

**The Florida Senate**  
**BILL ANALYSIS AND FISCAL IMPACT STATEMENT**

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

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Prepared By: The Professional Staff of the Committee on Rules

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BILL: CS/CS/CS/SB 182

INTRODUCER: Rules Committee; Innovation, Industry, and Technology Committee; Health Policy Committee and Senator Brandes

SUBJECT: Medical Use of Marijuana

DATE: February 22, 2019

REVISED: 2-22-19

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	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Looke</u>	<u>Brown</u>	<u>HP</u>	<u>Fav/CS</u>
2.	<u>Oxamendi</u>	<u>Imhof</u>	<u>IT</u>	<u>Fav/CS</u>
3.	<u>Looke</u>	<u>Phelps</u>	<u>RC</u>	<u>Fav/CS</u>

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**Please see Section IX. for Additional Information:**

COMMITTEE SUBSTITUTE - Substantial Changes

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**I. Summary:**

CS/CS/CS/SB 182 amends various sections of the Florida Statutes related to the medical use of marijuana.

The bill:

- Eliminates the prohibition against the smoking of marijuana (cannabis) from the definition of the “medical use” of marijuana
- Specifies that low-THC cannabis may not be smoked in public and prohibits the medical use of marijuana by smoking in an “enclosed indoor workplace,” as defined in the Florida Clean Indoor Air Act.<sup>1</sup>
- Permits a qualified patient and his or her caregiver to purchase and possess delivery devices for the medical use of marijuana by smoking from a vendor that is not a Medical Marijuana Treatment Center (MMTC).
- Prohibits the certification of marijuana for medical use by smoking to patients under the age of 18 unless such patient is diagnosed with a terminal condition.<sup>2</sup>

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<sup>1</sup> Part II of ch. 386, F.S.; see s. 386.203(5)(5), F.S., for definition of “enclosed indoor workplace.”

<sup>2</sup> Section 381.986(1)(o), F.S., defines “terminal condition” as a progressive disease or medical or surgical condition that causes significant functional impairment, is not considered by a treating physician to be reversible without the administration of life-sustaining procedures, and will result in death within 1 year after diagnosis if the condition runs its normal course.

- For terminal patients under the age of 18 the bill requires a qualified physician to certify that smoking is the most effective means of administering medical marijuana to the patient; and
- A second physician, who is a pediatrician, must concur with this determination.
- Requires that the risks specifically associated with smoking marijuana must be included in the informed consent each patient must sign prior to being certified to receive medical marijuana.
- Requires the Board of Medicine (BOM) and the Board of Osteopathic Medicine (BOOM) to adopt practice standards in rule for the certification of the medical use of marijuana by smoking.
- Specifies that a physician may not certify more than six 35-day supplies of marijuana in a form for smoking and that a 35-day supply may not exceed four ounces.
- Requires each MMTC to produce and sell at least one type of pre-rolled marijuana cigarette.
- Specifies packaging and warning label requirements for medical marijuana intended for smoking and also specifies labeling and production requirements for marijuana delivery devices sold from an MMTC.
- Provides that s. 381.986, F.S., does not impair the ability of a private party to restrict or limit smoking on his or her private property, and does not prohibit the medical use of marijuana in a nursing home, hospice, or assisted living facility if the facility's policies do not prohibit the medical use of marijuana.
- Rename the "Coalition for Medical Marijuana Research and Education" as the "Consortium for Medical Marijuana Clinical Outcomes Research" The Consortium is housed under the bill in the H. Lee Moffitt Cancer Center and Research Institute, Inc. (Moffitt) and must organize a program of research that contributes to the body of scientific knowledge on the effects of the medical use of marijuana and informs both policy and medical practice related to the treatment of debilitating medical conditions with marijuana.
- Repeals proviso language in the 2018 General Appropriations Act requiring that the DOH adopt all rules required as a condition for the release of specified reserved funds to the DOH.

The bill's provisions take effect upon becoming law.

