



Health Quality Subcommittee

Wednesday, October 11, 2017
1:00 PM - 3:00 PM
Mashburn Hall (306 HOB)

Committee Meeting Notice

HOUSE OF REPRESENTATIVES

Health Quality Subcommittee

Start Date and Time: Wednesday, October 11, 2017 01:00 pm
End Date and Time: Wednesday, October 11, 2017 03:00 pm
Location: Mashburn Hall (306 HOB)
Duration: 2.00 hrs

Implementation updates on SB 8-A (2017), Medical Use of Marijuana:

- Christian Bax, Director of Office of Medical Marijuana Use, Florida Department of Health
- Jennifer Langston, Legislative Affairs Administrator, Florida Department of Highway Safety and Motor Vehicles

NOTICE FINALIZED on 10/04/2017 11:47AM by Iseminger.Bobbye

FLORIDA DEPARTMENT OF HEALTH

Office Of Medical Marijuana Use

Low-THC Cannabis & Medical Marijuana

MedicalMarijuanaUse@FLHealth.gov



**Florida
HEALTH**

Medical Marijuana in Florida



- Medical marijuana was first legalized in Florida under the Compassionate Medical Cannabis Act of 2014. The act authorized a low tetrahydrocannabinol (low-THC) and high cannabidiol (CBD) form of marijuana for medical use by patients suffering from cancer or seizures.
- The 2016 Right to Try Act allowed patients with terminal illnesses access to “full potency” medical marijuana.
- In November, 2016, 71 percent of Florida voters voted for Amendment 2, which created Article X, section 29 of the Florida Constitution. Amendment 2 expanded access to both low-THC and full-potency medical marijuana for a larger list of medical conditions.
- SB 8-A (2017) implemented Amendment 2.

Timeline



Jun 6, 2014

SB 1030 “Compassionate Medical Cannabis Act of 2014” signed into law

Mar 25, 2016

HB 307 “The Right to Try Act” signed into law

Nov 8, 2016

Amendment 2 passed

Jan 3, 2017

Amendment 2 became effective

June 9, 2017

Senate Bill 8-A passed in special session

June 23, 2017

Senate Bill 8A signed into law

July 1, 2017

Rule 1-1.01, Medical Marijuana for Debilitating Medical Conditions, became effective

What is *Medical Marijuana* in Florida



Authorized Use

- Full potency medical marijuana, *and* low-THC cannabis under 381.986, F.S., for all qualifying conditions.
- Medical use is the acquisition, possession, use, delivery, transfer, or administration of marijuana authorized by a qualified ordering physician.
- Medical marijuana is only provided through an approved MMTC.

Unauthorized Use

- Marijuana that was not purchased or acquired from a MMTC.
- Marijuana in forms for smoking, commercially produced food items other than edibles, and marijuana seeds or flower, except for flower in a sealed, tamper-proof receptacle for vaping.
- Use in a manner inconsistent with the qualified physician's directions or certification.
- Transfer of marijuana to a person other than and authorized qualified patient or the qualified patient's caregiver on their behalf.

