HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 7117 PCB HHS 19-02 Medical Use of Marijuana
SPONSOR(S): Appropriations Committee, Health & Human Services Committee, Rodrigues, R.
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Orig. Comm.: Health & Human Services Committee	12 Y, 5 N	Royal	Calamas
1) Appropriations Committee	19 Y, 7 N, As CS	Mielke	Pridgeon

SUMMARY ANALYSIS

Art. X, Sec. 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 Fla Const. art. X, s. 29 by passing the Medical Use of Marijuana Act.

Under current law, a medical marijuana patient must obtain a physician certification from a qualified physician and an identification card from the Department of Health (DOH). To certify a patient for medical use of marijuana, a qualified physician must determine that medical marijuana would likely outweigh the health risks to the patient and obtain the informed consent of the patient using a standardized form. 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 smoking. A 35-day supply of marijuana in a form for smoking cannot exceed 2.5 ounces. Current law requires DOH to set a daily dose amount limit for all forms of marijuana. Current law places a limit on the amount of tetrahydrocannabinol (THC) in edible products only. Edibles may only contain 200 mg of THC in the total product and 10 mg of THC per serving. Edibles have no supply limit.

The full extent of the health impact of consuming products with high concentration of THC is unknown however, there is research indicating that use of such products significantly increases the risk of marijuana-associated psychosis. Studies have found daily use, especially of high-potency marijuana (over 10% 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% or less is sufficient 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.

The bill limits the amount of THC that a MMTC may dispense for dried leaves and flowers of marijuana to 10% THC. The bill allows a qualified physician to certify a patient for six 35-day supply limits of edibles. A 35-day supply limit of edibles may not exceed 7000 mg of THC. The bill also sets the daily dose limit amount for marijuana in a form for smoking at 0.08 ounces and for edibles at 200 mg of THC. DOH is still required to set a daily dose limit amount for all other forms of marijuana. The bill requires MMTCs to test all forms of its marijuana and also authorizes DOH to possess and test samples of all forms of marijuana from MMTCs to ensure that it meets safety and potency requirements before it is dispensed.

The bill also 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.

The bill waives the $75 identification card fee for qualified patients who can demonstrate veteran status to DOH. The bill also grants DOH and the applicable boards limited emergency rulemaking authority in order for DOH to implement the Medical Use of Marijuana Act.

The bill appropriates $350,000 in nonrecurring funds from the Grants and Donations Trust Fund to the DOH to implement the requirements of the bill. The bill has no fiscal impact on local governments. The bill provides an effective date of July 1, 2019.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Art. X, Sec. 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.

During the 2017A Special Session, the legislature implemented Fla Const. art. X, s. 29 by passing the Medical Use of Marijuana Act.

Physician and Patient Requirements

Under current law, for a patient to obtain marijuana for medical use from a MMTC, the patient must obtain a physician certification from a qualified physician[1] and an identification card from the Department of Health (DOH). The current fee for the patient identification card is $75 and it must be renewed annually.[2] As of March 29, 2019, there are 201,708 patients with an active identification card.[3]

To certify a patient for medical use of marijuana, a qualified physician must determine that medical marijuana would likely outweigh the health risks to the patient and 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. The informed consent form must contain the following information:

- The Federal Government's classification of marijuana as a Schedule I controlled substance.
- The approval and oversight status of marijuana by the Food and Drug Administration.
- The current state of research on the efficacy of marijuana to treat the qualifying conditions set forth in this section.
- The potential for addiction.
- 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.

[1] 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.
[2] Rule 64-4.011, F.A.C.
[3] Department of Health, *Office of Medical Marijuana Use Updates March 29, 2019,* available at http://s27415.pcdn.co/wp-content/uploads/ommu_updates/2019/032919-OMMU-Update.pdf (last viewed March 30, 2019).

- The potential side effects of marijuana use, including the negative health risks associated with smoking.
- The risks, benefits, and drug interactions of marijuana.
- That the patient's de-identified health information contained in the physician certification and medical marijuana use registry may be used for research purposes.

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 smoking. A 35-day supply of marijuana in a form for smoking cannot exceed 2.5 ounces. The qualified physician must recertify the patient every 30 weeks.

Pursuant to Fla. Const. art. X s. 29(d)(1)d, an amount of marijuana that could reasonably be presumed to be an adequate supply for a qualifying patient's medical use must be defined. Current law allows a patient to obtain a 70-day supply of marijuana not in a form for smoking and a 35-day supply for marijuana in a form for smoking.

