11, Section 11, Number 5.: Please explain what the department means by "has a medical director at all times." It appears this could mean, for example, having a medical director employed, on the premises, or available during operating hours. *See* § 120.52(8)(d), Fla. Stat.

Page 11, Section 12: This section is worth 50 points, and the applicant is limited to a four page narrative to address six items. See comments regarding page 6, section 1.

Page 11, Section 12, Number 1.: Please explain why the second sentence of this item is included in the application, but omitted from the scorecard in Form DH8014-OMMU-08/2017, page 16, for this section. It appears the language should be identical.

Page 11, Section 12, Number 3.: It appears that "key personnel" should be defined. *See* § 120.52(8)(d), Fla. Stat.

Page 12, Section 13: This section is worth 100 points, and the applicant is limited to a four page narrative to address three items. See comments regarding page 6, section 1.

Page 12, Section 14: Please explain why this section refers to "audited" certified financials. It does not appear that the scorecard in Form DH8014-OMMU-08/2017, page 16, for this section refers to "audited" certified financials. It appears the language should be identical.

Pages 12 and 13, Section 15: This section is worth 100 points, and the applicant is limited to an eight page narrative, plus a four page addendum, to address 16 items. See comments regarding page 6, section 1.

Page 12, Section 15: Please explain why the language in bolded type is included in the application but omitted from the scorecard for this section in Form DH8014-OMMU-08/2017 on page 19.

Page 12, Section 15, Number 8: It appears "hold direct or indirect ownership or control" should be "holds direct or indirect ownership or control."

Page 13, Section 16: This section is worth 50 points, and the applicant is limited to an eight page narrative, plus a six page addendum, to address five items. See comments regarding page 6, section 1.

Page 13, Section 16: Please explain why the "NOTE" and bolded language in this section is not included on the scorecard for this section in Form DH8014-OMMU-08/2017 on page 20.

Page 14, Part III: Please explain whether the department will accept applications hand-delivered by the United States Postal Service or other delivery services, and whether "hand delivery" is used to distinguish from "electronic delivery." *See* § 120.52(8)(d), Fla. Stat.

Page 14, Part III: See comment to 64ER17-2(1)(a) regarding the non-refundable application fee.

64ER17-2(1)(a): Please explain why this rule paragraph states that the application fee is non-refundable. Absent statutory authority to the contrary, it appears that if an individual requests a refund of this fee prior to any action being taken concerning the applicant's qualifications, the fee should be refundable. *See* Op. Att'y Gen. Fla. 75-293 (1975).

64ER17-2(1)(b): Please explain how documentation from the Florida Department of Revenue demonstrates that the applicant has been registered to do business in the state for the previous five consecutive years.

64ER17-2(1)(d): Please explain the department's statutory authority to require an applicant to be "majority-owned by (an) African-American farmer(s)" who would otherwise meet the qualifications set forth in rule subparagraphs (1)(d)1. through 4. Section 381.986(8)(a)2.b. requires the actual "applicant" for such a license to be a recognized class member of *Pigford v. Glickman*, 185 F.R.D. 82 (D.D.C. 1999) or *In Re Black Farmers Litig*., 856 F. Supp. 2d 1 (D.D.C. 2011). If the applicant is only "majority-owned" (as that term is defined in 64ER17-1(14)) by a recognized class member, it appears this may be enlarging, modifying, or contravening section 381.986(8)(a)2.b. *See* § 120.52(8)(c), Fla. Stat.

64ER17-2(1)(d)3.: Please explain why the department will accept a letter from the Black Farmers and Agriculturalists Association – Florida Chapter as evidence to demonstrate that the applicant qualifies for registration pursuant to section 381.986(8)(a)2.b. Specifically, please explain how the Black Farmers and

Agriculturalists Association – Florida Chapter can document that an applicant was a recognized class member of *Pigford v. Glickman*, 185 F.R.D. 82 (D.D.C. 1999) or *In Re Black Farmers Litig.*, 856 F. Supp. 2d 1 (D.D.C. 2011).

64ER17-2(1)(e)1.: This subparagraph describes what an applicant applying pursuant to section 381.986(8)(a)3. must submit. One of the options that the applicant may provide is, "documentation that the applicant currently holds or has held a registration certificate *or* a citrus fruit dealer license pursuant to sections 601.40 and 601.55, F.S, respectively." (Emphasis added.) It does not appear that a license held pursuant to section 601.55 is sufficient; it appears that the applicant must also hold a registration pursuant to section 601.40.

Furthermore, it does not necessarily appear that holding registrations pursuant to section 601.40 and section 601.55 is sufficient. It appears in order to qualify for licensure preference pursuant to section 381.986(8)(a)3. that the applicant must be registered as a citrus processing plant pursuant to section 601.40. *See* § 601.03(32), Fla. Stat. (defining "processor" as "any person engaged in this state in the business of canning, concentrating, or otherwise processing citrus fruit for market other than for shipment in fresh fruit form."). It does not appear that a citrus packinghouse licensed pursuant to section 601.40 is eligible to receive a licensure preference pursuant to section 381.986(8)(a)3. because a packinghouse is a place "where citrus fruit is packed or otherwise prepared for market or shipment in fresh form." *See* § 601.03(29), Fla. Stat. Please explain how the department will know if the applicant is registered as a packinghouse or a processor pursuant to section 601.40. *See* § 120.52(8)(c), Fla. Stat.

64ER17-2(3): Please explain which statute exempts the department from complying with the requirements of section 120.60(1). See comment to 64ER17-2(1) regarding the applicability of section 120.60(1).

Please explain why this subsection refers to "this regulation." It appears it should refer to "this rule" or "this emergency rule."

64ER17-2(4): Unless the department publishes another emergency rule setting forth these dates, please explain why publishing the date upon which the department will begin accepting applications and the deadline to receive the applications in the Florida Administrative Register and on the department's website is not an unadopted rule. *See* § 120.52(20), Fla. Stat.

64ER17-2(5): Section 381.986(8)(a) requires the department to license medical marijuana treatment centers. Likewise, rule subsection (6) states that licenses will be awarded, subject to availability, based on the highest total score. The award of the licenses appears to be based on the scores assigned by the subject matter experts referenced in this subsection. Please advise whether these subject matter experts are department personnel. If they are not agency personnel, please explain how this rule is not an unauthorized delegation of the award of licenses by the department to third parties that score various sections of the applications. *Cf. Booker Creek Preserv., Inc. v. Sw. Fla. Water Mgmt. Dist*., 534 So. 2d 419, 424 (Fla. 5th DCA 1988) ("[An agency] . . . cannot delegate its statutory duty to other state agencies.").

This subsection incorporates by reference Form DH8014-OMMU-08/2017, Scorecard for Medical Marijuana Treatment Center Selection." The title of the form provided for review is "Evaluation Rubric and Scorecard for Medical Marijuana Treatment Center Selection." The rule text does not refer to the "Evaluation Rubric" in the title of the form. The titles of the form should be consistent.

Form DH8014-OMMU-08/2017:
Page 3, Section 1: See comments regarding Section 1 of Form DH8013-OMMU-08/2017.

Page 4, Section 2: See comments regarding Section 2 of Form DH8013-OMMU-08/2017.

Page 5, Section 3: See comments regarding Section 3 of Form DH8013-OMMU-08/2017.

Page 6, Section 4: See comments regarding Section 4 of Form DH8013-OMMU-08/2017.

Page 7, Section 5: See comments regarding Section 5 of Form DH8013-OMMU-08/2017.

Page 8, Section 6: See comments regarding Section 6 of Form DH8013-OMMU-08/2017.

Page 9, Section 7: See comments regarding Section 7 of Form DH8013-OMMU-08/2017.

Page 10, Section 8: See comments regarding Section 8 of Form DH8013-OMMU-08/2017.

Page 10, Section 8, Number 1.c.: It appears that "dispense to patient" should be "dispense to patients."

Page 11, Section 9: See comments regarding Section 9 of Form DH8013-OMMU-08/2017.

Page 11, Section 9, Number 1.: It appears that "proposed floor plan" should be "proposed floor plans."

Page 11, Section 9, Number 1.b.: Please explain whether more than one alarm system will be required. The scorecard uses "Alarm systems," for Section 9, while this section in Form DH8013-OMMU-08/2017 uses "Alarm System." It appears the requirement should be identical in both documents.

Pages 12-13, Section 10: See comments regarding Section 10 of Form DH8013-OMMU-08/2017.

Page 14, Section 11: See comment regarding Page 2, Section 1 of Form DH8013-OMMU, regarding the "Blind Grading Number" header on this section of the score card. It appears the language in the application and the scorecard should be identical.

Pages 14-15, Section 11: See comments regarding Section 11 of Form DH8013-OMMU-08/2017.

Page 16, Section 12: See comments regarding Section 12 of Form DH8013-OMMU-08/2017.

Page 17, Section 13: See comments regarding Section 13 of Form DH8013-OMMU-08/2017.

Page 18, Section 14: See comment regarding Page 2, Section 1 of Form DH8013-OMMU, regarding the "Blind Grading Number" header on this section of the scorecard.

Page 18, Section 14: See comments regarding Section 14 of Form DH8013-OMMU-08/2017.

Page 19, Section 15: See comment regarding Page 2, Section 1 of Form DH8013-OMMU, regarding the "Blind Grading Number" header on this section of the score card.

Page 19, Section 15: See comments regarding Section 15 of Form DH8013-OMMU-08/2017.

Page 20, Section 16: See comments regarding Section 16 of Form DH8013-OMMU-08/2017.

Page 20, Section 16, Number 4.: There is a typographical error in this question. "[A]pplicantshas" should be "applicant has."