## II. Present Situation:

### Smoking Ban: Timeline of Events

#### *Amendment 2*

On November 4, 2016, Amendment 2 was voted into law and established Article X, section 29 of the Florida Constitution. This section of the constitution became effective on January 3, 2017, and created several exemptions from criminal and civil liability for:

- Qualifying patients medically using marijuana in compliance with the amendment;
- Physicians, solely for issuing physician certifications with reasonable care and in compliance with the amendment; and
- Medical marijuana treatment centers (MMTCs) and their agents and employees for actions or conduct under the amendment and in compliance with rules promulgated by the DOH.

### ***Implementation***

Subsequently, the Legislature passed SB 8-A in Special Session A of 2017.<sup>3</sup> The bill revised the Compassionate Medical Cannabis Act of 2014<sup>4</sup> in s. 381.986, F.S., to implement Article X, section 29 of the Florida Constitution.

### ***Constitutional Challenge of Smoking Ban***

SB 8-A defined the term “medical use” to exclude the “possession, use, or administration of marijuana in a form for smoking<sup>5</sup>...or of marijuana seeds or flower,<sup>6</sup> except for flower in a sealed, tamper-proof receptacle for vaping.” This provision, which became colloquially known as the smoking ban, was challenged in the Circuit Court for the Second Judicial Circuit on July 6, 2017.

In its complaint, People United for Medical Marijuana, Inc., challenged the smoking ban on two counts:<sup>7</sup>

- That the smoking ban impermissibly altered the definition of “marijuana” established in Article X, section 29(b)(4), of the Florida Constitution, by excluding the right to possess forms of marijuana for smoking; and
- That Article X, section 29, of the Florida Constitution, implicitly authorized smoking marijuana in a private place by allowing the prohibition of smoking in public.

On May 25, 2018, Judge Karen Gievers issued an order agreeing with the plaintiffs on both counts and ruling the smoking ban unconstitutional. In her order, Judge Gievers held that “qualifying patients have the right to use the form of medical marijuana for treatment of their debilitating medical conditions as recommended by their certified physicians, including the use of smokable marijuana in private places.”<sup>8</sup>

The DOH appealed the ruling to the First District Court of Appeal on May 29, 2018. The appeal is ongoing. However, on January 17, 2019, newly-elected Governor Ron DeSantis held a press conference in which he announced his intention to withdraw the appeal should the Legislature not act to remove the smoking ban from Florida Statutes by mid-March 2019.<sup>9</sup> Additionally, both parties filed a motion to stay the appeal until March 15, 2019. The motion was granted on January 24, 2019.<sup>10</sup>

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<sup>3</sup> Chapter 2017-232, Laws of Fla.

<sup>4</sup> Chapter 2014-157, Laws of Fla.

<sup>5</sup> Smoking is defined in s. 381.986(1)(n), F.S., to mean “burning or igniting a substance and inhaling the smoke.”

<sup>6</sup> Marijuana is a mixture of dried, shredded flowers of the cannabis plant, *Cannabis sativa*. See National Institute on Drug Abuse, *Want to Know More? Some FAQs about Marijuana*, available at: <https://www.drugabuse.gov/publications/marijuana-facts-teens/want-to-know-more-some-faqs-about-marijuana> (last visited on Feb. 6, 2019).

<sup>7</sup> *People United for Medical Marijuana, et al. v. Florida Dept. of Health, et al.*, Complaint, No. 2017-CA-1394, (Fl. 2<sup>nd</sup> Cir. Ct., July 7, 2017).

<sup>8</sup> Order and Final Judgement, *People United for Medical Marijuana, et al. v. Florida Dept. of Health, et al.*, No. 2017-CA-1394, (Fla 2<sup>nd</sup> Cir. Ct., May 5, 2018) p. 21.

<sup>9</sup> Governor’s Announcement on Medical Marijuana (Jan. 17, 2019), available at: <https://thefloridachannel.org/videos/1-17-19-governors-announcement-on-medical-marijuana/> (last visited on Feb. 6, 2019).

<sup>10</sup> Motion to Stay, *People United for Medical Marijuana, et al. v. Florida Dept. of Health, et al.*, No. ID18-2206 (Fla. 1<sup>st</sup> DCA Jan, 2019).

