HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 7015 PCB HHS 19-01 Medical Use of Marijuana
SPONSOR(S): Appropriations Committee, Health & Human Services Committee, Rodrigues, Ray
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Orig. Comm.: Health & Human Services Committee	14 Y, 2 N	Royal	Calamas
1) Appropriations Committee	28 Y, 1 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, for a patient to obtain marijuana for medical use from a MMTC, the patient must obtain a physician certification from a qualified physician. 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 of the Board of Medicine and the Board of Osteopathic Medicine.

Current law prohibits possession, use, or administration of medical marijuana in a form for smoking and marijuana seeds or flower, except for flower in a sealed, tamper-proof receptacle for vaping. Current law prohibits the use of medical marijuana in public, except for the use of low-THC marijuana.

The bill allows smoking of medical marijuana only in the form of pre-rolled marijuana cigarettes dispensed by MMTCs. The bill imposes packaging and labeling requirements for pre-rolled marijuana cigarettes.

The bill establishes a process for physicians who wish to certify smoking as a route of administration for patients. The bill requires qualified physicians certifying smoking as a route of administration for a patient, other than a terminally ill patient, to submit certain documentation to the Board of Medicine or Board of Osteopathic Medicine. The bill prohibits smoking as a route of administration for patients under 18 years of age. The bill also requires the informed consent form provided to all patients include the negative health risks associated with smoking marijuana.

The bill eliminates the Coalition for Medical Marijuana Research and Education at the H. Lee Moffitt Cancer Center and Research Institute, Inc., and creates Consortium for Medical Marijuana Clinical Outcomes Research (consortium) consisting of public and private universities. The bill directs the Board of Governors to designate a state university to house the consortium. The bill directs the consortium to create a research plan that includes research on clinical outcomes, certification standards, dosing standards, routes of administration, efficacy, side effects, and the effects of smoking marijuana to treat debilitating medical conditions.

The bill has a significant negative fiscal impact on the Department of Health and on the state university designated by the Board of Governors to house the consortium. The bill appropriates $1.5 million in recurring General Revenue to the Board of Governors to implement the consortium. The bill appropriates to DOH $705,331 in recurring and $215,000 in nonrecurring trust fund authority to implement the bill.

The bill becomes effective upon becoming law.

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 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]. 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.
- The potential side effects of marijuana use.
- 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.

[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.

If a physician issues a physician certification for a patient diagnosed with a condition of the same kind or class as or comparable to one of the enumerated debilitating medical conditions, the physician must submit the following documentation to the applicable board within 14 days after issuing the certification:

- Documentation supporting the qualified physician's opinion that the medical condition is of the same kind or class as one of the debilitating medical conditions enumerated;
- Documentation that establishes the efficacy of marijuana as treatment for the condition.
- Documentation supporting the qualified physician's opinion that the benefits of medical use of marijuana would likely outweigh the potential health risks for the patient.
- Any other documentation as required by board rule.

MMTC Packaging and Labeling Requirements

Under current law, MMTCs must label all packaging of marijuana for medical use with the following information:

- Statement that cannabis meets testing and safety requirements;
- Name of MMTC;
- Batch number and harvest number of origin;
- Recommend dose;
- Name of physician who issued certification;
- Name of patient;
- Product name, if applicable;
- Dosage form;
- Concentration of THC and CBD;
- Warning transfer to another person is illegal; and
- Medical Marijuana Universal Symbol developed by the Department of Health (DOH).

In addition to the packaging and labeling requirements for all marijuana products, current law requires edibles be packaged in a plain, white receptacle with no images other than the MMTC's DOH-approved logo and the Medical Marijuana Universal Symbol established by DOH. Edible packaging must also contain a prominent and legible warning to keep away from children and pets, and a warning that the edible has not been produced or inspected pursuant to federal food safety laws.

Routes of Administration: Smoking Prohibition

Current law prohibits the possession, use, or administration of medical marijuana in a form for smoking or of marijuana seeds or flower, except for flower in a sealed, tamper-proof receptacle for vaping.[2] Current law prohibits the use of medical marijuana in public, except for the use of low-THC marijuana.

[2] This prohibition on smoking medical marijuana 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 prohibition on two counts:

- That the smoking prohibition impermissibly altered the definition of "marijuana" established in article X, section 29(b)(4), of the State Constitution, by excluding the right to possess forms of marijuana for smoking; and
- That article X, section 29, of the State Constitution, implicitly authorized smoking marijuana in a private place by allowing the prohibition of smoking in public. (See Complaint, case no. 2017-CA-1394, Florida Circuit Court for the Second Judicial Circuit, July 7, 2017).

On May 25, 2018, the Court issued an order agreeing with the plaintiffs on both counts and declaring the smoking ban unconstitutional. In her order, the Court found 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." (See Order and Final Judgement, case no. 2017-CA-1394, Florida Circuit Court for the Second Judicial Circuit, May 5, 2018, p. 21).