Current law requires DOH to set a daily dose amount limit and use the daily dose amount limit to calculate a 70-day supply of marijuana. Current law, consistent with the Constitution, allows a qualified physician to request an exception from DOH from the daily dose amount limit. If DOH fails to approve or deny the request within 14 days, the requested amount is deemed approved. The qualified physician must submit the following to DOH when requesting an exception:

- 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.

DOH has not yet set a daily dose limit amount by rule, therefore, other than marijuana in a form for smoking, the amount of marijuana, including edibles, that would be sufficient for a 70-day supply has not been determined.

Products and Routes of Administration

Current law allows for the medical use of marijuana in any form except for marijuana seeds and commercially produced food items that do not meet the definition of edibles[4] in the Medical Use of Marijuana Act. Current law also requires each MMTC to provide at least one low-THC cannabis product.[5]

Current law allows MMTCs to produce edibles if they obtain a food establishment permit from the Department of Agriculture and Consumer Services (DACS) before producing edibles and comply with the Florida Food Safety Act. Current law limits the amount of delta-9-tetrahydrocannabinol (THC) in each edible product and each serving size. Edibles may only contain 200 mg of THC in the total product and 10 mg of THC per serving. Current law prohibits a potency variance for edibles greater than 15%. Current law does not set an amount of THC that would be sufficient for a 70-day supply of edibles.

[4] Edibles are defined as commercially produced food items made with marijuana oil, but no other form of marijuana, that are produced and dispensed by a medical marijuana treatment center. See S. 381.986(1)(d), F.S.
[5] Low-THC cannabis is defined as a plant of the genus Cannabis, the dried flowers of which contain 0.8 percent or less of tetrahydrocannabinol and more than 10 percent of cannabidiol weight for weight; the seeds thereof; the resin extracted from any part of such plant; or any compound, manufacture, salt, derivative, mixture, or preparation of such plant or its seeds or resin that is dispensed from a medical marijuana treatment center. See S. 381.986(1)(e), F.S.

Current law also allows for the smoking of medical marijuana. A patient may obtain a 35-day supply for marijuana in a form for smoking. Current law sets the 35-day supply limit for marijuana in a form for smoking at 2.5 ounces. However, current law does not provide a THC limit for marijuana in a form for smoking.

Current law allows the use of hydrocarbon gases and solvents, such as butane, propane, and hexane, to process marijuana. This method extracts essential oils from marijuana to create products with exceedingly high THC content. The average marijuana concentrate[6] contains 50% THC content[7] and concentrates made with butane extraction can contain THC content of 60%-90%, which is significantly higher than the average 17% - 20% THC concentration found in other marijuana products, including raw flower.[8]

Testing Requirements

Current law requires processed marijuana products be tested for contaminants that are harmful for human consumption and to ensure that products meet the THC and CBD potency requirements. DOH must adopt rules determining what contaminants must be tested for and at what levels such contaminants are unsafe for human consumption. Current law requires DACS to assist DOH in developing rules for testing edibles. DOH must adopt rules for treatment of marijuana products that fail the safety and potency requirements.

Current law requires DOH to establish a certification program for marijuana testing laboratories. 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.

Current law requires MMTCs to contract with a certified marijuana testing laboratory to perform testing of its processed marijuana before it is dispensed. MMTCs may contract with a laboratory that is not certified until at least one laboratory becomes certified or until July 2019. DOH has not yet established the certification program for marijuana testing laboratories.

Current law authorizes DOH to select random samples of edible products available for purchase for testing to determine whether the THC and CBD potency on the label is accurate and whether the edible is safe for human consumption. Current law requires that edibles that fail to meet the safety and potency requirements must be recalled along with all edibles made from the same batch of marijuana.

Rulemaking Authority

The Florida Administrative Procedures Act, Ch. 120, F.S. (APA), governs the rulemaking process. The formal rulemaking process begins by an agency giving notice of the proposed rule.[9] The notice is published by the Department of State in the Florida Administrative Register[10] and must provide certain information, including the text of the proposed rule, a summary of the agency's statement of estimated regulatory costs (SERC), if one is prepared, and how a party may request a public hearing on the proposed rule.

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[6] Marijuana concentrates are often referred to as 710 (the word "OIL" flipped and spelled backwards), wax, ear wax, honey oil, budder, butane hash oil, butane honey oil (BHO), shatter, dabs (dabbing), black glass, and errl. *What You Should Know About Marijuana Concentrates Also Known As: The Extractions,* United States Department of Justice, Drug Enforcement Administration, December 2014, available at https://www.dea.gov/sites/default/files/resource-center/Publications/marijuana-concentrates.pdf (last viewed March 25, 2019).

