2018 Legislative Reports

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2018 Legislative Report: Medical Cannabis Advertising and Marketing Regulations

2018 Legislative Report: Treatment of Opioid Use Disorder with Medical Cannabis

2018 Legislative Report: Compassionate Use Fund Report

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December 31, 2018

The Honorable Thomas V. Mike Miller, Jr.
President of the Senate
H-107 State House
Annapolis, MD 21401-1991

The Honorable Michael E. Busch
Speaker of the House
H-101 State House
Annapolis, MD 21401-1991

RE: House Bill 2, Chapter 598 of the Acts of 2018, Section 12
2018 Legislative Report on Medical Cannabis Advertising and Marketing Regulations

Dear President Miller and Speaker Busch:

Pursuant to Section 12 of House Bill 2/Chapter 598 of the Acts of 2018, the Natalie M. LaPrade Medical Cannabis Commission (the "Commission") respectfully submits this report to the Maryland General Assembly on potential rules regulating the marketing and advertising of medical cannabis and medical cannabis products. Specifically, the Natalie M. LaPrade Medical Cannabis Commission Reform Act (the "Act") requires:

> *That, on or before January 1, 2019, the Natalie M LaPrade Medical Cannabis Commission shall report to the General Assembly, in accordance with § 2-1246 of the State Government Article, on potential rules and regulations governing marketing and advertising practices of entities licensed and certified by the Commission.*

The Commission appreciates your partnership and commitment to providing a safe, effective, and successful medical cannabis program for Maryland patients, providers, and businesses. If you have questions about this report, please contact Will Tilburg, JD, MPH, Director, Policy and Government Relations, at (410) 487-8069 or william.tilburg@maryland.gov.

Sincerely,

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Joy A. Strand, MHA
Executive Director

849 International Drive, Suite 450, Linthicu.m, Maryland 21090
Phone: 410-487-8100 • Fax: 443-681-1033
Website: www.mmcc.maryland.gov

cc: The Honorable Larry Hogan, Governor, State of Maryland
Brian Lopez, Chair, Maryland Medical Cannabis Commission
William C. Tilburg, Director, Policy and Government Relations, Maryland Medical Cannabis Commission
Sarah Albert, Mandated Reports Specialist, Department of Legislative Services

Legislative Report on Medical Cannabis Advertising and Marketing Regulations

Submitted by the Natalie M. LaPrade Medical Cannabis Commission

December 2018

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I. Introduction

House Bill 2/Chapter 598 of the Acts of 2018, Section 12, requires the Natalie M. LaPrade Medical Cannabis Commission (the "Commission") to submit a report to the Maryland General Assembly (the "General Assembly") on potential rules and regulations governing the advertising and marketing of medical cannabis in the State. In 2013, the General Assembly established the Commission to oversee the State's medical cannabis program and regulate the entities licensed to operate medical cannabis businesses. Health-General Article, §13-3301 *et seq.,* which authorizes the Commission to regulate the medical cannabis program does not include specific restrictions on cannabis advertising and marketing. Likewise, the Commission regulations promulgated in 2015, and codified in Code of Maryland Regulations (COMAR), Title 10, Subtitle 62, do not restrict cannabis advertising or marketing by certifying providers or licensed medical cannabis businesses.

In order to prepare a report on potential regulations governing the advertising and marketing of medical cannabis, the Commission took the following steps: (1) reviewed current Maryland law to identify any restrictions on advertising and marketing that would apply to certifying providers or licensed medical cannabis businesses, (2) evaluated laws and regulations governing cannabis marketing in other states, (3) developed draft proposals to regulate cannabis advertising and marketing by certifying providers and licensed medical cannabis businesses in Maryland, and (4) accepted written and oral public comment on proposed regulations governing advertising and marketing. This report summarizes the Commission's findings and the proposed regulations developed pursuant to the legislative mandate. Specifically, Section II reviews current advertising and marketing restrictions on certifying providers and medical cannabis businesses; Section III evaluates cannabis advertising and marketing restrictions in other states with medical cannabis programs; Section IV reviews advertising and marketing bills considered by the General Assembly during the 2018 legislative session; and Section V summarizes the steps taken by the Commission since HB 2 became effective on May 15, 2018.

II. CurrentLaw

Maryland has not adopted cannabis-specific advertising and marketing restrictions; however, certifying providers and licensed medical cannabis businesses are subject to current statutory and regulatory provisions governing the content, time, place, and manner of medical cannabis advertising, marketing, and promotion.

Oversight of Certifying Providers

The Health Occupations Article and the Maryland health occupations boards (which include the boards that oversee certified medical cannabis providers - the Maryland Board of Physicians, Maryland Board of Nursing, State Board of Dental Examiners, and State Board of Podiatric Medical Examiners.} restrict advertising and soliciting among all licensed health care providers in the State. For example, the Maryland Board of Physicians allows licensed physicians to advertise or promote their medical services, but these advertisements may not "mislead or deceive" patients,

include claims that are "likely to create false or unjustified expectations of favorable results" (e.g., "schedule an appointment and receive a medical cannabis certification"), or make any statement that cannot be verified for truthfulness by the Board. These restrictions also apply to any agent, partnership, organization, or professional association the physician may belong to, including their employer. The licensing board for each of the other certifying provider groups have adopted similar restrictions governing advertising, marketing, and promotion of professional services.

Consumer Protection Act

The Commercial Law Article, §§ 13-101 to 13-501 (the "Consumer Protection Act") prohibits false or misleading advertising, including unsubstantiated medical or therapeutic claims. The legal standard, established in *T-Up, Inc. v. Consumer Protection Div.,* 145 Md.App. 27 (2002), requires any medical or therapeutic claim to be substantiated by at least two adequate, well-controlled-double-blinded clinical studies. Medical cannabis businesses are subject to this legal standard and may only advertise or market medical claims if the claim is supported by multiple clinical studies.

The Consumer Protection Division at the Office of the Attorney General is responsible for enforcing the Consumer Protection Act and investigating consumer complaints. The division may attempt to reconcile the matter, issue a cease and desist order, or file a civil action in court. Any individual or entity who violates the Consumer Protection Act is subject to a fine of up to $1,000 for the first violation, and up to $5,000 for each subsequent violation. In addition, any individual who violates the Consumer Protection Act may be found guilty of a criminal misdemeanor, and subject to a fine ofup to $1,000, imprisonment for up to one year, or both.

The Bureau of Enforcement and Compliance (BEC) at the Commission is responsible for enforcing the Commission's regulations and otheiwise ensuring licensees comply with Maryland law. BEC investigators monitor licensee advertising and marketing practices and educate licensees on the legal standard for making medical or therapeutic claims. Any advertisement making unsubstantiated medical or therapeutic claims will be referred to the Consumer Protection Division for review.

Additional State and Local Advertising/Marketing Restrictions

A number of other Maryland laws governing advertising and marketing practices apply to certifying providers and medical cannabis businesses. Transportation Article §§ 8-701 to 8-752 prohibits outdoor advertising within a state highway right-of-way or on state property. This provision applies to road-side signs and similar advertising displays. Criminal Law Article §11-205 prohibits indecent or obscene advertising, including nude, partially nude, or sexually explicit advertising and marketing.

County and municipal ordinances and zoning regulations establish additional restrictions on outdoor advertisements on public property, and frequently limit the size and quantity of external signs. For instance, Baltimore County restricts advertising and signs on government property, rights-of-way, and within certain distances of schools and residential areas. County zoning ordinances also restrict the location and usage of illuminated signs.

State and local agencies are authorized to enforce these existing requirements, and may remove illegal medical cannabis advertisements, issue civil or criminal penalties, and/or suspend or revoke

a violator's license or permit. The State Highway Administration at the Maryland Department of Transportation and state and local law enforcement officials may remove and issue civil citations for illegal placement of signs on state property or a state right-of-way. Likewise, county and municipal officials may remove and issue citations for signs or advertisements violating local ordinances.

m. Laws in Other States

The Commission, in consultation with the Network for Public Health Law and the University of Maryland Francis King Carey School of Law conducted a survey of the advertising and marketing restrictions in 30 states and the District of Columbia that have implemented medical cannabis programs as ofJuly 1, 2018 (See Appendix A for the research materials). Of these jurisdictions, at least twenty-seven (27) have cannabis-specific advertising and marketing restrictions, and four (4) states - Hawaii, Louisiana, Montana, and Vermont - implemented a total ban on cannabis-related advertising. In addition, at least seven (7) states implemented bans on specific types of advertising, such as radio, television, print publication and billboards, while permitting other types of advertising and marketing practices (Delaware, Florida, Michigan, Minnesota, New Hampshire, North Dakota, and Ohio). Maryland is among the four (4) states that have not adopted any laws or regulations governing cannabis advertising and marketing.

Cannabis remains a Schedule I drug under the federal Controlled Substances Act (CSA), meaning it is illegal to manufacture, distribute, possess, or use cannabis. Due to the federal prohibition, and concerns sl.llTounding the promotion of youth use and illicit use, states generally restrict cannabis advertising and marketing more than other medical products. The types of advertising and marketing restrictions fall into three broad categories: (1) medium restrictions, (2) content restrictions, and (3) physical restrictions. Medium restrictions refer to laws and regulations governing the type of media where cannabis products and businesses may be advertised or marketed. Content restrictions are limitations on the substance or subject of the advertising (e.g. cartoon images, a cannabis leaf, or references to recreational use). Physical restrictions govern the location, size, and other physical characteristics of the advertisement. A brief summary of the medium, content, and physical restrictions adopted in other jurisdictions is included in Table 1 below.

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Jurisdiction	Citation	Restrictions
Alaska	Alaska Ad.min. Code tit. 3, § 306.360	Restrictions on the content and number of signs; proximity of advertising to schools and other youth-related facilities; websites must include verification that individuals are 21 years or older; at least 70% of advertising audience must be 21 years or older; requires warning labels.
Arkansas	006.02.7-17 Ark. Code R. § 17.1	Cultivation facilities may not advertise to the public; dispensaries may advertise to the public, but audience may not be more than 30% under the age of 18, ads must meet content restrictions (e.g. no cartoons) and include mandatory warnings.
California	Cal. Bus. & Prof. Code § 26150-26156 (2016)	May only advertise through media demonstrated to reach 71.6% or more of the audience who is **18** years or older; may not advertise near schools or on public property.
Colorado	Colo. Code Regs.§ 212-2	May only advertise through media demonstrated to reach 70% or more of the audience who is 18 years or older; ads must include warnings and may not be near schools.
Connecticut	Conn. Agencies Regs. § 21a-408-66(b)	State must approve aJl ads; restrictions on time, place, and manner of advertising; no false or misleading ads; no ads near schools or other youth facilities.
Delaware	Del. Code Ann. 16 § 4919A (2016)	No print or broadcast advertising is permitted; dispensaries may host websites and have on-site sie:ns.
District of Columbia	D.C. Mun. Regs. 22, § 5801 (2011).	Location, size, and content of signs restricted; no false or misleading statements.
Florida	Fla. Stat 381.986(h) (2017).	Advertising may not be visible to members of the public from any street, sidewalk, park, or other public place; may advertise on-line if aooroved by the health department.
Hawaii	Haw. CodeR. § 11-850-93 (2015)	No print, broadcast, or electronic advertising is permitted.
Illinois	Ill. Ad.min. Code tit. 68, § 1290.455	No advertising near schools or other youth-facilities, or on public property.
Louisiana	7 LA ADC Pt XLIX, § 2907	Businesses may not advertise through any public medium, including but not limited to new spapers, television, radio, internet, or any other means designated to market its products to the general public.
Maine	7-5 M.R.S § 417 (2018)	State licensing authority directed to adopt rules to prohibit certain types of advertising, including those likely to reach individuals under 21 years of age.

Massachusetts	935 Mass. Code Regs. 500.000	May only advertise through media demonstrated to reach 85% or more of the audience who is 21 years or older; may not advertise near schools or on public property.
Michigan	MI ADC R 333E-1.2018	Advertising may not be visible to the public from any street, sidewalk, park, or other public place.
Minnesota	MN ADC 4770 .0800	Advertising limited to on-site signs, a business website, and informational materials provided to patients.
Montana	Mont. Code Ann. § 50-46-341	Advertising is not permitted in any media, including electronic media.
Nevada	Nev Tax Com Erner. Reg July 2017; Nev. Rev. Stat. S453A	May not advertise in any publicatio n, or on radio, television, or any other medium if 30% or more of the audience is reasonably expected to be persons who are less than 21 years of age.
New Hampshire	NH ADC He-C 402.23	Advertising is prohibited except for certain on-site siims and a business website.
New Jersey	NJ. Admin. Code 8:64-12.1 (2011)	Dispensary signs must be restricted to black and white text and a certain size.
New York	N.Y. Comp. Codes R& Regs. tit. 10 1004.16 (2018)	Review and approval required by the health department prior to dissemination of any advertising. Restrictions on advertising content and location and warning statements required.
North Dakota	N.D. Admin. Code 33-44-01-23 (2018)	Medical cannabis businesses may advertise on signs and host a website. Advertising content is restricted to name, logo, contact information and cannabis strain information.
Ohio	Ohio Admin. Code 3796 (2017)	Businesses may not advertise on radio, television, billboards, or any public property.
Oregon	Or. Admin. R. 333-008-2070	Advertising may not make false or misleading claims, target children or youth, and must comply with warning statement requirements.
Pennsylvania	28 Pa. Code 1141.50	Advertising must comply with federal prescription drug regulations.
Vermont	VT ADC 17-2-3:6	May not advertise through any means including electronic means or social media
Washington	Wash. Rev. Code S 69.50.369; Wash. Admin. Code S 314-55-155	Outdoor advertising is restricted to signs near the retail location. Advertising may not target children or youth, be near youth facilities, or make false or misleading claims.
West Virginia	W. Va. C.S.R. §64-109-24	Advertising must comply with federal orescriotion drug regulations.

IV. 2018 General Assembly

During the 2018 legislative session, the General Assembly considered two bills governing cannabis advertising. House Bill 1348/Senate Bill 1078 proposed significant content and physical restrictions on cannabis advertising and marketing and would have required all medical cannabis

businesses and certifying providers to receive Commission approval before dissemination of the advertisement. HB 1348/SB 1078 were modeled after regulations adopted in Connecticut and New York, each of which have significantly more restricted programs with fewer licensees, providers, and patients than the Maryland program. HB 1348 received an unfavorable report from the House Health and Government Operations Committee (18-0) and the identical crossfiled bill, SB 1078, did not receive a vote in the Senate Finance Committee. House Bill 1366 proposed a ban on any advertising of a Schedule I controlled dangerous substance . Since cannabis remains a Schedule I controlled dangerous substance, medical cannabis businesses and certifying providers would have been prohibited from advertising, marketing or promoting their products or services. The bill received an unfavorab]e report (11-7) from the House Judiciary Committee.

V. Steps Taken by the Commission

Pursuant to Section 12 of House Bill 2/Chapter 598 of the Acts of 2018, the Commission researched and evaluated potential regulations governing the advertising and marketing of medical cannabis. As previously mentioned, at least 27 of the 31 states with medical cannabis and/or adult use cannabis programs as of July l, 2018, have laws and regulations restricting cannabis advertising and marketing. Maryland is among the four (4) states without cannabis-specific advertising and marketing restrictions.