The only reference to smoking in the constitution is in the limitations section, which states:

> Nothing in this section shall require any accommodation of… smoking medical marijuana in any public place.[3]

This appears to be insufficient to create a right to smoke; rather, it appears to clarify that the constitution does not establish policy on public smoking, should smoking occur.

The prohibition on smoking medical marijuana was challenged in the Circuit Court for the Second Judicial Circuit on July 6, 2017. On May 25, 2018, the Court issued an order agreeing with the plaintiffs and declared the smoking ban unconstitutional. DOH appealed the ruling to the First District Court of Appeal on May 29, 2018. The appeal is ongoing; however, both parties filed a motion to stay the appeal until March 15, 2019, that was granted on January 24, 2019.[4]

Research on Smoking Marijuana

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

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.[5] 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 from the lungs.[6] This is likely because "THC is highly lipophilic, distributing rapidly to highly perfused tissues and later to fat."[7] The study also found that "a trial of 11 healthy subjects administered 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."[8] Additionally, there is evidence that the use of a cannabis preparation, such as would be delivered to the body by smoking cannabis, with multiple cannabinoids and terpenes, versus a single molecule preparation (with pure THC or CBD[9]) may be more effective in treating seizure disorders[10] and potentially breast cancer.[11]

However, smoking does not allow for accurate or consistent dosing measures.[12] Also, as with any smoked substance, smoking marijuana has inherent risks. 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

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[3] Fla. Const. article X, section 29(c)(6).
[4] Motion to Stay, case no. 1D18-2206, Florida First District Court of Appeal, Jan. 24, 2019.
[5] THC, or tetrahydrocannabinol, is the main active ingredient in cannabis and is responsible for most of the psychological effects of cannabis.
[6] Bridgeman MB, Abazia DT. Medicinal Cannabis: History, Pharmacology, and Implications for the Acute Care Setting. P T. 2017;42(3):180-188.
[7] Id.
[8] Id.
[9] CBD, or cannabidiol, is another cannabinoid that is found in cannabis. In the form of the drug Epidiolex CBD has been approved by the Federal Food and Drug Administration to treat two childhood seizure disorders, Dravet syndrome and Lennox-Gastaut syndrome. (see https://www.epidiolex.com/seizure-reduction-and-risk-information, last visited on Jan. 31, 2019). CBD does not have the same psychoactivity as THC.
[10] Russo EB. The Case for the Entourage Effect and Conventional Breeding of Clinical Cannabis: No "Strain," No Gain. Front Plant Sci. 2019;9:1969. Published 2019 Jan 9. doi:10.3389/fpls.2018.01969.
[11] 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
[12] Douglas C. Throckmorton, M.D., *Researching the Potential Medical Benefits and Risks of Marijuana*, Testimony before the U.S. Senate Subcommittee on Crime and Terrorism, July 13, 2016, available at: https://www.fda.gov/newsevents/testimony/ucm511057.htm (last visited February 9, 2019).

> 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.[13]

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 risk for cancer and lung disease. However, the association between smoking cannabis and the development of lung cancer is not decisive.[14]

A 1999 Institute of Medicine study concluded that smoked marijuana is a crude THC delivery system that delivers harmful substances.[15] The Institute of Medicine's study, which warned that smoking marijuana is harmful, was corroborated by a study published in the New England Journal of Medicine in 2014.[16] Smoking marijuana is associated with worse respiratory symptoms such as coughing, wheezing, and chest tightness and more frequent episodes of chronic bronchitis.[17] Marijuana smoke contains many of the same toxins as tobacco smoke, including those that cause cardiovascular disease.[18] A recent study found that one minute of exposure to second hand marijuana smoke diminishes blood vessel function to the same extent as second hand tobacco smoke, but the harmful cardiovascular effects last three times longer.[19]

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 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.

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[13] National Institutes of Health, 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).
[14] Ayan J., Rasche K. (2016) Damaging Effects of Cannabis Use on the Lungs. In: Pokorski M. (eds) Advancements in Clinical Research. Advances in Experimental Medicine and Biology, vol 952. Springer, Cham.
[15] Institute of Medicine, *Marijuana and Medicine: Assessing the Science Base*, The National Academies Press, 1999, available at http://www.nap.edu/catalog/6376/marijuana-and-medicine-assessing-the-science-base (last visited on February 9, 2019).
[16] 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 visited on February 9, 2019).
[17] The National Academies of Sciences, Engineering, and Medicine, *The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research* (2017), available at https://www.nap.edu/catalog/24625/the-health-effects-of-cannabis-and-cannabinoids-the-current-state (last visited on February 9, 2019).
[18] Wang, X., Derakhshandeh, R., Liu, J., Narayan, S., Nabavizadeh, P., Le, S.,Springer, M. L. (2016). *One Minute of Marijuana Secondhand Smoke Exposure Substantially Impairs Vascular Endothelial Function.* Journal of the American Heart Association: Cardiovascular and Cerebrovascular Disease, 5(8), e003858. http://doi.org/10.1161/JAHA.116.003858 (last visited on February 9, 2019).
[19] *Id.*

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.[20]

Regulation of Smoking Medical Marijuana in Other States

Regulation 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 minors 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.[21]

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 15th 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.

