

Professions and Public Health Subcommittee

Tuesday, March 9, 2021
9:30 AM – 11:30 AM
Webster Hall (212 Knott)

Meeting Packet

Chris Sprowls
Speaker

Will Robinson
Chair

Committee Meeting Notice

HOUSE OF REPRESENTATIVES

Professions & Public Health Subcommittee

Start Date and Time: Tuesday, March 09, 2021 09:30 am

End Date and Time: Tuesday, March 09, 2021 11:30 am

Location: Webster Hall (212 Knott)

Duration: 2.00 hrs

Consideration of the following bill(s):

HB 1455 Regulation of Medical Marijuana by Roach

This meeting will be live-streamed on https://thefloridachannel.org/. Persons who wish to attend must register at www.myfloridahouse.gov, and pick up a pass at the Legislative Welcome Center on the 4th Floor of the Capitol beginning one hour before the start of the meeting. Audience seating will be socially distanced and will be available on a first-come, first-served basis. Registration closes three hours before the meeting starts.

NOTICE FINALIZED on 03/05/2021 4:03PM by Osborne.Erin

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1455 Regulation of Medical Marijuana
SPONSOR(S): Roach
TIED BILLS: **IDEN./SIM. BILLS:** SB 1958

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Professions & Public Health Subcommittee		McElroy	McElroy
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Art. X, section 29 of the Florida Constitution, Use of Marijuana for Debilitating Medical Conditions, authorizes patients with an enumerated debilitating medical condition to obtain medical marijuana from Medical Marijuana Treatment Centers (MMTC). During the 2017A Special Session, the legislature implemented this constitutional provision by passing the Medical Use of Marijuana Act.

A medical marijuana patient must obtain a physician certification from a qualified physician, who may only certify a patient for three 70-day supply limits of marijuana not in a form for smoking and six 35-day supply limits for marijuana in a form for smoking before issuing a new certification. A 35-day supply of marijuana in a form for smoking cannot exceed 2.5 ounces. The Department of Health (DOH) is required to set a daily dose limit for all forms of marijuana, but has not done so, leaving the determination of an adequate supply at the sole discretion of a qualified physician.

Delta-9-tetrahydrocannabinol (THC) is the psychoactive chemical in marijuana. The full extent of the health impact of consuming products with high concentration of THC is unknown; however, research indicates that such use significantly increases the risk of marijuana-associated psychosis. Studies have found daily use, especially of high-potency marijuana (over 10 percent THC), is strongly associated with earlier onset of psychosis and the development of schizophrenia in marijuana users. Some studies have also shown that marijuana with a THC concentration of 10 percent or less is effective for medical treatment, including the relief of neuropathic pain and pain caused by conditions such as HIV/AIDS, multiple sclerosis, and post-traumatic surgical pain. Currently, MMTCs produce and dispense products ranging from 0.4% THC to 100% THC.

HB 1455 limits a 35-day supply of marijuana to 15,000 mg of THC and limits the potency to 10 percent THC for marijuana in a form for smoking and 60 percent THC for all other forms of marijuana products, excluding edibles. The bill limits the amount of marijuana a MMTC may dispense within any 70-day period to two 35-day supplies. The bill provides an exception to the potency limits for patients with terminal illnesses.

The bill prohibits qualified physicians from certifying medical marijuana for minors (under age 18), other than low-THC cannabis, unless the qualified physician determines that it is the most effective treatment for the patient and a second physician, who is a board-certified pediatrician, concurs with such determination.

The bill also prohibits a certified medical marijuana testing laboratory from having an economic interest in a MMTC and prohibits MMTCs from employing qualified physicians or having an economic interest in qualified physicians' practices, to align with similar provisions in current law applicable to physicians. The bill restricts advertising by qualified physicians and expands current MMTC advertising restrictions.

The bill requires MMTCs to recall all marijuana that fails to meet the safety and potency requirements, authorizes DOH to test samples of all forms of marijuana from MMTCs, and immunizes DOH staff from prosecution for possessing marijuana for this purpose.

The bill has a significant, indeterminate, negative fiscal impact on DOH and no fiscal impact upon local governments.

The bill provides an effective date of July 1, 2021, except as otherwise provided.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Research on the Health Effects of THC

Although there are more than 100 cannabinoids in a marijuana plant, the two main cannabinoids are Delta-9-tetrahydrocannabinol THC and cannabidiol (CBD).[1] THC is a mind-altering chemical that increases appetite and reduces nausea and may also decrease pain, anxiety, and muscle control problems.[2] Though CBD may also have an effect on the mind, it does not produce the high or sense of euphoria associated with THC. CBD has been shown to help with anxiety, depression, reducing pain and inflammation, controlling epileptic seizures, and possibly treating psychosis or mental disorders.[3]

Marijuana has changed over time. The THC concentration in commonly cultivated marijuana plants increased three-fold between 1995 and 2014 (4% and 12% respectively).[4] Conversely, the CBD content decreased from .28% in 2001 to .15% in 2014. In 1995, the level of THC was 14 times higher than its CBD level. In 2014, the THC level was 80 times the CBD level.[5] The marijuana available today is much stronger than previous versions.

Some studies have shown that marijuana with a THC concentration of 10% or less is effective for medical treatment, including the relief of neuropathic pain and pain caused by conditions such as HIV/AIDS, multiple sclerosis, post-traumatic surgical pain.[6] Studies on the use of marijuana for pain relief found that marijuana cigarettes with a THC concentration between 2% and 10% THC provided sufficient pain relief,[7] with one study finding that medium-dose marijuana cigarettes with 3.5% THC were as effective as higher dosed marijuana cigarettes at 7% THC.[8]

A 2014 New England Journal of Medicine study warned that long-term marijuana use can lead to addiction and that adolescents are more vulnerable to adverse long-term outcomes from marijuana use.[9] Specifically, the study found that, as compared with persons who begin to use marijuana in adulthood, those who begin in adolescence are approximately 2 to 4 times as likely to have symptoms of marijuana dependence within 2 years after first use.[10] The study also found that marijuana-based treatments with THC may have irreversible effects on brain development in adolescents as the brain's endocannabinoid system undergoes development in childhood and adolescence.[11]