[7] *A Rise in Marijuana's THC Levels*, Department of Health and Human Services, National Institute on Drug Abuse, available at https://archives.drugabuse.gov/rise-in-marijuanas-thc-levels (last viewed on March 25, 2019).

[8] Id; Supra, FN 4.; Based upon 2014-15 data, the THC content in Colorado retail flower lies between 8%-22%, with a mean estimate of roughly 17%. *Marijuana Equivalency in Portion and Dosage*: *An assessment of physical and pharmacokinetic relationships in marijuana production and consumption in Colorado*, Colorado Department of Revenue, August 10, 2015, available at https://www.colorado.gov/pacific/sites/default/files/MED%20Equivalency_Final%2008102015.pdf (last viewed March 25, 2019).

[9] Section 120.54(3)(a)1, F.S.

[10] Sections 120.54(3)(a)2., 120.55(1)(b)2, F.S.

A SERC must be prepared if the proposed rule will have a negative impact on small business or if the proposed rule is likely to directly or indirectly increase the total regulatory costs by more than $200,000, within one year of the rule's implementation.[11] The SERC must include an economic analysis projecting a proposed rule's adverse effect on specified aspects of the state's economy or increase in regulatory costs.[12]

The law distinguishes between a rule being "adopted" and becoming enforceable or "effective."[13] A rule must be filed for adoption before it may go into effect[14] and cannot be filed for adoption until completion of the rulemaking process.[15] A rule may be adopted but cannot go into effect if the analysis shows the projected impact of the proposed rule in any one of these areas will exceed $1 million in the aggregate for the 5 year period.[16] Such a rule must be ratified by the Legislature before it may go into effect.[17] Ratification is accomplished through passage of a bill that ratifies the rule.

The APA also authorizes agencies to adopt emergency rules if the agency finds that an immediate danger to the public health, safety, or welfare requires emergency action, the agency may adopt any rule necessitated by the immediate danger. Emergency rules are only effective for 90 days and are not renewable unless an agency has initiated non-emergency rulemaking adopt rules addressing the subject of the emergency rule and either a challenge to such rules is pending or such rules are pending ratification by the Legislature.

The Medical Use of Marijuana Act required DOH to adopt rules to implement provisions of the bill related to the licensure of MMTCs, daily dose and supply limits, patient and caregiver identification cards, edibles, safety standards for the processing of marijuana, and the certification of medical marijuana testing laboratories. The Medical Use of Marijuana Act provided emergency rulemaking authority to DOH to adopt rules necessary to implement these provisions. DOH's emergency rulemaking authority expired January 1, 2018. DOH is now required to use the non-emergency procedures of the APA to adopt rules to implement these provisions. DOH has only adopted rules governing the patient and caregiver identification cards, pesticide use, and the procedure for MMTCs to receive a variance from their application requirements.

Research on the Health Effects of THC

Although there are more than 100 cannabinoids in a marijuana plant, the two main cannabinoids of medical interest are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD). THC is a mind-altering chemical that increases appetite and reduces nausea and may also decrease pain, inflammation, and muscle control problems.[18] CBD is a chemical that does not affect the mind or behavior, but may be useful in reducing pain and inflammation, controlling epileptic seizures, and possibly treating mental illness and addictions.[19]

The THC potency of illicit marijuana has consistently increased over time from 4% in 1995 to 12% in 2014. The CBD content has 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.[20]

[11] Section 120.54(1)(b), F.S.
[12] Section 120.541(2)(a), F.S.
[13] Section 120.54(3)(e)6. Before a rule becomes enforceable, thus "effective," the agency first must complete the rulemaking process and file the rule for adoption with the Department of State.
[14] Section 120.54(3)(e)6., F.S.
[15] Section 120.54(3)(e), F.S.
[16] Section 120.541(3), F.S.
[17] Section 120.541(3), F.S.
[18] U.S. Department of Health & Human Services, National Center for Complementary and Integrative Health, *What is medical marijuana?*, available at http://www.drugabuse.gov/publications/drugfacts/marijuana-medicine (last visited April 9, 2019).
[19] Id.
[20] 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; 79:613-619.