64ER17-2(5)(a)1., 2., 3., and 4.: Please explain what the department means by "advanced degree." It is unclear whether this means a post-graduate degree or whether a bachelor's degree will satisfy this requirement. *See* § 120.52(8)(d), Fla. Stat.

64ER17-2(5)(a)1.: Please explain how many subject matter experts will substantively and comparatively review, evaluate, and score section 1, section 2, and section 3 of the application, respectively, or alternatively whether only one subject matter expert that meets the qualifications set forth in this subparagraph will review each of these sections of the application. Also, please advise whether the same subject matter expert(s) will score each of these sections of each application. If more than one subject matter expert is used to score the applicants, please explain how the final score is assigned for each of these sections of the application; it appears if multiple subject matter experts review various sections of the application, there will be multiple scores assigned to each section. *See* §§ 120.52(8)(d), .545(1)(i), Fla. Stat.

Please advise whether the subject matter experts receive any training or guidelines as to how to substantively and comparatively review, evaluate, and score any or all sections of the application.

64ER17-2(5)(a)2.: Please explain how many subject matter experts will substantively and comparatively review, evaluate, and score section 4 and section 5 of the application, respectively, or alternatively whether only one subject matter expert that meets the qualifications set forth in this subparagraph will review each of these sections of the application. See comments above regarding rule subparagraph (5)(a)1.

64ER17-2(5)(a)3.: Please explain how many subject matter experts will substantively and comparatively review, evaluate, and score section 6, section 7, and section 8 of the application, respectively, or alternatively whether only one subject matter expert that meets the qualifications set forth in this subparagraph will review each of these sections of the application. See comments above regarding rule subparagraph (5)(a)1.

64ER17-2(5)(a)4.: Please explain how many subject matter experts will substantively and comparatively review, evaluate, and score section 9, section 10, section 12, and section 16 of the application, respectively, or alternatively

whether only one subject matter expert that meets the qualifications set forth in this subparagraph will review each of these sections of the application. See comments above regarding rule subparagraph (5)(a)1.

64ER17-2(5)(a)5.: Please explain how many subject matter experts will substantively and comparatively review, evaluate, and score section 13 of the application, or alternatively whether only one subject matter expert that meets the qualifications set forth in this subparagraph will review this section of the application. See comments above regarding rule subparagraph (5)(a)1.

Please explain what kind of "experience working in human resources" is a prerequisite to be a subject matter expert pursuant to this rule subparagraph. *See* § 120.52(8)(d), Fla. Stat.

64ER17-2(5)(a)6.: Please explain how many subject matter experts will substantively and comparatively review, evaluate, and score section 11 of the application, or alternatively whether only one subject matter expert that meets the qualifications set forth in this subparagraph will review this section of the application. See comments above regarding rule subparagraph (5)(a)1.

Please explain whether the criteria to be a subject matter expert set forth in this subparagraph as a medical doctor or as a doctor of osteopathic medicine requires an active, unrestricted license pursuant to chapter 458 or chapter 459.

64ER17-2(5)(a)7.: Please explain how many subject matter experts will substantively and comparatively review, evaluate, and score section 14 and section 15 of the application, respectively, or alternatively whether only one subject matter expert that meets the qualifications set forth in this subparagraph will review each of these sections of the application. See comments above regarding rule subparagraph (5)(a)1.

Please explain whether the criteria to be a subject matter expert set forth in this subparagraph as a CPA requires an active license pursuant to chapter 473. Also, please explain whether a person qualified to be a subject matter expert pursuant to this subparagraph must have an active license to practice law in Florida.

64ER17-2(5)(b): This rule paragraph states that: "Scores for each Section of the application will be combined to create an applicant's total score. The department shall generate a final ranking of the applicants in order of highest to lowest scores." If more than one subject matter expert evaluates and scores a section of each applications, please explain how the applications are ranked and how the ultimate scores assigned to each section will be

determined, i.e., whether the scores assigned by each subject matter expert for each section will be averaged.

This rule paragraph states that any application that demonstrates a failure to comply with the minimum statutory requirements for cultivation, processing, dispensing, security, or general operations shall be denied and will not be considered in the final ranking of applicants. If this is due to an error or omission in the application, please explain why the applicant will not be provided an opportunity to correct the error or omission or to provide such additional information pursuant to section 120.60(1). See comment to 64ER17-2(1) regarding the applicability of section 120.60(1).

Please explain what the department means by "minimum statutory requirements for cultivation, processing, dispensing, security, or general operations." It appears that 381.986(8) sets forth the minimum statutory requirements for medical marijuana treatment centers. *See, e.g.*, §§ 381.986(8)(b)1.-7., Fla. Stat. ("An applicant for licensure as a medical marijuana treatment center must demonstrate: . . . ."); 381.986(8)(e)6.a.-d., Fla. Stat. (stating what a medical marijuana treatment center must do when growing marijuana). While the statutory requirements are set forth in section 381.986(8), the application referenced in this rule paragraph includes items that are not established in the statute. It is unclear what the department is requiring an applicant to demonstrate to avoid having an application denied and not considered in the final ranking of applicants. *See* § 120.52(8)(d), Fla. Stat.

Please how this rule paragraph complies with the requirements of section 120.60(1). See comment to 64ER17-2(1) regarding the applicability of section 120.60(1).

64ER17-2(6)(a): A period should be inserted at the end of this rule paragraph.

64ER17-2(6)(b): It appears that instead of referring to "applicants that own citrus and molasses facilities," perhaps it would be clearer to refer to rule paragraph (5)(c) or section 381.986(8)(a)3. instead. *See* § 120.545(1)(i), Fla. Stat.

64ER17-2(6)(c): This rule paragraph refers to the awarding of contingent licensees and contingent licenses. Please explain the department's statutory authority to award licenses contingent upon meeting the 100,000 active patient threshold set forth in section 381.986(8)(a)4. at some unknown date in the future. It appears that awarding such contingent licenses now could foreclose application by certain applicants who will meet the requirements of section 381.986(8)(b) at the time that threshold is met. It appears that such licenses, contingent or otherwise, should not be awarded until after

the 100,000 active patient threshold is reached. *See* § 120.52(8)(c), Fla. Stat.

Please explain how the department ensures that any owners, officers, board members, and managers of an applicant that is awarded a contingent license will have continued to pass the background screening required by section 381.986(9).

Please explain whether the provisions of section 120.60(3) apply to the award of these contingent licenses.

64ER17-2(7)(a)4.: This rule subparagraph addresses the requisite $5 million performance bond and states that, "The surety company can use any form it prefers for the performance bond as long as it complies with this regulation." It appears this should refer to "this rule" or "this emergency rule."

The rule text incorporates by reference Form DH8015-OMMU-08/2017, Florida Medical Marijuana Performance Bond," which the surety company can use for convenience. As the conditions of the bond appear to be included within Form DH8015-OMMU-08/2017 and not in the rule text, please advise whether the same conditions are required if the surety company uses a different form of the bond. *See* § 120.52(8)(d), Fla. Stat.

Form DH8015-OMMU-08/2017:
Second unnumbered page, Items b. and c.: Please explain the department's statutory authority to recover costs on behalf of anyone other than the department, and how the department will advise patients and other medical marijuana treatment centers that have costs attributable to the revocation of the principal's license that they may assign those costs and expenses to the department. *See* § 120.52(8)(b) and (d), Fla. Stat.

Second unnumbered page, Item c.: It appears that "MEDICAL MARIJUANA TREATMENT CENTER" should be "MEDICAL MARIJUANA TREATMENT CENTERS."

Second unnumbered page, Number 2.: It appears "nor DEPARTMENT" should be "or DEPARTMENT."

Second unnumbered page, Number 5.: Please explain the department's statutory authority to obtain an assignment of claims.

Please let me know if you have any questions. Otherwise, I look forward to your response as soon as possible.

Sincerely,

Marjorie C. Holladay
Chief Attorney

cc: Ms. Nichole C. Geary, General Counsel
Mr. Christian J. Bax, Director
Ms. Renee C. Harkins, Assistant General Counsel

MCH:SA WORD/MARJORIE/EMERGENCY RULE 17-02LS100917_#6891

Notice of Emergency Rule

DEPARTMENT OF HEALTH

RULE NO.: RULE TITLE:

64ER17-6 Disciplinary Guidelines and Fines

SPECIFIC REASONS FOR FINDING AN IMMEDIATE DANGER TO THE PUBLIC, HEALTH, SAFETY, OR WELFARE: Pursuant to Chapter 2017-232, § 14, at 45, Laws of Florida, the Department is not required to make findings of an immediate danger to the public, health, safety, or welfare.

REASONS FOR CONCLUDING THAT THE PROCEDURE USED IS FAIR UNDER THE CIRCUMSTANCES: The Department of Health is directed by Chapter 2017-232, § 14, at 45, Laws of Florida, to adopt emergency rules to implement section 381.986, Florida Statutes.

SUMMARY: Emergency rule 64ER17-6 provides for the disciplinary guidelines and fines for violations of section 381.986, Florida Statutes and department rules.

THE PERSON TO BE CONTACTED REGARDING THE EMERGENCY RULE IS: Courtney Coppola at Courtney.Coppola@flhealth.gov.

THE FULL TEXT OF THE EMERGENCY RULE IS:

64ER17-6 Disciplinary Guidelines and Fines

(1) The penalties listed for the following violations of section 381.986, Florida Statutes, or department rule, shall be used as guidelines in disciplinary cases, absent aggravating or mitigating circumstances and subject to other provisions of this rule. Penalties are applicable per instance of each violation and every day that a violation occurs shall be considered a separate violation.

(a) Approval and renewal violations.

1. Attempt by any person or entity to procure initial medical marijuana treatment center approval by bribery, fraudulent misrepresentation, or extortion. Any violation, revocation or denial of approval and $5,000 fine.