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[1] U.S. Department of Health & Human Services, National Center for Complementary and Integrative Health, *Cannabis (Marijuana) and Cannabinoids: What You Need To Know*, available at https://www.nccih.nih.gov/health/cannabis-marijuana-and-cannabinoids-what-you-need-to-know (last visited February 9, 2021).
[2] Healthline, *CBD vs. THC: What's the Difference?*, https://www.healthline.com/health/cbd-vs-thc (last visited February 16, 2021).
[3] *Id*.
[4] *U.S. Surgeon General's Advisory: Marijuana Use and the Developing Brain*, https://www.hhs.gov/surgeongeneral/reports-and-publications/addiction-and-substance-misuse/advisory-on-marijuana-use-and-developing-brain/index.html (last visited February 8, 2021).
[5] ElSohly, M.A., Mehmedic, Z., Foster, S., Gon, C., Chandra, S. and Church, J.C. *Changes in Cannabis Potency Over the Last 2 Decades (1995-2014): Analysis of Current Data in the United States,* Biological Psychiatry. April 1, 2016; 79(7):613-619.
[6] Igor Grant,1 J. Hampton Atkinson, Ben Gouaux, and Barth Wilsey. *Medical Marijuana: Clearing Away the Smoke.* Open Neurol J. 2012; 6: 18–25. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3358713/; Ellis RJ, Toperoff W, Vaida F, et al. *Smoked Medicinal Cannabis for Neuropathic Pain in HIV: A Randomized, Crossover Clinical Trial,* Neuropsychopharmacology, 2009; 34(3):672-680, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3066045/ (last viewed on March 6, 2021); Abrams DI, Jay CA, Shade SB, et al. *Cannabis in Painful HIV-associated Sensory Neuropathy: A Randomized Placebo-controlled Trial.* Neurology. 2007; 68(7):515-521 available at https://pubmed.ncbi.nlm.nih.gov/17296917/ (last viewed on March 6, 2021); Wilsey B, Marcotte T, Tsodikov A, et al. *A Randomized, Placebo-controlled, Crossover Trial of Cannabis Cigarettes in Neuropathic Pain,* J Pain. 2008;9(6):506-521, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4968043/ (last viewed on March 6, 2021); Wallace M, Schulteis G, Atkinson JH, et al. *Dose-dependent Effects of Smoked Cannabis on Capsaicin-induced Pain and Hyperalgesia in Healthy Volunteers.* Anesthesiology. 2007; 107(5):785–96, available at https://pubs.asahq.org/anesthesiology/article/107/5/785/7080/Dose-dependent-Effects-of-Smoked-Cannabis-on (last viewed on March 6, 2021).
[7] *Id*.
[8] Wilsey B, Marcotte T, Tsodikov A, et al. *A Randomized, Placebo-controlled, Crossover Trial of Cannabis Cigarettes in Neuropathic Pain*. J Pain. 2008; 9(6):506–21, available at https://pubmed.ncbi.nlm.nih.gov/18403272/ (last viewed on March 6, 2021).
[9] Volkow, N.D., Baler, R.D., Compton, W.M. and Weiss, S.R., *Adverse Health Effects of Marijuana Use,* NEW ENG. J. MED., June 5, 2014, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4827335/ (last viewed on March 6, 2021).
[10] *Id*.
[11] *Id*.

Heavy use of marijuana by adolescents is associated with impairments in attention, learning, memory, poor grades, high drop rates and I.Q. reduction.[12] Though the full extent of the health impact of consuming products with high concentration of THC is unknown, research indicates that use of such products significantly increases the risk of marijuana-associated psychosis,[13] regardless of age at first use or the type of marijuana used.[14] A 2019 European study showed that the use of high-potency marijuana (over 10% THC) only modestly increased the odds of a psychotic disorder compared to never using it; however, individuals who started using high-potency marijuana by age 15 showed a doubling of risk.[15] The European study also found that daily use of high-potency cannabis increased the risk of psychotic disorder nearly five times compared with never having used marijuana.[16]

Another study found that frequent use of marijuana or use of marijuana with high THC potency increased the risk of schizophrenia six-fold.[17] According to a literature review of studies on the impact of marijuana use on mental health published in the Journal of the American Medical Association Psychiatry, there is strong physiological and epidemiological evidence supporting a link between marijuana use and schizophrenia.[18] High doses of THC can cause acute, transient, dose-dependent psychosis, which are schizophrenia-like symptoms.[19] Additionally, prospective, longitudinal, and epidemiological studies have consistently found an association between marijuana use and schizophrenia in which marijuana use precedes psychosis, independent of alcohol consumption, and even after removing or controlling for those individuals who had used other drugs.[20]

Even though marijuana use may have been discontinued long before the onset of psychosis, studies have found that the age at which marijuana use begins appears to correlate with the age of onset of psychosis, which suggests that early marijuana use plays a role in initiating psychosis that is independent of actual use.[21] Overall, studies have found that the association between marijuana use and chronic psychosis (including a schizophrenia diagnosis) is stronger in those individuals who have had heavy or frequent marijuana use, use marijuana during adolescence, or use marijuana with high THC potency.[22]

While studies have not shown that marijuana use alone is either necessary or sufficient for the development of schizophrenia, studies suggests that marijuana use may initiate the emergence of a lasting psychotic illness in some individuals, especially those with a genetic vulnerability to develop a psychotic illness.[23]

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[12] *See* footnote 9; *see also The Influence of Marijuana Use on Neurocognitive Functioning in Adolescents*, Schweinsburg AD, Brown SA, Tapert SF, Curr Drug Abuse Rev. 2008;1(1):99-111, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2825218/ (last viewed on March 6, 2021).
[13] Robin Murray, Harriet Quigley, Diego Quattrone, Amir Englund and Marta Di Forti, *Traditional Marijuana, High-Potency Cannabis and Cannabinoids: Increasing Risk for Psychosis*, World Psychiatry, 2016 Oct; 15(3): 195–204, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5032490/ (last viewed February 18, 2021).
[14] Di Forti et al. *The Contribution of Cannabis Use to Variation in the Incidence of Psychotic Disorder Across Europe (EU-GEI): A Multicenter Case-control Study*. Lancet Psychiatry. 2019; 6:427-36, available at https://www.thelancet.com/article/S2215-0366(19)30048-3/fulltext (last viewed on March 6, 2021); *High-Potency Cannabis and Incident Psychosis: Correcting the Causal Assumption*, The Lancet, Volume 6, Issue 6, June 2019, available at https://www.thelancet.com/journals/lanpsy/article/PIIS2215-0366(19)30174-9/fulltext (last viewed March 7, 2021); *High-Potency Cannabis and Incident Psychosis: Correcting the Causal Assumption – Author's Reply*, The Lancet, Volume 6, Issue 6, June 2019available at https://www.thelancet.com/journals/lanpsy/article/PIIS2215-0366(19)30176-2/fulltext (last viewed March 7, 2021).
[15] *Id*. at 430.
[16] *Id*. at 431. The odds were lower for those who use low-potency marijuana daily.
[17] Nora D. Volkow, MD; James M. Swanson, PhD; A. Eden Evins, MD; Lynn E. DeLisi, MD; Madeline H. Meier, PhD; Raul Gonzalez, PhD; Michael A. P. Bloomfield, MRCPsych; H. Valerie Curran, PhD; Ruben Baler, PhD., *Effects of Cannabis Use on Human Behavior, Including Cognition, Motivation, and Psychosis: A Review.* JAMA Psychiatry. 2016; 73(3):292-297, available at https://www.yellowbrickprogram.com/ArticlePDF/Cannabis-and-Behavior-JAMA.pdf (last viewed February 16, 2021).
[18] *Id*.
[19] *Id*.
[20] *Id*.
[21] *Id*.
[22] *Id*.
[23] *Id*.