On April 16, 2018, the Commission's Policy Committee held an open meeting where public comment was solicited on "information the Commission should consider in addressing medical cannabis advertising and marketing." Students from the University of Maryland School of Law presented research to the Policy Committee on advertising and marketing laws and regulations in other states and answered committee member questions on the topic. In addition, at least 10 members of the public, including patients, medical cannabis businesses, and certifying providers, testified on potential rules and regulations governing advertising.

Based on the research conducted by the University of Maryland School of Law and Commission staff, and public comment, the Commission developed proposed regulations governing advertising and marketing of medical cannabis products and services. The proposal allowed (1) certifying providers to advertise their ability to certify patients for medical cannabis, and (2) medical cannabis growers, processors, and dispensaries to advertise on radio and television or in print *if* "at least 85 percent of the audience is reasonably expected to be 18 years or older based on reliable audience composition data." On May 24, 2018, the Policy Committee heard public comment on the advertising proposal. Since a quorum of commissioners was not established at the meeting, the Policy Committee was unable to consider the advertising proposal. As a result, the Policy Committee held another open meeting to consider the advertising proposal on June 25, 2018. Written and oral public comment was again solicited at the meeting. The Office of the Attorney General testified on the Consumer Protection Act, and the evidentiary support needed to make a medical or therapeutic claim. Committee members expressed concern that the proposal allowed cannabis products and services to be advertised across media commonly viewed by children, including radio, television and print media. The Policy Committee noted that cannabis use remains illegal for 99.2% of Marylanders, and therefore that advertising and marketing may need to be further restricted to protect non-patients, particularly young children, from accessing cannabis advertisements.

Following the June 25 meeting, members of the Policy Committee worked closely with Commission staff to refine the proposal. On September 25, 2018, a revised proposal was considered by the Policy Committee. The revised proposal placed a prohibition on radio, television, and billboard ads, age restrictions on website and social media ads, and restricted print ads to publications where at least 85 percent of the audience is 18 years or older. In addition, the proposal prohibited advertisements on public property and required any cannabis advertising to include certain warnings. The Policy Committee voted unanimously to approve the proposed advertising regulations.

On September 27, 2018, the Commission solicited oral comment on the advertising proposal recommended by the Policy Committee. In addition, the Commission permitted written comment to be submitted on or before October 5, 2018. The proposal received more than 200 written submissions, the vast majority of which were from patients concerned that the proposal would prohibit social media advertising. Medical cannabis businesses and certifying providers also submitted comments expressing concerns that the proposal was too restrictive, and that the bans on radio, television, and billboard advertising would more appropriately be amended to content (e.g. no targeting children, using cartoon characters) and physical restrictions (e.g. 500 feet or more from a school or playground). Copies of the written submissions and a summary of the most common issues were shared with the Commissioners.

The Commission again introduced the advertising proposal at its open meeting held on December 6, 2018. Based on written and oral comment, Commissioners considered amendments to (1) clarify that the proposal does not prohibit social media advertising, (2) permit certifying providers to advertise consistent with the Health Occupations Article and the regulations promulgated by their licensing boards, and (3) regulate advertising by third-party vendors (e.g. secure medical cannabis transport companies). After deliberation, the Commission voted unanimously to approve the proposal with the three above-described amendments.

A copy of the proposed regulations approved by the Commission are attached to this report (See Appendix B). The Commission must now submit a copy of the draft regulations to the Joint Committee on Administrative, Legislative, and Executive Review (AELR) for consideration. AELR does not review regulatory proposals immediately before and during the beginning of the legislative session, so any regulatory proposals are put on "hold" during this period. This year, the hold period for submitting regulatory proposal to AELR extends from December 10, 2018 to February 11, 2019. The Commission will submit the proposed regulation to AELR after the hold period ends. Once submitted to AELR, the Commission must submit the proposal to the Division of State Documents for publication in the Maryland Register as a draft regulation. A 30-day comment period is required before the Commission may consider whether to move forward with a final regulation.

Table 2. Timeline of Events

Date	Action
May 15, 2018	House Bill 2 is signed by Governor Hogan. Section 12 of the Act required the Commission to submit a report on potential rules and regulations governing cannabis advertising and marketing.
April 16, 2018	Commission's Policy Committee solicits public comment on information related to potential regulations governing cannabis advertising and marketing.
May25,2018	Commission ' s Policy Committee solicits public comment on proposal regulating advertising by medical cannabis businesses and certifying providers.
June 24, 2018	Commission's Policy Committee solicits public comment on advertising proposal.
September 25, 2018	Commission's Policy Committee votes unanimously to approve advertising proposal.
September 27, 2018	Commission solicits public comment on advertising proposal aooroved by the Policy Committee.
December 6, 2018	Commission votes unanimously to approve proposal to rerulate cannabis advertising and marketing.

VI. Conclusion

Section 12 of House Bill 2/Chapter 598 of the Acts of2018 requires the Commission to submit a report on potential regulations governing cannabis advertising and marketing. In response, the Commission researched and evaluated the advertising laws and regulations in other states with medical cannabis and adult use cannabis programs. The research demonstrated that at least 27 out of 31 states, including the District of Columbia, restrict cannabis advertising and marketing. Of these, four states Hawaii, Louisiana, Montana, and Vermont, ban all cannabis-related advertising and marketing. An additional seven (7) states ban specific types of advertising, such as radio, television, billboards, or print. Based on this research, the Commission developed a proposal regulating cannabis advertising that is consistent with the vast majority of other jurisdictions and seeks to strike a balance between (1) allowing businesses to advertise their products and services and (2) protecting Marylanders, particularly young children, from being exposed to advertising for a product that is illegal at federal level and illegal for 99.2% of residents at the state level. The Commission solicited public comment on the proposal at four separate meetings, and modified the proposal based on the comments received from medical cannabis businesses, certifying providers, the Office of the Attorney General, and other interested persons. On December 6, 2018, the Commission voted unanimously to approve a regulatory proposal that would regulate advertising and marketing by medical cannabis businesses and certifying providers. The proposal will be submitted to AELR and the Division of State Documents for publication in the *Maryland Regi,ster* in February 2019, as required by law. Following a 30-day public comment the Commission may withdraw the draft regulations, amend the draft regulations, or submit the draft regulations for publication in the *Maryland Regi,ster* as a final regulation.

Appendix A

(See Next Page)

CONTENT RESTRICTION $ BIAS PHYSICAL

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MEDICAL CANNABIS
Environmental Scan

Medical Cannabis Advertising

This Environmental Scan analyzes the statutory and regulatory provisions related to advertising restrictions in the 30 states and the District of Columbia that have passed medical cannabis legislation. Nine states do not restrict cannabis advertisements; two states, Hawaii and Montana , prohibit all cannabis advertisements. This scan is broken up into broad categories of restrictions contained within the statutory or regulatory authority of the remaining 19 states and the District of Columbia, as they contain one or more of the following restrictions or requirements on cannabis advertisements.

1. Medium Restrictions

a. Radio/Television

Out of the 19 states and the District of Columbia that legalized medical cannabis, seven restrict television and radio advertisements. Five states limit these forms of advertisements to stations that reach primarily adults, with each state setting the percentage adult audience required. For example, California (71.6%), Nevada (70%), Colorado (70%), and Massachusetts (85%) require the designated percentage of the audience to be at least 21. Similarly, Arkansas prohibits radio or television advertisements unless the licensee has reliable evidence that at least 70% of the audience is reasonably expected to be at least 18. Ohio is the only jurisdiction that allows some advertising but prohibits all radio or television advertisements for cannabis. Pennsylvania requires cannabis advertisements to meet the federal regulations governing prescription drug advertising and marketing found in 21 C.F.R. 202.1(1)(1), which requires radio or television advertisements to include information relating to major side effects and contraindications of the drug.

b. Print

Seven states restrict print advertising. Five states restrict print advertisements to publications with a primarily adult audience. California (71.6%), Nevada (70%), Colorado (30%), and Massachusetts (85%) require the listed percentage of the audience to be at least 21. Arkansas prohibits print advertisements unless at least 70% of the audience is reasonably expected to be 18 years of age or older. Delaware explicitly prohibits print

advertisements for cannabis. Washington requires print advertising for cannabis to state that cannabis products may be lawfully purchased or possessed only by individuals 21 years of age or older.

c. Internet

Six states restrict internet advertisements. Four of those states prohibit advertising to minors via the internet in some capacity. Colorado (70%) and Massachusetts (85%) require a percentage of the audience to be at least 21. Arkansas requires at least 70% of the audience to be at least 18 for internet advertisements. Florida, whose regulations on internet advertising for medical cannabis are the most comprehensive compared to the other states, prohibits content that specifically targets individuals under the age of 18. Ohio explicitly prohibits internet advertisements for medical cannabis. California requires internet advertisements to display the license number of the licensee.

2. Content Restrictions

a. Children/Content Associated with Children

Out of the 19 states and the District of Columbia that legalized medical cannabis and have some advertising restrictions, more than half (14) restrict advertisements targeting children or content associated with children. While defining these restrictions is relatively consistent between the states, some jurisdictions have enhanced the definitions to include specifics such as cartoon characters and toys and to include catch all provisions prohibiting "any depiction otherwise attractive to a minor" (including Oregon, Ohio, Massachusetts, Alaska, Arkansas, and Colorado).

b. Statements Promoting Recreational Use/Non-Debilitating Medical Conditions

Five states and the District of Columbia prohibit advertisements from encouraging or promoting recreational use of cannabis or use for a non-debilitating medical condition. Two states, Florida and New York, prohibit advertisements that promote recreational use of cannabis. Ohio similarly prohibits advertisements from encouraging use of medical cannabis for a condition other than a qualifying medical condition. Connecticut prohibits both advertisements encouraging recreational use and advertisements encouraging use for a condition other than a qualifying medical condition. Arkansas has adopted slightly different language by prohibiting advertisements that encourage cannabis "for use as an intoxicant." The District of Columbia also utilizes alternative language by prohibiting advertisements that encourage use or purchase of medical cannabis "without a registration card."

c. Validity of Statements

Thirteen states and the District of Columbia restrict the content of statements within advertisements to insure all advertisements are accurate and valid. These states prohibit advertising statements that are "false", "misleading",and/or "deceptive." California goes further by defining what can create a misleading impression, such as ambiguity, omission or inference, or by the addition of irrelevant, scientific, or technical matters.

d Safety/Efficacy Claims

Five states prohibit statements on the safety and efficacy of medical cannabis in advertising. Three states, New York, Ohio, and Connecticut, prohibit advertisements containing claims related to the safety or efficacy of medical cannabis unless supported by substantial scientific evidence. The District of Columbia similarly prohibits statements as to health benefits. Colorado also prohibits establishments from engaging in advertising asserting its products are safe "because they are regulated by the State Licensing Authority."

e. Curative/Therapeutic Claims

Six states prohibit the use of curative or therapeutic claims in medical cannabis advertising, Alaska, Ohio, California, Massachusetts, Pennsylvania, and Oregon. California defines curative or therapeutic specifically as claims suggesting a relationship between medical cannabis consumption and purported health benefits. Additionally, Oregon and Massachusetts only allow for such claims if supported by substantial evidence or clinical data, including well-designed studies with significant scientific agreement among experts.

j Gifts/Prizes/Other Inducements

Seven states prohibit advertisements offering gifts, prizes, or other inducements relating to cannabis sales. Three states, Nevada, California and Colorado, prohibit advertisements offering "free" or "donated" medical cannabis. Additionally, Colorado, along with four other states, New York, Connecticut, Alaska, and Arkansas, prohibits advertising and marketing through promotional items including prizes; inducements; and coupons to certified patients, caregivers, or practitioners.

g. Product Warnings

Required warnings are laws that require advertisements to contain one or more of the following warnings: possible mental or impairment effects of consumption of cannabis, intoxicatingor addictive effects of cannabis, health risks associated with consumption of cannabis, and to keep out of the reach of minors (set at 18 or 21 depending on the state). These regulations only pertain to product warnings in advertisements and not product warnings on labels or otherwise required to be provided at time of sale.

Eight states require product warnings in advertisements. Model statutory language is typically split into two parts: first, a clause requiring the advertisement to contain certain language regarding use of cannabis; and second, specific warning statements. For example, in Arkansas and Oregon department regulations require: first, "Adve rtisingand marketing for medical cannabis shall include the following statements ... " and second, the following four specific warning statements:

1. Cannabis is for use by qualified patients only. Keep out of reach of children.
2. Cannabis use during pregnancy or breastfeeding poses potential harms.
3. Cannabis is not approved by the FDA to treat, cure, or prevent any disease.
4. Do not operate a vehicle or machinery under the influence of cannabis.

Nevada and Washington regulations are slightly different, requiring advertisements to contain only words or phrases stating that cannabis may only be purchased, possessed, or used by adults over the minimum sales age, and to keep out of reach of children. Those states do not require any of the health warnings other states impose.

3. Bias

a. Steering Toward/Away from Entities

Three states prohibit advertisements containing statements showing bias toward or against specific entities or providers. Both New York and Colorado prohibit statements within advertisements that have the "purpose or effect of steering or influencing patient or caregiver choice with regard" to the selection of a physician or certifying provider. Massachusetts similarly prohibits advertising that includes false or misleading statements concerning other licensees.

b. Steering Toward/Away from Products

Five states prohibit advertisements containing statements showing bias toward or against specific medical cannabis products or brands. Connecticut prohibits advertisements that have "the purpose or effect of steering or influencing patient or caregiver choice with regard to the selection" of a cannabis product. New York contains slightly different language, prohibiting advertisements that represent one cannabis brand as "better, more effective or useful" than other treatment options, including other brands, unless supported by substantial scientific or clinical experience. Additionally, Connecticut and New York further prohibit statements that falsely disparage competitors' products; Colorado, Ohio, and Massachusetts impose that same limitation.

4. Physical Restrictions

Twelve states and the District of Columbia regulate advertising in the physical space. Physical restrictions are typically restrictions on the proximity to schools, on public property or public transit, visibility by the general public, and the size of the sign. While not all jurisdictions restrict all of these aspects, a majority, eleven (11), restrict at least the visibility of signs to the general public. Model regulatory language is restrictive, with elements relating to each of the factors described below.

a. Signs within Close Proximity to Schools

Eight states restrict placement of any signs within 1,000 feet of the perimeter of a school or child-centered facility. Only one state, Ohio, restricts the distance to 500 feet. By administrative regulation, Nevada's Department of Taxation will not approve any alternative treatment centers that dispense medical marijuana within 1,000 feet of a school. Combined with restrictions on outdoor signage, Nevada imposes a de facto ban any advertisement within the proximity of a school. Some states, such as Washington, Alaska, and Ohio, expand the term "facilities" to include playgrounds, public parks, library, and game arcades.

b. Signs on Public Property/Transportation

Seven states prohibit sign placement on public property and public transit. Model regulatory language typically separates public property and public transit, although most states prohibit advertisements on both public property and public transit vehicles, if they restrict on one. Nevada only prohibits advertisements on public property in terms of schools, public parks, and libraries. All states prohibit advertisements on shelters used for public transportation and only three states prohibit advertisements on privately owned transit vehicles.

c. Signs Visible to General Public

Ten states and the District of Columbia regulate signs visible to or by the general public. These are predominantly signs that are on the exterior of buildings visible to the general public. Six states explicitly prohibit signs visible to the general public from a public right of way, such as a street, sidewalk, park, or other public place. Five states, and the District of Columbia, prohibit signs placed on the exterior of the building, regardless of their visibility by the general public.

d. Size/Other Features

Seven states and the District of Columbia restrict the physical characteristics of signage for medical cannabis advertisements. More than half of those jurisdictions (5) regulate the permitted size of signage: Alaska (<4,800 sq. inches), Arkansas (<36 sq. feet), Connecticut (<16"x18"), Ohio (<288 sq. inches), and Washington (<1,600 sq. inches). Five jurisdictions prohibit signs from being illuminated or neon, including the District of Columbia, Connecticut, New Jersey, Massachusetts, and Ohio. New Jersey differs by restricting signage to black text on a white background.