2. Attempt by any person or entity to renew a license by bribery or fraud. For the first violation, revocation of the license with the ability to reapply upon payment of a $5,000 fine to permanent revocation. After the first violation, permanent revocation with a $5,000 fine.

(b) Improper Dispensations and Misuse of the Medical Marijuana Use Registry (MMUR).

1. Dispensation by a MMTC of more than a 70-day supply of low-THC cannabis or medical cannabis to a patient or caregiver. First violation, from a letter of warning to a $500 fine; second violation, $500 fine; subsequent violation, from a $1,000 fine to a $1,000 fine and suspension or revocation.

2. Failure of a MMTC to enter an employee name or unique employee identifier into the MMUR for each dispensation of low-THC cannabis, medical cannabis, or cannabis delivery device. First violation, from a letter of warning to a $500 fine; second violation, $500 fine; subsequent violation, from a $1,000 fine to a $1,000 fine and suspension or revocation.

3. Failure of a MMTC to verify in the MMUR, prior to dispensing to the patient or their caregiver, that a physician has entered a valid order for low-THC cannabis, medical cannabis, or a cannabis delivery device for that patient. First violation, from a letter of warning to a $500 fine; second violation, $500 fine; subsequent violation, from a $1,000 fine to a $1,000 fine and suspension or revocation.

4. Failure of a MMTC to verify in the MMUR, prior to dispensing to the patient or their caregiver, that: (1) the patient has an active registration in the MMUR, (2) the patient or the patient's caregiver holds a valid and active identification card, and (3) that there is a sufficient number of milligrams of recommended product remaining to fill an order. Failure to verify any of these three requirements constitutes a violation. First violation, from a letter of warning to a $500 fine; second violation, $500 fine; subsequent violation, from a $1,000 fine to a $1,000 fine and suspension or revocation.

5. Failure of a MMTC to record in the MMUR the: (1) date, (2) time, (3) quantity of medical marijuana dispensed, (4) form of medical marijuana dispensed, (5) type of marijuana delivery device dispensed if applicable, and (6) the name and MMUR identification number of the patient or caregiver for each dispensation. Failure to

record any of these six requirements constitutes a violation. First violation, from a letter of warning to a $500 fine; second violation, $500 fine; subsequent violation, from a $1,000 fine to a $1,000 fine and suspension or revocation.

6. Dispensation of low-THC cannabis, medical cannabis, or cannabis delivery device by a MMTC to a qualified patient who is younger than 18 years of age. First violation, $500 fine; subsequent violation, from a $500 fine to a $500 fine and suspension or revocation.

7. Dispensation or selling of any other type of cannabis, alcohol, or illicit drug-related product, including pipes, bongs, or wrapping papers, other than a marijuana delivery device required for the medical use of marijuana as specified in a physician certification, by an MMTC at a dispensing facility. First violation, $500 fine; subsequent violation, from a $500 fine to a $500 fine and suspension or revocation.

8. Dispensation of low-THC cannabis, medical cannabis, or a cannabis delivery device from the premises of a MMTC between the hours of 9 p.m. and 7 a.m. First violation, $500 fine; subsequent violation, from a $500 fine to a $500 fine and suspension or revocation.

9. Creates a patient or caregiver in the MMUR using misleading, incorrect, false, or fraudulent information. Any qualified ordering physician who violates this subparagraph is subject to a 180-day suspension from access to the MMUR. This penalty does not prohibit any further appropriate action by the department or respective board against the qualified ordering physician.

10. Creates a duplicate patient or caregiver in the MMUR. Any qualified ordering physician who violates this subparagraph is subject to a 180-day suspension from access to the MMUR. This penalty does not prohibit any further appropriate action by the department or respective board against the qualified ordering physician.

11. Failure to update the MMUR within 7 days after any change(s) is made to the original physician certification to reflect such change(s). Any qualified ordering physician who violates this subparagraph is subject to a 180-day suspension from access to the MMUR. This penalty does not prohibit any further appropriate action by the department or respective board against the qualified ordering physician.

12. Improper disclosure of personal information of a qualified patient or caregiver. Personal information includes the patient and caregiver names, birth dates, telephone numbers, addresses, electronic mail addresses, social security numbers and biometric identifiers. Violations of this subparagraph by an MMTC or an approved law enforcement MMUR user, first violation, from a letter of warning to a $500 fine; second violation, $500 fine and a 180-day suspension from access to the MMUR; subsequent violation, from a $1,000 fine to a $1,000 fine and suspension or revocation of access to the MMUR. Any physician who violates this subparagraph is subject to a 180-day suspension from access to the MMUR and this penalty does not prohibit any further appropriate action by the department or respective board against the physician.

13. Misuse of or improper access to the MMUR. Misuse or improper access includes:

a. Failure of a MMTC or other approved user to establish or enforce policies and procedures restricting access to the MMUR only to those individuals authorized by section 381.986, Florida Statutes, and whose access has been approved by the department;

b. Failure of a MMTC or other approved user to establish or enforce policies and procedures preventing personnel from sharing login and password information or accessing the MMUR on another individual's account; and

c. Use of data from the MMUR for cold-calling or otherwise soliciting patients or caregivers.

Violations of this subparagraph by an MMTC or an approved law enforcement MMUR user, first violation, from a letter of warning to a $500 fine; second violation, $500 fine and a 180-day suspension from access to the MMUR; subsequent violation, from a $1,000 fine to a $1,000 fine and suspension or revocation of access to the MMUR. Any physician who violates this subparagraph is subject to a 180-day suspension from access to the MMUR and this penalty does not prohibit any further appropriate action by the department or respective board against the physician.

(c) MMTC operational violations.

1. Failure of a MMTC to maintain qualifications for approval. Suspension or revocation of MMTC license.

2. Endangering the health, safety, or security of a qualified patient by a MMTC. First violation, a letter of warning and a fine up to $500; second violation, $1,000 fine; subsequent violation, $1,000 fine to a $1,000 fine and suspension or revocation.

3. Employment of an owner, officer, board member, manager, or employee by a MMTC who has been rendered ineligible under section 381.986(9), Florida Statutes, or who has been convicted or found guilty of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which directly relates to the business of a medical marijuana treatment center. First violation, a $250 to $500 fine and license suspension. Subsequent violation, from a $1,000 fine and license suspension to a $5,000 fine and license revocation.

4. Employment of an owner, officer, board member, manager, or employee by a MMTC whose license or the authority to engage in any regulated profession, occupation, or business that is related to the business practices of a medical marijuana treatment center has been suspended, revoked, or otherwise acted against by the licensing authority of any jurisdiction, including its agencies or subdivisions, for a violation that would constitute a violation under Florida law. First violation, a $250 fine to $500 fine and license suspension; subsequent violation, from a $1,000 fine and license suspension to a $5,000 fine and license revocation. If the license or authority to engage in a regulated profession, occupation, or business has been reinstated or otherwise cleared of disciplinary obligations, the department will consider such reinstatement as a mitigating factor.

5. Making or filing a report or record that the MMTC knows to be false. First violation, from a letter of warning to a $500 fine; second violation, $1,000 fine; subsequent violations, from a $1,000 fine to a $1,000 fine and suspension or revocation.

6. Willfully failing to maintain a record required by section 381.986, Florida Statutes, or department rule. First violation, letter of warning and a fine up to $500; second violation, $1,000 fine; subsequent violation, from a $1,000 fine to a $1,000 fine and suspension or revocation.

7. Willfully impeding or obstructing an employee or agent of the department in furtherance of his or her official duties. First violation, letter of warning to a $500 fine; subsequent violation, from a $1,000 to $5,000 fine up to a $1,000 to $5,000 fine and suspension or revocation.

8. Engaging in fraud or deceit, negligence, incompetence, or misconduct in the business practices of a MMTC. First violation, letter of warning and a fine up to $500; second violation, $1,000 fine; subsequent violation, from a $1,000 fine to a $1,000 fine and suspension or revocation.

9. Making misleading, deceptive, or fraudulent representations in or related to the business practices of a MMTC. First violation, from a letter of warning to a $500 fine; second violation, $1,000 fine; subsequent violation, from a $1,000 fine to a $1,000 fine and suspension or revocation.

10. Making misleading, deceptive, or fraudulent representations in its advertising. Advertising means the act of providing consideration for the publication, dissemination, solicitation, or circulation of visual, oral, or written communication, to induce directly or indirectly any person to patronize a particular MMTC, or to purchase particular medical marijuana or a medical marijuana-infused product. Advertising includes marketing, but does not include packaging or labeling. Advertising proposes a commercial transaction or otherwise constitutes commercial speech. First violation, from a letter of warning to a $500 fine; second violation, $1,000 fine; subsequent violation, from a $1,000 fine to a $1,000 fine and suspension or revocation.

11. Violating a lawful order of the department or an agency of the state, or failure to comply with a lawfully issued subpoena of the department or an agency of the state. First violation, from a letter of warning to a $500 fine; subsequent violation, from a $1,000 fine to a $1,000 fine and suspension or revocation.

12. Employment of a qualified physician by a MMTC or independent testing laboratory. First violation, from a letter of warning to a $500 fine; subsequent violation, from a $1,000 fine to a $1,000 fine and suspension or revocation.

13. Use of a pesticide, fungicide, or herbicide other than those permitted for use by department rule. The presence of an unapproved pesticide, fungicide, or herbicide in the proximity of a MMTC facility or a failed test for an unapproved pesticide, fungicide, or herbicide constitute the use of an unapproved pesticide, fungicide, or herbicide. In addition to the mitigating or aggravating factors listed in subsection (2) below, the following factors will be considered:

a. The toxicity of the unapproved pesticide, fungicide, or herbicide;

b. The number of plants exposed; and

c. The number of individuals exposed.