Marijuana for Medical Use

Article X, section 29 of the Florida Constitution, Use of Marijuana for Debilitating Medical Conditions, authorizes patients with any of the following debilitating medical conditions to obtain medical marijuana from Medical Marijuana Treatment Centers (MMTC):

- Cancer
- Epilepsy
- Glaucoma
- Positive status for human immunodeficiency virus
- Acquired immune deficiency syndrome
- Post-traumatic stress disorder
- Amyotrophic lateral sclerosis
- Crohn's disease
- Parkinson's disease
- Multiple sclerosis
- Medical conditions of the same kind or class as or comparable to those enumerated above

The legislature executed this constitutional provision by passing the Medical Use of Marijuana Act (Act) of 2017, implemented by the Department of Health (DOH).[24]

The medical use of marijuana is permitted in any form except for marijuana seeds and commercially produced food items that do not meet the definition of edibles[25] in the Act.[26] MMTCs are authorized to produce edibles if they obtain a food establishment permit from the Florida Department of Agriculture and Consumer Services (DACS) before production and comply with the Florida Food Safety Act.[27] Each MMTC is also required to provide at least one low-THC cannabis product.[28]

Physician and Patient Requirements

Under current law, to obtain marijuana for medical use from a MMTC, and maintain the immunity from criminal prosecution granted by the Constitution, the patient must obtain a physician certification from a qualified physician[29] and an identification card from DOH. As of February 26, 2021, there are 2,630 qualified physicians and 497,068 patients with an active identification card.[30]

To certify a patient for medical use of marijuana, a qualified physician must determine that the patient has a qualifying medical condition and that medical marijuana would likely outweigh the health risks to the patient. The qualified physician must obtain the informed consent of the patient using a standardized form created by rule by the Board of Medicine and the Board of Osteopathic Medicine.[31]

Adequate Supply and Supply Limits

The Florida Constitution requires DOH to define an amount of marijuana that could reasonably be presumed to be an adequate supply for a qualifying patient's medical use. The Act executes this provision by defining time increments for certifying and dispensing marijuana: A qualified physician may only certify a patient for three 70-day supply limits of marijuana not in a form for smoking and six 35-day supply limits for marijuana in a form for

[24] S. 381.986, F.S (2017).
[25] Edibles are commercially produced food items made with marijuana oil, but no other form of marijuana, that are produced and dispensed by MMTCs and must only be in the forms of lozenges, gelatins, baked goods, chocolates, or drink powders. *See* s. 381.986(1)(d), F.S. and R. 64ER20-35, F.A.C.
[26] S. 381.986(1)(j), F.S.
[27] S. 381.986(8)(e)8., F.S.
[28] S. 381.986(8), F.S. Low-THC cannabis is defined as a plant of the genus Cannabis, the dried flowers of which contain 0.8 % or less of tetrahydrocannabinol and more than 10 % 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. *See* s. 381.986(1)(e), F.S.
[29] To certify patients for medical use of marijuana, a physician must hold an active, unrestricted license as an allopathic physician under chapter 458 or as an osteopathic physician under chapter 459 and comply with certain physician education requirements. See ss. 381.986(1)m, F.S. and 381.986(3)(a), F.S.
[30] Department of Health, *Office of Medical Marijuana Use Weekly Updates, Feb. 26, 20201,* available at https://s27415.pcdn.co/wp-content/uploads/ommu_updates/2021/022621-OMMU-Update.pdf (last visited Mar. 2, 2021).
[31] S. 381.986(4)(a)8., F.S.

smoking[32], and requires the physician to recertify the patient every 30 weeks. In addition, the Act gives additional guidance to DOH in complying with the constitutional directive, by requiring DOH to set a daily dose amount limit and use the daily dose amount limit to calculate a 70-day supply of marijuana. In 2019, when the Act was amended to allow medical use of marijuana in a form for smoking, it also set the 35-day supply of marijuana in a form for smoking (flower) of up to 2.5 ounces.[33] Current law does not have supply limits for other products.

Consistent with the Constitution, the Act allows a qualified physician to request an exception from DOH from the daily dose amount limit[34], and the requested amount is deemed approved if DOH fails to approve or deny the request within 14 days.[35] The qualified physician must submit the following to DOH when requesting an exception:[36]

- The qualified patient's qualifying medical condition;
- The dosage and route of administration that was insufficient to provide relief to the qualified patient;
- A description of how the patient will benefit from an increased daily dose amount;
- The minimum daily dose amount of marijuana that would be sufficient for the treatment of the qualified patient's qualifying medical condition; and
- The qualified patient's records, upon the request of DOH.

To date, DOH has not set a daily dose limit amount by rule. Therefore, other than marijuana in a form for smoking, the amount of marijuana certified and dispensed for a 70-day supply is at the sole discretion of a qualified physician. According to the 2021 Physician Certification Pattern Review Panel[37] Report, the average daily dose for the various routes of administration, once outliers are removed, are as follows.[38]

Product	Milligrams THC
Edible	175 mg
Inhalation	225 mg
Oral	197 mg
Sublingual	189 mg
Suppository	194 mg
Topical	148 mg

The report identifies the top 5 qualified physicians with the highest average daily doses per route of administration. The daily doses of this group range from approximately 1,600 mg of THC to approximately 43,000 mg of THC or a range of 56,000 mg of THC to 5 million mg of THC over a 35-day period.[39] The report also shows that the greatest number of certifications were issued by a small percentage of qualified physicians, a ratio that has been increasing since 2019:[40]

- 2019: 41% of certifications were issued by 4% of qualified physicians;
- 2020: 61% of certifications were issued by 9% of qualified physicians; and
- 2021: 71% of certifications were issued by 12% of qualified physicians.