5. Requiring Commission Approval

Six states require licensed entities to submit to all advertisements to the department or board regulating the medical cannabis program. While some states delegate enforcement power to the board to review advertisements *post hoc,* only Connecticut, Florida, New York, North Dakota, Ohio, and Pennsylvania require approval of all advertisements before release to the public.

This document was developed by Tessa Devereaux and Hansi Wei, student attorneys, under the supervision of Kathleen Hoke, Professor and Director of the Network for Public Health Law - Eastern Region Office at the University of Maryland Carey School of Law. The Network for Public Health Law is a national initiative of the Robert Wood Johnson Foundation. The Network provides information and technical assistance on issues related to public health. The legal information and assistance provided in this document does not constitute legal advice or legal representation. For legal advice, please consult specific legal counsel

The Network for Public Health Law

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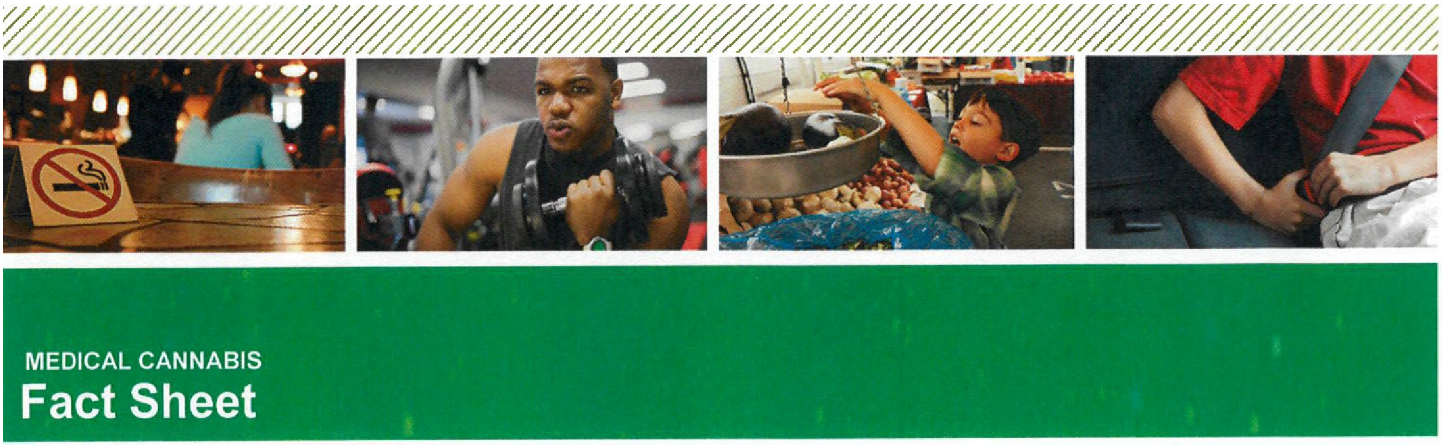

MEDICAL CANNABIS
Fact Sheet

Medical Cannabis Advertising

30 states and the District of Columbia have passed medical cannabis legislation.
19 states and the District of Columbia have laws on advertisements for medical cannabis.
9 states have no restrictions on medical cannabis advertising.
2 states have prohibit all medical cannabis advertising.
6 states require Commission approval of medical cannabis advertisements before release to the public.

Medium Restrictions - restricting or prohibiting advertisements in print, radio or television, or the internet.

- 7 states restrict advertisements in print or radio and television.
- 6 states restrict advertisements on the internet.

Content Restrictions - restricting, prohibiting, or requiring content within the advertisements.

- 13 states and the District of Columbia prohibit advertisements that depict children or use images, symbols, or other content associated with children.
- 13 states and the District of Columbia equate the validity of statements - prohibiting false, misleading, or untrue statements; and requiring data to support claims made.
- 7 states require mandatory warning statements in advertisements for medical cannabis.
- 6 states prohibit curative or therapeutic effects of medical cannabis; some permit with substantial clinical data in support of such statements.
- 4 states and the District of Columbia restrict safety and efficacy claims.
- 7 states prohibit advertising gifts, prizes, or other inducements containing marijuana.

Physical Restrictions - restricting or prohibiting placement or location of physical signs.

- 12 states and the District of Columbia prohibit or restrict signs from being visible to the general public.
- 7 states prohibit signs in physical proximity to the perimeter of a school.
- 7 states prohibit signs on public property.
- 7 states prohibit signs on public transit vehicles or shelters for public transit.
- 8 states restrict the physical dimensions of signs on the exterior of buildings.

Bias - restricting advertisements that state a bias for or against a competitor or a competitor's product.

- 3 states prohibit steering to or away from a dispensary or provider.
- 5 states prohibit steering to or away from a specific marijuana product.

SUPPORTERS

The Network for Public Health Law is a national initiative of the Robert Wood Johnson Foundation.

This document was developed by Tessa Devereaux, JD Candidate '19, and Hansi Wei, JD Candidate '19, at the University of Maryland Francis King Carey School of Law, with direction and assistance from Kathleen Hoke, JD, Director of the Network for Public Health Law - Eastern Region. *The Network for Public Health Law provides information and technical assistance on issues related to public health. The legal information and assistance provided in this document does not constitute legal advice or legal representation. For legal advice, please consult specific legal counsel.*

Robert Wood Johnson Foundation

AppendixB

(See NextPage)

Title 10

MARYLAND DEPARTMENT OF HEALTH

Subtitle 62 NATALIE M. LAPRADE MEDICAL CANNABIS COMMISSION

10.62.36 Advertising

.01 Advertising Restrictions.

A. No grower, processor, dispensary, independent testing laboratory, or third-party vendor authorized by the Commission may place or maintain, or cause to be placed or maintained, an advertisement for medical cannabis, medical cannabis products, or medical cannabis-related services on:

(1) Radio, television, or a billboard;

(2) A print publication, unless at least 85 percent of the audience is reasonably expected to be 18 years of age or older, as determined by reliable and current audience composition data;

(3) Public property;

(4) A handbill, leaflet, or flyer directly handed, deposited, fastened, or otherwise distributed on:

(a) Public property; or

(b) Private property without the consent of the owner; or

(5) Any website, mobile application, social media, or other electronic communication that fails to employ a neutral age-screening mechanism that the user is at least 18 years of age, including an age-gate, age-screen, or age-verification mechanism.

B. Certifying Provider.

(1) A certifying provider may advertise the certifying provider's ability to certify a qualifying patient to receive medical cannabis.

(2) An advertisement by a certifying provider shall comply with COMAR 10.32.0l.13(b).

C. An advertisement for a grower, processor, dispensary, independent testing laboratory, certifying provider, or third-party vendor may not make any statement that is false or misleading in any material way or is otherwise a violation of Commercial Law Article,§§ 13-301-13-320, Annotated Code of Maryland.

D. All advertising/or medical cannabis or medical cannabis products shall include:

(1) A statement that the product is for use only by a qualifying patient;

(2) A warning that there may be health risks associated with consumption of the medical cannabis or medical cannabis product; and

(3) Any other warnings required by the commission.

MARYLAND MMCC

Natalie M. LaPrade
Maryland Medical Cannabis Commission

Maryland Medical Cannabis Commission

LEGISLATIVE REPORT

TREATMENT OF OPIOID USE DISORDER

WITH MEDICAL CANNABIS

Joy A. Strand, MHA
Executive Director
Maryland Medical Cannabis Commission

Larry Hogan, Governor Boyd R. Rutherford, Lieutenant Governor Robert R. Neall, Secretary of Health

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MARYLAND MMCC
Natalie M. LaPrade
Maryland Medical Cannabis Commission

I. BACKGROUND

Pursuant to Section 13 of House Bill 2/Chapter 598 of the Acts of 2018, the Natalie M. LaPrade Medical Cannabis Commission (the "Commission") is mandated to submit this report on the treatment of opioid use disorder by using medical cannabis. This reporting requirement emerges as states grapple to find new ways to mitigate the increasingly grim and destructive consequences of the opioid epidemic.

The term "opioids" encompasses a wide range of drugs, including prescription pain relievers such as codeine, morphine, oxycodone, and hydrocodone, and illicit drugs heroin and fentanyl. The U.S. Centers for Disease Control and Prevention (CDC) warns that fentanyl is up to 50 times more potent than heroin and 50 to 100 times more potent than morphine.[1] In 2016, more than 42,000 Americans died from opioid-related overdoses, a 67% increase from 2014 (28,000). At least one-half of the total opioid-related deaths involve a prescription opioid. CDC data show that from 1999 to 2016, more than 200,000 individuals died in the U.S. from prescription opioid-related overdoses. Overdose deaths involving prescription opioids were five times higher in 2016 than in 1999.[2] In addition, data from the Substance Abuse and Mental Health Services Administration (SAMHSA) indicate that dependence on, or abuse of, prescription opioid pain relievers is the single greatest risk factor for heroin or fentanyl abuse or dependence.

Through the first six months of 2018, opioid-related overdoses in Maryland accounted for 1,185 deaths, which represents a 15% increase compared over the same period in 2017. (Attachment A) Maryland saw 153 more opioid-related deaths during the first six months of 2018 than the first six months of 2017. (Attachment B) Moreover, Maryland has experienced an alarming escalation in opioid-related deaths during the past five years – 888 (2014); 1,089 (2015); 1,856 (2016); 2,009 (2017); and 1,185 (YTD 2018 through June). (Attachment C) In 2018 alone, Maryland has seen 199 prescription opioid-related intoxication deaths, 469 heroin-related intoxication deaths, and 1,038 fentanyl-related intoxication deaths through June. There have been 133 more heroin-related deaths and 917 more fentanyl-related deaths when compared to death tolls from January through June of 2015. See the Maryland Department of Health data here.

Overdose is not the only way in which opioid drugs are threatening public health. Misuse and opioid use disorder (OUD) are among the fastest growing and monumental problems facing our nation. The CDC estimates that prescription opioid sales nearly quadrupled from 1999 to 2010, without an overall change/increase in the amount of pain reported by Americans.[3] Between 2007 and 2012, over 40% of all alcohol- and drug-related overdose deaths in Maryland involved one or more prescription opioids according to Maryland Department of Health data. In 2017, there was

[1] Algren D, Monteilh C, Rubin C, et al. *Fentanyl-associated Fatalities Among Illicit Drug Users in Wayne County, Michigan.* Journal of Medical Toxicology. March 2013: 9(1):106-115.
[2] Seth P, Rudd R, Noonana, R, Haegerich, T. *Quantifying the Epidemic of Prescription Opioid Overdose Deaths.* American Journal of Public Health, March 2018; 108(4), el-e3.
[3] Reiman, A, Welty, M, Solomon, P. *Cannabis as a Substitute for Opioid-Based Pain Medication: Patient Self-Report.* Cannabis Cannabinoid Res. 2017. 2(1): 160-166. Published online Jun 1 doi: 10.1089/can.2017.0012.

an estimated 49,198 Maryland residents age 12 and older who were taking opioids or suffering from an opioid use disorder.

Increasingly states are looking to medical cannabis as a tool in the fight against the nation's opioid epidemic. These policy discussions stem largely from the growing evidence base that cannabis may be an effective and a safer alternative for pain treatment. Recent data also indicate that implementation of medical cannabis laws is associated with a reduction in opioid prescriptions among Medicaid and Medicare enrollees, and that states with medical cannabis programs experience fewer opioid overdose deaths.[4][5]

Consequently, policymakers are considering cannabis not only as an alternative pain treatment to opioids, but as an opioid replacement therapy for OUD to help ease withdrawal symptoms and aid in relapse prevention. Continued high rates of opioid overdose deaths necessitate effective interventions, which may include cannabis use. Legislation authorizing cannabis-related OUD treatment has been introduced in at least seven states and passed in Hawaii, Maine, and New Mexico (before being struck down by Governor veto). A hurdle consistent among the states that have considered such legislation is the overriding concern that high-quality clinical research on the use of cannabis to combat OUD is first needed to better inform these important policy discussions.

II. MEDICAL CANNABIS IN THE TREATMENT OF OPIOID USE DISORDER

Opioid use disorder is a broad term used to describe opioid dependence and addiction. The *Diagnostic and Statistical Manual of Mental Disorders*, Fifth Edition, (DSM-5) defines OUD by evaluating the number of diagnostic criteria an individual meets. Specifically, opioid use disorder applies to a person who (1) uses opioids (illicit or prescription) and (2) experiences two or more of the following symptoms in a 12 month period:

- Taking more opioids than intended
- Wanting or trying to control opioid use without success
- Spending a lot of time obtaining, taking, or recovering from the effects of opioids
- Craving opioids
- Failing to carry out important roles at home, work, or school because of opioid use
- Continuing to use opioids despite relationship or social problems
- Giving up or reducing other activities because of opioid use
- Using opioids even when it is unsafe
- Knowing that opioids are causing a physical or psychological problem, but using them anyway
- Tolerance to opioids
- Withdrawal symptoms when opioids are not taken

[4] Wen H, Hockenberry JM, *Association of Medical and Adult-Use Marijuana Laws with Opioid Prescribing for Medicaid Enrollees,* JAMA Intern Med. 2018;178(5):673-679.doi: 10.1001/jamainternmed. 2018. 1007.
[5] Bradford AC, Bradford WD, Abraham A, Bagwell Adams G. *Association Between US State Medical Cannabis Laws and Opioid Prescribing in Medicare Part D Population. JAMA Intern. Med.* 2018; 178(5):667-672. Doi:10.1001/jamainternalmed.2018.0266.

Support for Treatment of OUD with Medical Cannabis

There is mounting anecdotal evidence from patients and caregivers who have provided testimony in the states that have considered adding OUD for treatment with medical cannabis suggesting that medical cannabis may offer an effective tool for lowering opioid withdrawal cravings and addressing many withdrawal symptoms individuals in recovery experience, including nausea, diarrhea, muscle spasms, insomnia, and anxiety. Patients report that cannabis promotes restful sleep and helps reduce the intensity of cravings. It may also pose less of a risk than existing FDA-approved opioid-based treatments (methadone, buprenorphine, and naltrexone) since FDA-approved medications that are used in any manner other than prescribed can increase the risk of addiction and overdose.[6] Further, there is anecdotal evidence that patients receiving medication for OUD have been shown to have better treatment outcomes when they are also able to access medical cannabis.[7] Individual providers have testified to observing high-dose opiate patients eliminate or reduce use of opiates through the use of medical cannabis.

Recent animal models suggest that cannabinoids may have long-lasting therapeutic effects relevant to OUD.[8][9][10] Cannabinoids are a class of active chemical compounds produced by the cannabis plant. A specific cannabinoid, cannabidiol, has been seen to reduce heroin cravings in animals and appears to restore some of the neurobiological damage induced by opioid use.[11] A small pilot, conducted by Dr. Yasmin L. Hurd, PhD, of the Friedman Brain Institute, Departments of Psychiatry and Neuroscience, Icahn School of Medicine at Mount Sinai Center for Addictive Disorders in New York City and her colleagues mirrored these findings. In the study, cannabidiol helped heroin users abstaining from use relieve anxiety related to cravings.[12] Proponents suggest cannabis extracts may reduce cravings and ease withdrawal symptoms in heroin users, but these claims are largely unproven in clinical trials.