For the first violation, from a $1,000 to $5,000 fine up to a $1,000 to $5,000 fine and license suspension; subsequent violations, from a $1,000 to $10,000 fine up to a $1,000 to $10,000 fine and license suspension or revocation.

14. The wholesale of low-THC cannabis, medical cannabis, low-THC cannabis products, or medical cannabis products to any entity other than a licensed MMTC. The sale of each plant or cannabis product constitutes a separate violation. From a $1,000 to $10,000 fine up to a $1,000 to $10,000 fine and suspension or revocation.

15. Operating a cultivation, processing, or dispensing facility without prior authorization from the department. First violation, a letter of warning and fine up to $500; subsequent violation, from a $1,000 fine to a $1,000 fine and suspension or revocation.

16. Operating a number of dispensing facilities that exceed the provision of section 381.986(8)(a)5., Florida Statutes. First violation, a letter of warning and fine up to $500; subsequent violation, from a $1,000 fine to a $1,000 fine and suspension or revocation.

17. Failure to notify the department of a sale of a dispensing facility slot within 3 days of sale. First violation, a letter of warning and fine up to $500; subsequent violation, $1,000 fine to a $1,000 fine and suspension or revocation.

18. Failure to possess a valid certification of registration issued by the Department of Agriculture and Consumer Services pursuant to section 581.131, Florida Statutes, unless the licensee was licensed under the provisions of section 381.986(8)(a)2.b., Florida Statutes. First violation, a letter of warning and fine up to $500; subsequent violation, $1,000 fine to a $1,000 fine and suspension or revocation.

19. Failure to employ a medical director to supervise the activities of the MMTC. Any violation, $1,000 fine to a $1,000 fine and suspension or revocation.

20. The wholesale purchase of marijuana or low-THC cannabis from, or a distribution of marijuana or low-THC cannabis to, another MMTC, without the MMTC seeking to make a wholesale purchase of marijuana submitting proof of harvest failure to and approval from the department. Harvest failure means a catastrophic loss of growing plants that presents a substantial risk of severe impact of a MMTC's ability to supply patients with low-THC or medical cannabis products. Any violation, a $1,000 to $10,000 fine up to a $1,000 to $10,000 fine and suspension or revocation.

21. Contracting for services related to the operations of a MMTC in violation of section 381.986(8)(e), Florida Statutes. Any violation, $1,000 to $10,000 fine up to a $1,000 to $10,000 fine and suspension or revocation.

22. Failure to notify the department in writing at least 60 days prior to the anticipated date of a change in ownership of a MMTC. Any violation, $1,000 to $10,000 fine up to a $1,000 to $10,000 fine and suspension or revocation.

23. Executing a change in ownership of a MMTC without prior department approval. Any violation, from a $1,000 to $5,000 fine up to a $1,000 to $5,000 fine and suspension or revocation.

24. Failure to execute a recall as required by the department. Any violation, a $1,000 to $5,000 fine up to a $1,000 to $5,000 fine and suspension or revocation.

25. Operating a MMTC dispensing facility within 500 feet of the real property that comprises a public or private elementary, middle, or secondary school, unless the county or municipality approves the location through a formal proceeding. Any violation, from a $1,000 fine up to a $1,000 fine and suspension or revocation.

26. Growing low-THC cannabis or medical marijuana in an environment other than an enclosed structure. Any violation, $500 fine per plant to $500 fine per plant and suspension or revocation.

27. Growing low-THC cannabis or medical marijuana in the same enclosed structure as other plants. Any violation, a $500 fine per plant to a $500 fine per plant and suspension or revocation.

28. Failure to inspect seeds and growing plants for plant pests that endanger or threaten the horticultural and agricultural interests of the state, or failure to notify the Department of Agriculture and Consumer Services within 10 calendar days after a determination that a plant is infested or infected by such plant pest, and implement and maintain phytosanitary policies and procedures. Any violation, a $500 fine to a $500 fine and suspension or revocation.

29. Failure to perform fumigation or treatment of plants, or remove and destroy infested or infected plants, in accordance with Chapter 581, Florida Statutes, and any rules adopted thereunder. Any violation, a $500 fine to a $500 fine and suspension or revocation.

30. Processing of low-THC cannabis, medical cannabis, low-THC cannabis products, or medical cannabis products in an environment other than an enclosed structure. Any violation, a $500 fine to a $500 fine and suspension or revocation.

31. Processing of low-THC cannabis or medical cannabis in the same enclosed structure as other plants or products. Any violation, a $500 fine to a $500 fine and suspension or revocation.

32. Failure to package low-THC cannabis products or medical cannabis products in compliance with the United States Poison Prevention Packaging Act of 1970, 15 U.S.C. ss. 1471 et seq. Any violation, a $500 fine to a $500 fine and suspension or revocation.

33. Failure to label low-THC cannabis products or medical cannabis products in compliance with section 381.986(8)(e)10.f., Florida Statutes. Any violation, a $500 fine to a $500 fine and suspension or revocation.

34. Failure to reserve two processed samples from each batch and retain such samples for at least 9 months in compliance with Section 381.986(8)(e)10.d., Florida Statutes. Any violation, a $500 fine to a $500 fine and suspension or revocation.

35. Failure to maintain a security system or video surveillance system in compliance with section 381.986(8)(f), Florida Statutes. Any violation, a $500 fine to a $500 fine and suspension or revocation.

36. Failure to ensure at least two MMTC employees, or two employees of a security agency with whom the MMTC contracts, are on site at cultivation, processing, and storage facilities at all times. Any violation, a $500 fine to a $500 fine and suspension or revocation.

37. Failure to establish or enforce policies and procedures which require each employee to wear a photo identification badge at all times while on the premises. Any violation, a $500 fine to a $500 fine and suspension or revocation.

38. Failure to establish or enforce policies and procedures which require each visitor to wear a visitor's pass at all times while on the premises. Any violation, a $500 fine to a $500 fine and suspension or revocation.

39. Failure to establish or enforce policies and procedures which require an alcohol and drug-free workplace. Any violation, a $1,000 to $10,000 fine to a $1,000 to $10,000 fine and suspension or revocation.

40. Failure to report to local law enforcement within 24 hours after the MMTC is notified or becomes aware of the theft, diversion, or loss of low-THC cannabis or medical cannabis. Any violation, a $1,000 to $10,000 fine to a $1,000 to $10,000 fine and suspension or revocation.

41. Failure to establish or enforce policies and procedures which require the safe transport of low-THC cannabis or medical marijuana to MMTC facilities, independent testing laboratories, or patients or caregivers in compliance with section 381.986(8)(g), Florida Statutes. Any violation, a $500 fine to a $500 fine and suspension or revocation. The minimum requirements for safe transport are:

a. Maintenance of a transportation manifest for each delivery, which must be retained for at least 1 year;

b. Ensuring that only vehicles in good working order are used to transport low-THC and medical cannabis;

c. Ensuring that low-THC cannabis and medical cannabis is locked in a separate compartment or container within the vehicle;

d. Ensuring that at least two persons are in a vehicle transporting low-THC cannabis or medical cannabis, and that at least one person remains in the vehicle while low-THC cannabis or medical cannabis is being delivered; and

e. Ensuring that all employees transporting or delivering low-THC cannabis or medical cannabis receive specific safety and security training.

42. Materially deviating from an application for licensure without prior approval from the department. Any violation, a $1,000 fine to $10,000 fine up to a $1,000 fine to $10,000 fine and suspension or revocation.

43. Failure to comply with a record inspection request from the department within 14 days. Any violation, a $500 fine to a $500 fine and suspension or revocation.

44. Failure to ensure that all employees are at least 21 years of age or older. Any violation, a $500 fine to a $500 fine and suspension or revocation.

45. Failure to ensure that all marijuana and marijuana products are secured in a secured, locked room or vault. Any violation, a $1,000 to $10,000 fine up to a $1,000 fine to $10,000 fine and suspension or revocation.

46. Displaying marijuana or marijuana products in a waiting room of a dispensing facility, or dispensing in a waiting room of a dispensing facility. Any violation, $500 fine to $500 fine and suspension or revocation.

(d) Violation of any other provision of section 381.986, Florida Statutes, or of department rule. The full range of penalties listed in this rule shall be considered for violations pursuant to this paragraph.

(2) Circumstances which shall be considered for the purposes of mitigation or aggravation of penalty shall include the following:

(a) Severity of the violation;

(b) Danger to the public;

(c) Actual damage, physical or otherwise, to the patient;

(d) Effort to prevent the violation;

(e) Effort to correct the violation, or the refusal to correct or stop the violation;

(f) Level of cooperation with the department's investigation into the violation;

(g) The number of previous violations for failure to comply with provisions of the Florida Statutes or department rules;

(h) Efforts to conceal violations; and

(i) Any other mitigating or aggravating circumstances.

(3) Where several of the violations occur in one case, or several cases being considered together, the penalties shall be cumulative and consecutive.

(4) A MMTC may not avoid penalty for a violation or application of the provision for subsequent violations by changing the corporate structure, for example, by adding or dropping a partner or converting to another form of legal entity when the individuals who own, operate, or control the MMTC are substantially similar.

Rulemaking Authority 381.986(10)(h) FS. Law Implemented 381.986 FS. History–New

THIS RULE TAKES EFFECT UPON BEING FILED WITH THE DEPARTMENT OF STATE UNLESS A LATER TIME AND DATE IS SPECIFIED IN THE RULE.

EFFECTIVE DATE: October 24, 2017

JOE NEGRON
President

RICHARD CORCORAN
Speaker

THE FLORIDA LEGISLATURE

JOINT ADMINISTRATIVE PROCEDURES COMMITTEE

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October 30, 2017

Ms. Amanda G. Bush
Senior Attorney
Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin A-02
Tallahassee, Florida 32399-1703

Re: Department of Health
Existing Rule 64-4.011, F.A.C.