Currently, 33 state have medical marijuana programs. Of these, 18 states limit the supply of THC a patient may obtain over a set period of timer their medical marijuana programs. Some states list a single, cumulative amount, without specifying or differentiating between different products, as follows.[41]

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[32] S. 381.986(4)(f), F.S.
[33] S. 381.986(8)(e)16.b., F.S.
[34] S. 381.986(4)(f), F.S.
[35] *Id*.
[36] *Id*.
[37] The Physician Certification Pattern Review Panel is required to review all physician certifications submitted to the medical marijuana use registry; track and report the number of physician certifications and the qualifying medical conditions, dosage, supply amount, and form of marijuana certified; report the data both by individual qualified physician and in the aggregate, by county, and statewide; and 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.
[38] *Physician Certification Pattern Review 2021 Annual Report*, Physician Certification Pattern Review Panel, January 2021, available at https://flboardofmedicine.gov/pdfs/Physician-Certification-Pattern-Review-2021-Annual-Report.pdf (last visited March 6, 2021).
[39] *Id.*
[40] *Id.*
[41] New Jersey-N.J.A.C. 8:64–10.6; Vermont-18 V.S.A. § 4474b; D.C.-D.C. Mun. Regs. Tit. 22-C, § 5608; Nevada-NAC 453A.704; Maine-22 M.R.S.A. § 2430-C; Arkansas-Ark. Admin. Code 006.02.7-14; Arizona- A.R.S. Title 36, Ch. 28.1; Illinois-8 Ill. Adm. Code 1000.420; Massachusetts-935 CMR 501.001; Missouri-19 CSR 30-95.030; New Hampshire-N.H. Rev. Stat. § 126-X:2; Delaware-16 Del. C. § 4902A; Maryland- COMAR 10.62.01.01; Hawaii- Haw. Admin. Rules (HAR) § 11-850-92.

State	35-Day Dose Limit (mg THC)[42]
New Jersey	11,310 mg
Vermont	11,310 mg
D.C.	22,166 mg
Nevada	25,000 mg
Maine	28,300 mg
Arkansas	30,298 mg
Arizona	30,298 mg
Illinois	30,298 mg
Massachusetts	30,298 mg
Missouri	32,625 mg
New Hampshire	33,935 mg
Delaware	36,358 mg
Maryland	42,000 mg
Hawaii	45,250 mg

Some states differentiate between products or types of products. North Dakota, for example, limits the supply to 2,333 mg of "usable marijuana" and 4,667 mg of concentrate or product (in 35 days), while Montana limits infused products to 4,667 mg and concentrates to 46,667 mg (in 35 days).[43]

Potency Limits

Current law does not regulate the THC potency of medical marijuana. THC potency levels vary greatly based upon the product. On the low end are balms, body oil, capsules, suppositories and tinctures which contain no more than 5% THC and on the high end there is powder which is 95% to 100% THC.[44] Marijuana concentrates[45] comprise the majority of product types available under the program and contain THC levels ranging from 60% to 90%.[46] Whole flower marijuana, whose THC content is limited by genetics, has a THC potency range of 10% to 28%.[47]

Florida THC Potency Ranges[48]		
Product	**Low**	**High**
Balm	0.4%	0.9%
Body Oil	0.7%	1.2%
Capsule	0.5%	3.0%
Suppository	1.3%	3.0%
Oil (tincture)	1.3%	5.0%
Flower	10%	28%
Transdermal Patch	11%	90%
Concentrate[49]	60%	90%
Powder	95%	100%

[42] States have marijuana supply limits that vary in measurements, ounces versus milligrams, and the number of days allotted for such supply. For comparative purposes, this analysis converts all supply limits to milligrams, assumes 17% THC potency and establishes a daily dose using the formula established by the Colorado Department of Revenue. *Marijuana Equivalency in Portion and Dosage*, Colorado Department of Revenue, August 2015, available at https://www.colorado.gov/pacific/sites/default/files/MED%20Equivalency_Final%20081020 15.pdf (last viewed on March 7, 2021).
[43] *Id.* North Dakota-NDCC 19-24.1-01;Montana-MCA 50-46-319
[44] *See* Christopher K. Ferguson, Director, OMMU, *OMMU: Medical Marijuana Program Update,* prepared for Florida Legislature, Feb. 2021, and *Presentation to the Professions and Public Health Subcommittee on Feb. 16, 2021*, slide 26.
[48] *Id.*
[49] This includes crumble, rosin, RSO, sauce, shatter, wax, inhaler, kief, vaporizer cartridge and vaporizer disposable products.

Other state medical marijuana programs limit potency. However, the methods and product focus vary significantly, making comparison difficult. For example, California imposes milligram-based limits on topicals, concentrates and orally-dissolving edibles, while Delaware imposes a percentage-based cap on oils.[50] Several states limit potency by percentage of THC in the product. New Jersey imposes a 10 percent cap on all products.[51] North Dakota, Oregon and Michigan all impose a 6% cap on topicals.[52] Ohio imposes a 23-35 percent cap on flower, and a 70% cap on all other products.[53]

Florida law does not impose potency limits on medical marijuana products. Current law does define servings of edibles by THC milligram amounts: each edible product may contain up to 200 mg of THC and each single serving portion of an edible may contain up to 10 mg. of THC, with a variance of up to 15 percent of the THC limit per product or single serving portion.[54] These are serving increments, not supply limits or daily doses.

Testing

Presently, processed marijuana products must be tested for contaminants that are harmful for human consumption and to ensure that products meet the THC and CBD potency requirements.[55] The DOH must adopt rules determining what contaminants must be tested for and at what levels such contaminants are unsafe for human consumption, as well as rules for treatment of marijuana products that fail the safety and potency requirements.[56]

Current law also requires the DACS to assist the DOH in developing rules for testing edibles.[57] It further authorizes the DOH to select random samples of edible products available for purchase for testing to determine whether the THC and CBD potency level on the label is accurate and whether the edible is safe for human consumption. Edibles that fail to meet the safety and potency requirements must be recalled along with all edibles made from the same batch of marijuana.[58]

Each MMTC is required to contract with a certified marijuana testing laboratory (CMTL) to test processed marijuana before it is dispensed. [59] Testing results must indicate that the low-THC cannabis meets the statutory definition; THC potency meets statutory requirements; THC and CBD are labelled accurately; and the marijuana is safe for human consumption and free from contaminants that are unsafe for human consumption.[60]

The Office of Medical Marijuana Use (OMMU), housed within the DOH, licenses and regulates CMTLs in the state of Florida. To qualify, a laboratory must have a DOH-approved accreditation or certification by a DOH-approved accreditation or certification body, and must meet additional requirements specific to marijuana testing established by DOH in rule.[61] As of March 2021, the OMMU has certified the following CMTLs:[62]

- AccuScience Laboratories
- ACS Laboratory
- Green Scientific
- Kaycha Labs Davie
- Kaycha Labs Gainesville
- Modern Canna Labs

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[47] *Id.*
[48] *Id.*
[49] This includes crumble, rosin, RSO, sauce, shatter, wax, inhaler, kief, vaporizer cartridge and vaporizer disposable products.
[50] California-17 CCR § 40315; Delaware- 16 Del. C. § 4902A.
[51] The rule expressly prohibiting any medical product to have a THC potency greater than 10% was repealed. However, N.J.A.C. 8:64–10.6(c)5. currently provides that each package of medicinal marijuana that an alternative treatment center prepares to dispense must have a label that contains "[t]he cannabinoid profile of the medicinal marijuana contained within the package, including THC level not to exceed 10 percent."
[52] North Dakota- NDCC 19-24.1-01; Oregon-OAR 333-007-0220; Michigan- M.C.L.A. 333.26421.
[53] Ohio- OAC 3796:3-2-07.
[54] S. 381.986(8)(e)8., F.S.
[55] S. 381.986(8)(e)11.d., F.S.
[56] *Id.*
[57] *Id.*
[58] *Id.*
[59] *Id.*
[60] *Id.*
[61] S. 381.988, F.S.
[62] *OMMU: Certified Marijuana Testing Laboratories*, https://knowthefactsmmj.com/cmtl/ (last visited Mar. 2, 2021).

