

Florida Department of Health
“Use of Marijuana for Debilitating Medical Conditions”
Constitutional Amendment Analysis

I. CONFERENCE PLANNING ASSUMPTIONS

This analysis assumes the proposed Constitutional Amendment entitled “Use of Marijuana for Debilitating Medical Conditions” will be approved by the Florida voters and will have an effective date of January 3, 2017. These planning assumptions are based on the best information available as of October 19, 2015 and may be amended as additional information becomes available. These assumptions are not a statement of position from the Florida Department of Health (Department). The analysis further assumes the Department will: (1) promulgate rules by June 30, 2017, (2) issue qualified patient and caregiver identification cards prior to October 1, 2017, and (3) register Medical Marijuana Treatment Centers prior to October 1, 2017.

The Department analysis provides general planning assumptions, as well as a series of assumptions specific to marijuana, physician authority under state and federal law and regulations, patient and caregiver identification cards, Medical Marijuana treatment Centers, and the Department’s responsibilities.

Based on the most recent estimate from the Office of Economic and Demographic Research of 440,552 qualified patients, the Department estimates that when the program is fully implemented, the number of caregivers to be 130,844 and registered Medical Marijuana Treatment Centers to be 1,965. These estimates were derived from experience data for the State of Colorado.

1.0 Conference General Planning Assumptions

- 1.1. The Constitutional Amendment will appear on the ballot in November 2016.
- 1.2. The Constitutional Amendment will be approved by voters and be effective January 3, 2017.
- 1.3. The constitutional amendment has three components: (1) Physician certification, (2) Patient and caregiver identification cards, and (3) Medical Marijuana Treatment Center registration and regulation.

2.0 Marijuana

- 2.1. Marijuana is a Schedule 1 Controlled Substance under the Federal Controlled Substances Act, [21CFR1308.11](#).
- 2.2. Cannabis is a Schedule 1 Controlled Substance in section 893.03(1)(c)7, Florida Statutes (2014).
- 2.3. The U.S. Food and Drug Administration (FDA) has not recognized or approved the marijuana plant as medicine. The Department of Health does not have expertise in the regulation of healthcare products.
- 2.4. Section 381.986, Florida Statutes, authorizes the medical use of low-THC cannabis by qualified Florida patients.

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3.0 Physicians

- 3.1. Florida licensed physicians authorized to provide certification of a qualified patient include medical doctors licensed under Chapter 458 Florida Statutes, and doctors of osteopathy as licensed under Chapter 459 Florida Statutes.
- 3.2. Currently, licensed physicians cannot prescribe marijuana under Florida law.
- 3.3. Licensed physicians in Florida can prescribe low-THC cannabis under 381.986, Florida Statutes.
- 3.4. Licensed physicians will not be required to offer patients a certification for use of medical marijuana.
- 3.5. Pharmacies and dispensing physicians are not authorized to dispense Schedule 1 Controlled Substances.
- 3.6. Physician certification and other documentation that links the patient to their medical condition are protected health information and exempt from public records release.
- 3.7. Physical exam and full assessment of patient’s medical history will be required prior to issuing a physician certification.

4.0 Qualifying Patients & Caregivers

- 4.1. Qualifying patient and caregiver identification cards will authorize the holder to acquire and possess medical marijuana.
- 4.2. Qualifying patients under the age of eighteen will have custodial parent or legal guardian permission to obtain an identification card.
- 4.3. Caregivers will be at least twenty-one (21) years old and have agreed to assist a qualifying patient.
- 4.4. All records of the qualifying patients will be exempt from public records release.

5.0 Medical Marijuana Treatment Centers

- 5.1. Medical Marijuana Treatment Centers will register with the Florida Department of Health (DOH).
- 5.2. Medical Marijuana Treatment Centers will be inspected by DOH for issuance, renewal, suspension and revocation of registration.

6.0 Department of Health

- 6.1. The DOH will promulgate rules by June 30, 2017 to implement the program regulation outlined in the Constitutional Amendment.
- 6.2. The DOH will begin issuance of patient and caregiver identification cards prior to October 1, 2017.
- 6.3. The DOH will begin registering Medical Marijuana Treatment Centers prior to October 1, 2017.

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II. PROGRAM DESCRIPTION

If the proposed Constitutional Amendment is enacted, the Florida Department of Health will facilitate the: (1) acceptance of physician certifications, (2) patient and caregiver identification cards, (3) qualifications and standards for caregivers, (4) Medical Marijuana Treatment Center registration and regulation, and (5) regulation of the adequate supply of marijuana for a qualifying patient’s medical use. For each of these components, the Department’s analysis cites relevant definitions as provided in the constitutional amendment and indicates the Department’s responsibilities relative to each component.

1. Physician Certification

Definitions from Proposed Constitutional Amendment

- 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.
- Marijuana has the meaning given cannabis in section 893.02(3), Florida Statutes, and, in addition, “Low-THC cannabis” as defined in section 381.986(1)(b), Florida Statutes, shall also be included in the meaning of the term “marijuana.”
- 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.
- Physician means a physician who is licensed to practice medicine in Florida.
- 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.