Dear Ms. Bush:

In accordance with the Committee's responsibilities pursuant to section 120.545(1) and Joint Rule 4.6 of the Florida Legislature, I have reviewed the above-referenced existing rule, and I have the following comments.

64-4.011: Please remove the citation to section 381.986(7)(f) and (j) as rulemaking authority. Section 381.986 does not have paragraphs (7)(f) and (j).

It appears that section 381.986(7)(b) should be cited as rulemaking authority.

Please explain why section 499.0295 is cited as a law implemented. *See* Ch. 2017-232, § 3, Laws of Fla.

64-4.011(1): This rule refers to a "Compassionate Use Registry identification card." It appears the name of the registry is the "Medical Marijuana Use Registry." *See* § 381.986(5), Fla. Stat. It also appears that the rule should be amended to change the reference to this registry throughout the rule. *See* § 120.52(8)(c), Fla. Stat.

This rule subsection refers to "medical cannabis" and "medical cannabis delivery device." Section 381.986, as amended in chapter 2017-232,

section 3, Laws of Florida, refers to "marijuana" and "marijuana delivery device." *See* § 381.986(1)(f) and (g), Fla. Stat. It appears the rule should be amended to change these references throughout the rule. *See* § 120.52(8)(c), Fla. Stat.

64-4.011(2)(a): This rule paragraph states what a patient must present as evidence of Florida residency, specifically: a copy of a valid Florida Driver's license or identification card; a utility bill in the person's name including a Florida address; or a Florida voter registration card. The rule requires that a minor establish residency by proving residency of the parent or designated legal representative.

Section 381.986(5)(b), as amended in chapter 2017-232, section 3, Laws of Florida, changed the documentation that the department must use to determine residency. Specifically that statute requires:

> The department shall determine whether an individual is a resident of this state for the purpose of registration of qualified patients and caregivers in the medical marijuana use registry. To prove residency:
> 1. An adult resident must provide the department with a copy of his or her valid Florida driver license issued under s. 322.18 or a copy of a valid Florida identification card issued under s. 322.051.
> 2. An adult seasonal resident who cannot meet the requirements of subparagraph 1. may provide the department with a copy of two of the following that show proof of residential address:
> a. A deed, mortgage, monthly mortgage statement, mortgage payment booklet or residential rental or lease agreement.
> b. One proof of residential address from the seasonal resident's parent, step-parent, legal guardian or other person with whom the seasonal resident resides and a statement from the person with whom the seasonal resident resides stating that the seasonal resident does reside with him or her.
> c. A utility hookup or work order dated within 60 days before registration in the medical use registry.
> d. A utility bill, not more than 2 months old.
> e. Mail from a financial institution, including checking, savings, or investment account statements, not more than 2 months old.
> f. Mail from a federal, state, county, or municipal government agency, not more than 2 months old.
> g. Any other documentation that provides proof of residential address as determined by department rule.

> 3. A minor must provide the department with a certified copy of a birth certificate or a current record of registration from a Florida K-12 school and must have a parent or legal guardian who meets the requirements of subparagraph 1.
>
> For the purposes of this paragraph, the term "seasonal resident" means any person who temporarily resides in this state for a period of at least 31 consecutive days in each calendar year, maintains a temporary residence in this state, returns to the state or jurisdiction of his or her residence at least one time during each calendar year, and is registered to vote or pays income tax in another state or jurisdiction.

Thus, it appears that the rule should be amended to change the documentation required of adults and minors seeking registration in the medical marijuana use registry. *See* § 120.52(8)(c), Fla. Stat.

Additionally, section 381.986, as amended in chapter 2017-232, section 3, Laws of Florida, no longer refers to "legal representative." This term is used throughout the rule text. It appears this rule should be amended. *See* § 120.52(8)(c), Fla. Stat.

64-4.011(2)(b): This rule paragraph refers to an "authorized physician." Section 381.986, as amended in chapter 2017-232, section 3, Laws of Florida, now refers to a "qualified physician." *See* § 386.986(1)(m), Fla. Stat. Further, it appears the qualifications of such physicians include holding, "an active, unrestricted license as an allopathic physician under chapter 458 or as an osteopathic physician under chapter 459 and [the qualified physician must be] in compliance with the physician education requirements of subsection [381.986](3)." It appears this rule paragraph should be amended. *See* § 120.52(8)(c), Fla. Stat.

64-4.011(2)(c): This rule paragraph incorporates by reference form DH8009-OCU-10/2016, Compassionate Use Registry Identification Card Qualified Patient Application.

Form DH8009-OCU-10/2016:
See comments above regarding references to the "compassionate use registry," "medical cannabis," "cannabis delivery device," "legal representative," the proof of residency requirements, and the requirements to be a qualified physician.

Additionally, the form refers to "authorized Florida dispensing organization." Section 381.986, as amended in chapter 2017-232, section 3, Laws of Florida,

now refers to "medical marijuana treatment centers." *See* § 386.986(8), Fla. Stat. It appears this form should be amended. *See* § 120.52(8)(c), Fla. Stat.

64-4.011(3): This subsection refers to applying for a legal representative compassionate use registry identification card. See comments above regarding use of the terms "compassionate use registry" and "legal representative." It appears the rule should be amended. *See* § 120.52(8)(c), Fla. Stat.

This subsection incorporates by reference form DH8010-OCU-10/2016, Compassionate Use Registry Identification Card Legal Representative Application.

Form DH8010-OCU-10/2016:
Section 381.986, as amended in chapter 2017-232, section 3, Laws of Florida, no longer refers to "legal representative." Please explain whether the department still uses this form. *See* § 120.52(8)(c), Fla. Stat.

Please explain what form applicants for a caregiver identification card must use. *See* § 381.986(7)(d), Fla. Stat.

64-4.011(9): This subsection incorporates by reference form DH8012-OCU-10/2016, Change, Replacement or Surrender Request.

Form DH8012-OCU-10/2016:
See comments above regarding references to the "compassionate use registry," "legal representative," and the proof of residency requirements.

Please let me know if you have any questions, and I look forward to your response.

Sincerely,

Marjorie C. Holladay
Chief Attorney

cc: Ms. Nichole C. Geary, General Counsel
Mr. Christian J. Bax, Director
Ms. Renee C. Harkins, Assistant General Counsel

MCH:DF WORD/MARJORIE/ERR 64_4.011LS103017_4280

November 17, 2017

Mr. Christian J. Bax, Director
Office of Medical Marijuana Use
Department of Health
4052 Bald Cypress Way
Tallahassee, Florida 32399

Dear Mr. Bax:

On October 30, 2017, the Department of Health (the "Department") published a notice of rule development for Rule 64-4.014, Standards for Production of Edibles. As stated in the purpose and effect of the notice, "This rule implements s. 381.986(8)(e)8., Florida Statutes, to establish the criteria under which medical marijuana treatment centers may produce edible products. Under section 120.54(7)(a), Florida Statutes, this rule development is responsive to the Petition to Initiate Rulemaking received by the Department of Health on September 29, 2017."

Section 381.986, Note 1B, Florida Statutes, states, in pertinent part:

> B. Section 14(1), chapter 2017-232, provides that:
> "(1) EMERGENCY RULEMAKING
> "(a) The Department of Health and the applicable boards shall adopt emergency rules pursuant to s. 120.54(4), Florida Statutes, and this section necessary to implement ss. 381.986 and 381.988, Florida Statutes.
> * * *
> "(c) By January 1, 2018, the department and the applicable boards shall initiate nonemergency rulemaking pursuant to the Administrative Procedures Act to replace all emergency rules adopted under this section by publishing a notice of rule development in the Florida Administrative Register."

Notwithstanding the fact that the notice of rule development was published in response to a Petition to Initiate Rulemaking, any action taken by the Department in response to the petition does not supersede or otherwise negate the requirement under section 381.986, Note 1B, Florida Statutes, that the Department adopt emergency rules necessary to implement section 381.986, Florida Statutes. Since the stated purpose of the notice of rule development is to implement section 381.986(8)(e)8., the Department is mandated to adopt an emergency rule establishing the criteria under which medical marijuana treatment centers may produce edible products, to be followed by a notice of rule development to replace the emergency rule. Therefore, the purpose of the notice of rule development should be to replace the emergency rule, not to create a new rule. In light of the foregoing, an emergency rule setting forth the criteria under which medical marijuana treatment centers may produce edible products should be adopted and published no later than December 31, 2017.

Please let me know if you have any questions.

Sincerely,

Kenneth J. Plante
Coordinator

cc: Nichole Geary, General Counsel
Amanda Bush, Senior Attorney
Renee Harkins, Assistant General Counsel

JOE NEGRON
President

RICHARD CORCORAN
Speaker

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November 20, 2017

Mr. Christian J. Bax, Director
Office of Medical Marijuana Use
Department of Health
4052 Bald Cypress Way
Tallahassee, Florida 32399

Re: Section 381.986, Florida Statutes, Emergency Rulemaking

Dear Mr. Bax:

You will recall that my letter of October 3, 2017, reiterated the requirement under section 381.986, Note 1B, Florida Statutes, that, "The Department of Health and the applicable boards shall adopt emergency rules pursuant to s. 120.54(4), Florida Statutes, and this section necessary to implement ss. 381.986 and 381.988, Florida Statutes." The letter also identified a number of rulemaking requirements mandated by section 381.986, Florida Statutes, and requested that you advise the Committee of the timeframe for the promulgation of the required rules.