Conflicts of Interest

Currently, a MMTC, 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 MMTC.[63] A MMTC may also not own or control a CMTL.[64]

There is no prohibition against a MMTC employing a qualified physician or having a direct or indirect economical interest in a qualified physicians' practice or for a CMTL from having a direct or indirect economical interest in a MMTC.

Advertising

MMTCs are currently prohibited from engaging in advertising that is visible to members of the public from any street, sidewalk, park, or other public place, except they may:[65]

- Have a sign on 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, as long as the trade name and logo does not contain wording or images commonly associated with marketing targeted toward children or which promote the recreational use of marijuana; and
- Engage in Internet advertising and marketing under the following conditions:
    - All advertisements are approved by the DOH;
    - An advertisement's content does not specifically target individuals under the age of 18;
    - An advertisement is not an unsolicited pop-up advertisement; and
    - Any opt-in marketing includes an easy and permanent opt-out feature.

These regulations do not address radio or television advertisements.

Current law does not address advertising by a qualified physician with respect to his or her practice relating to marijuana for medical use.

Effect of Proposed Changes

The bill's provisions have two different effective dates, to allow sufficient time for the medical marijuana industry to come into compliance with certain provisions.

Effective July 1, 2022

Supply and Potency Limits

HB 1455 limits the 35-day supply of marijuana that a qualified physician may certify to 15,000 mg of THC and limits the potency a qualified physician may certify for marijuana in a form for smoking to 10 percent THC and 60 percent THC in the final product for all other forms of marijuana, excluding edibles. Similarly, the bill limits the amount of marijuana a MMTC may dispense within any 70-day period to two 35-day supplies and prohibits MMTCs from dispensing marijuana with potency greater than 10 percent THC for smokeable marijuana and 60 percent THC in the final product for all other forms of marijuana, excluding edibles. The bill provides an exception to the potency limits for terminal patients.

The bill prohibits qualified physicians from certifying qualified patients under the age of 18 for marijuana, other than low-THC cannabis, unless the qualified physician determines that it is the most effective treatment for the patient and a second physician, who is a board-certified pediatrician, concurs with such determination. marijuana, excluding edibles, unless the qualified physician certifies that the qualified patient is terminally ill.

Effective July 1, 2021

Testing

[63] S. 381.986(8)(e)2., F.S.
[64] S. 381.988(1)(a).
[65] S. 381.986(8)(h), F.S.

The bill requires MMTCs to test all forms of its marijuana, not only processed marijuana, to ensure that it meets safety and potency requirements before it is dispensed. The bill requires MMTCs to recall all forms of marijuana that fail to meet the safety and potency requirements, rather than only edibles.

The bill authorizes the DOH to select available samples of all forms of marijuana available in a cultivation facility, processing facility, or for purchase for testing to determine that the marijuana is safe for human consumption and that the THC and CBD potency level on the label is accurate or to verify medical marijuana testing laboratory results. The bill also authorizes the DOH to sample marijuana delivery devices from a dispensing facility to determine that the marijuana delivery device is safe for use by qualified patients. The bill permits the DOH, including employees acting within the scope of their employment, to acquire, possess, test, transport, and lawfully dispose of marijuana.

Conflicts of Interest

The bill prohibits MMTCs and certain other individuals and entities from employing qualified physicians or having direct or indirect economic interests in qualified physician practices or medical marijuana testing laboratories. This aligns with the reverse provisions in current law (prohibiting a qualified physician from having an economic interest in a MMTC). The bill also prohibits a CMTL from having a direct or indirect economic interest in, or financial relationship with, a MMTC.

Advertising

With respect to his or her practice relating to marijuana for medical use, the bill prohibits a qualified physician from engaging in radio or television advertising and other specified advertising, except he or she may:

- Have a sign on 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, as long as the trade name and logo does not contain wording or images commonly associated with marketing targeted toward children or which promote the recreational use of marijuana; and
- Engage in Internet advertising and marketing under the following conditions:
    - All advertisements are approved by the DOH;
    - An advertisement's content does not specifically target individuals under the age of 18;
    - An advertisement is not an unsolicited pop-up advertisement; and
    - Any opt-in marketing includes an easy and permanent opt-out feature.

The bill expands advertising requirements for MMTCs to include prohibitions against radio and television advertising so that the advertising restrictions for MMTCS are identical to those for qualified physicians.

The bill provides an effective date of July 1, 2021, except as otherwise provided.

B. SECTION DIRECTORY:

Section 1: Amends s. 381.986, F.S., relating to medical use of marijuana.
Section 2: Amends s. 381.986, F.S., relating to medical use of marijuana.
Section 3: Amends s. 381.988, F.S., relating to medical marijuana testing laboratories; marijuana tests conducted by a certified laboratory.
Section 4: Provides an effective date of July 1, 2021, except as otherwise provided.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The bill has a significant, indeterminate negative fiscal impact on DOH related to IT system enhancements.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

MMTCs may experience costs associated with complying with the THC limits for marijuana established by the bill.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   Not Applicable. This bill does not appear to affect county or municipal governments.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