Advocates also point to the substantial challenges many patients face in accessing medication-assisted treatment (MAT) (counseling combined with one of the three FDA-approved medications for OUD) for opioid use disorders as a reason to support allowing cannabis to treat OUD. Issues related to insurance coverage, provider availability, and access to treatment facilities remain considerable barriers to traditional OUD treatment options.

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[6] Lucas et al. *Substituting Cannabis for Prescription Drugs, Alcohol and Other Substances Among Medical Cannabis Patients: The Impact of Contextual Factors*. Drug and Alcohol Review, 2016; 35: 326-333.
[7] Degenhardt L, Lintzeris N, Campbell G, et al. *Experience of Adjunctive Marijuana Use for Chronic Non-cancer Pain: Findings from the Pain and Opioids IN Treatment (POINT) Study.* Drug Alcohol Depend. 2015;147:44-150.
[8] Gamage et al. *Differential Effects of Endocannabinoid Catabolic Inhibitors on Morphine Withdrawal in Mice.* Drug and Alcohol Dependence, 2015 January 1; 146: 7-16.
[9] Manwell and Mallet. *Comparative Effects of Pulmonary and Parenteral Δ^9 –Tetrahydrocannabinol (THC) Exposure on Extinction of Opiate-induced Conditioned Aversion in Rats*. Psychopharmacology, 2015 May; 232(9):1655-65.
[10] Ramesh et al. *Blockade of Endocannabinoid Hydrolytic Enzymes Attenuates Precipitated Opioid Withdrawal Symptoms in Mice.* The Journal of Pharmacology and Experimental Therapeutics, 2011; Vol. 339, No. 1.
[11] Hurd, et al. *Cannabidiol, a Nonpsychotropic Component of Cannabis, Inhibits Cue-induced Heroin Seeking and Normalizes Discrete Mesolimbic Neuronal Disturbances*, The Journal of Neuroscience, 2009, 14764-14769.
[12] Hurd, et al. *Early Phase in the Development of Cannabidiol as a Treatment for Addiction: Opioid Relapse Takes Initial Center Stage,* Neurotherapeutics, 2015 October; 12(4): 807-815.

Opposition to Treatment of OUD with Medical Cannabis

A comprehensive review of existing medical literature shows that there is no credible scientific evidence backing up the claims that cannabis is beneficial in treating addiction, and that there is some evidence suggesting that it may exacerbate substance use and dependency issues.[13] Although there is limited human-subject research on the treatment of OUD with medical cannabis, the studies have not been widely accepted within the medical establishment and leading addictions organizations due to their limited scope and underlying methodology.[14][15][16] In contrast, decades of high quality clinical research conclusively demonstrates that medication assisted treatment (MAT) combined with social support is an effective treatment for OUD.[17][18][19][20][21][22][23][24]

Health care providers and health care organizations, particularly addiction specialists, maintain strong opposition to treating OUD with medical cannabis. During the committee hearings on Senate Bill 181 and House Bill 268 which were introduced during Maryland's 2018 legislative session and would have added OUD as a qualifying condition for treatment with medical cannabis, leading professional addiction societies in Maryland issued forceful statements opposing medical cannabis as an OUD treatment. Of primary concern is the absence of high-quality clinical research involving humans that demonstrates cannabis may be an effective treatment for OUD. Due to the lack of scientific evidence, the potential of medical cannabis to prevent opioid misuse, mitigate withdrawal symptoms, and reduce the likelihood of relapse is unknown. Rigorous human clinical trials that quantitatively measure the effectiveness of medical cannabis therapy for reducing opiate dependency are needed.

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[13] Olfson M, Wall mm, Liu S-M, Blanco C. *Cannabis Use and Risk of Prescription Opioid Use Disorder in the United States.* Am J Psychiatry. 2017; 175(1): 47-53. doi:10.1176/appi.ajp.2017.17040413.

[14] Reiman, Amanda, Welty, Mark, Solomon, Perry. *Cannabis as a Substitute for Opioid-Based Pain Medication: Patient Self-Report.* Cannabis and Cannabinoid Research, Volume 2.1. doi: 10.1089/can.2017.0012.

[15] Degenhardt L, Lintzeris N, Campbell G, et al. *Experience of Adjunctive Marijuana Use for Chronic Non-cancer Pain: Findings from the Pain and Opioids IN Treatment (POINT) Study.* Drug Alcohol Depend. 2015; 147:44-150.

[16] Haroutounian S, Ratz Y, Ginosar Y, et al. *The Effect of Medicinal Marijuana on Pain and Quality of Life Outcomes in Chronic Pain: A Prospective Open-label Study.* Clin J Pain. 2016; 32:1036-1043.

[17] Reed K, Day E, Keen J, et al. *Pharmacological Treatments for Drug Misuse and Dependence*. Expert Opin Pharmacother. 2015;16:325–333.

[18] Kosten TR, O'Connor PG. *Management of Drug and Alcohol Withdrawal.* N Engl J Med. 2003;348:1786–1795.

[19] Copenhaver MM, Bruce RD, Altice FL. *Behavioral Counseling Content for Optimizing the Use of Buprenorphine for Treatment of Opioid Dependence in Community-based Settings: a Review of the Empirical Evidence.* Am J Drug Alcohol Abuse. 2007;33:643–654.

[20] Montoya ID, Schroeder JR, Preston KL, et al. *Influence of Psychotherapy Attendance on Buprenorphine Treatment Outcome.* J Subst Abuse Treat. 2005;28:247–254.

[21] Bart G. *Maintenance Medication for Opiate Addiction: the Foundation of Recovery*. J Addict Dis 2012; 31(5): 207–25.

[22] 12 Volkow ND, Frieden TR, Hyde PS, Cha SS. *Medication-assisted Therapies—Tackling the Opioid-overdose Epidemic.* N Engl J Med 2014; 370: 2063–6

[23] Mattick RP, Breen C, Kimber J, Davoli M. *Methadone Maintenance Therapy Versus No Opioid Replacement Therapy for Opioid Dependence.* Cochrane Database Syst Rev 2009;(3): CD002209.

[24] Weiss RD, Potter JS, Fiellin DA, et al. *Adjunctive Counseling during Brief and Extended Buprenorphine-Naloxone Treatment for Prescription Opioid Dependence: A 2-Phase Randomized Controlled Trial.* Arch Gen Psychiatry 2011; 68: 1238–46.

Opponents of treating OUD with medical cannabis include:

- American Society of Addiction Medicine (ASAM) (the oldest and largest medical specialty organization in the U.S., representing over 5,500 physicians and other providers who specialize in addiction treatment)
- Maryland-DC Society of Addiction Medicine (MDDCSAM)
- Maryland Affiliate of the National Council on Alcoholism and Drug Dependence (NCADD-Maryland)
- Maryland Association for the Treatment of Opioid Dependence (MATOD)
- National Council on Alcoholism and Drug Dependency (NCADD)
- National Institute on Drug Abuse (NIDA)

Further, there may be dangers to exposing individuals with substance use disorders or substance dependence to another intoxicating substance, which could create yet another drug dependency. Dr. Leah Bauer of the Maine Association of Psychiatric Physicians and the Addiction Resource Center at Mid Coast Hospital stated in a petition to the Maine State Legislature that using medical cannabis to treat OUD would encourage individuals with substance use disorders or substance dependence to use another toxic and habit-forming substance. The petition stated that adding OUD as a qualifying condition would be asking Maine to embark on an experiment the best medical science does not support.

III. LAWS IN OTHER STATES

The alarming and continued rise in the opioid overdose death rate, and the estimated 2.1 million Americans suffering from OUD underscores the need for effective OUD treatments. Policymakers in several states have identified medical cannabis as a potential alternative to FDA-approved medication assisted treatments in addressing OUD. Since 2016, at least nine states have considered legislation or regulations to allow medical cannabis as an opioid replacement therapy to help ease withdrawal symptoms and aid in relapse prevention. The following is a summary of the legislative and regulatory proposals considered in other states to allow medical cannabis in the treatment of OUD.

A. States Permitting Treatment of OUD with Medical Cannabis

In 2018, Pennsylvania, New Jersey, and New York became the first states to expressly allow medical cannabis for the treatment of OUD. Each state permits the use of medical cannabis to treat OUD, but with significant restrictions. A brief summary of the laws and programs is included below.

Pennsylvania

The Pennsylvania Department of Health promulgated temporary regulations to permit the use of medical cannabis to treat OUD on May 17, 2018, based on the recommendation of the State's Medical Marijuana Advisory Board. The regulations permit physicians to make medical cannabis available to patients only if all other traditional treatments are tried first and fail, or if the medical cannabis is used in conjunction with traditional therapies. Pennsylvania Secretary of Health Dr. Rachel Levine emphasized that "It's important to note that medical cannabis is not a

substitute for proven treatments for opioid use disorder." Critical to the Department's decision was that the state statute restricts clinical research to qualifying medical conditions. Therefore, only by adding OUD to the list of qualifying medical conditions could the Department authorize certified research centers in the State to initiate clinical trials on the use of cannabis to treat OUD.

The Pennsylvania Department of Health approved eight local universities as Certified Academic Clinical Research Centers to begin research on medical cannabis in May 2018. The universities include:

- Drexel University College of Medicine, Philadelphia
- Lewis Katz School of Medicine at Temple University, Philadelphia
- Penn State College of Medicine, Hershey
- Sidney Kimmel Medical College at Thomas Jefferson University, Philadelphia
- Perelman School of Medicine at the University of Pennsylvania, Philadelphia
- University of Pittsburgh School of Medicine, Pittsburgh
- Lake Erie College of Osteopathic Medicine (LECOM), Erie
- Philadelphia College of Osteopathic Medicine, Philadelphia

According to Pennsylvania Governor Tom Wolfe the "research component of Pennsylvania's medical marijuana program sets it apart from the rest of the nation." Due to federal restrictions on cannabis research, only a small number of physicians have access to cannabis for clinical trials. By adding OUD to the list of qualifying medical conditions the State's medical schools are positioned to conduct critical clinical research on the effectiveness of cannabis to treat certain medical conditions, including OUD.

New Jersey

In March of 2018, New Jersey expanded the list of qualifying conditions under the State's medical cannabis program. Included among the five new categories of conditions was "chronic pain related to musculoskeletal disorders." The condition includes any petitions that fall within this category. Subsequently, the Department of Health granted a petition seeking to add OUD (Medical Marijuana Petition (MMP)-063) as a qualifying medical condition, *if* the disorder results from the treatment of chronic pain with opioids under the category titled "chronic pain related to musculoskeletal disorders. The approved petition to add opioid use disorder may be viewed at https://www.nj.gov/health/medicalmarijuana/documents/petitions/MMP-063.pdf.

New York

On July 12, 2018, the New York State Department of Health filed emergency regulations adding "any condition for which an opioid could be prescribed" as a qualifying condition for medical cannabis. Effective immediately, registered practitioners may certify patients to use medical cannabis as a replacement for opioids, provided that the precise underlying condition for which an opioid would otherwise be prescribed is stated on the patient's certification. This allows patients with severe pain that does not meet the definition of chronic pain to use medical marijuana as a replacement for opioids. In addition, the regulation adds opioid use disorder as an associated

condition. However, the regulations only allow a patient with opioid use disorder to use medical cannabis as an opioid replacement if the patient is enrolled in a certified treatment program.

New York State Health Commissioner Dr. Howard Zucker noted that research indicates that marijuana can reduce opioid use and therefore has the potential to save countless lives. Opioid use disorder joins the list of 12 other qualifying conditions, including cancer, HIV, Parkinson's disease, multiple sclerosis, and epilepsy. In a press release following the emergency regulations the Department of Health indicated that "marijuana can be an effective treatment for pain, greatly reduces the chances of dependence, and eliminates the risk of fatal overdose compared to opioid-based medications." Moreover, the agency pointed to studies of states with medical cannabis programs that have found "notable associations of reductions in opioid deaths and opioid prescribing with the availability of cannabis products."

B. States Rejecting Treatment of OUD with Medical Cannabis

From 2016-2018, at least seven state legislatures considered bills that would expressly add OUD to the list of medical cannabis qualifying conditions. Of these, the majority rejected the legislation seeking to add OUD to the list of qualifying conditions. As previously stated, three states – Hawaii, Maine, and New Mexico – passed legislation authorizing the use of medical cannabis to treat OUD; however, the State's Governor vetoed the legislation in each instance following significant pressure from health care providers, health care organizations, and addiction specialists. A brief summary of each bill is included below.

Arizona

House Bill 2508 would have added opioid use disorder to the list of conditions for which medical cannabis may be prescribed in the State. The bill received a public hearing, but the overseeing committee did not hold a vote. The bill would have required at least a three-fourths majority in each house of the legislature to become law.

Hawaii

Hawaii has one of the lowest opioid prescribing rates in the country, according to National Institute on Drug Abuse. The State's opioid overdose death rate is less than half of the national average. Nonetheless, the number of opioid-related overdoses deaths has increased in recent years.

In July 2018, Hawaii Governor David Ige vetoed Senate Bill 2407, which would have allowed for the use of medical cannabis "to treat opioid use, substance use, and withdrawal symptoms resulting from the treatment of those conditions." SB 2407 moved through Hawaii's legislative process quickly with overwhelming support from lawmakers. Governor Ige vetoed the legislation on the grounds that the Department of Health in Hawaii already has the ability to add new qualifying conditions for medical cannabis treatments. Patients and physicians can initiate the formal petition process annually. The evidence-based process allows caregivers and patients to apply to add new conditions, including opioid use and withdrawal symptoms.

Maine

Maine has one of the highest opioid overdose death rates in the U.S. From 2012 to 2016, the number of opioid-related overdose deaths increased 400 percent, which is significantly higher than the national average. In April of 2016, Maine became the first state to formally consider medical cannabis in the treatment of OUD. In response to a petition submitted by caregivers in the State, health regulators convened to hear testimony on a proposal to make opioid use disorder a qualifying condition for the use of medical cannabis.

Four physicians, accompanied by medical cannabis patients and caregivers, testified in support of the proposal. The patients and caregivers presented personal experiences of using medical cannabis to prevent the development of a tolerance to opioids, and to eliminate the need for increased dosages of opioid medication. Patient testimony also suggested that the use of medical cannabis eased opioid-related withdrawal symptoms. Conversely, Maine's medical establishment, including representatives from the substance use disorder prevention community, expressed strong opposition to the proposal. The chief concern presented by opponents was the lack of scientific research indicating that cannabis is an effective OUD treatment. Some supporters of the petition acknowledged the lack of rigorous scientific evidence due to the continued Schedule I status of the drug under the federal Controlled Substances Act. After substantial deliberation, review of public testimony and written comments, and further consultation with physicians, the Department of Health rejected the petition to permit medical cannabis in the treatment of OUD.

In 2018, the Maine State Legislature passed a bill that would have permitted the use of medical cannabis for any medical reason. The bill, which had strong bipartisan support among state legislators, was originally introduced to permit the use of medical cannabis to treat OUD. In July 2018, Maine Governor Paul LePage vetoed the bill, largely for reasons unrelated to OUD. The bill will return to the Maine legislature for consideration of a veto override.