Although the Committee has yet to receive a response to this request, in your November 15, 2017, presentation before the House Health Quality Subcommittee, you indicated that the Department of Health (the "Department") was in the process of, or had already completed, developing rules for the following:

MMTC license applications (emergency rule published)
MMTC fines (emergency rule published)
Edible standards
Pesticide use
MMTC license renewals
Labeling and packaging standards
Dosing guidelines
Testing laboratory certification

Missing from this list are the following rulemaking requirements set forth in sections 381.986 and 381.988, Florida Statutes:

381.986(8)(e)10.b.	Determine requirements for MMTCs to use solvents or gases exhibiting potential toxicity to humans.
381.986(8)(e)10.c.	Determine procedures for the storage, handling, transportation, management, and disposal of solid and liquid waste generated during marijuana production and processing.
381.986(8)(e)10.d.	Determine which contaminants must be tested for, and the maximum levels of each contaminant which are safe for human consumption.
381.986(8)(e)10.d.	Develop testing requirements for contaminants that are unsafe for human consumption in edibles.
381.986(8)(e)10.d.	Determine procedures for the treatment of marijuana that fails to meet the testing requirements of section 381.988 or department rules.
381.986(8)(h)1.	Develop standards for approving trade names and logos.
381.986(8)(h)2.a.	Develop standards for approval of MMTC advertisements.

With respect to the Department's statement that it is in the process of developing rules for "testing laboratory certification," it is unclear whether the proposed rule(s) will include all of the following statutory requirements:

381.988(1)(b)	Develop an application and application fee for medical testing laboratories.
381.988(1)(c)	Adopt a list of approved accreditations or certifications and accreditation or certification organizations.
381.988(2)	Establish a procedure for initial certification and biennial renewal.
381.988(3)	Establish standards for certification of marijuana testing laboratories.
381.988(5)	Adopt disposal procedures for all samples received by the laboratory, unless transferred to another marijuana testing laboratory, after all necessary tests have been conducted and any required period of storage has elapsed.

381.988(8)	Adopt a schedule for the imposition of fines for violations of section 381.988, F.S.

I would again request that the Department advise the Committee of the timeframe for the Department's adoption of emergency rules for both those rules identified in your November 15, 2017, presentation to the House Quality Subcommittee, and the additional rulemaking requirements under sections 381.986 and 381.988, Florida Statutes, set forth herein.

In your November 15 presentation, you also indicated that, as part of Phase 3 of the Department's implementation of MMTC Licensure and Procurements, the Department "adopted rules and noticed proposed regulations that establish the MMTC application procedure pursuant to s. 381.986, F.S. and Art. X, S. 29 Fla. Const. (Notice of Proposed Regulation 1-1.02 & 2-1.01 Emergency Rule 64ER17-1 & 64ER17-2) [*sic*]." As I indicated in my October 3, 2017, letter, the Committee has some concerns regarding the Department's simultaneous adoption of regulations pursuant to Article X, Section 29, of the Florida Constitution, and the emergency rules adopted pursuant to section 381.986, Florida Statutes. Section 381.986, Note 2, Florida Statutes, states:

> Section 14(2), ch. 2017-232, provides that:
> "(2) CAUSE OF ACTION
> "(a) As used in s. 2(d)(3), Article X of the State Constitution, the term:
> "1. "Issue regulations" means the filing by the department of a rule or emergency rule for adoption with the Department of State."

Thus, it would appear that any "regulation" published under the authority of Article X, Section 29(d)(3), of the Florida Constitution, was intended by the Legislature to be a rule or emergency rule adopted pursuant to chapter 120, Florida Statutes, and not a stand-alone regulation or statement of the Department's position issued outside of the procedural requirements of chapter 120, Florida Statutes. I would, therefore, again request that the Department provide the Committee with an explanation of the Department's authority to adopt regulations and how the Department intends to address the interaction between the regulations and rules.

I look forward to your response. Please let me know if you have any questions.

Sincerely,

Kenneth J. Plante
Coordinator

cc: Nichole Geary, General Counsel
Amanda Bush, Senior Attorney
Renee Harkins, Assistant General Counsel

JOE NEGRON
President

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November 27, 2017

Mr. Christian J. Bax, Director
Office of Medical Marijuana Use
Department of Health
4052 Bald Cypress Way
Tallahassee, Florida 32399

Re: Rule 64-4.013, Pesticide Use on Marijuana

Dear Mr. Bax:

On November 22, 2017, the Department of Health (the "Department") published a notice of proposed rule for Rule 64-4.013, Pesticide Use on Marijuana. The purpose and effect of the rule is to implement "s. 381.986(8)(e)6.a., Florida Statutes, to establish the criteria under which certain pesticides may be legally used on marijuana by approved medical marijuana treatment centers." The proposed effective date of the rule is March 1, 2018.

As I indicated in my letter of November 17, 2017, regarding the notice of rule development for Rule 64-4.014, Standards for Production of Edibles, section 381.986, Footnote 1B, Florida Statutes, states, in pertinent part:

> B. Section 14(1), chapter 2017-232, provides that:
> "(1) EMERGENCY RULEMAKING
> "(a) The Department of Health and the applicable boards shall adopt emergency rules pursuant to s. 120.54(4), Florida Statutes, and this section necessary to implement ss. 381.986 and 381.988, Florida Statutes.
>
> * * *
>
> "(c) By January 1, 2018, the department and the applicable boards shall initiate nonemergency rulemaking pursuant to the Administrative Procedures Act to replace all emergency rules adopted under this section by publishing a notice of rule development in the Florida Administrative Register." [Emphasis added.]

A preliminary review of the proposed rule suggests that, procedurally, Rule 64-4.013, Pesticide Use on Marijuana, should have been published as an emergency rule, effective as of the date of publication, as required by section 381.986, Footnote 1B, Florida Statutes. The purpose and effect of the notice of proposed rule should be to replace the emergency rule, not to adopt a rule with an effective date of March 1, 2018. In light of the requirement of section 381.986, Footnote 1B, Florida Statutes, an emergency rule setting forth the criteria under which certain pesticides may be used on marijuana by medical marijuana treatment centers should be adopted and published at your earliest convenience, but no later than December 31, 2017.

Please let me know if you have any questions.

Sincerely,

Kenneth J. Plante
Coordinator

cc: Nichole Geary, General Counsel
Amanda Bush, Senior Attorney
Renee Harkins, Assistant General Counsel

November 28, 2017

Ms. Amanda G. Bush
Senior Attorney
Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin A-02
Tallahassee, Florida 32399-1703

Re: Department of Health
Emergency Rule 64ER17-6

Dear Ms. Bush:

I have reviewed the above-referenced emergency rule, which was filed with the Department of State on October 24, 2017, and published in the Florida Administrative Register on October 25, 2017. I have the following comments.

64ER17-6: This rule establishes more than 60 disciplinary guidelines for violations of section 381.986 and department rules. It appears this rule would be more easily comprehensible if each disciplinary guideline identified the provision of section 381.986 or department rule that must be violated in order to impose the discipline set forth in each of these guidelines. *See* § 120.545(1)(i), Fla. Stat.

Most of these disciplinary guidelines include suspension or revocation as possible penalties. Please explain what criteria the department uses to determine to impose revocation of a license over suspension. *See* § 120.52(8)(d), Fla. Stat.

Please explain how the qualified patients and caregivers obtain medical marijuana or low-THC cannabis during the pendency of the suspension of a medical marijuana treatment center's license.

Please explain why the penalties that result in a medical marijuana treatment center's suspension do not state the length of time of licensure suspension. Alternatively, please explain the criteria the department uses to determine the length of any suspension. *See* § 120.52(8)(d), Fla. Stat.

Please explain whether the MMTC must discontinue all operations while its license is suspended, or whether it is only prohibited from dispensing low-THC cannabis, marijuana, or marijuana delivery devices. *See* § 120.52(8)(d), Fla. Stat.

Please explain what happens to the marijuana, low-THC cannabis, medical marijuana delivery devices, and plants which are owned and/or sold by a medical marijuana treatment center whose license is revoked and during the pendency of any suspension of its license.

The Florida Medical Marijuana Performance Bond, Form DH8015-OMMU-08/2017, incorporated by reference in Rule 64ER17-2 states in part that a medical marijuana treatment center's license is "subject to revocation during the effective period for any of the reasons identified in 64-4.004, *Florida Administrative Code,* which section is incorporated by reference as if fully set forth herein[.]" Please explain why the bond form does not reference these disciplinary guidelines, a violation of which may subject the medical marijuana treatment center to license revocation. *See* § 120.545(1)(i), Fla. Stat.

Please explain why the rule text does not advise that, in the event a medical marijuana treatment center's license is revoked, the mandatory $5 million performance bond will become null and void. See DH8015-OMMU-08/2017.

64ER17-6(1): Please explain what the department means by "subject to other provisions of this rule." *See* § 120.52(8)(d), Fla. Stat.

This subsection states that, "Penalties are applicable per instance of each violation and every day that a violation occurs shall be considered a separate violation." Please explain when the department considers the violation to have begun and when the violation ends. *See* §§ 120.52(8)(d), .545(1)(i), Fla. Stat.

64ER17-6(1)(a)1.: Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(a)2.: Please explain why the violations listed when a medical marijuana treatment center attempts to renew a license differ from those listed when a medical marijuana treatment center attempts to procure a license. As it appears these violations are intended to implement the provisions of section 381.986(10)(f)5., it appears this rule subparagraph should refer to "fraudulent misrepresentation" instead of "fraud," and should also include extortion. *See* § 120.52(8)(c), Fla. Stat.

This guideline states that for the first violation, a penalty may be "revocation of the license with the ability to reapply upon payment of a $5,000 fine." Please explain whether the opportunity to reapply is after a certain period of time following revocation or whether the revoked licensee must wait until the department is accepting new applications for medical marijuana treatment centers. *See* §§ 120.52(8)(d), .545(1)(i), Fla. Stat.