Current law currently provides the DOH sufficient rulemaking authority to implement the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to the regulation of medical marijuana; amending s. 381.986, F.S.; providing a definition; prohibiting qualified physicians from engaging in certain advertising for their practices relating to marijuana for medical use; providing exceptions; prohibiting medical marijuana treatment centers and certain other individuals and entities from employing qualified physicians or having direct or indirect economic interests in qualified physician practices and medical marijuana testing laboratories; revising a provision relating to the potency of tetrahydrocannabinol in edibles dispensed by a medical marijuana treatment center; authorizing the Department of Health to select samples of marijuana available in certain facilities for testing for specified purposes; authorizing the department to sample marijuana delivery devices from a dispensing facility to determine safety; requiring that a medical marijuana treatment center recall all marijuana, rather than only edibles, under certain circumstances; revising advertising requirements for medical marijuana treatment centers to prohibit radio and television advertising; authorizing the department and certain employees to acquire, possess, test, transport, and

dispose of marijuana; prohibiting a qualified physician from issuing a physician certification to a minor patient for marijuana, except for low-THC cannabis; providing an exception; revising the supply limits of marijuana for which a physician certification may be issued; limiting the potency of tetrahydrocannabinol in such supply; prohibiting a qualified physician from certifying a certain potency of tetrahydrocannabinol in marijuana; providing an exception; prohibiting a medical marijuana treatment center from dispensing a certain daily supply within a specified period to conform to changes made by the act; prohibiting a medical marijuana treatment center from dispensing marijuana that exceeds a certain potency of tetrahydrocannabinol; providing an exception; amending s. 381.988, F.S.; prohibiting a certified medical marijuana testing laboratory from having an economic interest in or financial relationship with a medical marijuana treatment center; providing construction; authorizing the department and certain employees to acquire, possess, test, transport, and dispose of marijuana; providing effective dates.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Paragraphs (l) through (o) of subsection (1) of section 381.986, Florida Statutes, are redesignated as paragraphs (m) through (p), respectively, paragraph (a) of subsection (3) and paragraphs (e) and (h) of subsection (8) are amended, and a new paragraph (l) is added to subsection (1), paragraph (d) is added to subsection (3), and paragraph (i) is added to subsection (14) of that section, to read:

381.986 Medical use of marijuana.—

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

(l) "Potency" means the relative strength of cannabinoids, and the total amount, in milligrams, of tetrahydrocannabinol as the sum of delta-9-tetrahydrocannabinol plus (0.877 multiplied by tetrahydrocannabinolic acid plus delta-8-tetrahydrocannabinol) and cannabidiol as the sum of cannabidiol plus (0.877 multiplied by cannabidiolic acid) in the final product dispensed to a patient or caregiver.

(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.

(d) With respect to his or her practice relating to marijuana for medical use under this section, a qualified physician may not engage in radio or television advertising or advertising that is visible to members of the public from any street, sidewalk, park, or other public place, except:

1. The qualified physician's practice may have a sign that is affixed to the outside or hanging in the window of the premises which identifies the qualified physician, a department-approved practice name, or a department-approved logo. A qualified physician's practice name and logo may not contain wording or images commonly associated with marketing targeted toward children or which promote the recreational use of marijuana.

2. A qualified physician may engage in Internet advertising and marketing for his or her practice 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.

(8) MEDICAL MARIJUANA TREATMENT CENTERS.—

(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 and any individual or entity that 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 employ a qualified physician or have any direct or indirect economic interest in a qualified physician's practice or a marijuana testing laboratory.

4.~~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.

5.~~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).

6.~~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.

7.~~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.

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

9.~~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 of the 10 milligrams of tetrahydrocannabinol per single serving limit or 15 percent of the 200 milligrams of tetrahydrocannabinol per product limit. 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.

10.~~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.

11.~~10.~~ A medical marijuana treatment center that produces prerolled marijuana cigarettes may not use wrapping paper made with tobacco or hemp.

12.~~11.~~ 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.

13.~~d.~~ A medical marijuana treatment center must 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 samples of marijuana ~~a random sample from edibles~~ available in a cultivation facility, processing facility, or for purchase in a dispensing facility which shall be tested by the department to determine that the marijuana ~~edible~~ meets the potency requirements of this section, is safe for human consumption, and the labeling of the tetrahydrocannabinol and cannabidiol concentration is accurate or to verify medical marijuana testing laboratory results. The department may also sample marijuana delivery devices from a dispensing facility to determine that the marijuana delivery device is safe for use by qualified patients. A medical marijuana treatment center may not require payment from the department for the sample. A medical marijuana treatment center must recall all marijuana which fails ~~edibles, including all edibles made from the same batch of marijuana, which fail~~ to meet the potency requirements of this section, which is ~~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.

14. When packaging marijuana, a medical marijuana treatment center must:

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

b.~~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 subparagraph 13 ~~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.

15.~~12.~~ 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.

16.~~13.~~ In addition to the packaging and labeling requirements specified in subparagraphs 14. and 15., ~~11. and 12.,~~ marijuana in a form for smoking must be packaged in a

sealed receptacle with a legible and prominent warning to keep away from children and a warning that states marijuana smoke contains carcinogens and may negatively affect health. Such receptacles for marijuana in a form for smoking 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.

17.~~14.~~ The department shall adopt rules to regulate the types, appearance, and labeling of marijuana delivery devices dispensed from a medical marijuana treatment center. The rules must require marijuana delivery devices to have an appearance consistent with medical use.

18.~~15.~~ 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 14. and 15. ~~11. and 12.~~, 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 of all 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.

19.~~16.~~ 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 within any 70-day period to a qualified patient or caregiver. May not dispense more than one 35-day supply of marijuana in a form for smoking within any 35-day period to a qualified patient or caregiver. A 35-day supply of marijuana in a form for smoking may not exceed 2.5 ounces unless an exception to this amount is approved by the department pursuant to paragraph (4)(f).

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 or wrapping papers made with tobacco or hemp, 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.

(h) A medical marijuana treatment center may not engage in <u>radio or television advertising or</u> 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.

(14) EXCEPTIONS TO OTHER LAWS.—

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

Section 2. Effective July 1, 2022, paragraphs (g) through

(k) of subsection (4) of s. 381.986, Florida Statutes, are redesignated as paragraphs (h) through (l), respectively, paragraphs (a), (d), and (f) of that subsection, paragraph (e) of subsection (8), and paragraph (a) of subsection (14) are amended, and a new paragraph (g) is added to subsection (4) of that section, to read:

381.986 Medical use of marijuana.—

(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, including the negative health risks associated with smoking marijuana.

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.

(d) A qualified physician may not issue a physician certification to a patient under 18 years of age for marijuana, except for low-THC cannabis, unless the qualified physician determines that marijuana other than low-THC cannabis is the most effective treatment for the patient and a second physician who is a board-certified pediatrician concurs with such determination. A qualified physician may not issue a physician certification for marijuana in a form for smoking to a patient under 18 years of age unless the patient is diagnosed with a terminal condition, the qualified physician determines that smoking is the most effective route of administration for the patient, and a second physician who is a board-certified pediatrician concurs with such determination. Such determinations ~~determination~~ and concurrences ~~concurrence~~ must be documented in the patient's medical record and in the medical marijuana use registry. The certifying physician must obtain the written informed consent of such patient's parent or legal guardian before issuing a physician certification to the patient for marijuana or marijuana in a form for smoking. 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 information concerning the negative

health effects of marijuana and smoking marijuana on persons under 18 years of age and an acknowledgment that the qualified physician has sufficiently explained the contents of the form.