Maryland

As previously mentioned, during the 2018 legislative session, the Maryland General Assembly considered two bills – Senate Bill 181 and House Bill 268 – that would have added OUD as a qualifying condition for treatment with the use of medical cannabis. Both bills received an initial hearing, but only HB 268 was scheduled for a vote. The House and Government Operations Committee unanimously voted unfavorably on the bill. Representatives from numerous leading professional addictions organizations in Maryland strongly opposed the bills due to insufficient evidence of the efficacy of treating OUD with medical cannabis.

Massachusetts

In 2017, the State legislature in Massachusetts (the Massachusetts General Court) introduced H. 1050, which directed the Department of Public Health to establish a pilot program for veterans to use medical marijuana to treat medical conditions that are currently being treated with opioid-based medication and combat opioid use disorder. The bill was introduced through a public petition process. A hearing was held, but no vote was taken on the bill.

New Mexico

On September 7, 2018, New Mexico Department of Health Secretary Lynn Gallagher rejected (for the second time) a recommendation from the board of medical professionals to add opioid use disorder to the list of the State's 21 qualifying conditions. The measure was rejected due to lack of medical evidence on cannabis as a treatment for opioid addiction. The Department reasoned that clinical studies have not shown the use of medical cannabis to treat OUD to be safe or effective. It was noted, however, that in April 2017, two faculty members at University of New Mexico released findings from a study they conducted in which they observed that patients who used medical cannabis reduced their opioid use by 31%, while the control group saw a slight increase in overall opioid use.

In April 2017, New Mexico Governor Susana Martinez vetoed House Bill 527, which would have added 14 qualifying conditions to the medical cannabis program, including OUD. Governor Martinez vetoed the bill because the Department of Health and the Medical Cannabis Advisory Board were authorized to expand the qualifying conditions, and the legislative action circumvented this process and the expertise of the Department and the Board. Governor Martinez stressed that maintaining the integrity of New Mexico's medical marijuana program was vital.

New York

During the 2018 legislative session, the New York State Assembly introduced two cross-filed (identical) bills, Assembly Bill 9016 and Senate Bill 7564, which sought to add OUD to the list of conditions covered for lawful use of medical cannabis. Neither bill was passed. AB 9016 passed the Assembly but was referred to the Rules Committee in the Senate, and SB 7564 did not receive a hearing.

C. Need for Clinical Research

A review of the legislative and regulatory proposals in other states, and SB 181 and HB 268 in Maryland, underscore the need for high-quality clinical research on the effectiveness of medical cannabis to treat OUD. Adding OUD as a qualifying condition absent substantial clinical research on the effectiveness and safety of medical cannabis as a treatment presents significant public health and safety concerns. As such, the U.S. Centers for Disease Control and Prevention (CDC), the National Institute on Drug Abuse (NIDA), the American Society of Addiction Medicine (ASAM), the National Council on Alcoholism and Drug Dependency (NCADD), and many other medical and addiction organizations oppose adding OUD as a qualifying condition without objective data.

The continued federal prohibition on cannabis hinders clinical research on cannabis. Due to its Schedule I status cannabis products are not tested for safety and effectiveness like FDA-approved medications; measured and dosed like food products; subjected to agricultural-safety and pesticide standards like crops; and held to labeling standards like alcohol. In August 2016, the U.S. Drug Enforcement Administration (DEA) denied two petitions to re-schedule cannabis as a less dangerous drug under the Controlled Substances Act. Cannabis remains a Schedule I controlled substance because there is no accepted medical use, and it has a high potential for abuse. Schedule I is the most restrictive category for law enforcement purposes and includes heroin and LSD. Other

highly addictive substances such as oxycodone and methamphetamine are classified as Schedule II drugs, and therefore may be prescribed in limited circumstances.

Nonetheless, the DEA and FDA acknowledge that more research is needed on the medical effectiveness of cannabis, and each has begun to loosen the restrictions on cannabis research. Previously, the University of Mississippi, operating under a contract with the National Institute on Drug Abuse (NIDA), was the only entity authorized to cultivate cannabis for research purposes in the United States. In the future, additional entities may apply to grow and distribute cannabis for FDA-authorized research purposes. DEA currently has 350 individuals registered to conduct research on cannabis and its components. Notably, DEA has approved every application for registration submitted by researchers seeking to use NIDA-supplied marijuana to conduct research that the U.S. Department of Health and Human Services (HHS) determined to be scientifically meritorious.

IV. EFFORTS TO REDUCE NUMBER OF OPIOID PRESCRIPTIONS

Over-prescribing is a key factor in the opioid epidemic in Maryland and across the country. Prescription drug sales nearly quadrupled from 1999 to 2010, while the percent of Americans reporting acute and chronic pain was constant. Concurrently, heroin-related deaths more than tripled between 2010 and 2014. The opioid epidemic has fueled a spike in fatal and non-fatal drug overdoses, and claimed the lives of 2,009 Marylanders last year, up from 888 in 2014 and 529 in 2011.

Opioid use disorder or opioid dependence often begins with treatment of acute pain. To address this danger, the CDC Guidelines for Prescribing Opioids for Chronic Pain issued in March of 2016, suggest that "when opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed." CDC experts noted that each day of unnecessary opioid use increases the likelihood of physical dependence without adding any benefit.

Based on this growing body of evidence, legislators in Maryland have sought to modify provider prescribing habits. In 2017, the Maryland General Assembly enacted legislation limiting the initial length of opioid prescriptions. Health Occupations Article, §1-223, Annotated Code of Maryland requires that for the treatment of pain, a health care provider shall prescribe the lowest effective dose of an opioid and in a quantity that is no greater than the quantity needed for the expected duration of pain severe enough to require an opioid. In addition, when a patient is prescribed an opioid, the patient must be advised of the benefits and risks associated with the drug.

Local hospitals and health care providers have also taken steps to curb opioid prescriptions. Johns Hopkins Hospital established opioid prescribing guidelines for patients following 20 common surgeries, which reduce the length of opioid prescriptions in most cases. The guidelines were published in the Journal of the American College of Surgeons on August 14, 2018. (See https://www.journalacs.org/article/S1072-7515(18)31129-3/pdf) The guidelines recommend one to 15 oxycodone 5-mg tablets for 11 of the 20 procedures, 16 to 20 for six of the procedures, and no opioids for the remaining three procedures. In implementing the guidelines the hospital noted

that reducing the amount of opioids prescribed is critical because surgery is a common way in which individuals are initially exposed to opioids and 1 in 16 surgical patients eventually become long-term users after surgery.[25]

V. THE ROLE OF MEDICAL CANNABIS IN THE OPIOID EPIDEMIC

Chronic pain is among the most widespread and costly medical conditions, impacting over 100 million Americans and with total direct and individual costs of up to $635 billion per year.[26] Data suggest that cannabis legalization reduces prescription opioid use by serving as an alternative pain treatment. Medical cannabis laws may also have downstream policy effects on reducing opioid-related hospitalizations, overdose deaths, and traffic fatalities. The following section examines existing literature on the association between medical cannabis and opioid use, including as a treatment for opioid use disorder.

A. Medical Cannabis as an Alternative Pain Treatment

Identifying alternative pain treatment options is critical to reducing the number of opioid-related overdose deaths and the prevalence of opioid use disorder and dependence. In 2016, the U.S. Surgeon General issued a first-ever report on drug addiction, which concluded that evidence-based harm reduction approaches are cost effective and successful at reducing opioid-related hospitalizations, deaths, and traffic fatalities. Recent data indicate that cannabis is an effective and safer alternative for pain treatment. The National Academies of Sciences, Engineering, and Medicine (NAM) found "conclusive or substantial evidence" from randomized controlled trials to support its findings that cannabis is effective for the treatment of chronic pain in adults. The implementation of medical cannabis laws is also associated with significant decreases in opioid prescriptions among Medicaid and Medicare enrollees. These findings are briefly summarized below.

- **States with laws legalizing medical cannabis experienced 24.8% fewer opioid-related overdose deaths between 1999 and 2010**. The study compared the mean annual opioid overdose mortality rate between states with medical cannabis laws and states without medical cannabis laws. From 1999-2010, 13 states enacted medical cannabis laws (California, Oregon, Washington, Alaska, Colorado, Hawaii, Maine, Michigan, Montana, Nevada, New Mexico, Rhode Island, and Vermont). Analyzing the opioid-related overdose deaths in each state following implementation of the medical cannabis laws showed that medical cannabis laws were associated with a lower rate of overdose-deaths. *See* M.A. Bachhuber, et al., *Medical Cannabis Laws and Opioid Analgesic Overdose Mortality in the United States, 1999-2010,* JAMA Intern Med. 2014;174(10):1668–1673. doi:10.1001/jamainternmed.2014.4005.

[25] Brummett CM, Waljee JF, Goesling J, et al. *New persistent opioid use after minor and major surgical procedures in US adults*. JAMA Surg 2017; 152:e170504.

[26] Pergolizzi J. Boger RH, Budd K, et al. Opioids and the management of chronic severe pain in the elderly: consensus statement of an International Expert Panel with focus on the six clinically most often used World Health Organization Step II opioids (buprenorphine, fentanyl, hydromorphone, methadone, morphine, oxycodone). Pain Pract. 2008;8(4):287-313.

- **Strong evidence exists to support the conclusion that cannabis effectively treats chronic pain in adults**. The 2017 report issued by NAM reviewed observational and clinical studies conducted since 1999. The comprehensive literature review concluded that cannabis is effective at treating chronic pain in adults. *See* The National Academies of Sciences, Engineering, and Medicine, *The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research*, National Academies Press, 2017, *available* at http://www.nap.edu/24625.
- **Medical cannabis patients report using medical cannabis as a substitute for prescription drugs**. A self-selected convenience sample of 2,774 individuals who have used cannabis at least once in the past 90 days were surveyed for responses on effectiveness of medical cannabis to treat pain. Nearly 1 in 2 (46%) reported using cannabis as a substitute for prescription drugs, with opioids being the most common class of drugs substituted (35.8%). The patient-reported outcomes support prior research that individuals are using cannabis as an opioid substitute. See J.M Corroon et al., *Cannabis as Substitute for Prescription Drugs – A Cross-Sectional Study*, Journal of Pain Research, 2017. https://doi.org/10.2147/JPR.S134330.
- **Evidence suggests cannabis may be an effective alternative to opioid analgesics for cancer-associated chronic and neuropathic pain**. A review of clinical studies from 1975-2014 indicates that medical cannabis reduces chronic and neuropathic pain in advanced cancer patients do not respond well to opioid analgesics. See A. Blake et al., *A Selective Review of Medical Cannabis in Cancer Pain Management*, Ann Palliat Med., 2017:

B. Association Between Cannabis Legalization and Opioid Prescribing Among Medicaid and Medicare Enrollees

Implementation of medical cannabis laws is associated with a reduction in the number of opioid prescriptions among Medicaid and Medicare enrollees. In 2018, two highly-publicized cross-sectional studies concluded that implementation of state medical cannabis programs was associated with a significant decrease in the rate of opioid prescribing among each population. The findings of each study are summarized below.

Medicaid

States with medical cannabis and adult-use cannabis laws have lower opioid prescribing rates. From 2011-2016, state implementation of medical cannabis laws was associated with a 5.88% lower rate of opioid prescribing (95% CI, -11.55% to -.21%). A cross-sectional study compared opioid prescribing rates among Medicaid enrollees between states that started to implement medical and adult-use cannabis laws between 2011 (the first year of the mandatory data reporting requirements under the Affordable Care Act) and 2016, and the rest of the country.[27]

During this period, an estimated one-third of opioid prescriptions were misused or abused, of which Medicaid had a disproportionately large share. Medicaid/low-income adults included in the Medicaid expansion are shown to have disproportionately high risks for chronic pain, as well

[27] Wen H, Hockenberry JM. *Association of Medical and Adult-Use Marijuana Laws with Opioid Prescribing for Medicaid Enrollees*. JAMA Intern Med. 2018;178(5):673–679. doi:10.1001/jamainternmed.2018.1007.

as opioid use disorder and overdose. Implementation of medical and adult-use marijuana laws was associated with a lower Medicaid-covered opioid prescribing rate.

Among the eight states that implemented medical cannabis laws during the study period (2011-2016), one-half (Delaware, Massachusetts, Minnesota and New Hampshire) had significantly lower opioid prescribing rates. Maryland was among the states that did not have statistically significant changes in opioid prescribing rates. However, the medical cannabis program did not become operational in Maryland until December 1, 2017. This means that implementation of the State law was outside the scope of the data analyzed in this study.

Medicare

In August 2018, a cross-sectional study published in *JAMA Internal Medicine* found that the use of all pain medications, including opioids, decreased among Medicare Part D enrollees following implementation of state medical cannabis laws.[28] Medicare Part D is an optional prescription drug benefit plan that covers more than 42 million Americans age 65 years or older. This population uses prescription drugs at significantly higher rates than the overall adult population, and is among the fastest growing populations using medical cannabis.

The study reviewed the total number of daily opioid doses in each state from 2010 to 2015. During this period there were on average more than 23 million daily doses of any opioid dispensed per year in each U.S. state. Utilizing multiple regression analyses found that Medicare enrollees in states with medical cannabis laws filled significantly fewer daily doses of opioids than Medicare enrollees in other states. States with medical cannabis dispensaries experienced 3.742 million fewer daily doses (95% CI, -6.289 to -1.194). This represents a 14.4% decrease in the use of prescription opioids in states with medical cannabis dispensaries.

Summary

Each study suggests that implementation of medical cannabis laws may reduce opioid prescribing and daily use. However, neither study evaluated whether individuals were switching from prescription opioids to medical cannabis or whether any individuals used medical cannabis to treat OUD. Additional research is needed to determine whether there is a causal relationship between medical cannabis laws and reductions in prescription opioid use.

To this end, a study was published in the "To the Editor" section of *JAMA Internal Medicine* in September 2018, which found that the opioid-related overdose death rate was accelerating in states where medical and/or adult use cannabis laws had been implemented.[29] Moreover, the death rate surpassed that of nonlegalizing states. The study reviewed opioid-related overdose death data from 2010 to 2016, and determined that the age-adjusted death rate was higher in states with cannabis legalization and that the age-adjusted death rate was increasing at a faster rate than in non-legalizing states. While several researchers have challenged the methodology of

[28] Bradford AC, Bradford WD, Abraham A, Bagwell Adams G. *Association Between US State Medical Cannabis Laws and Opioid Prescribing in the Medicare Part D Population*. JAMA Intern Med. 2018;178(5):667–672. doi:10.1001/jamainternmed.2018.0266.

[29] A. Bleyer and B. Barnes, *Opioid Death Rate Acceleration in Jurisdictions Legalizing Marijuana Use*, JAMA Internal Med. 2018:178(9):1280-1281.

this study – including the inaccurate assessment of states that have legalized medical and adult-use cannabis – the results call attention to the need for further investigation of the association between cannabis legalization and opioid-related overdose deaths.