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.

Florida Clean Indoor Air Act (FCIAA)

The FCIAA prohibits smoking of tobacco in an enclosed indoor workplace, unless it is a:[22]

- Private residence that is not being used commercially to provide child care, adult care, or health care, or any combination thereof;
- Retail tobacco shop;
- Designated smoking guest room in a public lodging establishment;
- Stand-alone bar;[23]

[20] National Institutes of Health, 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-secondhandexposure-to-marijuana-smoke, (last visited on Jan 29, 2019).
[21] State-by-State Medical Marijuana Laws Report, Marijuana Policy Project, *available at* https://www.mpp.org/issues/medical-marijuana/state-by-state-medical-marijuana-laws/state-by-state-medical-marijuanalaws-report/ (last visited on Jan. 30, 2019).
[22] Ss. 386.204 and 386.2045, F.S. Additionally, s. 386.203(5)(c), F.S., by definition of an "enclosed indoor workplace," excludes 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.

- Smoking cessation program or medical or scientific research; or
- Customs smoking room in an airport.

However, an owner, lessee, or a person otherwise in control of an enclosed indoor workplace may further prohibit or limit smoking therein.[24]

Effect of the Bill

The bill allows smoking of medical marijuana in the form of pre-rolled marijuana cigarettes dispensed by MMTCs. The bill retains the ban on public use of medical marijuana in all forms, except for low-THC marijuana, but adds a prohibition on smoking low-THC marijuana in public. The bill prohibits smoking marijuana in an enclosed indoor workplace, consistent with the FCIAA. The bill also clarifies that it does not limit the ability of a private property owner to restrict or limit smoking on his or her private property. The bill also states that it does not prohibit the use of medical marijuana in a nursing home, hospice, or assisted living facility if the facility's policy does not prohibit its use.

The bill retains the ban on the sale of flower with the exception of flower in a sealed, tamper-proof receptacle and adds an exception for flower in pre-rolled marijuana cigarettes. The bill prohibits the use of wrapping paper made with tobacco or hemp.

Similar to the requirements for edible packaging under current law, the bill requires MMTCs package pre-rolled marijuana cigarettes in in a sealed, plain, opaque, white receptacle with a legible and prominent warning to keep away from children and a warning that states marijuana smoke contains carcinogens and may negatively affect health. The bill prohibits packaging with depictions of the product or images other than the medical marijuana treatment center's department-approved logo and the Marijuana Universal Symbol.

The bill requires qualified physicians certifying smoking as a route of administration for a patient, other than a terminally ill patient, to submit the following documentation to the applicable board:

- A list of other routes of administration, if any, certified by a qualified physician that the patient has tried, the length of time the patient used the route of administration, and an assessment of the effectiveness of those routes of administration in treating the patient's qualifying condition.
- Research documenting that smoking is an effective route of administration to treat the qualified patient's qualifying condition.
- A statement signed by the qualified physician supporting the physician's opinion that the benefits of smoking as a route of administration would likely outweigh the potential health risks for the qualified patient.

The bill requires the Board of Medicine and the Board of Osteopathic Medicine to create practice standards by rule for certifying smoking as a route of administration based upon review of the documentation submitted by the qualified physician. The boards must adopt such rules by July 1, 2021.

The bill prohibits a qualified physician from certifying smoking as a route of administration for a qualified patient under 18 years of age. The bill also requires the informed consent form provided to all patients include the negative health risks associated with smoking marijuana.

The bill eliminates the Coalition for Medical Marijuana Research and Education at Moffitt and creates the Consortium for Medical Marijuana Clinical Outcomes Research (consortium) consisting of public

[23] A stand-alone bar is a licensed premises that predominantly or totally serves alcoholic beverages and in which serving food is merely incidental to the sale of alcohol. Also, it must not share a common entryway or indoor area with a business that predominantly serves food during the hours the stand-alone bar is operating its business, s. 386.203(11), F.S. *See also* s. 561.695, F.S.

[24] FLA. CONST., art X, sec. 20(b).

and private universities. The bill requires the Board of Governors to designate a state university to house the consortium. The bill establishes the Medical Marijuana Research Board to direct the operations of the consortium. The bill directs the board to create a research plan that organizes a program of research to contribute to the body of scientific knowledge on the effects of the medical use of marijuana and informs both policy and practice related to the treatment of debilitating medication conditions. The bill requires research including tracking clinical outcomes, certification standards, dosing standards, routes of administration, efficacy, and side effects. Research must also include the study of the effects of smoking marijuana to treat debilitating medical conditions.