(f) A qualified physician may not issue a physician certification for ~~more than three 70-day supply limits of marijuana or~~ more than six 35-day supply limits of marijuana ~~in a form for smoking~~. The department may ~~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. A 35-day supply of marijuana may not exceed 15,000 milligrams of tetrahydrocannabinol ~~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 35-day supply limit of marijuana ~~in a form for smoking~~, and the 4-ounce possession limit of marijuana in a form for smoking established in paragraph (14)(a). 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.

(g) A qualified physician may not issue a physician certification for marijuana that has a tetrahydrocannabinol potency, by weight or volume, of greater than 10 percent for marijuana in a form for smoking or greater than 60 percent in the final product for all other forms of marijuana, excluding edibles. A qualified physician may certify marijuana with any potency of tetrahydrocannabinol, if the qualified patient is diagnosed with a terminal condition and the qualified physician indicates such diagnosis on the physician certification.

(8) MEDICAL MARIJUANA TREATMENT CENTERS.—

(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 and any individual or entity that 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 employ a qualified physician or have any direct or indirect economic interest in a qualified physician's practice or a marijuana testing laboratory.

4. 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.

5. 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).

6. 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.

7. 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.

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

9. 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 of the 10 milligrams of tetrahydrocannabinol per single serving limit

or 15 percent of the 200 milligrams of tetrahydrocannabinol per product limit. 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.

10. 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.

11. A medical marijuana treatment center that produces prerolled marijuana cigarettes may not use wrapping paper made with tobacco or hemp.

12. 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.

13. A medical marijuana treatment center must test 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 samples of marijuana available in a cultivation facility, processing facility, or for purchase in a dispensing facility which shall be tested by the department to determine that the marijuana meets the potency requirements of this section, is safe for human consumption, and the labeling of the tetrahydrocannabinol and cannabidiol concentration is accurate or to verify medical marijuana testing laboratory results. The department may also sample marijuana delivery devices from a dispensing facility to determine that the marijuana delivery device is safe for use by qualified patients. A medical marijuana treatment center may not require payment from the department for the sample. A medical marijuana treatment center must recall all marijuana which fails to meet the potency requirements of this section, which is

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.

14. When packaging marijuana, a medical marijuana treatment center must:

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

b. 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 subparagraph 13.

(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.

15. 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.

16. In addition to the packaging and labeling requirements specified in subparagraphs 14. and 15., marijuana in a form for smoking must be packaged in a sealed receptacle with a legible and prominent warning to keep away from children and a warning that states marijuana smoke contains carcinogens and may negatively affect health. Such receptacles for marijuana in a form for smoking 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.

17. The department shall adopt rules to regulate the types, appearance, and labeling of marijuana delivery devices dispensed from a medical marijuana treatment center. The rules must require marijuana delivery devices to have an appearance consistent with medical use.

18. 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 14. and 15., 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 of all 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.

19. 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 two 35-day supplies ~~a 70-day supply~~ of marijuana within any 70-day period to a qualified patient or caregiver. ~~May not dispense more than one 35-day supply of marijuana in a form for smoking within any 35-day period to a qualified patient or caregiver.~~ A 35-day supply of marijuana ~~in a form for smoking~~ may not exceed 15,000 milligrams of tetrahydrocannabinol ~~2.5 ounces~~ unless an exception to this amount is approved by the department pursuant to paragraph (4)(f).

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 marijuana that has a tetrahydrocannabinol potency, by weight or volume, of greater than 10 percent for marijuana in a form for smoking or greater than 60 percent in the final product for all other forms of marijuana, excluding edibles, to a qualified patient or caregiver, unless the qualified physician certification indicates that the qualified patient has been diagnosed with a terminal condition.

g.~~f.~~ May not dispense or sell any other type of cannabis, alcohol, or illicit drug-related product, including pipes or wrapping papers made with tobacco or hemp, other than a marijuana delivery device required for the medical use of

marijuana and which is specified in a physician certification.

h.~~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.

i.~~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.

(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 two 35-day supplies ~~a 70-day supply~~ of marijuana, or the greater of 4 ounces of marijuana in a form for smoking or an amount of marijuana in a form for smoking approved by the department pursuant to paragraph (4)(f), at any given time and all marijuana purchased must remain in its original packaging.

Section 3. Subsection (11) of section 381.988, Florida Statutes, is renumbered as subsection (13), and new subsections (11) and (12) are added to that section, to read:

381.988 Medical marijuana testing laboratories; marijuana tests conducted by a certified laboratory.—

(11) A certified medical marijuana testing laboratory and its officers, directors, and employees may not have a direct or indirect economic interest in, or financial relationship with, a medical marijuana treatment center. Nothing in this subsection may be construed to prohibit a certified medical marijuana testing laboratory from contracting with a medical marijuana treatment center to provide testing services.

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

Section 4. Except as otherwise expressly provided in this act, this act shall take effect July 1, 2021.

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Committee/Subcommittee hearing bill: Professions & Public Health Subcommittee

Representative Eskamani offered the following:

Amendment (with directory and title amendments)

Between lines 107 and 108, insert:

(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 every 2 years ~~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.

D I R E C T O R Y A M E N D M E N T

Remove line 55 and insert:
subsection (3), paragraph (a) of subsection (7), and paragraphs (e) and (h) of subsection (8) are

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T I T L E A M E N D M E N T

Remove line 7 and insert:
exceptions; revising the frequency with which medical marijuana use registry identification cards must be renewed; prohibiting medical marijuana treatment

Amendment No. 2

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Committee/Subcommittee hearing bill: Professions & Public Health Subcommittee

Representative Rayner offered the following:

Amendment (with directory and title amendments)

Between lines 107 and 108, insert:

(4) PHYSICIAN CERTIFICATION.—

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

1. Conducted a physical examination for the initial patient visit while physically present in the same room as the patient and a full assessment of the medical history of the patient. Telehealth may be used to issue a physician certification for an existing qualified patient with an existing certification that was issued by that qualified physician

without the need to conduct a physical examination while physically present in the same room as 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, including the negative health risks associated with smoking marijuana.

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.

D I R E C T O R Y A M E N D M E N T

Remove line 55 and insert:
subsection (3), paragraph (a) of subsection (4), and paragraphs (e) and (h) of subsection (8) are

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T I T L E A M E N D M E N T

Remove line 4 and insert:
definition; revising and providing conditions for a qualified physician to issue a physician certification; prohibiting qualified physicians from

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Committee/Subcommittee hearing bill: Professions & Public Health Subcommittee

Representative Eskamani offered the following:

Amendment (with directory and title amendments)

Between lines 457 and 458, insert:

(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:

(n) Addiction to or dependence on an opioid drug.