Please explain why this rule subparagraph refers to "permanent revocation." If there is a difference between "permanent revocation" and "revocation" for all instances where revocation may be imposed, it appears that distinction should be explained in the rule text. *See* § 120.545(1)(i), Fla. Stat.

Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(b)1.: Please explain why the rule text refers to "medical cannabis" instead of "marijuana." *See* § 381.986(1)(f), Fla. Stat. It appears the rule text should use the same term used in the statute. *See* § 120.545(1)(i), Fla. Stat.

Please explain how the department can discipline a medical marijuana treatment center for dispensing more than a 70-day supply of low-THC cannabis or medical cannabis, when the department has not proposed or adopted a rule establishing the daily dose amount. *See* § 381.986(4)(c), Fla. Stat. ("The department shall quantify by rule a daily dose amount with equivalent dose amounts for each allowable form of marijuana dispensed by a medical marijuana treatment center. The department shall use the daily dose amount to calculate a 70-day supply.").

Please explain the department's statutory authority to issue a letter of warning. *See* § 381.986(10)(f) and (g), Fla. Stat.

Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(b)2.: Please explain why the rule text refers to "medical cannabis" and "cannabis delivery device" instead of "marijuana" and "marijuana delivery device." *See* § 381.986(1)(f) and (g), Fla. Stat. It appears the rule text should use the same terms used in the statute. *See* § 120.545(1)(i), Fla. Stat.

Please explain the department's statutory authority to issue a letter of warning. *See* § 381.986(10)(f) and (g), Fla. Stat.

Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(b)3.: Please explain why the rule text refers to "medical cannabis" and "cannabis delivery device" instead of "marijuana" and "marijuana delivery device." *See* § 381.986(1)(f) and (g), Fla. Stat. It appears the rule text should use the same terms used in the statute. *See* § 120.545(1)(i), Fla. Stat.

Please explain the department's statutory authority to issue a letter of warning. *See* § 381.986(10)(f) and (g), Fla. Stat.

Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(b)4.: Please explain the department's statutory authority to issue a letter of warning. *See* § 381.986(10)(f) and (g), Fla. Stat.

Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(b)5.: This disciplinary guideline lists six potential violations, then lists potential penalties for the first violation and subsequent violations. Please explain whether a medical marijuana treatment center will be subject to the potential penalties for subsequent violations if found to have committed different offenses listed in this subparagraph as part of the same transaction or at the same time. *See* § 120.545(1)(i), Fla. Stat.

Please explain the department's statutory authority to issue a letter of warning. *See* § 381.986(10)(f) and (g), Fla. Stat.

Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(b)6.: Please explain why the rule text refers to "medical cannabis" and "cannabis delivery device" instead of "marijuana" and "marijuana delivery device." *See* § 381.986(1)(f) and (g), Fla. Stat. It appears the rule text should use the same terms used in the statute. *See* § 120.545(1)(i), Fla. Stat.

Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(b)7.: Please explain what the department means by "any other type of cannabis." *See* § 120.52(8)(d), Fla. Stat.

Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(b)8.: Please explain why the rule text refers to "medical cannabis" and "cannabis delivery device" instead of "marijuana" and "marijuana delivery device." *See* § 381.986(1)(f) and (g), Fla. Stat. It appears the rule text should use the same terms used in the statute. *See* § 120.545(1)(i), Fla. Stat.

Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(b)9.: It appears the word "Creates" should be "Creation of."

Please explain why this rule subparagraph refers to a "qualified ordering physician." It appears that section 381.986 refers to a "qualified physician." *See* § 381.986(1)(m), Fla. Stat. It appears the rule text should use the same term as the statute. *See* §§ 120.545(1)(i), Fla. Stat.

Please explain which statutory provision authorizes this disciplinary guideline. *See* §§ 120.52(8), .536(1), Fla. Stat.

Please explain what the department means by "further appropriate action by the department or respective board." *See* § 120.52(8)(d), Fla. Stat.

Please explain which statutory provision(s) authorizes the department to discipline a qualified physician who violates this rule subparagraph and the department's authority to adopt rules that discipline physicians licensed pursuant to chapter 458 and chapter 459. *See* § 120.52(8)(b) Fla. Stat.; *cf.* § 381.986(12)(g), Fla. Stat. ("A qualified physician who issues a physician certification for marijuana or a marijuana delivery device and receives compensation from a medical marijuana treatment center related to the issuance of a physician certification for marijuana or a marijuana delivery device is subject to disciplinary action under the applicable practice act and s. 456.072(1)(n).").

64ER17-6(1)(b)10.: It appears the word "Creates" should be "Creation of."

Please explain why this rule subparagraph refers to a "qualified ordering physician." It appears that section 381.986 refers to a "qualified physician." *See* § 381.986(1)(m), Fla. Stat. It appears the rule text should use the same term as the statute. *See* § 120.545(1)(i), Fla. Stat.

Please explain which statutory provision authorizes this disciplinary guideline. *See* §§ 120.52(8), .536(1), Fla. Stat.

Please explain what the department means by "further appropriate action by the department or respective board." *See* § 120.52(8)(d), Fla. Stat.

Please explain which statutory provision(s) authorizes the department to discipline a qualified physician who violates this rule subparagraph and the department's authority to adopt rules that discipline physicians licensed pursuant to chapter 458 and chapter 459. *See* § 120.52(8)(b) Fla. Stat.; *cf.* § 381.986(12)(g), Fla. Stat. ("A qualified physician who issues a physician certification for marijuana or a marijuana delivery device and receives compensation from a medical marijuana treatment center related to the issuance of a physician certification for marijuana or a marijuana delivery device is subject to disciplinary action under the applicable practice act and s. 456.072(1)(n).").

64ER17-6(1)(b)11.: Please explain why this rule subparagraph refers to a "qualified ordering physician." It appears that section 381.986 refers to a "qualified physician." *See* § 381.986(1)(m), Fla. Stat. It appears the

rule text should use the same term as the statute. *See* §§ 120.545(1)(i), Fla. Stat.

Please explain what the department means by "further appropriate action by the department or respective board." *See* § 120.52(8)(d), Fla. Stat.

Please explain which statutory provision(s) authorizes the department to discipline a qualified physician who violates this rule subparagraph and the department's authority to adopt rules that discipline physicians licensed pursuant to chapter 458 and chapter 459. *See* § 120.52(8)(b) Fla. Stat.; *cf.* § 381.986(12)(g), Fla. Stat. ("A qualified physician who issues a physician certification for marijuana or a marijuana delivery device and receives compensation from a medical marijuana treatment center related to the issuance of a physician certification for marijuana or a marijuana delivery device is subject to disciplinary action under the applicable practice act and s. 456.072(1)(n).").

64ER17-6(1)(b)12.: Please explain which statutory provision authorizes a violation for the improper disclosure of personal information of a caregiver. If this is a disciplinary guideline for violating section 381.986(10)(f)4., it appears that statute only addresses the disclosure of personal and confidential information of the qualified patient. *See* § 120.52(8)(c), Fla. Stat.

Please explain the department's statutory authority to discipline an approved law enforcement medical marijuana use registry user or physician. *See* § 120.52(8)(b), Fla. Stat.

Please explain the department's statutory authority to issue a letter of warning. *See* § 381.986(10)(f) and (g), Fla. Stat.

Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

Please explain what the department means by "further appropriate action by the department or respective board." *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(b)13.: Please explain the department's statutory authority to discipline an approved law enforcement medical marijuana use registry user or physician. *See* § 120.52(8)(b), Fla. Stat.

Please explain the department's statutory authority to issue a letter of warning. *See* § 381.986(10)(f) and (g), Fla. Stat.

Please explain what the department means by "further appropriate action by the department or respective board." *See* § 120.52(8)(d), Fla. Stat.

Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(b)13.a.: Please explain what the department means by "or other approved user" in these rule subparagraphs, and the department's statutory authority to discipline such users. *See* § 120.52(8)(c) and (d), Fla. Stat.

64ER17-6(1)(b)13.b.: Please explain what the department means by "or other approved user" in these rule subparagraphs, and the department's statutory authority to discipline such users. *See* § 120.52(8)(c) and (d), Fla. Stat.

64ER17-6(1)(b)13.c.: Please explain which statutory provision authorizes this disciplinary guideline. *See* §§ 120.52(8), .536(1), Fla. Stat.

64ER17-6(1)(c)1.: Please explain what the department means by "qualifications for approval." *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(c)2.: Please explain the department's statutory authority to issue a letter of warning. *See* § 381.986(10)(f) and (g), Fla. Stat.

Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(c)3.: Please explain which statutory provision authorizes this disciplinary guideline. *See* §§ 120.52(8), .536(1), Fla. Stat.

Please explain whether this disciplinary guideline is intended to implement section 381.986(9) or section 381.986(10)(f)6. If it is intended to implement section 381.986(10)(f)6., please explain why this violation refers to "owner, officer, board member, manager, or employee by an MMTC." *See* § 120.52(8)(c), Fla. Stat.

Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(c)4.: Please explain whether this disciplinary guideline is intended to implement section 381.986(10)(f)12. If so, please explain why this

violation refers to "owner, officer, board member, manager, or employee by an MMTC." If not, please explain which statutory provision this disciplinary guideline is intended to implement.

Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(c)5.: Please explain the department's statutory authority to issue a letter of warning. *See* § 381.986(10)(f) and (g), Fla. Stat.

Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(c)6.: Please explain the department's statutory authority to issue a letter of warning. *See* § 381.986(10)(f) and (g), Fla. Stat.

Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(c)7.: Please explain the department's statutory authority to issue a letter of warning. *See* § 381.986(10)(f) and (g), Fla. Stat.

Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(c)8.: Please explain the department's statutory authority to issue a letter of warning. *See* § 381.986(10)(f) and (g), Fla. Stat.

Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(c)9.: Please explain the department's statutory authority to issue a letter of warning. *See* § 381.986(10)(f) and (g), Fla. Stat.

Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(c)10.: Please explain whether this disciplinary guideline is intended to implement section 381.986(8)(h), and in particular,

section 381.986(8)(h)2.a., which addresses Internet advertising and marketing. As it appears the department is required to approve all Internet advertising, *see* § 381.986(8)(h)2.a., Fla. Stat., please explain whether a medical marijuana treatment center will be disciplined for advertising that the department has approved. *See* § 120.545(1)(i), Fla. Stat.

Please explain the department's statutory authority to issue a letter of warning. *See* § 381.986(10)(f) and (g), Fla. Stat.

Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(c)11.: Please explain the department's statutory authority to issue a letter of warning. *See* § 381.986(10)(f) and (g), Fla. Stat.

Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(c)12.: Please explain whether this rule subparagraph is intended to implement section 381.986(3)(b). If so, please explain why this disciplinary guideline does not state that a qualified physician may not "have any direct or indirect economic interest in" a medical marijuana treatment center or marijuana testing laboratory. *See* § 120.52(8)(c), Fla. Stat.

Please explain the department's statutory authority to issue a letter of warning. *See* § 381.986(10)(f) and (g), Fla. Stat.

Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(c)13.: Please explain which statutory provision authorizes the department to determine which fungicides or herbicides are approved, and which department rule(s) approves such fungicides and herbicides. It appears that the Department of Agriculture and Consumer Services is authorized to adopt rules governing fumigation or treatment of plants pursuant to section 381.986(8)(e)6.d. *See* § 120.52(8)(c), Fla. Stat.

Please explain how medical marijuana treatment centers that are disciplined for this violation are expected to treat or dispose of any affected plants.

This disciplinary guideline lists aggravating and mitigating factors, in addition to those listed in subsection (2) that will be considered when imposing a penalty for this violation. Please explain how the factors listed in this subparagraph will be applied.

Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(c)14.: Please explain why the rule text refers to "medical cannabis" and "medical cannabis products" instead of "marijuana" and "marijuana products." *See* § 381.986(1)(f), Fla. Stat. It appears the rule text should use the same terms used in the statute. *See* § 120.545(1)(i), Fla. Stat.

Please explain which statutory provision authorizes this disciplinary guideline. *See* §§ 120.52(8), .536(1), Fla. Stat.

Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(c)15.: Please explain which statutory provision authorizes this disciplinary guideline. *See* §§ 120.52(8), .536(1), Fla. Stat.

Please explain the department's statutory authority to issue a letter of warning. *See* § 381.986(10)(f) and (g), Fla. Stat.

Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(c)16.: Please explain the department's statutory authority to issue a letter of warning. *See* § 381.986(10)(f) and (g), Fla. Stat.

Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(c)17.: Please explain which statutory provision authorizes this disciplinary guideline. *See* §§ 120.52(8), .536(1), Fla. Stat.

Please explain the department's statutory authority to issue a letter of warning. *See* § 381.986(10)(f) and (g), Fla. Stat.

Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(c)18.: Please explain the department's statutory authority to issue a letter of warning. *See* § 381.986(10)(f) and (g), Fla. Stat.

Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(c)19.: Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(c)20.: Please explain why the rule text refers to "medical cannabis products" instead of "marijuana products." *See* § 381.986(1)(f), Fla. Stat. It appears the rule text should use the same term used in the statute. *See* § 120.545(1)(i), Fla. Stat.

Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(c)21.: Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(c)22.: Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(c)23.: Please explain which statutory provision authorizes this disciplinary guideline. *See* §§ 120.52(8), .536(1), Fla. Stat.

Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(c)24.: Please explain which statutory provision authorizes this disciplinary guideline. *See* §§ 120.52(8), .536(1), Fla. Stat.

Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(c)25.: Please explain whether this rule subparagraph is intended to implement section 381.986(11)(c). If so, it appears that the description of this violation may be incomplete. *See* § 120.52(8)(c), Fla. Stat.

Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(c)26.: Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(c)27.: Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(c)28.: Please explain whether this rule subparagraph is intended to implement section 381.986(8)(e)6.c. If so, please explain why the rule text does not include "in accordance with chapter 581 and any rules adopted thereunder." *See* § 120.52(8)(c), Fla. Stat. Further, it appears that such rules adopted pursuant to chapter 581 should be identified and specifically incorporated by reference.

Please explain the department's statutory authority to discipline a medical marijuana treatment center for its "failure to notify the Department of Agriculture and Consumer Services within 10 calendar days after a determination that a plant is infested or infected by a plant pest, and to implement and maintain phytosanitary policies and procedures." *See* §§ 120.52(8), .536(1), Fla. Stat.

64ER17-6(1)(c)29.: Please explain why this rule subparagraph does not identify which statutory provisions of chapter 581 and which rules adopted thereunder, may subject a medical marijuana treatment center to discipline. *See* § 120.52(8)(d), Fla. Stat.

Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(c)30.: Please explain why the rule text refers to "medical cannabis" and "medical cannabis products" instead of "marijuana" and "marijuana products." *See* § 381.986(1)(f), Fla. Stat. It appears the rule text should use the same terms used in the statute. *See* § 120.545(1)(i), Fla. Stat.

Please explain how the department expects a medical marijuana treatment center to handle low-THC cannabis, low-THC cannabis products, medical marijuana, and medical marijuana products that are improperly processed in the manner described in this violation.

Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(c)31.: Please explain why the rule text refers to "medical cannabis" instead of "marijuana." *See* § 381.986(1)(f), Fla. Stat. It appears the rule text should use the same term used in the statute. *See* § 120.545(1)(i), Fla. Stat.

Please explain how the department expects a medical marijuana treatment center to handle low-THC cannabis, medical marijuana, and other plants that are improperly processed in the manner described in this violation.

Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(c)32.: Please explain why the rule text refers to "medical cannabis products" instead of "marijuana products." *See* § 381.986(1)(f), Fla. Stat. It appears the rule text should use the same term used in the statute. *See* § 120.545(1)(i), Fla. Stat.

Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(c)33.: Please explain why the rule text refers to "medical cannabis products" instead of "marijuana products." *See* § 381.986(1)(f), Fla. Stat. It

appears the rule text should use the same term used in the statute. *See* § 120.545(1)(i), Fla. Stat.

Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(c)34.: Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(c)35.: Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(c)36.: Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(c)37.: Please explain whether this rule subparagraph is intended to implement section 381.986(8)(f)7. If so, please explain why it does not include requiring contractors to wear a photo identification badge at all times while on the premises. *See* § 120.52(8)(c), Fla. Stat.

Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(c)38.: Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(c)39.: Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(c)40.: Please explain why the rule text refers to "medical cannabis" instead of "marijuana." *See* § 381.986(1)(f), Fla. Stat. It appears the rule text should use the same term used in the statute. *See* § 120.545(1)(i), Fla. Stat.

Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(c)41.: Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(c)41.b.: Please explain why the rule text refers to "medical cannabis" instead of "marijuana." *See* § 381.986(1)(f), Fla. Stat. It appears the rule text should use the same term used in the statute. *See* § 120.545(1)(i), Fla. Stat.

64ER17-6(1)(c)41.c.: Please explain why the rule text refers to "medical cannabis" instead of "marijuana." *See* § 381.986(1)(f), Fla. Stat. It appears the rule text should use the same term used in the statute. *See* § 120.545(1)(i), Fla. Stat.

64ER17-6(1)(c)41.d.: Please explain why the rule text refers to "medical cannabis" instead of "marijuana." *See* § 381.986(1)(f), Fla. Stat. It appears the rule text should use the same term used in the statute. *See* § 120.545(1)(i), Fla. Stat.

64ER17-6(1)(c)41.e.: Please explain why the rule text refers to "medical cannabis" instead of "marijuana." *See* § 381.986(1)(f), Fla. Stat. It appears the rule text should use the same term used in the statute. *See* § 120.545(1)(i), Fla. Stat.

64ER17-6(1)(c)42.: Please explain which statutory provision authorizes this disciplinary guideline. *See* §§ 120.52(8), .536(1), Fla. Stat. If this rule paragraph is intended to implement section 381.986(10)(f)2., it does not appear to track the statutory language. *See* § 120.52(8)(c), Fla. Stat.

Please explain what the department means by "materially deviating from an application for licensure." *See* § 120.52(8)(c), Fla. Stat.

Furthermore, the penalty for this violation is "a $1,000 fine to $10,000 fine up to a $1,000 fine to $10,000 fine and suspension or revocation." However, it appears that rule subparagraph (1)(c)1. is a disciplinary guideline for violating section 381.986(10)(f)2., and the penalty to be imposed for that violation is "suspension or revocation of the medical marijuana treatment license." It appears the penalties in these two guidelines are inconsistent. *See* § 120.545(1)(i), Fla. Stat.

Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(c)43.: Please explain which statutory provision authorizes this disciplinary guideline. *See* §§ 120.52(8), .536(1), Fla. Stat.

Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(c)44.: Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(c)45.: Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(c)46.: Please explain how the wide range of potential penalties that may be imposed by this violation does not vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(1)(d): It does not appear that this rule paragraph provides entities or persons who may be disciplined with notice of potential violations and penalties that may be imposed. It appears this paragraph may vest unbridled discretion in the department. *See* § 120.52(8)(d), Fla. Stat.

64ER17-6(3): Please explain what the department means by, "the penalties shall be cumulative and consecutive." *See* § 120.52(8)(d), Fla. Stat.

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

Sincerely,

Marjorie C. Holladay
Chief Attorney

cc: Ms. Nichole C. Geary, General Counsel
Mr. Christian J. Bax, Director
Ms. Renee C. Harkins, Assistant General Counsel

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