## Prohibited Locations for the Use of Medical Marijuana

The term medical marijuana includes two distinct forms of the plant genus *Cannabis*:

1. Marijuana without any limitation or restriction on the percentage of THC,<sup>11</sup> and
2. “Low-THC cannabis” in which the percentage of THC is limited to 0.8 percent or less and has more than 10 percent of cannabidiol<sup>12</sup> weight for weight.<sup>13</sup>

The medical use or administration of marijuana is prohibited in or on any of the following locations (with specific exceptions for low-THC cannabis as noted):<sup>14</sup>

- On any form of public transportation (low-THC cannabis is permitted in such a place).
- In any public place (low-THC cannabis is permitted in such a place).
- In a qualified patient’s place of employment.
- In a state correctional institution, including facilities managed by the Department of Corrections or the Department of Juvenile Justice, a county or municipal detention facility, or a detention facility operated by a private entity.
- On the grounds of a preschool, primary school, or secondary school.
- In a school bus, a vehicle, an aircraft, or a motorboat (low-THC cannabis is permitted in such a place).

## Effectiveness and Risks of Smoking Medical Marijuana

Although much of the scientific research is inconclusive, studies have shown that there are both benefits and risks associated with smoking as a delivery method for marijuana.

Some studies have shown that the administration of marijuana by inhalation, either by smoking or by vaping, increases the rate and consistency of the uptake of the active ingredients in marijuana, specifically THC. In one randomized controlled trial, THC was detected in plasma immediately after the first inhalation of marijuana smoke, attesting to the efficient absorption of THC by the lungs.<sup>15</sup> This is likely because “THC is highly lipophilic, distributing rapidly to highly perfused tissues and later to fat.”<sup>16</sup> The study also found that “a trial of 11 healthy subjects administered  $\Delta^9$ -THC (Delta-9-THC) intravenously, by smoking, and by mouth demonstrated that plasma profiles of THC after smoking and intravenous injection were similar, whereas plasma levels after oral doses were low and irregular, indicating slow and erratic absorption.”<sup>17</sup> Additionally, there is evidence that the use of a cannabis preparation, such as would be delivered

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<sup>11</sup> THC, or tetrahydrocannabinol, is the main active ingredient in cannabis and is responsible for most of the psychological effects of cannabis.

<sup>12</sup> Cannabidiol (CBD) is a chemical compound, known as a cannabinoid, found in cannabis. CBD does not have the same psychoactivity as THC. See Michael J Breus, *Despite What You May Think... CBD Is Not Weed* (Sept. 20, 2018), Psychology Today, available at: <https://www.psychologytoday.com/us/blog/sleep-newzzz/201809/despise-what-you-may-think-cbd-is-not-weed> (last visited Feb. 6, 2019).

<sup>13</sup> See ss. 381.986(1)(e) and (f), F.S.

<sup>14</sup> Section 381.986(1)(j)5., F.S.

<sup>15</sup> Mary B. Bridgeman and Daniel T. Abazia, *Medicinal Cannabis: History, Pharmacology, and Implications for the Acute Care Setting*, Pharmacy and Therapeutics (March 2017), available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5312634/> (last visited Feb. 11, 2019).

<sup>16</sup> *Id.*

<sup>17</sup> *Id.*

to the body by smoking cannabis, with multiple cannabinoids and terpenes,<sup>18</sup> versus a single molecule preparation (with pure THC or CBD) may be more effective in treating seizure disorders<sup>19</sup> and potentially breast cancer.<sup>20</sup>

Although potentially more efficacious than other methods of delivery, smoking as a method of delivery for marijuana does not allow for accurate or consistent dosing measures.<sup>21</sup> Also, as with any smoked substance, smoking marijuana has inherent risks that have been identified. The National Institutes of Health (NIH) states that:

Marijuana smoking is associated with large airway inflammation, increased airway resistance, and lung hyperinflation, and those who smoke marijuana regularly report more symptoms of chronic bronchitis than those who do not smoke. One study found that people who frequently smoke marijuana had more outpatient medical visits for respiratory problems than those who do not smoke. Some case studies have suggested that, because of THC's immune-suppressing effects, smoking marijuana might increase susceptibility to lung infections, such as pneumonia, in people with immune deficiencies; however, a large AIDS cohort study did not confirm such an association. Smoking marijuana may also reduce the respiratory system's immune response, increasing the likelihood of the person acquiring respiratory infections, including pneumonia. Animal and human studies have not found that marijuana increases risk for emphysema.<sup>22</sup>

Additionally, the NIH indicates that smoking cannabis, much like smoking tobacco, can introduce levels of volatile chemicals and tar into the lungs that may raise concerns about the risk for cancer and lung disease. However, the association between smoking cannabis and the development of lung cancer is not decisive.<sup>23</sup>

One other risk that may be associated with smoking cannabis is the unintentional introduction of cannabis and other harmful chemicals to other people present by second-hand smoke. The NIH states that:

The known health risks of secondhand exposure to cigarette smoke—to the heart or lungs, for instance—raise questions about whether secondhand exposure to

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<sup>18</sup> Terpenes are hydro-carbons largely found as constituents of essential oils. See Science Direct, *Terpene*, available at <https://www.sciencedirect.com/topics/medicine-and-dentistry/terpene> (last visited on Feb. 6, 2019).

<sup>19</sup> Ethan B. Russo, *The Case for the Entourage Effect and Conventional Breeding of Clinical Cannabis: No "Strain," No Gain* (January 9, 2019), *Frontiers in Plant Science*, available at: <https://doi.org/10.3389/fpls.2018.01969> (last visited on Feb. 6, 2019).

<sup>20</sup> Blasco-Benito, et al., *Appraising the "entourage effect": Antitumor action of a pure cannabinoid versus a botanical drug preparation in preclinical models of breast cancer*, *Biochemical Pharmacology*, Volume 157, November 2018, Pages 285-293.

<sup>21</sup> See Appellant's Initial Brief, case no. 2017-CA-1394, Florida Circuit Court for the Second Judicial Circuit, Aug. 3, 2017, p. 5.

<sup>22</sup> See National Institutes on Drug Abuse, *Marijuana, What are Marijuana's Effects on Lung Health?* (June 2018), available at: <https://www.drugabuse.gov/publications/research-reports/marijuana/what-are-marijuanas-effects-lung-health>, (last visited on Jan. 29, 2019).

<sup>23</sup> Josef Yayan and Kurt Rasche, *Damaging Effects of Cannabis Use on the Lungs*, *Advancements in Clinical Research. Advances in Experimental Medicine and Biology* (2016), vol. 952, Abstract. Available at [https://link.springer.com/chapter/10.1007/5584\\_2016\\_71](https://link.springer.com/chapter/10.1007/5584_2016_71) (last visited Feb. 6, 2019).

marijuana smoke poses similar health risks. At this point, very little research on this question has been conducted. A 2016 study in rats found that secondhand exposure to marijuana smoke affected a measure of blood vessel function as much as secondhand tobacco smoke, and the effects lasted longer. One minute of exposure to secondhand marijuana smoke impaired flow-mediated dilation (the extent to which arteries enlarge in response to increased blood flow) of the femoral artery that lasted for at least 90 minutes; impairment from 1 minute of secondhand tobacco exposure was recovered within 30 minutes. The effects of marijuana smoke were independent of THC concentration; i.e., when THC was removed, the impairment was still present. This research has not yet been conducted with human subjects, but the toxins and tar levels known to be present in marijuana smoke raise concerns about exposure among vulnerable populations, such as children and people with asthma.<sup>24</sup>

### **Smoking Medical Marijuana in Other States**

As with most aspects of the implementation of medical marijuana laws, the treatment of smoking medical marijuana varies from state to state. Several states, including New York, Ohio, Minnesota, and Pennsylvania, prohibit patients from smoking marijuana but allow vaporization. Other states allow smoking but include time, place, and manner prohibitions. For example:

- Connecticut prohibits minor patients from smoking, inhaling, or vaporizing medical marijuana;
- Arkansas, New Hampshire, Maryland, and Illinois specifically allow landlords to prohibit the smoking of medical marijuana on their premises;
- New Hampshire also prohibits the smoking and vaporizing of medical marijuana in a public place;
- Massachusetts and Washington specify that nothing requires the accommodation of smoking marijuana in any public place; and
- Hawaii allows condominiums to prohibit smoking medical marijuana if they also prohibit smoking tobacco.<sup>25</sup>

### **Florida Clean Indoor Air Act**

The Florida Clean Indoor Air Act (act) in part II of ch. 386, F.S., implements the constitutional prohibition in Section 20, Art. X, Florida Constitution, to prohibit tobacco smoking in an enclosed indoor workplace. Specifically, s. 386.204, F.S., prohibits smoking in an enclosed indoor workplace, unless the act provides an exception. An “enclosed indoor workplace” is:

any place where one or more persons engages in work, and which place is predominantly or totally bounded on all sides and above by physical barriers, regardless of whether such barriers consist of or include, without

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<sup>24</sup> National Institutes on Drug Abuse, *Marijuana, What are Marijuana’s Effects of Secondhand Exposure to Marijuana Smoke?*, (June 2018), available at <https://www.drugabuse.gov/publications/research-reports/marijuana/what-are-effects-secondhand-exposure-to-marijuana-smoke>, (last visited on Feb 6, 2019).

<sup>25</sup> Marijuana Policy Project, *State-by-State Medical Marijuana Laws Report*, available at: <https://www.mpp.org/issues/medical-marijuana/state-by-state-medical-marijuana-laws/state-by-state-medical-marijuana-laws-report/> (last visited on Feb. 6, 2019).

limitation, uncovered openings; screened or otherwise partially covered openings; or open or closed windows, жалousies, doors, or the like. A place is “predominantly” bounded by physical barriers during any time when both of the following conditions exist:

- (a) It is more than 50 percent covered from above by a physical barrier that excludes rain, and
- (b) More than 50 percent of the combined surface area of its sides is covered by closed physical barriers. In calculating the percentage of side surface area covered by closed physical barriers, all solid surfaces that block air flow, except railings, must be considered as closed physical barriers. This section applies to all such enclosed indoor workplaces and enclosed parts thereof without regard to whether work is occurring at any given time.
- (c) The term does not include any facility owned or leased by and used exclusively for noncommercial activities performed by the members and guests of a membership association, including social gatherings, meetings, dining, and dances, if no person or persons are engaged in work as defined in [s. 386.203(12), F.S.]<sup>26</sup>

The act also provides exceptions for private residences whenever not being used for certain commercial purposes;<sup>27</sup> stand-alone bars;<sup>28</sup> designated smoking rooms in hotels and other public lodging establishments;<sup>29</sup> and retail tobacco shops, including businesses that manufacture, import, or distribute tobacco products and tobacco loose leaf dealers,<sup>30</sup> a smoking cessation program approved by the DOH, medical or scientific research conducted in such smoking cessation program,<sup>31</sup> and a customs smoking room in airport in-transit lounge.<sup>32</sup> On November 6, 2018, the voters of Florida approved Amendment 9 to the Florida Constitution, to ban the use of vapor-generating electronic devices, such as electronic cigarettes (e-cigarettes), in enclosed indoor workplaces.<sup>33</sup>

### **Coalition for Medical Marijuana Research and Education**

The Coalition for Medical Marijuana Research and Education (Coalition) at the H. Lee Moffitt Cancer Center and Research Institute, Inc. (Moffitt) was created for the purpose of conducting research and providing education regarding the medical use of marijuana. The Coalition must annually adopt a plan for medical marijuana research and must issue a report by February 15<sup>th</sup> of each year to the Governor, President of the Senate, and Speaker of the House on research projects, community outreach initiatives, and future plans for the coalition. DOH must submit to the Coalition a data set that includes, for each patient in the registry, the patient’s qualifying medical condition, the daily dose amount and forms of marijuana certified for the patient.

<sup>26</sup> Section 386.203(5), F.S.