Some studies have shown that marijuana with a THC concentration of 10% or less is sufficient for medical treatment, including the relief of neuropathic pain and pain caused by conditions such as HIV/AIDS, multiple sclerosis, post-traumatic surgical pain.[21] 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,[22] with one study finding that medium-dose marijuana cigarettes with 3.5% THC were as effective as higher dosed marijuana cigarettes at 7% THC.[23]

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.[24] 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.[25] The study also found that marijuana-based treatment with THC may have irreversible effects on brain development in adolescents as the brain's endocannabinoid system undergoes development in childhood and adolescence.[26] Heavy use of marijuana by adolescents is associated with impairments in attention, learning, memory, poor grades, high drop rates and I.Q. reduction.[27]

The full extent of the health impact of consuming products with high concentration of THC is unknown;[28] research indicates that use of such products significantly increases the risk of marijuana-associated psychosis.[29] Studies have found daily use, especially of high-potency marijuana (over 10% THC), is strongly associated with earlier onset of psychosis and the development of schizophrenia in marijuana users.[30] One study found that frequent use of marijuana or use of marijuana with high THC potency increased the risk of schizophrenia six-fold.[31]

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.[32] High doses of THC can cause acute, transient, dose-dependent psychosis, which are schizophrenia-like symptoms.[33] Additionally, prospective, longitudinal, and epidemiological studies have consistently found an association between marijuana use and schizophrenia in which marijuana use precedes psychosis,

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[21] 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.; 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.; 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.; 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.

[22] Id.

[23] 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.

[24] 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 April 1, 2019).

[25] Id.

[26] Id.

[27] Bertha K. Madras, PhD., Dept. of Psychiatry, McLean Hospital, Harvard Medical School, *Marijuana: Risks and Consequences,* prepared for Florida Legislature, February 2016 and *Presentation to the Health Quality Subcommittee on January 11, 2017*. On file with the Health Quality Subcommittee.

[28] Supra, FN 5.

[29] 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 March 25, 2019).

[30] Di Forti et al.; Schizophr Bull. 2014 Nov;40(6):1509-17; Di Forti M, Marconi A, Carra E, et al. *Proportion of patients in south London with first-episode psychosis attributable to use of high potency cannabis: a case-control study*. Lancet Psychiatry. 2015;2(3):233-238.

[31] 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 March 25, 2019).

[32] Id.

[33] Id.

independent of alcohol consumption, and even after removing or controlling for those individuals who had used other drugs.[34]

Studies have also found that even though marijuana use may have been discontinued long before the onset of psychosis, the age at which marijuana use began 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.[35] Studies have also 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 during adolescence, earlier use, or use of marijuana with high THC potency.[36]

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.[37]

THC Limits in Other Medical Marijuana States

Several states with medical marijuana programs impose some form of THC limit. Some states impose THC limits upon the products themselves, while others impose a limit on the amount of THC that may be within a container. Some states impose a limit on the amount of THC a patient may obtain within a certain period. The chart below illustrates the various ways that states with medical marijuana programs impose THC limits:

State	Plant	Flower	Marijuana Products	Supply Limit
Colorado			Edibles: 100 mg/product	
Delaware			7% THC limit for minors	
Maryland				3600 mg/30 day supply
Michigan			Tinctures: 1000 mg/container Beverages: 500 mg/container Other marijuana infused products: 1000 mg/container	
New Jersey[38]		10%	10%	
New Mexico			Concentrates: 70% by weight	
North Dakota			6% THC limit for minors	2000 mg/30 day supply
Ohio	35%		Concentrates: 70%	
Oregon			Topicals: 6%/container Edibles: 100 mg/product Other marijuana infused products: 4000 mg/container	
Washington			Edibles: 100 mg/product	

[34] Id.
[35] Id.
[36] Id.
[37] Id.
[38] New Jersey based their THC limit upon research studies that showed marijuana that contained no more than 10% THC had a medicinal effect and a ban by the Dutch government in 2011 on the sale of cannabis with a THC content greater than 15% based on the reasoning that marijuana with a greater THC concentration should be categorized with hard drugs such as cocaine and heroin. (See N.J.A.C. 8:64)

Effect of Proposed Changes

Potency and Supply Limits

The bill limits the amount of THC to 10% in the dried leaves and flowers of marijuana that a MMTC may dispense. The bill requires MMTCs to begin meeting the THC requirement for dried leaves and flowers of marijuana beginning January 1, 2020. The bill limits the amount of THC in a 35-day supply of edibles to 7000 mg. The bill allows a qualified physician to certify a patient for six 35-day supply limits of edibles.

The bill also sets the daily dose limit amount for marijuana in a form for smoking at 0.08 ounces and for edibles at 200 mg of THC, based on the 35-day supply limits. DOH is still required to set a daily dose limit amount and calculate a 70-day supply limit for all other forms of marijuana.