Medical Marijuana Treatment Center (MMTC) Qualifications



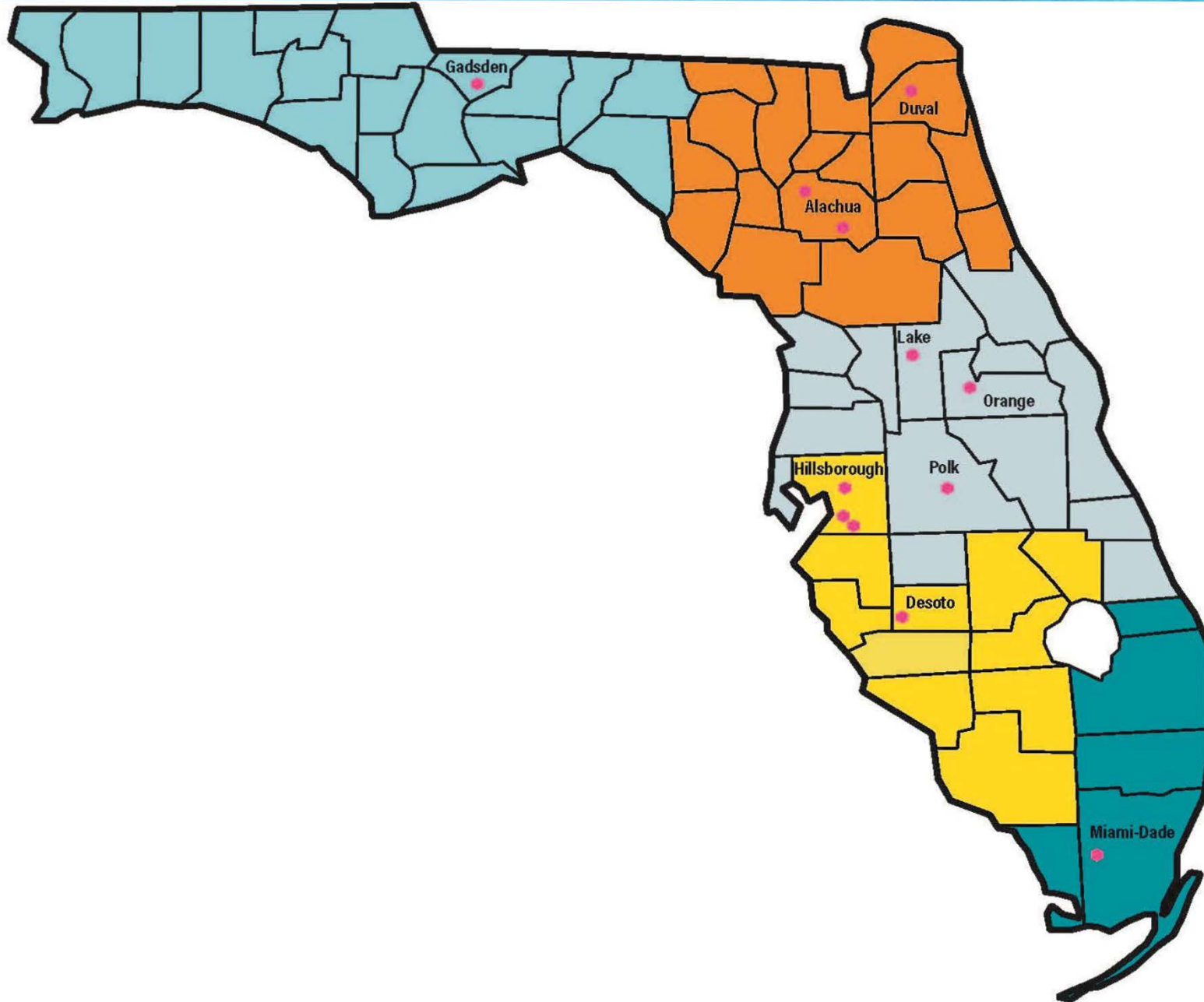
All Medical Marijuana Treatment Centers (MMTCs) must:

- Be vertically integrated
- Have been registered to do business in the state for at least 5 consecutive years before submitting an application
- Possess a valid certificate of registration issued by the Department of Agriculture and Consumer Services pursuant to s. 581.131 F.S.
- Upon approval, post a \$5 million performance bond issued by an authorized surety insurance company

MMTC Licensure Phases

- Phase 1: By July 3, 2017, DOH must license any entity that holds an active, license under former Compassionate Use Act.
- Phase 2: By August 1, 2017, DOH must license any applicant whose application was scored but denied a license by DOH under the Compassionate Use Act, and which had an ongoing administrative or judicial challenge as of January 1, 2017, or had a final ranking within one point of the highest final ranking in its region.
- Phase 3: By October 3, 2017, DOH must license 5 more MMTCs, one of which is a recognized class member of Pigford v. Glickman and is a member of the Black Farmers and Agriculturalists Association (Florida Chapter).
- Phase 4: Upon reaching 100,000 patients in the registry, and for each additional 100,000 patients thereafter, DOH must license 4 more MMTCs within 6 months.