<sup>27</sup> Section 386.2045(1), F.S. *See also* definition of the term “private residence” in s. 386.203(1), F.S.

<sup>28</sup> Section 386.2045(4), F.S. *See also* definition of the term “stand-alone bar” in s. 386.203(11), F.S.

<sup>29</sup> Section 386.2045(3), F.S. *See also* definition of the term “designated guest smoking room” in s. 386.203(4), F.S.

<sup>30</sup> Section 386.2045(2), F.S. *See also* definition of the term “retail tobacco shop” in s. 386.203(8), F.S.

<sup>31</sup> Section 386.2045(5), F.S.

<sup>32</sup> Section 386.2045(6), F.S.

<sup>33</sup> Amendment 9 also bans offshore oil and natural gas drilling on lands beneath state waters. *See* FLA. CONST. art II, s. 7.

The legislature appropriated \$750,000 in nonrecurring funds from the General Revenue Fund to Moffitt to cover costs associated with administering the Coalition for FY 2017-2018. For FY 2018-2019, the legislature appropriated \$150,000 in nonrecurring funds from the General Revenue Fund to the Coalition; however, Governor Scott vetoed the appropriation. Additionally, s. 381.986(8)(b), F.S., requires that the DOH to establish a supplemental licensing fee for MMTCs that is sufficient to cover the costs associated with the Coalition. However, the DOH proposed rule establishing the supplemental fee was challenged and subsequently withdrawn. Currently no supplemental licensing fees have been collected by the DOH.

### III. Effect of Proposed Changes:

CS/CS/CS/SB 182 amends s. 381.986, F.S., to:

- Provide that a delivery device intended for the medical use of marijuana by smoking need not to be dispensed from an MMTC in order to qualify as medical marijuana delivery device.
- Exempt a qualified patient and a qualified patient's caregiver from the criminal prohibitions against the purchase and possession of a marijuana delivery by smoking device from a vendor other than MMTC.
- Permit the smoking of medical marijuana by amending the definition of the term "medical use" in s. 381.986(1)(j), F.S., to delete the prohibition against the possession, use, or administration of marijuana in a form for smoking and of marijuana flower.
- Prohibit the medical use of marijuana by smoking in an "enclosed indoor workplace," as defined in the Florida Clean Indoor Air Act.
- Specify that the smoking of low-THC cannabis is not permitted in or on the locations listed in s. s. 381.986(1)(j)5., F.S., which permit the use or administration of low-THC cannabis.
- Require the risks specifically associated with smoking marijuana be included in the informed consent each patient must sign prior to being certified to receive medical marijuana.
- Prohibit a physician from certifying the medical use of marijuana by smoking to a patient under the age of 18 unless:
  - The patient has a terminal condition;
  - The physician determines that smoking is the most effective means of medical use for the patient;
  - A second physician, who is a pediatrician, concurs with that determination; and
  - Such determination and concurrence is recorded in the patient's medical record.
- Limit physicians to certifying six 35-day supplies of marijuana in a form for smoking and specify that a 35-day supply may not exceed 4 ounces.
- Require the Board of Medicine and the Board of Osteopathic Medicine to each adopt in rule practice standards for the certification of smoking. Rules must be adopted by July 1, 2021.
- Require the DOH to provide the boards with de-identified information from the medical marijuana use registry as necessary for the adoption of the practice standards.
- Require each MMTC to produce and sell at least one type of pre-rolled marijuana cigarette.
- Require that marijuana in a form for smoking to be packaged in a sealed receptacle with a legible and prominent warning to keep away from children and that marijuana smoke contains carcinogens and may negatively affect health. Such receptacle must be plain, opaque, and white without depictions of the product or images other than the medical marijuana treatment center's DOH-approved logo and the marijuana universal symbol.