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2. Patient and Caregiver Identification Cards

Definitions from Constitutional Amendment

- Identification card means a document issued by the Department that identifies a qualifying patient or a caregiver.
- 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.

FDOH Responsibilities

1. Develop and maintain procedures for:
 - Issuance and renewal of qualifying patient identification cards.
 - Issuance and renewal of caregiver identification cards.
2. Update registry to maintain qualified patient information and caregiver information.
3. Educate patients and caregivers on identification card issuance processes.
4. Ensure qualifying patient information is kept confidential.
5. Collect fees for identification cards.
6. Issue identification cards.
7. Replace lost identification cards, if necessary.
8. Renew identification cards.

3. Qualifications and Standards for Caregivers

Definitions from Constitutional Amendment

- 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.

FDOH Responsibilities

1. Establish qualifications and standards for caregivers.
2. Conducting appropriate background checks.
3. Establish procedures for the issuance and annual renewal of caregiver identification cards.

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4. Medical Marijuana Treatment Center Licensure and Regulation

Definitions from Constitutional Amendment

- 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.

FDOH Responsibilities

1. Develop and maintain procedures to:
 - Define procedures for registration of Medical Marijuana Treatment Centers, including issuance, renewal, suspension and revocation of registration.
 - Establish standards to ensure security, record-keeping, testing, labeling, inspection and safety.
2. Develop a treatment center registry.
3. Educate treatment center owners on laws, rules and procedures.
4. Issue registrations to treatment centers.
5. Inspect treatment centers based on established standards.
6. Investigate, suspend and revoke registrations as established procedures.
7. Renew treatment center registrations

5. Regulation of Adequate Supply for Qualifying Patients’ Medical Use

Definition from Constitutional Amendment

- 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.

FDOH Responsibilities

1. Develop and maintain administrative rules which:
 - On the basis of best evidence available, define adequate supply for qualifying patients.
 - Outlines a threshold for a particular patient’s appropriate medical use.
2. Educate physicians, caregivers, patients and law enforcement on administrative rules concerning adequate supply of qualifying patients’ medical use.

III. Limitations

Limitations established in the amendment

1. Nothing in this section allows for a violation of any law other than for conduct in compliance with the provisions of this section.

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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.
 - * According to a study published by the Columbia University School of Public Health in 2011, the risk of an automobile crash is almost 2.7 times higher among marijuana users than nonusers. The more marijuana smoked in terms of frequency and potency, the greater likelihood of a crash.
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.

IV. DIFFERENCES AMENDMENT 15-01 V. AMENDMENT 13-02

Substantive changes

- The current constitutional amendment contemplates the use of medical marijuana for *debilitating* medical conditions as opposed to certain medical conditions.
- The definition for “debilitating medical condition” removed hepatitis C, and added epilepsy, post-traumatic stress disorder (PTSD), and other debilitating medical conditions of the same kind or class as or comparable to those enumerated.
 - The Department does not have any classification of medical conditions of the same kind, same class, or comparable conditions to those listed in the amendment. The conditions enumerated include neurological, immune, behavioral health, gastrointestinal, etc. Each condition can include an innumerable number of variables to which they can be classified or compared.
- The definition of “marijuana” was expanded to include “Low-THC cannabis” as defined in section 381.986(1)(b), Florida Statutes.
- The definition of “medical use” was broadened to include an amount of marijuana or not in conflict with Department rules.
 - There is currently no “amount of marijuana” defined in rule by the Department. Section 381.986(2)(d), Florida Statutes., states that patient treatment plan includes the dose, route of administration, planned duration as established by the ordering physician.
- Caregivers are no longer required to assist no more than 5 qualifying patients at a time. In amendment 15-01 the Department may limit the number of qualifying patients a caregiver may assist.
- The definition of “physician” was changed to: means person who is licensed to practice medicine in Florida.

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- The definition of “physician certification” was expanded to include: for a physician certification to be issued to a minor, a parent or legal guardian of the minor must consent in writing.
- In amendment 15-01 the physician must receive written consent from the minor’s parent or legal guardian, prior to issuing the physician certification.
- In amendment 15-01 the Department must develop procedures establishing qualifications and standards for caregivers, including conducting appropriate background checks, and procedures for the issuance and annual renewal of caregiver identification cards

V. DIFFERENCES AMENDMENT 15-01 V. SB 1030

The Compassionate Medical Cannabis Act of 2014 (SB 1030) allows for the medical use of low-THC cannabis. The term does not include the possession, use, or administration by smoking. “Low-THC cannabis” means specifically 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.