VI. CONCLUSION

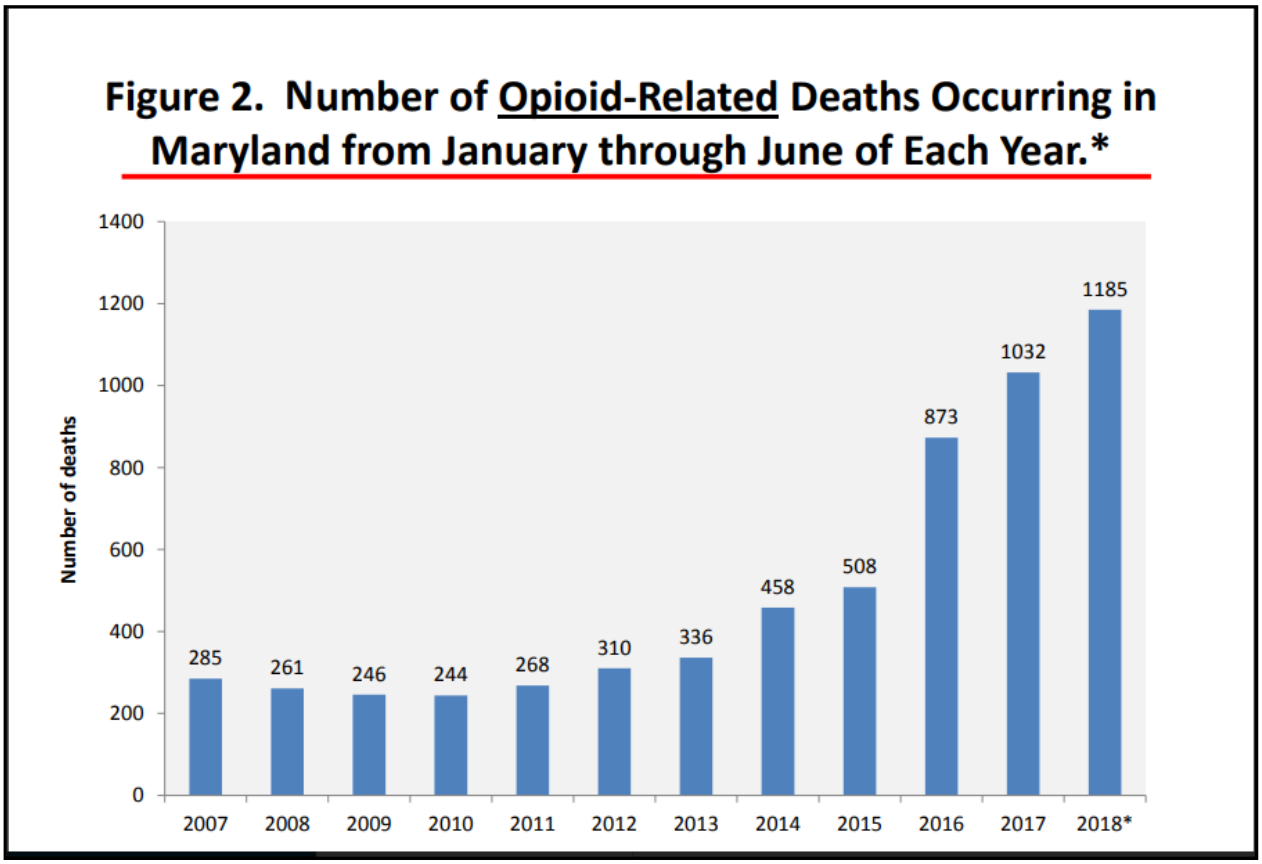
Maryland Health-General Article §13-3304 establishes certain qualifying medical conditions for which the Maryland Medical Cannabis Commission ("the Commission) may authorize medical providers to certify patients to obtain medical cannabis. The list of qualifying medical conditions includes: cachexia, anorexia, wasting syndrome, severe or chronic pain, severe nausea, seizures, and severe or persistent muscle spasms. In addition, the statute authorizes the Commission to approve applications for "any other condition that is severe and for which other medical treatment have been ineffective if the symptoms reasonably can be expected to be relieved by the medical use of cannabis."

Pursuant to this statutory authority, the Commission added glaucoma and post-traumatic stress disorder (PTSD) to the list of qualifying medical conditions through its regulations under COMAR 10.62.03.01. The Commission also allows each provider who registers with the Commission to treat other severe conditions for which traditional treatments have proven ineffective. In order to certify for a medical condition outside the list of expressly authorized conditions, the provider must include the medical condition as part of the provider's registration with the Commission. Subsequently, certifying providers may certify patients to obtain medical cannabis to treat OUD under the current regulatory system. While it is not listed among the qualifying medical conditions, a certifying provider may treat OUD with medical cannabis if in their professional judgment the condition is (1) severe, (2) other treatments such as FDA-approved MAT has been ineffective, and (3) the symptoms reasonably can be expected to be relieved by the use of medical cannabis.

The Commission's regulations establish that any person may submit a petition to add a medical condition or disease to the list of qualifying conditions codified in COMAR 10.62.01. In December 2018, the Commission received two petitions requesting the addition of OUD to the list of medical cannabis qualifying conditions. If the Commission determines that either or both of these petitions are "facially substantial" then it must conduct a public hearing within the next 12 months to evaluate whether the medical condition or disease should be included in the list of qualifying conditions. The Commission's Research Committee, which includes two physicians, a scientist, addiction specialist, and horticulturist, is currently evaluating the petitions to determine whether they are facially substantial and require a public hearing. The Commission will provide the General Assembly with updates on the status of the OUD petitions, including information on any public hearings to consider adding OUD as a qualifying medical condition.

ATTACHMENT A

Note: Maryland saw 1,185 opioid-related deaths during the first six months of 2018.



ATTACHMENT B

Note: Maryland saw 153 more opioid-related deaths during the first six months of 2018 compared to the first six months of 2017.

Table 2. Comparison of Opioid-Related Intoxication Deaths[1,2] by Place of Occurrence, Maryland, January -- June, 2018[3] and 2017.

Jurisdiction	Opioid Intoxication Deaths		2018 vs 2017
	Jan. - Jun. 2018	Jan. - Jun. 2017	# DIFFERENCE
Maryland Total	1185	1032	153
Allegany	16	26	-10
Anne Arundel	129	102	27
Baltimore City	442	358	84
Baltimore County	194	163	31
Calvert	11	9	2
Caroline	3	4	-1
Carroll	46	26	20
Cecil	32	23	9
Charles	8	16	-8
Dorchester	4	6	-2
Frederick	44	34	10
Garrett	2	2	0
Harford	46	50	-4
Howard	21	28	-7
Kent	1	1	0
Montgomery	41	44	-3
Prince George's	51	63	-12
Queen Anne's	4	4	0
Somerset	5	1	4
St. Mary's	16	16	0
Talbot	3	7	-4
Washington	44	25	19
Wicomico	14	15	-1
Worcester	8	9	-1

[1]Includes deaths that were the result of recent ingestion or exposure to any opioid, prescribed or illicit.

[2]Includes only deaths for which the manner of death was classified as accidental or undetermined.

[3]Counts for 2018 are not complete.

ATTACHMENT C

Table 6. Number of Opioid-Related Intoxication Deaths[1,2] by Place of Occurrence, Maryland, 2007-2017 and YTD 2018 Through June.[3]

Jurisdiction	Opioid Intoxication Deaths											
	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018 YTD
Maryland Total	628	523	570	504	529	648	729	888	1,089	1,856	2,009	1,185
Allegany	12	7	6	11	8	10	11	11	20	55	36	16
Anne Arundel	54	57	45	44	53	68	67	85	89	169	198	129
Baltimore City	256	154	199	139	142	189	212	275	354	628	692	442
Baltimore County	95	92	83	95	93	104	125	146	195	305	323	194
Calvert	12	6	11	4	10	11	5	16	19	25	27	11
Caroline	0	2	1	2	8	4	2	7	3	9	8	3
Carroll	12	15	16	12	7	27	21	29	34	44	51	46
Cecil	23	9	21	21	24	22	22	25	26	28	57	32
Charles	8	9	10	9	10	12	9	16	17	36	34	8
Dorchester	2	3	1	6	2	5	5	0	1	5	10	4
Frederick	12	7	18	12	28	23	33	34	37	80	66	44
Garrett	0	2	3	1	1	0	4	2	4	0	4	2
Harford	24	31	28	38	28	32	34	38	45	76	93	46
Howard	14	13	11	9	18	17	26	18	25	40	47	21
Kent	2	4	2	3	1	0	4	3	3	4	4	1
Montgomery	35	29	31	25	28	36	40	53	59	84	91	41
Prince George's	27	33	38	27	24	30	38	48	45	106	124	51
Queen Anne's	4	2	3	4	4	2	7	9	4	6	6	4
Somerset	5	3	2	1	3	2	4	2	4	6	3	5
St. Mary's	3	9	7	10	6	9	10	8	12	13	33	16
Talbot	3	3	2	2	1	3	6	4	5	10	8	3
Washington	11	21	14	13	16	20	26	34	57	63	51	44
Wicomico	6	7	10	10	10	17	14	15	17	44	28	14
Worcester	8	5	8	6	4	5	4	10	14	20	15	8

[1]Includes deaths that were the result of recent ingestion or exposure to prescription and illicit opioids.

[2]Includes only deaths for which the manner of death was classified as accidental or undetermined.

[3]Counts for 2018 are not complete.

ATTACHMENT D

Table 8. Number of Fentanyl-Related Intoxication Deaths[1,2] by Place of Occurrence, Maryland, 2007-2017 and YTD 2018 Through June.[3]

Jurisdiction	Fentanyl Intoxication Deaths											
	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018 YTD
Maryland Total	26	25	27	39	26	29	58	186	340	1,119	1,594	1,038
Allegany	3	0	1	2	1	1	1	1	5	29	29	13
Anne Arundel	3	5	3	5	2	3	6	23	29	98	152	108
Baltimore City	3	2	4	4	2	4	12	72	120	419	573	414
Baltimore County	6	9	9	6	4	5	11	36	65	182	244	168
Calvert	0	1	1	0	1	0	0	5	2	11	22	10
Caroline	0	0	0	1	4	0	0	0	1	3	7	3
Carroll	0	2	0	2	0	1	2	4	11	20	40	35
Cecil	2	1	0	2	2	0	0	1	7	9	44	27
Charles	0	0	0	0	1	1	3	1	4	17	26	7
Dorchester	0	0	0	2	0	0	2	0	1	3	7	3
Frederick	0	0	0	2	3	1	2	6	11	49	49	42
Garrett	0	1	0	0	1	0	0	0	2	0	2	1
Harford	1	1	0	3	2	1	1	2	16	46	73	38
Howard	1	0	0	0	0	2	3	5	7	27	36	19
Kent	0	0	0	0	0	0	0	1	0	3	3	1
Montgomery	2	0	1	1	0	2	0	8	17	43	72	26
Prince George's	1	0	2	2	0	1	6	7	15	58	103	41
Queen Anne's	1	0	0	0	0	0	1	1	0	4	5	4
Somerset	1	1	0	1	0	0	2	0	1	6	3	5
St. Mary's	0	0	1	1	1	0	1	3	3	4	26	14
Talbot	1	1	0	1	0	1	0	2	2	7	3	3
Washington	0	0	0	2	1	1	4	1	14	31	39	37
Wicomico	1	1	3	1	1	4	1	7	1	34	24	11
Worcester	0	0	2	1	0	1	0	0	6	16	12	8

[1]Includes deaths that were the result of recent ingestion or exposure to prescription or illicit fentanyl.

[2]Includes only deaths for which the manner of death was classified as accidental or undetermined.

[3]Counts for 2018 are not complete.

MARYLAND MMCC
Natalie M. LaPrade
Maryland Medical Cannabis Commission

December 11, 2018

The Honorable Larry Hogan
Governor
State of Maryland
Annapolis, MD 21401-1991

The Honorable Thomas V. Mike Miller, Jr.
President of the Senate
H-107 State House
Annapolis, MD 21401-1991

The Honorable Michael E. Busch
Speaker of the House
H-101 State House
Annapolis, MD 21401-1991

RE: Health-General Article, §13-3303.1(f), Natalie M. LaPrade Medical Cannabis Compassionate Use Fund

Dear Governor Hogan, President Miller, and Speaker Busch:

Pursuant to Health-General Article, §13-3303.1(f), Annotated Code of Maryland, the Natalie M. LaPrade Medical Cannabis Commission (the "Commission") respectfully submits this legislative report on the revenue necessary to implement the Natalie M. LaPrade Medical Cannabis Compassionate Use Fund (the "Compassionate Use Fund"). Specifically, the enclosed report evaluates:

1. The revenues the Commission anticipates are necessary to implement the program;
2. The types of funding mechanisms that may be used to implement the program; and
3. Any anticipated savings in prescription drug costs for the Maryland Medical Assistance Program that would result from the provision of medical cannabis under this Subtitle.

The Commission appreciates your commitment to providing a successful yet consumer-friendly medical cannabis industry in the State, and ensuring that patients have affordable and adequate access to medical cannabis. If you have questions about this report, please contact Will Tilburg, JD, MPH, Director, Policy and Government Relations, at (410) 487-8069 or william.tilburg@maryland.gov.

Sincerely,

Joy A. Strand, MHA
Executive Director

849 International Drive, Suite 450, Linthicum, Maryland 21090
Phone: 410-487-8100 • Fax: 443-681-1033
Website: www.mmcc.maryland.gov

cc: Brian Lopez, Chair, Maryland Medical Cannabis Commission
Robert R. Neall, Secretary, Maryland Department of Health
Webster Ye, Deputy Chief of Staff, Maryland Department of Health
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Report on the Natalie M. LaPrade Medical Cannabis Compassionate Use Fund

Submitted by the Natalie M. LaPrade Medical Cannabis Commission

December 2018

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I. Introduction

Health-General Article, §13-3303.1, as amended by Chapter 598 of the Acts of 2018 (HB 2), established the Natalie M. LaPrade Medical Cannabis Compassionate Use Fund ("Compassionate Use Fund"). The Compassionate Use Fund is a special, nonlapsing fund administered by the Maryland Department of Health (the "Department") to "provide access to medical cannabis for individuals enrolled in the Maryland Medical Assistance Program or in the Veterans Administration Maryland Health Care System." Md. Code Ann. Health-Gen., §13-3303.1(d).

Health-General Article, §13-3303.1 does not appropriate funds to the Compassionate Use Fund or otherwise provide funding to implement the program. Rather, the statute requires the Commission to submit a report to the General Assembly on the revenues that may be necessary to implement the program. The Department is required to (1) establish the program and (2) set any fees that may be necessary to provide medical cannabis at "no cost or a reduced cost" to eligible Maryland Medical Assistance Program and Veterans Administration Maryland Health Care System enrollees. Md. Code Ann. Health-Gen., §13-3303.1(c). No fees may be assessed on a medical cannabis business until at least two years following the issuance of a Stage One pre-approval of a license. Md. Code Ann. Health-Gen., §13-3303.1(c).

II. Background

Medical cannabis is not covered by any health insurance provider operating in the State. Cannabis remains a Schedule I drug under the federal Controlled Substances Act (CSA), meaning there is "no currently accepted medical use and a high potential for abuse." Since there is no accepted medical use under federal law health insurers do not consider cannabis to be "medical care" eligible for health insurance coverage. Moreover, private health insurance, Medicaid and Medicare are only required to cover drugs approved for use by the U.S. Food and Drug Administration (FDA). The FDA does not approve Schedule I drugs for medical use, and therefore insurance companies are not required to cover it as part of their insurance plans. Health insurance companies may cover Marinol, Syndros, and Epidiolex, which contain cannabinoids, but each drug was re-scheduled upon receiving FDA approval and is no longer considered cannabis under federal law.

In Maryland, the price of medical cannabis is not set by statute or regulation. Prices vary significantly based on content (i.e. THC or CBD concentration) or location, but 1 gram of flower typically ranges between $5-20. A patient is permitted to purchase up to 120 grams of medical cannabis in a rolling 30-day period, which means a patient purchasing the maximum allowable amount of flower product could spend $600-2,400 per 30-day period. The cost of medical cannabis concentrates and medical cannabis-infused products also vary significantly based on content and location, and are generally more expensive than flower products.