Phase 1 and 2 Approved MMTCs by Region



-  Approved Medical Marijuana Treatment Centers
-  Trulieve—Gadsden County
-  CHT Medical—Alachua County
The Green Solution—Alachua County
Loop's—Duval County
-  Knox Medical—Orange County
GrowHealthy—Polk County
Treadwell Nursery—Lake County
-  3 Boys—Hillsborough County
Plants of Ruskin—Hillsborough County
Surrterra Therapeutics—Hillsborough County
Sun Bulb Company—Hillsborough County
-  Modern Health Concepts—Miami-Dade County

Dispensary Distribution Method and Current Dispensing Locations



Dispensary Distribution	MMTC*	Retail Dispensary Locations
<ul style="list-style-type: none"> • Statewide Maximum - Each MMTC may have up to 25 dispensaries statewide, before the patient population reaches 100,000. Each MMTC gets an additional 5 dispensaries for each additional 100,000 patients. • Regional Maximum - The statewide maximum is distributed in the 5 regions (Northwest, Northeast, Central, Southwest and Southeast) based on regional population. • MMTCs may purchase dispensary slots from other MMTCs. • These limits sunset on April 1, 2020. 	<p>Surterra Therapeutics</p>	<p>Tallahassee, Tampa</p>
	<p>Trulieve</p>	<p>Bradenton, Clearwater, Edgewater, Jacksonville, Miami, Lady Lake, Pensacola, St. Petersburg, Tallahassee, Tampa</p>
	<p>Knox Medical</p>	<p>Gainesville, Jacksonville, Lake Worth, Orlando, Tallahassee</p>
	<p>Curaleaf</p>	<p>Kendall, Miami</p>

* These are the only MMTCs currently operating retail dispensaries.

Phase 3 MMTC Licensure and Procurements



- DOH 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).
- DOH is procuring outside specialists to evaluate new applications.
 - Request for Quotes issued to state term contracts; currently reviewing quotes received.
- DOH is currently negotiating with vendors to outsource the patient and caregiver identification card program.
- DOH has developed an Request for Proposals for the statewide seed-to-sale tracking system.

MMTC Rules and Regulations

The department is in the process of developing rules for:

- Pesticide use
- Fine and fee collection
- Labeling and packaging standards
- Edible standards
- Dosing guidelines
- Testing laboratory Certification

Qualified Physician Requirements

- Only a qualified physician may issue a certification for low-THC cannabis and medical marijuana for patients. 1,047 qualified physicians are currently registered with DOH.
- To be a qualified physician, a doctor must:
 - Have a clear/active license as a medical or osteopathic physician (ch. 458 and 459, F.S.)
 - Complete a course and examination provided by the Florida Medical Association or the Florida Osteopathic Medical Association.
- To issue a certification, a qualified physician must:
 - Conduct a physical examination while physically present in the same room as the patient and assess the patient's medical history.
 - Diagnose the patient with a qualifying medical condition
 - Determine that the benefits of medical marijuana would likely outweigh the potential health risks for the patient, and record this determination. If a patient is under age 18, a second physician must agree and record the agreement.

Qualified Physician Requirements, cont'd

- To issue a certification, a qualified physician must (continued):
 - Determine if the patient is pregnant and record it. A physician may not issue a physician certification, except for low-THC cannabis, to a patient who is pregnant.
 - Review the patient's controlled drug prescription history in the Prescription Drug Monitoring Program database.
 - Review the Medical Marijuana Use Registry and confirm that the patient does not have an active physician certification from another qualified physician.
 - Have registered for this patient in the Medical Marijuana Use Registry and entered the physician certification information into the registry, including the qualifying condition, dosage, amount and forms of marijuana authorized, and any types of marijuana delivery devices needed.
 - Evaluate the patient at least every 30 weeks.