Amendment 15-01 defines marijuana as having the meaning given cannabis in section 893.02(3), Florida Statutes, and “Low-THC cannabis” as defined in Section 381.986(1)(b), Florida Statutes. In amendment 15-01 “medical use” means the acquisition, possession, use, delivery, transfer, or administration of an amount of marijuana not in conflict with Department rules. The Department has no rules on the amount of marijuana, or low-THC cannabis. The physician, by section 381.986(2)(d), Florida Statutes, maintains the patient treatment plan that includes the dose, route of administration, and planned duration.

The Compassionate Medical Cannabis Act defines “Dispensing organization” as an organization approved by the Department of Health to cultivate, process, and dispense low-THC cannabis.

Amendment 15-01 creates a new business entity called a “Medical Marijuana Treatment Center” (MMTC) which is 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.

The addition of seven additional business functions (acquire, processes, transfer, transport, sell, distribute, and administer) and new products would substantially affect the market structure.

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III. COST ANALYSIS

Increased costs from this amendment to state and local governments cannot be determined. There will be additional regulatory and enforcement activities associated with the production and sale of medical marijuana. Fees will offset at least a portion of the regulatory costs.

The Department may need additional legislative authority to levy fees for the purpose of implementing this constitutional amendment.

Table 1
Florida Medical Marijuana Program
Qualified Patient, Caregiver & Treatment Facility Estimates

	Number	Methodology
<i>Estimated Number of Qualified Patients</i>	440,552	Estimated based on Office of Economic & Demographic Research estimated marijuana users for certain medical conditions in Florida based on registered users in states with legalized marijuana for medical conditions. Based on Colorado, the Florida 2017 estimate is: 440,552.
<i>Estimated Number of Caregivers</i>	130,844	Estimate assumes 29.7% of patients have designated a primary care-giver, based on the Colorado experience.
<i>Estimated Number of Medical Marijuana Treatment Centers to be Registered</i>	1,993	Estimated number of facilities based on Colorado program. (Currently in Colorado there are 515 licensed centers for 113,862 registered patients).

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Table 2
Florida Medical Marijuana Program
Cost Estimates, 2017 & 2018

Cost of Program Implementation	Year 1 2017	Year 2 2018	Description
Program Staff – State Health Office Year 1 – Program Administrator, Environmental Consultant, Gov’t Operations Consultant II and Senior Clerk Year 2 – Program Administrator, Environmental Consultant, Gov’t Operations Consultant II and Senior Clerk	\$264,686	\$299,950	<u>Year 1 Total Salary, Fringe, Expense & HR</u> 25% Lapse Factor Program Administrator (\$78,393) Environmental Consultant (\$71,733) Gov’t Operations Consultant II (\$79,578) Senior Clerk (\$34,982) <u>Year 2 Total Salary, Fringe, Expense & HR</u> Program Administrator (\$95,322) Environmental Consultant (\$85,096) Gov’t Operations Consultant II (\$79,578) Senior Clerk (\$39,954)
Support for rule development	\$59,406	\$0	Contracted operations management consultant \$20 hr. /2080 hours plus fringe (35%) and contract overhead (4%). One-time contractual.
Develop & disseminate educational materials	\$49,120	\$21,060	Contracted educator \$20.00 hr. /1500 hours plus fringe (35%) and contract overhead (4%). One-time contractual. Costs to disseminate materials to physician = \$7,000 Year 2 includes 750 hours of contracted time to refresh training materials.
Business Analyst for data system	\$88,400	\$0	\$85 per hours for 1040 hours. One-time contractual.
Data system for patient/caregiver registration & medical treatment center management	\$255,000	\$0	Cost to design, develop, test and data system based on business requirements. One-time contractual cost based on Five Points purchase order for the implementation of SB 1030.

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Annual data system user support and maintenance	\$0	\$129,600	Annual cost of help desk and software maintenance based on Five Points agreement for the implementation of SB 1030.
Field Staff (30 FTEs)– Treatment facility inspections, reinspections, and complaint investigations Year 1 – 3 months Year 2 – 12 months	\$1,121,156	\$2,216,804	Funds 30 Environmental Specialist II’s to conduct inspections & investigations. Environmental Specialist II (\$404,036) + non-recurring standard package (\$116,460) + recurring expense package (\$184,980) + maximum travel (\$405,360) + HR Costs (\$10,320) for a total of \$1,121,156. (Salary \$ Fringe \$53,871, Travel \$9,606, Expense \$6,166 Recurring \$3,882 Nonrecurring and HR \$344) for a total of \$2,216,804.
Regional Inspector Transportation, Computers and Connectivity	\$1,099,320	\$17,280	One-time cost for 30 state vehicles @ \$35,000 each and 30 pen tablets @ \$1,500 each for regional inspectors. Routine repair and maintenance in Year 2 included in cost per service. VPN connectivity service \$48 per month per inspector for 3 months in year 1 – \$4,320. Year 2 costs included in cost per service.
Total Estimated Costs	\$2,937,088	\$2,684,694	

NOTE: Based on the limited information regarding how the program would be implemented these cost estimates could change when more information becomes available.