HB 2 established the Compassionate Use Fund to fill the void created by the lack of health insurance reimbursement for medical cannabis and reduce the economic burden for medical cannabis patients enrolled in Medicaid or in the Veterans Administration Maryland Health Care System ("VA Health Care System"). In order to determine the amount necessary to fund the Compassionate Use Fund, HB 2 requires the Commission to submit a report the General Assembly on the revenues needed to fund the Compassionate Use Fund, potential funding mechanisms, and any anticipated savings in prescription drug costs for the State's Medicaid program. This report satisfies these requirements.

III. Reduced Cost Programs in other Jurisdictions

As of November 6, 2018, thirty-three states, the District of Columbia, and Puerto Rico have legalized medical cannabis (see Table 1). Medical cannabis dispensaries in these jurisdictions, including Maryland, commonly offer discounts for low-income individuals and veterans; however, only the District of Columbia and Vermont require dispensaries to provide discounted medical cannabis to these populations. Significantly, the D.C. and Vermont programs have fewer than 5,000 registered medical cannabis patients; less than $1/10^{th}$ the number of certified patients (51,304) in the Maryland program.

The City of Berkeley, California goes a step further, requiring dispensaries to provide medical cannabis at no cost to "very low-income City residents." Rather than imposing a flat fee on licensed medical cannabis businesses, each jurisdiction requires dispensaries to allocate a percent of their annual gross revenue to discount the cost of medical cannabis for eligible qualifying patients. Linking the discount to an individual dispensary's gross revenue reduces the economic burden on rural, independent, and/or small businesses that average fewer patients and generate less revenue. A brief summary of each medical cannabis discount program is included below. (See Appendix A for the statute and/or regulations implementing the medical cannabis discount programs).

(a) Berkeley, California

In 2014, the Council of the City of Berkeley adopted Ordinance No. 7,359-N.S., which requires a medical cannabis dispensary to provide at least 2% (by weight) of its annual medical cannabis sold at no cost to qualifying patients who are "very low income" The 2% figure is based on the amount dispensed during the previous six months. Very low income is defined as 50% or less of the area median income, or approximately $40,000.

(b) District of Columbia

In 2013, the District of Columbia enacted a first-in-the-nation program requiring medical cannabis dispensaries to allow qualifying low-income patients to be able to purchase medical cannabis on a sliding scale. Dispensaries must allocate 2% of their annual gross revenue to qualifying patients with an income at or below 200% of the federal poverty level. Patients must register with the D.C. Department of Health to qualify, and qualifying patients are entitled to a discount of at least 20% of the regular retail price.

(c) Vermont

The Vermont Administrative Code requires medical cannabis dispensaries to "implement and operate a sliding-scale fee system that takes into account a patient's ability to pay." However, the law does not establish a minimum amount of product to set aside, or revenue to allocate, for qualifying individuals. Vermont currently has four medical cannabis dispensaries operating in the State, and each provide discounts to low-income individuals and veterans. Patients must provide documentation proving eligibility. While discounts vary by dispensary, the discount range is 10-20%.

Table 1. U.S. jurisdictions with medical cannabis laws and year passed

State	Year Passed	State	Year Passed
1.Alaska	1998	18.Montana	2004
2.Arizona	2010	19.Nevada	2000
3.Arkansas	2016	20.New Hampshire	2013
4.California	1996	21.New Jersey	2010
5.Colorado	2000	22.New Mexico	2007
6.Connecticut	2012	23.New York	2014
7.Delaware	2011	24.North Dakota	2016
8.Florida	2016	25.Ohio	2016
9.Hawaii	2000	26.Oklahoma	2018
10.Illinois	2013	27.Oregon	1998
11.Louisiana	2016	28.Pennsylvania	2016
12.Maine	1999	29.Rhode Island	2006
13.Maryland	2014	30.Utah	2018
14.Massachusetts	2012	31.Vermont	2004
15.Michigan	2008	32.Washington	1998
16.Minnesota	2014	Washington, DC	2010
17.Missouri	2018	33.West Virginia	2017

IV. Current Discounts for Maryland Medical Assistance Program and Veterans Administration Maryland Health Care System Enrollees

Prior to passage of HB 2, Maryland law did not place any pricing or discount requirements on licensed medical cannabis dispensaries. Yet, each of the sixty-nine (69) licensed dispensaries operating in the State offer discounts to qualifying patients. The Maryland Medical Dispensary Association (MDMA), the trade association for medical cannabis dispensaries in the State, reported to the Commission that every dispensary offers a discount to veterans. The amount of the discount ranges from 10 to 22%, with 22% being the most common as a recognition of "the 22 veterans who commit suicide each day." (See Appendix B). In addition, many dispensaries offer a "compassion discount" for patients with terminal diagnoses, low-income patients, minor patients, and others. These discounts typically range from 10 to 25%.

Due to market competition and the deleterious effects of the federal tax code on medical cannabis businesses, discounts of 20 to 25% may result in a dispensary selling a product at or below cost. Under 26 U.S.C. 280E, businesses engaging in the trafficking of Schedule I or II controlled substances, including cannabis, are prohibited from deducting ordinary and necessary businesses expenses. Medical cannabis businesses may deduct the costs of goods sold (COGS), which are costs directly attributable to the production of a good, including the cost of labor and materials. However, the Department of Legislative Services estimates that 30% of a medical cannabis dispensary's expenses may not be deducted due to 280E restrictions, and that these businesses pay significantly higher federal tax bills than similar retail facilities.

V. Eligible Maryland Medical Assistance Program and Veterans Administration Maryland Health Care System Enrollees

Individuals enrolled in Medicaid or the Veterans Administration Maryland Health Care System ("VA Health Care System") make up a significant percent of the State's population. As of September 2018, Maryland has a combined enrollment of 1,299,510 individuals across Medicaid and CHIP. In total, more than 20% of the State's population is enrolled in Medicaid and CHIP. The Maryland Department of Veterans Affairs estimates that 399,036 or 8.87% of the adult population in Maryland are veterans and 152,216 veterans or 3.4% of the adult population in Maryland, are enrolled in the VA Health Care System.

The Maryland medical cannabis program is significantly smaller than either Medicaid or the VA Health Care System. As of November 6, 2018, there were 93,672 individuals who had submitted patient applications to the Commission since the patient registry open in April 2017. The number of individuals who are registered with the Commission and certified by a licensed Maryland provider to purchase, possess, and use medical cannabis ("certified patients") is considerably lower at 51,304. Overall, 1.5% of the total state population has submitted a patient application, and less than .9% of the total state population is a certified medical cannabis patient. In states with more established medical cannabis programs (e.g., 5 years or more post-implementation) the percent of residents who are qualifying patients typically falls between 1 and 3% of the total population.

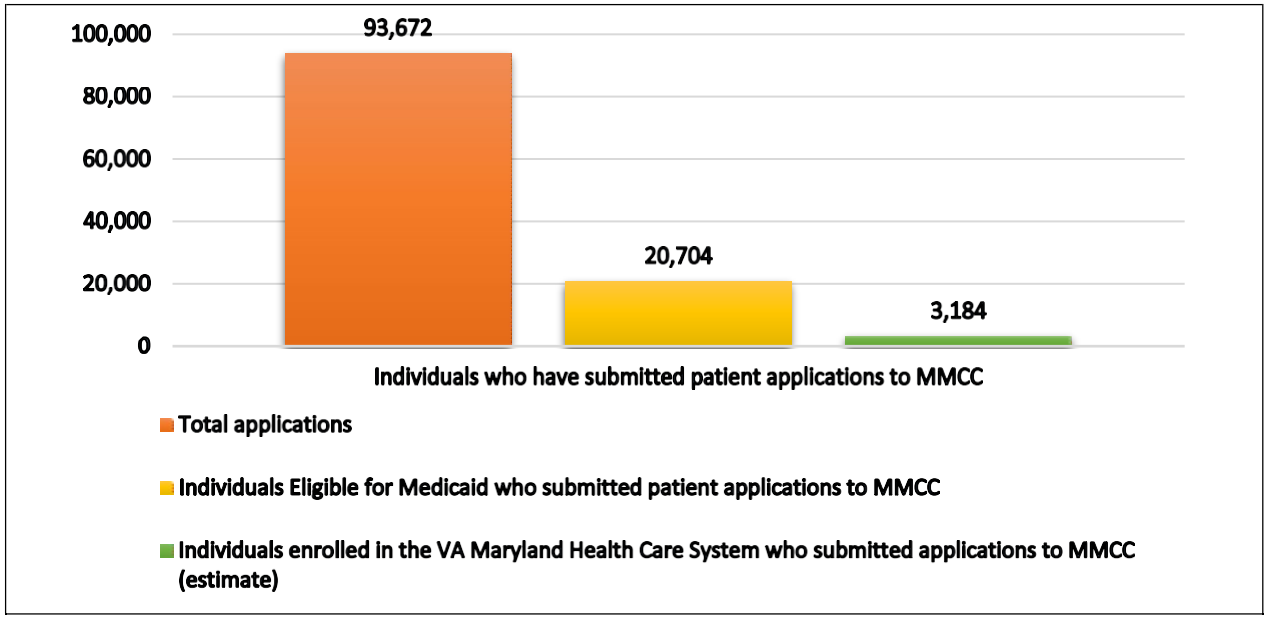
(a) Medicaid

At the request of the Department of Health, the Hilltop Institute at the University of Maryland Baltimore County (UMBC) identified Medicaid participants who were eligible to purchase, possess, and use medical cannabis. Applying first and last name, date of birth, and last 4 digits of Social Security Number criteria, the Hilltop Institute determined that 20,704, or 22.1%, of the individuals who submitted a medical cannabis patient application from April 2017 through October 2018 were eligible for Medicaid as of October 2018. Using this data, the Commission estimates that 11,388 certified patients were eligible for Medicaid as of October 2018.

(b) VA Health Care System

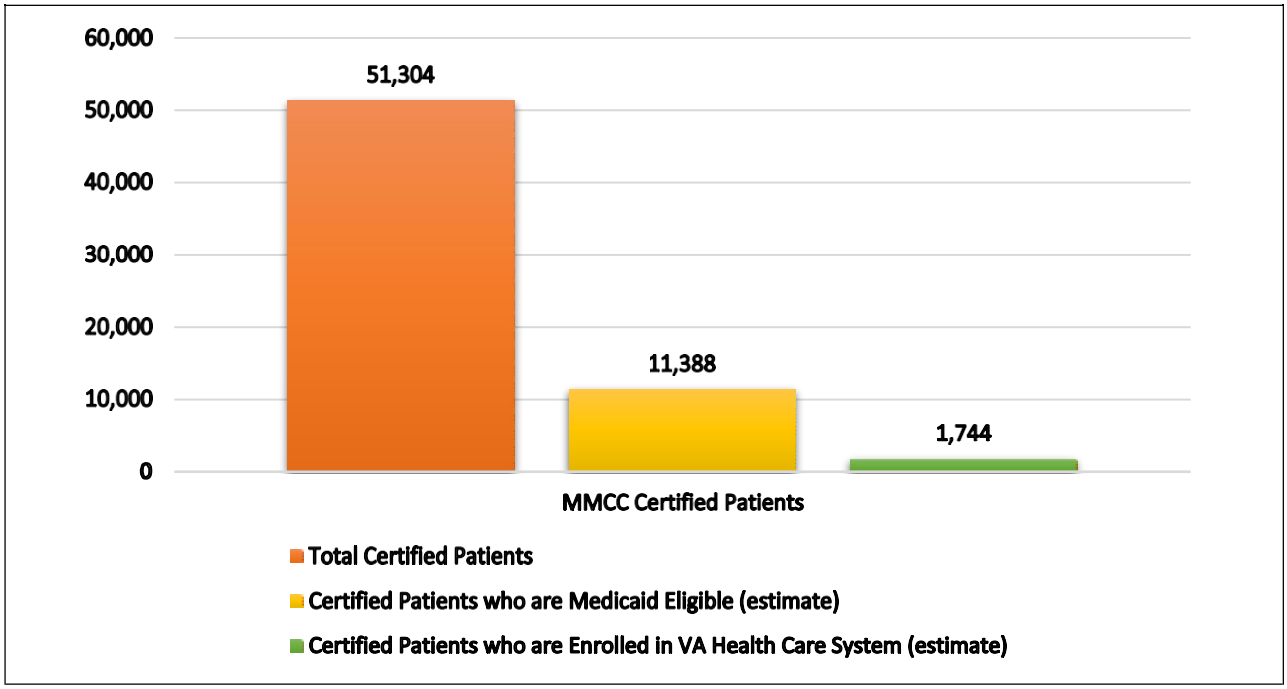
The U.S. Department of Veterans Affairs (VA) is required to follow all federal laws, including the federal Controlled Substances Act (CSA). Since cannabis remains a Schedule I drug under the federal CSA, VA health care providers may not recommend it or assist veterans to obtain it. Subsequently, the Commission was unable to identify the number of veterans currently registered or certified as patients within the State's medical cannabis program. The following analysis estimates that the number of medical cannabis patients who are enrolled in the VA Health Care System reflects the percent of this group as part of the total adult population of the State (3.4%).[1] Accordingly, the Commission estimates that 3,184 of the individuals who submitted a patient application from April 2017 through October 2018 are enrolled in the Veterans Administration Maryland Health Care System. In addition, the Commission estimates that 1,744 of the certified patients in the medical cannabis program are enrolled in the VA Health Care System.

Figure 1. Total number of patient applications submitted to MMCC (through November 6, 2018)



[1] While the medical cannabis program does permit minor patients, individuals under the age of 18 currently represent less than .2% of the total patient population.

Figure 2. Total number of MMCC certified patients (through November 6, 2018)



(c) Anticipated Program Growth

The number of patients enrolled in a state medical cannabis program typically ranges from 1 to 3% of the total state population. Through November 6, 2018, 1.5% of the total state population had submitted a patient application to MMCC, and .084% of the population were certified patients. The projections for the revenue necessary to fund the Compassionate Use Fund anticipate that patient registration and certification rates will increase at current rates until achieving 2% of the total state population by FY 2021. Beginning in FY 2022 the patient population is anticipated to increase consistent with the State's population rate of change.

Table 2. Estimated patient applications and certified patients, FY 2020-FY 2022

	FY 2020	FY 2021	FY 2022
Maryland Total Population	6,098,109	6,144,179	6,190,248
Certified Patients	88,744	117,304	123,805
Certified Patients Eligible for Medicaid	19,612	25,924	27,360
Certified Patients Enrolled in VA Health System	3,017	3,988	4,209

VI. Revenues Necessary for Compassionate Use Fund

The anticipated revenues necessary to fund the Compassionate Use Fund are included below. The necessary revenue was calculated using patient estimates included in Table 2 (above) and current average per patient sales figures ($138.38 per month or $1,660.56 per year). Estimates were calculated for a 15% discount, 20% discount, and no cost (i.e. 100% discount) for Medicaid and VA Health Care System enrollees.

Important: The anticipated revenues necessary to fund the Compassionate Use Fund (Table 3) are based on projections that the percent of certified patients who are Medicaid and VA Health Care System enrollees will be constant in FY 2020 through FY 2022 (e.g. 22.1% and 3.4%, respectively). However, the Commission anticipates that providing reduced cost or no cost medical cannabis to Medicaid and VA Health Care System enrollees would significantly increase the number of each group who become certified patients. Since no other jurisdiction in the United States has implemented a medical cannabis discount program of the size and scope of the Compassionate Use Fund, the Commission is unable to determine the impact that providing reduced cost or no cost medical cannabis to Medicaid and VA Health Care System enrollees will have on the total number of each group who become certified medical cannabis patients. Therefore, the figures below should be viewed as low-end cost estimates.