- Require that marijuana delivery devices sold from an MMTC be labeled with the MMTC's department-approved logo and not incorporate colors, shapes, forms, or designs that are likely to be attractive to children. The DOH must adopt rules specifying allowed colors, shapes, forms, and designs for marijuana delivery devices.
- Allow a medical marijuana treatment center to dispense the following smoking-related items: pipes, bongs, and wrapping papers.
- Provides that s. 381.986, F.S., does not impair the ability of a private party to restrict or limit smoking on his or her private property.
- Provides that s. 381.986, F.S., does not prohibit the medical use of marijuana in a nursing home, hospice, or assisted living facility if the facility's policies do not prohibit the medical use of marijuana. However, smoking of medical marijuana in such facilities would be subject to the prohibition in the bill against smoking in an enclosed indoor workplace, as defined in s. 386.203(5), F.S.

The bill repeals proviso language enacted in the 2018 General Appropriations Act requiring the DOH to adopt all rules required under ss. 381.986, 381.987, and 381.988, F.S., solely and exclusively pursuant to the Administrative Procedure Act in ch. 120, F.S., as a condition for the release of specified reserved funds to the DOH.<sup>34</sup>

The bill also amends s. 1004.4351, F.S., to rename the "Coalition for Medical Marijuana Research and Education" as the "Consortium for Medical Marijuana Clinical Outcomes Research" (Consortium). The bill eliminates the requirement for the Consortium related to providing education. Additionally, the bill specifies that Consortium:

- Is housed in the Moffitt Cancer Center (Moffitt) and consists of public and private universities that choose to participate.
- Is governed by a board that consists of a chairperson appointed by Moffitt, one member representing the University of Florida, and additional members representing other participating universities.
- Is administered by a director who is appointed by Moffitt and who oversees the activities of the Consortium and prepares the Consortium's plan for Medical Marijuana research. The research plan must organize a program of research that contributes to the body of scientific knowledge on the effects of the medical use of marijuana and informs both policy and medical practice related to the treatment of debilitating medical conditions with marijuana. The plan must be approved by the board and the board must award funds to members of the consortium to perform research consistent with the plan.

The bill's provisions take effect upon becoming law.

#### **IV. Constitutional Issues:**

##### **A. Municipality/County Mandates Restrictions:**

None.

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<sup>34</sup> See Chapter 2018-9, Laws of Florida, at 94, section 3, the provisos following Specific Appropriation 422 reserving \$126,424 from the General Revenue Fund and \$1,817,426 from the Administrative Trust Fund and following Specific Appropriation 424 reserving \$108,172 from the General Revenue Fund and \$281,961 from the Administrative Trust Fund, contingent on the DOH's adoption of the rules required under ss. 381.986, 381.987, and 381.988, F.S.

**B. Public Records/Open Meetings Issues:**

None.

**C. Trust Funds Restrictions:**

None.

**D. State Tax or Fee Increases:**

None.

**E. Other Constitutional Issues:**

None.

**V. Fiscal Impact Statement:****A. Tax/Fee Issues:**

None.

**B. Private Sector Impact:**

None.

**C. Government Sector Impact:**

The Department of Health (DOH) indicates that provisions of the bill related to smoking medical marijuana require certain changes in the Medical Marijuana Use Registry that would cost between \$90,000 and \$170,000.<sup>35</sup> Funding necessary for such costs could be authorized from fees collected by the DOH under section 381.986, Florida Statutes, and addressed in the Fiscal Year 2019-2020 General Appropriations Act.

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

None.

**VIII. Statutes Affected:**

This bill substantially amends section 381.986 of the Florida Statutes.

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<sup>35</sup> Email correspondence from Ty Gentle, Department of Health (Feb. 15, 2019) (on file with the Senate Committee on Rules).