Requirements for Patients



Only a qualified patient may use low-THC cannabis and medical marijuana. There are currently 41,300 qualified patients in Florida.

To be a qualified patient, a person must:

- Be a Florida resident
- Not fraudulently represent qualification
- Have debilitating medical condition
- Be placed in the registry by physician and linked to only one physician
- Have Office of Medical Marijuana Use Identification Card
- Not transfer product to anyone else
- Use only in permitted places

Requirements for Caregivers

Only registered caregivers may obtain and administer Low-THC cannabis and medical marijuana for qualified patients.

To qualify as a caregiver, a person must:

- Be 21 years old (with certain exceptions)
- Pass a background check (with certain exceptions)
- Complete a course and examination provided by DOH, when available

To obtain and assist qualified patients, a caregiver must:

- Only transfer product to qualified patients
- Not use a patient's medical marijuana
- Not administer medical marijuana in prohibited places
- Assist only one qualified patient (with certain exceptions)
- Not receive compensation
- Have the caregiver ID card in immediate possession at all times when possessing, delivering, administering

Identification Cards

Identification card statutory requirements:

- Must be renewed annually
- Must be resistant to counterfeiting and tampering
- Must include:
 - The name, address, and date of birth of the qualified patient or caregiver.
 - 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.
 - The expiration date of the identification card.
- DOH has released an ITN, and is currently in negotiations to outsource the production of cards, as directed by SB 8-A.
- Each qualified patient must have an approved application prior to filling an order at an MMTTC
- The current processing time for identification cards is approximately 30 days
- The OMMU has issued over 20,000 identification cards
- Common application deficiencies: Photo submitted is not a passport style photo, payment not signed, application not signed

Public Education



Education Campaign Requirements:

- Promote legal requirements for use and possession
- Promote information regarding safe use of marijuana, including prevention of unintended ingestion, particularly in children
- Publicize the short-term and long-term health effects of marijuana use, particularly on minors and young adults
- Educate on use of medical marijuana for individuals diagnosed with terminal conditions and those who provide palliative or hospice services
- **Conduct research to establish baseline knowledge**

Current Status:

- Established partnership with the Florida Survey Research Center (FSRC), based at UF and lead by Dr. Michael Scicchitano
- Survey in draft to be disseminated to five regions of the state to establish baseline knowledge and perception of medical marijuana in Florida
 - Data will be analyzed by FSRC and a report provided to DOH that will guide message development moving forward
- **Completed review of public education campaigns in other states that have already implemented medical marijuana**

Note: FAMU also received funding for education campaigns.

Statutory Deadlines



July 3, 2017	Grant MMTC licenses to licensed dispensing organizations
Aug 1, 2017	Grant MMTC licenses (5) to any denied DO with a pending legal challenge as of January 1, 2017, or a final ranking within one point the regional winner that proves it has the infrastructure and ability to begin cultivating within 30 days
Oct 3, 2017	Grant MMTC license to a member of the Black Farmers (1), give preference to (2) applicants that own citrus processing facilities and (2) more to reach the requirement
Oct 3, 2017	Must begin issuing patient and caregiver ID cards
Jan 1, 2018	Physician certification pattern review panel shall submit an annual report to Governor, President and Speaker. Department and applicable boards shall initiate nonemergency rulemaking pursuant to Ch. 120
Jan 15, 2018	DOH must submit to the research board and quarterly thereafter data sets for each patient registered in the registry, including condition and daily dose amounts
Jan 31, 2018	Submit to Governor, President and Speaker the annual evaluation of the marijuana use and prevention campaign as assessed by an independent entity
May 1, 2018	Establish supplemental fees to cover costs of marijuana education and use prevention campaign, as well as Medical Marijuana Research and Education at H. Lee Moffitt Cancer Center
July 1, 2018	Verify that MMTCs have a certified laboratory

