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	12 Y, 6 N	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%2008102015.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