**IX. Additional Information:****A. Committee Substitute – Statement of Substantial Changes:**  
(Summarizing differences between the Committee Substitute and the prior version of the bill.)**CS/CS/CS by Rules on February 20, 2019:****The CS/CS/CS:**

- Prohibits a physician from certifying the medical use of marijuana by smoking to a patient under the age of 18 unless the patient has a terminal condition; the physician determines that smoking is the most effective means of medical use for the patient; and a second physician, who is a pediatrician, concurs with that determination.
- Requires the Board of Medicine and the Board of Osteopathic Medicine to each adopt in rule practice standards for the certification of smoking. Rules must be adopted by July 1, 2021 and the Department of Health must provide the boards with de-identified information from the medical marijuana use registry as necessary for the adoption of the practice standards.
- Limits physicians to certifying six 35-day supplies of marijuana in a form for smoking and specifies that a 35-day supply may not exceed 4 ounces.
- Requires each MMTC to produce and sell at least one type of pre-rolled marijuana cigarette.
- Requires that marijuana delivery devices sold from an MMTC be labeled with the MMTC's department-approved logo and not be attractive to children.
- Eliminates the requirement in the underlying bill that a marijuana delivery device purchased from a vendor other than a MMTC and intended for the medical use of marijuana by smoking be the same or similar to a the marijuana delivery device specified in the patient's physician certification.
- Renames the "Coalition for Medical Marijuana Research and Education" as the "Consortium for Medical Marijuana Clinical Outcomes Research."
  - The Consortium is housed in the Moffitt Cancer Center and consists of public and private universities that choose to participate.
  - The Consortium's board consists of a chairperson appointed by Moffitt, one member representing the University of Florida, and additional members representing other participating universities.
  - Moffitt also appoints a director who oversees the activities of the Consortium and prepares the Consortium's plan for Medical Marijuana research.
  - The research plan must organize a program of research that contributes to the body of scientific knowledge on the effects of the medical use of marijuana and informs both policy and medical practice related to the treatment of debilitating medical conditions with marijuana. The plan must be approved by the board and the board must award funds to members of the consortium to perform research consistent with the plan.

**CS/CS by Innovation, Industry, and Technology on February 12, 2019:****The committee substitute for committee substitute (CS/CS):**

- Revises the definition of "marijuana delivery device" in s. 381.986(1)(g), F.S., to provide that delivery devices intended for the medical use of marijuana by smoking need not to be purchased from an MMTC.

- Prohibits the medical use of marijuana by smoking in an “enclosed indoor workplace” as defined in s. 386.203(5), F.S., of the Florida Clean Indoor Air Act.
- Amends the certification requirements in s. 381.986(4)(a)8.i., F.S., to narrow the two-physician requirement for certifying the use of marijuana by smoking to limit the requirement to patients under the age of 18 and who are not terminally ill. The CS/CS allows the certification of smoking for patients under the age of 18 if two physicians concur that smoking is the method of medical use that will be the most effective (rather than the only beneficial method) for the patient. The CS/CS requires the second physician be a pediatrician and deletes the requirement that the second physician be registered with the medical marijuana program.
- Amends s. 381.986(8)(e)12., F.S., to provides packaging and warning label requirements for medical marijuana intended for smoking.
- Amends s. 381.986(14)(b), F.S., to exempt a qualified patient and a qualified patient’s caregiver from the criminal prohibitions against the purchase and possession of a marijuana delivery by smoking device from a vendor other than an MMTC, if such device is specified in the patient’s certification issued by a qualified physician.
- Provides that s. 381.986, F.S., does not impair the ability of a private party to restrict or limit smoking on his or her private property.
- Provides that s. 381.986, F.S., does not prohibit the medical use of marijuana in a nursing home, hospice, or assisted living facility if the facility’s policies do not prohibit the medical use of marijuana.
- Repeals proviso language in the 2018 General Appropriations Act requiring that the DOH adopt all rules required under ss. 381.986, 381.987, and 381.988, F.S., solely and exclusively pursuant to ch. 120, F.S., as a condition for the release of specified reserved funds to the DOH.

**CS by Health Policy on February 4, 2019:**

The CS requires that, for a patient not diagnosed with a terminal condition, prior to issuing a certification in which the qualified physician intends to certify smoking, the certifying physician must determine that smoking is the only means of administering medical marijuana that is likely to benefit the qualified patient, and a second physician must concur with this determination. The second physician may not be registered with the DOH as a certifying physician for any qualified patients. Additionally, the bill adds that the risks specifically associated with smoking marijuana be included in the required informed consent that each patient must sign prior to being certified to receive medical marijuana.

**B. Amendments:**

None.