Implementation Update

- Granted seven MMTC licenses to existing Dispensing Organizations
- Approved five new MMTCs and have commenced cultivation authorization inspections
- Issued MMTC application grading RFQ
- Established 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 position
- Assembled screening and interview teams that have begun establishing these positions and hiring candidates
- Developed RFP for Statewide Seed-to-Sale Tracking
- Developed ITN for Medical Marijuana Identification Card outsourcing and have commenced negotiations with vendors
- Engaged Moffitt in order to fulfill their requirements of SB 8-A and are finalizing an agreement with the organization
- Established a relationship with the University of Florida to fulfill the research and educational requirements of SB 8-A

Legal Challenges

- Home Grow:
 - Redner v. DOH, et. al., 13th Judicial Circuit Case No. 17-CA-5677
- Smoking Ban:
 - People United for Medical Marijuana v. DOH, et. al.,
2d Judicial Circuit Case No. 2017-CA-1394
- Constitutionality of Black Farmers Provision 381.986(8)(a)2 F.S.
 - Smith v. DOH, 2d Judicial Circuit Case No. 2017-CA-001972
- MMTC Licensure:
 - Tropiflora, LLC v. DOH, 2d Judicial Circuit Case No. 2016-CA-1330
 - Keith St. Germain v. DOH Case No. 17-5011

Questions?

Mission:

To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.



Rick Scott
Governor

Celeste Phillip, MD, MPH
Surgeon General and Secretary

Vision: To be the Healthiest State in the Nation

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

The Honorable Travis Cummings
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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,



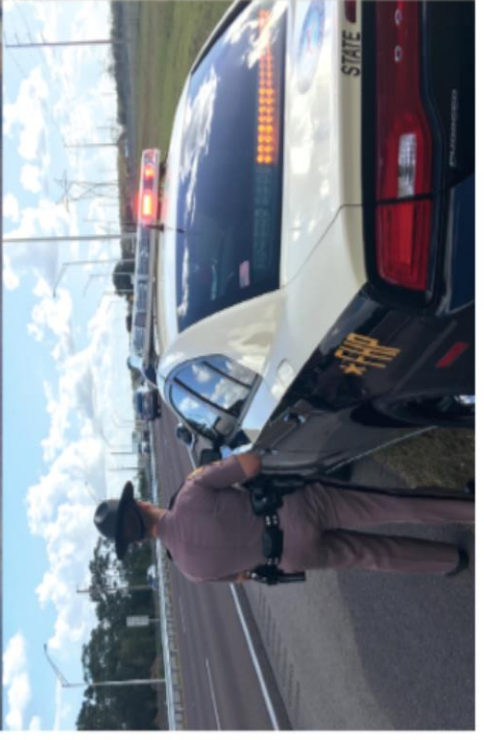
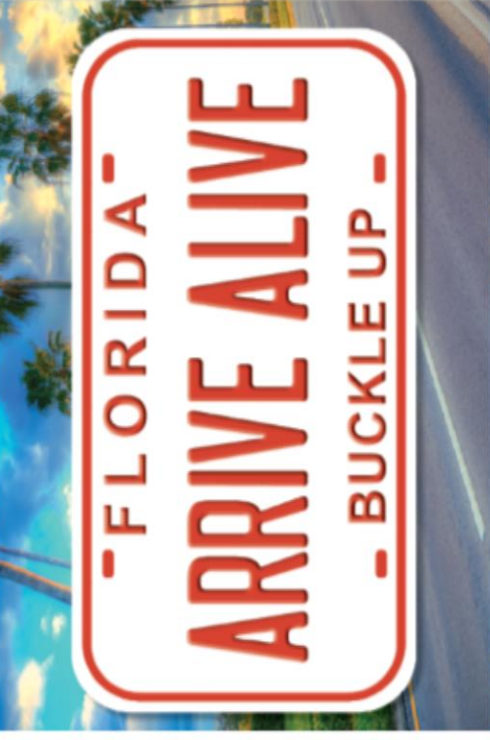
Christian Bax
Director
Office of Medical Marijuana Use

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

Implementation Update SB 8A Medical Use of Marijuana

October 11, 2017

House Health Quality Subcommittee



DHSMV Responsibilities

IDENTIFICATION CARDS

DOH is required to issue identification cards for qualified patients and caregivers. SB 8A requires, “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.”