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 also authorizes DOH to possess and test samples of all forms of marijuana, not only edibles, available from the cultivation facilities, processing facilities, and dispensing facilities of MMTCs in order to determine that the marijuana meets safety and potency requirements. The bill also prohibits certified medical marijuana testing laboratories and its officers, directors, and employees, from having a direct or economic interest in, or a financial relationship with, a MMTC. The bill clarifies that this prohibition does not prevent a certified medical marijuana testing laboratory from contracting with a MMTC to provide testing services.

Children

The bill prohibits qualified physicians from certifying qualified patients under the age of 18 for marijuana other than low-THC cannabis. A qualified physician may certify a patient under the age of 18 for marijuana other than low-THC cannabis if 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 qualified physician must document such determination and concurrence in the patient's medical record and in the medical marijuana use registry. The bill also requires the informed consent form created by the Board of Medicine and Board Osteopathic Medicine address the negative health effects of marijuana use on individuals under the age of 18.

Veterans

The bill waives the identification card fee for qualified patients who can demonstrate his or her veteran status to DOH through a copy of one the following documentation:[39]

- The qualified patient's DD Form 214, issued by the United States Department of Defense;
- The qualified patient's veteran health identification card, issued by the United States Department of Veterans Affairs; or
- The qualified patient's veteran identification card, issued by the United States Department of Veterans Affairs pursuant to the Veterans Identification Card Act of 2015, Pub. L. No. 114-31.

Rulemaking Authority

The bill grants DOH and the applicable boards limited emergency rulemaking authority in order for DOH to implement the Medical Use of Marijuana Act. The bill allows DOH and the applicable boards to adopt emergency rules necessary to implement the Medical Use of Marijuana Act. The bill allows DOH and the applicable boards to adopt emergency rules to replace any emergency rules that were held to be an invalid delegation of legislative authority or unconstitutional. However, the bill prohibits DOH and the

[39] The documentation required is identical to the documentation required for a veteran to provide the Department of Highway Safety and Motor Vehicles in order to have the word "veteran" exhibited on his or her drivers' license. See s. 322.14, F.S.

applicable boards from adopting emergency rules to replace those emergency rules if they are also held to be an invalid delegation of legislative authority or unconstitutional. The bill requires DOH and the applicable boards to begin replacing the emergency rules by July 1, 2020.

The bill also exempts DOH and the applicable boards from the statement of regulatory costs requirements and the emergency rulemaking requirement that there is an immediate danger to the public health, safety, or welfare which requires emergency action. The bill also exempts the emergency rules from the 90-day effective date and allows the emergency rules to remain in effect until replaced through non-emergency rulemaking procedures by DOH and the applicable boards.

The bill provides an effective date of July 1, 2019.

B. SECTION DIRECTORY:

Section 1: Amends s. 381.986, F.S., relating to medical use of marijuana.
Section 2: Amends s. 381.988, F.S., relating to medical marijuana testing laboratories; marijuana tests conducted by a certified laboratory.
Section 3: Amends ch. 2017-232, Laws of Fla., relating to emergency rulemaking.
Section 4: Provides an appropriation.
Section 5: Provides an effective date of July 1, 2019.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   DOH will experience a loss in revenues due to the waiver of the identification card fee for veterans. It is unknown how many identification cards are currently issued to veterans because this information is not collected. It is also unknown how many future veterans will be issued an identification card. The loss of revenue from identification cards issued to qualified veterans may be significant, however, it is not expected to impact program operations.

2. Expenditures:

   The Office of Medical Marijuana Use will be required to make updates to its medical marijuana use registry to reflect new marijuana certifying options and to prevent those under 18 years of age from being certified a prohibited method of delivery. The bill appropriates $350,000 in nonrecurring funds from the Grants and Donations Trust Fund to implement these updates.

   The Office of Medical Marijuana Use, the Board of Medicine, and the Board Osteopathic Medicine will incur costs related to rulemaking to implement the bill's requirements. Current resources are adequate to absorb these costs.

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 dried leaves and flowers of 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:

The bill provides sufficient rulemaking authority to DOH to implement the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On April 3, 2019, the Health and Human Services adopted an amendment and reported PCB HHS 19-02 favorably as amended. The amendment prohibits a physician from certifying a patient for more than six 35-day supply limits of edibles.

On April 9, 2019, the Appropriations Committee adopted one amendment that appropriated $350,000 in nonrecurring funds from the Grants and Donations Trust Fund to the DOH to make required updates to the medical marijuana use registry to reflect new marijuana certifying options and to prevent those under 18 years of age from being certified a prohibited method of delivery.

The analysis is drafted to bill as amended by the Appropriations Committee.