The board must issue a report by February 15th of each year to the Governor, President of the Senate, and Speaker of the House on research projects, research findings, community outreach initiatives, and future plans for the consortium. DOH must submit to the consortium a data set that includes, for each patient in the registry, the patient's qualifying medical condition, the daily dose amount, routes of administration and forms of marijuana certified for the patient.

The bill becomes effective upon becoming law.

B. SECTION DIRECTORY:

Section 1: Amends s. 381.986, F.S., relating to medical use of marijuana.
Section 2: Amends s. 381.987, F.S., relating to medical use of marijuana.
Section 3: Amends s. 1004.4351, F.S., relating to medical marijuana research and education.
Section 4: Provides appropriations.
Section 5: Providing an effective date upon becoming law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   DOH will incur costs associated with gathering and reviewing documentation provided to the Board of Medicine and Board of Osteopathic Medicine by qualified physicians certifying smoking as a route of administration for a patient. The Board of Medicine and Board of Osteopathic Medicine estimate four FTE and three OPS physician positions will be required to implement this provision. Resources provided in Chapter 2017-232, Laws of Florida (SB 8-A) for the OMMU are adequate to support the requested four FTE.

   DOH will incur information technology costs to update the Medical Marijuana Use Registry to reflect physicians certifying smoking as a route of administration and to update certification and dispensation records that will be provided to the Consortium for Medical Marijuana Clinical Outcomes Research.

   The below table provides a summary of the above costs.

Item	*Recurring*	*Nonrecurring*	*Total*
OPS	705,331		705,331
IT Updates		215,000	215,000
Total	$ 705,331	$ 215,000	$ 920,331

DOH will incur costs associated with enforcing MMTC compliance with the bill's requirements regarding smoking products, packaging, and labeling. Current resources provided for the enforcement of MMTC compliance can absorb this cost.

DOH will incur costs associated with rulemaking to create practice standards by rule for certifying smoking as a route of administration based upon review of the documentation submitted by the qualified physician. Current resources can absorb this cost.

The Board of Governors will incur costs associated with administering Consortium for Medical Marijuana Clinical Outcomes Research.

The bill appropriates $1.5 million in recurring General Revenue to the Board of Governors to implement the Consortium for Medical Marijuana Clinical Outcomes Research.

The bill also appropriates the following funds to DOH to implement the bill:

- $705,331 in recurring trust fund authority for three OPS physician positions to review the documentation for practice standards rule development.
- $215,000 in nonrecurring trust fund authority for information technology upgrades to the Medical Marijuana Use Registry.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

MMTCs will likely incur costs associated with meeting the packaging and labeling standards required by the bill.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

Current law provides sufficient rulemaking authority to DOH and the applicable boards to implement the requirements of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On February 12, 2019, the Health and Human Services Committee adopted an amendment and reported PCB 19-01 favorably as amended. The amendment:

- Removes the requirement for the Board of Medicine and Board of Osteopathic Medicine to create a Case Review Panel to approve smoking as a route of administration for a qualified patient.
- Removes the requirement for a qualified physician to obtain approval prior to certifying smoking for a qualified patient.
- Requires a qualified physician submit the documentation specified in the bill to the applicable board rather than the case review panel.
- Adds a requirement that the qualified physician sign the statement documenting the qualified physician's opinion that the benefits of smoking as a route of administration outweigh the risks for the qualified patient.
- Requires the Board of Medicine and Board of Osteopathic Medicine to create practice standards for certifying smoking as a route of administration based upon review of the submitted documentation. The board must adopt such rules by July 1, 2021.

On February 21, 2019, the Appropriations Committee adopted an amendment and reported HB 7015 favorably as amended. The amendment:

- Deletes the requirement that the pre-rolled marijuana cigarettes have a filter.
- Prohibits smoking marijuana in an enclosed indoor workplace.
- Clarifies that the bill does not limit the ability of a private property owner to restrict or limit smoking on his or her private property.
- Clarifies that the bill does not prohibit the use of medical marijuana in a nursing home, hospice, or assisted living facility.
- Requires the Board of Governors to designate the state university that will house the Consortium for Medical Marijuana Clinical Outcomes.
- Appropriates $1.5 million in recurring General Revenue to the Board of Governors to implement the Consortium for Medical Marijuana Clinical Outcomes Research.
- Appropriates to the Department of Health $705,331 in recurring trust fund authority for three OPS physician positions to review the documentation for practice standards rule development.
- Appropriates to the Department of Health $215,000 in nonrecurring trust fund authority for information technology upgrades to the Medical Marijuana Use Registry.

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