ACTION ITEM

The Department is working with DOH to facilitate an MOU to provide digital photographs for the purposes of issuing identification cards. The photos will be shared with DOH through real-time webservice access. Anticipated Completion of MOU: December 2017

DHSMV Responsibilities

STATEWIDE IMPAIRED DRIVING EDUCATION CAMPAIGN

\$5 million is appropriated to the Department to implement a statewide impaired driving education campaign to raise awareness and prevent marijuana-related and cannabis-related impaired driving.

The Department may contract with one or more vendors to implement the campaign and may use television messaging, radio broadcasts, print media, digital strategies, social media, and any other form of messaging deemed necessary and appropriate by the department to implement the campaign.

ACTION ITEMS

- DHSMV has contracted with Florida Survey Research Center to establish data for the initial baseline survey and post-media campaign survey. The focus of the surveys are based on awareness of the issue and stated behavior.
- The Department is taking steps to contract with a vendor to conduct an Impaired Driving Campaign. The Campaign will be targeted to 5 major media markets statewide through June 2018. The campaign will consist of multiple advertising methods and is slated to begin January 2018.

DHSMV Responsibilities

ANNUAL REPORT

“At a minimum, DHSMV or a contracted vendor shall establish baseline data on the number of certain marijuana-related DUIs, traffic arrests, traffic crashes, and traffic fatalities, which is to be tracked annually”

By January 31 each year, the Department, or a contracted vendor, shall annually evaluate and compile a report on the efficacy of the campaign based on those measures and other measures established by DHSMV and evaluation of the campaign to the Governor and legislature.

ACTION ITEM

The Department is building the necessary elements to collect the “marijuana-related” data by amending the Traffic Crash Reporting process required in SB 8A. A few of the impacts of the implementation efforts include internal programming of IT systems, technology changes to state and local law enforcement crash reporting systems, as well as, education to local and state law enforcement agencies just to name a few. Existing crash forms currently do not distinguish this level of detail. The anticipated roll out of the new Crash Reporting fields is January 2018.

DHSMV Responsibilities

DRUG RECOGNITION EXPERTS

\$100,000 was appropriated for training law enforcement officers as Drug Recognition Experts (DRE).

DREs are law enforcement officers who have:

- Received over 100 hours of specialized training; and
- Been certified by the International Association of Chiefs of Police to evaluate suspects and determine if a subject is impaired what drug category(s) is/are causing the impairment, and if a medical condition is causing the impairment.

DRE Prerequisites include:

- Successful completion of a 24-hour NHTSA DWI Detection and Standardized Field Sobriety Testing (SFST) Course
- Successful completion of a 16-hour Advanced Roadside Impaired Driving Enforcement (ARIDE) course
- Have an endorsement from their local Assistant State Attorney, another DRE and from their respective department chief or designee and provide two DUI case reports completed within the previous year.

DHSMV Responsibilities

DRUG RECOGNITION EXPERTS

ACTION ITEM

The Florida Highway Patrol is soliciting DRE applicants, in addition to the 48 current DREs, in an effort to meet their goal of 300 to effectively combat drug impaired driving.

The Florida Highway Patrol has certified 2 members as DRE instructors who will train troopers as DREs in order to increase the pool of troopers able to become DRE certified.

The cost of the DRE training is approximately \$3,000 not including salaries. Additionally, every two years the troopers must recertify at a cost of \$225 not including salaries or lodging expenses etc.

The Department would like to discuss the possibility of expanding the appropriated funds to be used for recertification and the precursor ARIDE Training Course. 6

DHSMV Responsibilities

Questions?