D I R E C T O R Y A M E N D M E N T

Remove line 455 and insert:

amended, and a new paragraph (n) is added to subsection (2) and a new paragraph (g) is added to subsection (4) of

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T I T L E A M E N D M E N T

Remove line 3 and insert:
marijuana; amending s. 381.986, F.S.; providing that addiction to or dependence on an opioid drug is a qualifying condition to receive marijuana or a marijuana delivery device; providing a

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Committee/Subcommittee hearing bill: Professions & Public Health Subcommittee

Representative Rayner offered the following:

Amendment (with directory and title amendments)

Between lines 457 and 458, insert:

(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:

(n) Sickle cell disease.

D I R E C T O R Y A M E N D M E N T

Remove line 455 and insert:

amended, and a new paragraph (n) is added to subsection (2) and a new paragraph (g) is added to subsection (4) of

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T I T L E A M E N D M E N T

Remove line 3 and insert:
marijuana; amending s. 381.986, F.S.; providing that sickle cell disease is a qualifying condition to receive marijuana or a marijuana delivery device; providing a

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	____	(Y/N)
ADOPTED AS AMENDED	____	(Y/N)
ADOPTED W/O OBJECTION	____	(Y/N)
FAILED TO ADOPT	____	(Y/N)
WITHDRAWN	____	(Y/N)
OTHER		

Committee/Subcommittee hearing bill: Professions & Public Health Subcommittee
Representative Smith, C. offered the following:

Amendment (with directory and title amendments)

Remove lines 528-908 and insert:

use registry may be used for research purposes. The Office of Program Policy Analysis and Government Accountability shall research the use of high concentrate THC, including any adverse patient outcomes recorded as a result of the use of THC using existing data from the medical marijuana use registry and patients' de-identified health information. The office shall report its findings to the Governor, the President of the Senate, and the Speaker of the House of Representatives by October 1, 2021.

(d) A qualified physician may not issue a physician

certification to a patient under 18 years of age for marijuana, except for low-THC cannabis, unless the qualified physician determines that marijuana other than low-THC cannabis is the most effective treatment for the patient and a second physician who is a board-certified pediatrician concurs with such determination. A qualified physician may not issue a physician certification for marijuana in a form for smoking to a patient under 18 years of age unless the patient is diagnosed with a terminal condition, the qualified physician determines that smoking is the most effective route of administration for the patient, and a second physician who is a board-certified pediatrician concurs with such determination. Such determinations ~~determination~~ and concurrences ~~concurrence~~ must be documented in the patient's medical record and in the medical marijuana use registry. The certifying physician must obtain the written informed consent of such patient's parent or legal guardian before issuing a physician certification to the patient for marijuana or marijuana in a form for smoking. 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 information concerning the negative health effects of marijuana and smoking marijuana on persons under 18 years of age and an acknowledgment that the qualified physician has sufficiently explained the contents of the form.

(f) A qualified physician may not issue a physician

certification for ~~more than three 70-day supply limits of marijuana or~~ more than six 35-day supply limits of marijuana ~~in a form for smoking~~. The department may ~~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. A 35-day supply of marijuana may not exceed 54,250 milligrams of tetrahydrocannabinol ~~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 35-day supply limit of marijuana ~~in a form for smoking~~, and the 4-ounce possession limit of marijuana in a form for smoking established in paragraph (14)(a). 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.

(8) MEDICAL MARIJUANA TREATMENT CENTERS.—

(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 and any individual or entity that 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 employ a qualified physician or have any direct or indirect economic interest in a qualified physician's practice or a marijuana testing laboratory.

4. 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.

5. 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).

6. 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.

7. 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.

8. Each medical marijuana treatment center must produce

and make available for purchase at least one low-THC cannabis product.

9. 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 of the 10 milligrams of tetrahydrocannabinol per single serving limit or 15 percent of the 200 milligrams of tetrahydrocannabinol per product limit. 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.

10. 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.

11. A medical marijuana treatment center that produces prerolled marijuana cigarettes may not use wrapping paper made with tobacco or hemp.

12. 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.

13. A medical marijuana treatment center must test 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 samples of marijuana available in a cultivation facility, processing

facility, or for purchase in a dispensing facility which shall be tested by the department to determine that the marijuana meets the potency requirements of this section, is safe for human consumption, and the labeling of the tetrahydrocannabinol and cannabidiol concentration is accurate or to verify medical marijuana testing laboratory results. The department may also sample marijuana delivery devices from a dispensing facility to determine that the marijuana delivery device is safe for use by qualified patients. A medical marijuana treatment center may not require payment from the department for the sample. A medical marijuana treatment center must recall all marijuana which fails to meet the potency requirements of this section, which is 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.

14. When packaging marijuana, a medical marijuana treatment center must:

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

b. 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 subparagraph 13.

(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.

15. 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.

16. In addition to the packaging and labeling requirements specified in subparagraphs 14. and 15., marijuana in a form for smoking must be packaged in a sealed receptacle with a legible and prominent warning to keep away from children and a warning that states marijuana smoke contains carcinogens and may negatively affect health. Such receptacles for marijuana in a form for smoking 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.

17. The department shall adopt rules to regulate the types, appearance, and labeling of marijuana delivery devices dispensed from a medical marijuana treatment center. The rules must require marijuana delivery devices to have an appearance consistent with medical use.

18. 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 14. and 15., 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 of all 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.

19. 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 two 35-day supplies ~~a 70-day supply~~ of marijuana within any 70-day period to a qualified patient or caregiver. ~~May not dispense more than one 35-day supply of marijuana in a form for smoking within any 35-day period to a qualified patient or caregiver.~~ A 35-day supply of marijuana ~~in a form for smoking~~ may not exceed 54,250 milligrams of tetrahydrocannabinol ~~2.5 ounces~~ unless an exception to this amount is approved by the department pursuant to paragraph (4)(f).

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 or wrapping papers made with tobacco or hemp, 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

D I R E C T O R Y A M E N D M E N T

Remove lines 450-456 and insert:

Section 2. Effective July 1, 2022, paragraphs (a), (d), and (f) of subsection (4), paragraph (e) of subsection (8), and paragraph (a) of subsection (14) of s. 381.986, Florida Statutes, are amended to read:

T I T L E A M E N D M E N T

Remove lines 26-41 and insert:

dispose of marijuana; requiring the Office of Program Policy Analysis and Government Accountability to research the use of high concentrate THC and report its findings to the Governor and Legislature by a specified date; prohibiting a qualified physician from issuing a physician certification to a minor patient for marijuana, except for low-THC cannabis; providing an exception; revising the supply limits of marijuana for which a physician certification may be issued; limiting the potency of tetrahydrocannabinol in such supply; prohibiting a medical marijuana treatment center from dispensing a certain daily supply within a specified period to conform to changes made by the act; amending s. 381.988, F.S.; prohibiting a