Table 3. Estimated revenue necessary to fund the Compassionate Use Fund, FY 2020-FY 2022

	FY 2020	FY 2021	FY 2022
15% Discount	$5,636,522	$7,450,601	$7,863,333
20% Discount	$7,515,362	$9,934,134	$10,484,444
No Cost	$37,576,812	$49,670,671	$52,422,219

From December 1, 2017 to November 30, 2018, the gross revenue for medical cannabis sales in Maryland was $96,091,758.08. Requiring dispensaries to provide no cost medical cannabis to Medicaid and VA Health Care System enrollees – using current Medicaid and veteran registration figures – would cost $37,576,812 in FY 2020. This low-end estimate represents nearly 40% of the gross revenue for medical cannabis sales during the past 12 months. Establishing a 20% discount would cost $7,515,362 in FY 2020, which represents 7.8% of the gross revenue. A 15% discount would cost $5,636,522 in FY 2020, or 5.8% of the gross revenue. By comparison, the programs in Washington D.C. and Berkeley, California require dispensaries to allocate 2% of the gross revenue to medical cannabis for qualifying low-income patients.

VII. Potential Funding Mechanisms

Pursuant to HB 2, the Commission identified potential funding mechanisms for the Compassionate Use Fund. Each of the proposals below would require regulatory and/or statutory authorization to implement.

(a) Flat Fees

The Maryland medical cannabis program has one hundred and two (102) licensed growers, processors, and dispensaries. An additional thirty-six (36) entities have received Stage-One pre-approval for licensing as a medical cannabis grower, processor, or Dispensary. Finally, the Commission has the authority to award up to an additional four (4) medical cannabis grower licenses, and ten (10) medical cannabis processor licenses. Therefore, the maximum total number of licenses currently allowed under law is one-hundred and fifty-two (152).

Table 4. Number of medical cannabis license holders and pre-approvals

License Category	License	Pre-Approval	Total
Grower	15	3	18
Processor	16	2	18
Dispensary	71	31	102

House Bill 2 restricts the Department from assessing fees until at least two years "immediately following the preapproval of the licensee for a license under this subtitle. The Commission issued the initial fifteen (15) grower and fifteen (15) processor pre-approvals in August 2016. The Commission issued one-hundred and two (102) dispensary pre-approvals in December 2016. As of July 1, 2019, a maximum of 132 growers, processors and dispensaries could be assessed fees to fund the Compassionate Use Fund. An additional 6 growers and processors could be assessed fees beginning in June 2020, and the yet-to-be awarded four (4) grower and ten (10) processor licensees could potentially be assessed fees beginning as early as July 2021. Table 5 below shows the fee per license holder to fund the Compassionate Use Fund beginning in FY 2020.

Dispensary revenue for Q1 of FY 2019 ranged from $380,000 to $1.9 million. Assessing a flat fee on all medical cannabis businesses could disproportionately impact Maryland small businesses. In other medical cannabis jurisdictions, fees are assessed based on a licensee's gross revenue. Therefore, the cost is directly linked to a licensee's ability to pay.

Important: The flat fees included in Table 5 are low-end estimates, because the fees are based on the percent of certified patients who are Medicaid or VA Health Care System enrollees remaining constant in FY 2020 through FY 2022 (i.e. 22.1% and 3.4%, respectively). The Commission anticipates that providing reduced cost or no cost medical cannabis to Medicaid and VA Health Care System enrollees will significantly increase the number of each who become certified medical cannabis patients. Since Maryland is the first medical cannabis jurisdiction to require price discounts for Medicaid and VA Health Care System enrollees, the Commission is unable to determine the impact that the discount will have on certified medical cannabis patient figures.

Table 5. Estimated flat fees per license holder.

	FY 2020	FY 2021	FY 2022
15% Discount	$42,701	$49,017	$51,733
20% Discount	$56,935	$65,356	$68,976
No Cost	$284,673	$326,781	$344,883.02

(b) Percent of Gross Revenue

The reduced cost programs implemented in Washington D.C. and Berkeley, California require medical cannabis dispensaries to allocate 2% of their annual gross revenue or product sold (by weight) to qualifying low-income patients. Rather than assessing fees or taxes on medical cannabis businesses, dispensaries are required to submit sales data biannually or annually. The gross revenue or product sold reported is used to determine the amount of revenue or product the dispensary must offer to qualifying patients. In addition, the authorizing ordinance establishes a minimum cost discount that each dispensary must provide (i.e. 20%).

The advantage of a "percent of gross revenue" program is that the cost is linked to a businesses' ability to pay. Therefore, small and rural dispensaries would not be subject to the same fees as larger businesses or those operating in more densely populated areas of the State. Dispensary gross revenue for Q1of FY 2019 ranged from $380,000 to $1,900,000. Assessing a flat fee across all licenses would disproportionately impact Maryland small businesses.

(c) Tax Check-Off

The Maryland tax return form enables taxpayers to contribute money to protect natural resources, support individuals with developmental disabilities, and support cancer research. Currently, individuals may contribute any amount to the Chesapeake Bay and Endangered Species Fund, Developmental Disabilities Services and Support Fund, Maryland Cancer Fund, and Fair Campaign Financing Fund. The amount contributed will either reduce an individual's state tax refund or increase the amount of additional state tax owed. Each contribution is tax deductible for the year it was made. Any money collected by the Comptroller is distributed to the designated fund, minus any costs associated with administering the tax checkoff program. Each tax checkoff program receives significant contributions each year. For instance, in FY 2016 $251,445 was contributed to the Maryland Cancer Fund.

A tax check off would likely not provide the revenue necessary to fund the Compassionate Use Fund, but would provide another potential funding mechanism. The General Assembly must authorize the Comptroller to include a tax checkoff for the Compassionate Use Fund on the state income tax return form.

(d) *Medical Cannabis Excise Tax*

The sale of medical cannabis in Maryland is not subject to an excise tax. Likewise, under the Tax-General Article, §11-211 the sale of medicine is exempt from the 6% sales and use tax. At least twelve (12) states levy an excise tax on the sale of medical cannabis. In at least four (4) additional states the sale of medical cannabis is subject to the state sales tax (Table 6). The excise tax rate in other medical cannabis states ranges from 1% to 37%. In addition, two states assess a $3.50 per gram tax on medical cannabis sales.

Table 6. State taxation rates on medical cannabis.

State	Medical Cannabis Tax
Arizona	6.6% excise tax
Arkansas	4% excise tax
Colorado	2.9% state sales tax
Connecticut	$3.50 per gram excise tax
Hawaii	4% state sales tax
Illinois	All sales subject to 1% pharmaceutical excise tax (dispensaries); 7% wholesale tax (cultivators)
Michigan	3% excise tax and 6% state sales tax
Minnesota	$3.50 per gram excise tax
Montana	2% excise tax
Nevada	2% excise tax
New Jersey	7% state sales tax
New York	7% excise tax
Ohio	5.75% state sales tax
Pennsylvania	5% wholesale tax
Rhode Island	4% excise tax and 7% state sales tax
Washington	37% excise tax (medical program merged with adult use program and subject to same tax rate)

The mean state medical cannabis excise tax rate is 7.56% and the median state medical excise tax rate is 5%. Table 7 below shows the projected tax revenue based on the medical cannabis gross revenue during the first year of program operation ($96, 091,758.08). An excise tax rate of 7.56% would provide $7,264,537 in revenue, which exceeds the anticipated revenue necessary to fund a 20% discount for Medicaid and VA Health Care System enrollees in FY 2020. An excise tax rate of 2% would provide projected revenue of $1,921,835, and an excise tax rate of 5% would provide projected revenue of $4,804,588. These revenue figures are less than the anticipated revenue necessary to fund the Compassionate Use Fund in FY 2020, but would enable the Department to provide reduced cost medical cannabis to a sizeable population of Medicaid and VA Health Care System enrollees.

Table 7. Excise tax rate revenue projections.

Excise Tax Rate	Projected Tax Revenue Based on Gross Revenue, 12/1/2017-11/30/2018
2%	$1,921,835
5%	$4,804,588
7.56%	$7,264,537

VIII. Anticipated Savings in Prescription Drug Costs

Due to federal restrictions on cannabis research, limited data exist on the impact medical cannabis laws may have on reducing prescription drug costs among Medicaid enrollees. Moreover, no published studies demonstrate that subsidizing medical cannabis costs for low-income patients will further reduce Medicaid prescription drug expenditures. This is likely due in part to no jurisdiction having implemented a reduced cost program of the size and scope of the Compassionate Use Fund. Existing data are summarized below.

- From 2011-2016, state implementation of medical cannabis laws was associated with a 5.88% reduction in opioid prescriptions among Medicaid enrollees. The study compared Medicaid prescription data between states with medical cannabis laws and those without during the relevant period. (H. Wen and J.M. Hockenberry, *Association of Medical and Adult-Use Marijuana Laws With Opioid Prescribing for Medicaid Enrollees*, JAMA Intern Med. 2018;178(5):673-679).
- From 2007-2014, the use of prescription drugs (not exclusive to opioids) in fee-for-service Medicaid was lower in states with medical marijuana laws than in states without such laws in five of the nine broad clinical areas examined. It showed a 17% reduction in drugs used to treat nausea, a 13% reduction in drugs used to treat depression, a 12% reduction for drugs used to treat psychosis and seizure disorders, and an 11% reduction in drugs used to treat pain. There was no association between Medicaid drugs used for anxiety, glaucoma, sleep disorders or spasticity and medical cannabis. See A.C. Bradford and W.D. Bradford, *Medical Marijuana Laws May Be Associated With A Decline In The Number Of Prescriptions For Medicaid Enrollees*, Health Affairs, 2016; 36(5):945-951.

- From 1993-2014, medical cannabis legalization was associated with a 29.6% reduction in the number of Schedule III opioid prescriptions. No association was found between medical cannabis legalization and reduction in Schedule II opioid prescriptions. The authors estimated that if all 50 states had legalized medical cannabis by 2014 annual Medicaid expenditures on prescription opioids would be reduced by $17.8 million per year. (D. Liang et al., *Medical cannabis legalization and opioid prescriptions: evidence on US Medicaid enrollees during 1993–2014*, Addiction, 2018 Nov;113(11):2060-2070).

The 2018 *Addiction* study concluded that if all fifty (50) states had legalized medical cannabis by 2014 annual Medicaid expenditures in the United States would be modestly reduced by $17.8 million, with $7.78 million in savings for state governments. While this study did not contemplate a reduced cost program for Medicaid enrollees, data clearly demonstrate that medical cannabis laws generally do not result in substantial Medicaid prescription drug savings.

IX. Conclusion

Cannabis remains a Schedule I drug under the federal Controlled Substances Act, which means private health insurance, Medicaid, and Medicare do not reimburse patients who use the drug. HB 2 established the Compassionate Use Fund to address this insurance gap and provide reduced cost or no cost medical cannabis to Medicaid and VA Health Care System enrollees. Currently, only the District of Columbia and Vermont require dispensaries to provide reduced cost medical cannabis to low-income patients, and the patient population in each jurisdiction is $1/10^{th}$ the current Maryland patient registry.

The revenue necessary to provide Medicaid and VA Health Care System enrollees with even modest price reductions is substantial. The Compassionate Use Fund would require at least $5.6 million in FY 2020 to provide a 15% discount, and $7.5 million to provide a 20% discount to Medicaid enrollees and veterans, based on current patient enrollment figures. Wholly subsidizing medical cannabis would require at least $37.5 million in FY 2020. In comparison, the gross revenue for December 1, 2017 to November 30, 2018 was $96,091,758. Due to existing licensing fees ($40,000 per year for dispensaries and processors, and $125,000 for growers) and the heavy federal tax burden carried by medical cannabis business, it may be difficult for license holders to fund the Compassionate Use Fund without significantly increasing retail prices.

The Commission identified four potential funding mechanisms for the Compassionate Use Fund: (1) flat fee, (2) percent of gross revenue, (3) tax checkoff, and (4) cannabis excise tax. Each funding mechanism would require additional legislation or regulations to implement. Other states most commonly levy a cannabis excise tax or require a percent of gross revenue in order to provide reduced cost or no cost medical cannabis, or otherwise fund the medical cannabis program.

Due to federal restrictions on cannabis research and no other state having implemented a program of the size and scope of the Compassionate Use Fund, limited data exist on whether and how prescription drug expenditures may be affected. However, recent studies suggest that expanded access to medical cannabis generally results in only a modest reduction in Medicaid prescription drug expenditures.

Appendix A

Reduced Cost Programs in Other Medical Cannabis Jurisdictions

Berkeley, California

12.27.080 Medical cannabis for low income Members

A. At least 2% (by weight) of the annual amount of Medical Cannabis in dried plant form provided by a Dispensary to all Members, shall be provided at no cost to very low income Members who are Berkeley residents. This amount shall be calculated every six months, based on the amount dispensed during the immediately preceding six months. Medical Cannabis provided under this Section shall be the same quality on average as Medical Cannabis that is dispensed to other members.

B. For purposes of this Section, income shall be verified using federal income tax returns or other reliable method approved by the City Manager.

C. For purposes this Section, "very low income" shall mean the household income established by the most recent annual City Council resolution that establishes the maximum income levels for qualification for exemption from specified local taxes and fees.

District of Columbia

22-C6300 DCMR

6300 SLIDING SCALE PROGRAM

6300.1 A registered dispensary shall devote two percent (2%) of its annual gross revenue to provide medical marijuana on a sliding scale to qualifying patients determined eligible pursuant to § 1300.4 of this subchapter.

6300.2 Not later than February 15th of each calendar year, each registered dispensary in the District of Columbia shall submit to the Director:

(a) A statement of its gross revenues for the previous calendar year;

(b) A statement detailing how the dispensary devoted two percent (2%) of its annual gross revenue to eligible qualifying patients on a sliding scale, which shall include:

(1) The name, patient registration number, and date of dispensing for each patient who received medical marijuana on a sliding scale during the previously calendar year; and

(2) The discounted amount provided to patients under this program; and

(c) An attestation, made under penalty of perjury, of the accuracy and truthfulness of the statements submitted pursuant to this subsection.

6300.3 A qualifying patient who establishes pursuant to § 1300.4 of this subchapter that his or her income is equal to or less than two hundred percent (200%) of the federal poverty level, shall be entitled to purchase medical marijuana directly, or through a caregiver, on a sliding scale from a registered dispensary in the District of Columbia.

6300.4 A registered dispensary shall sell medical marijuana to a qualifying patient, who is registered to purchase medical marijuana on a sliding scale, and possesses a registration card denoting such, at a discount of not less than twenty (20%) of its regular retail price.

6300.5 Not later than April 15th of each calendar year, the Department shall review the sliding scale program. As part of its review, the Department may adjust the percentage required to be devoted by dispensaries and the required discount to qualifying patients.

6300.6 The gross revenue amount to be devoted by each dispensary to the sliding scale program shall be subject to audit by the Department.

6300.7 In addition to any other applicable sanctions, any dispensary that fails to comply with the provisions of this chapter shall be subject to a civil fine under the Civil Infractions Act of two thousand dollars ($2,000.00) per offense, and each day of violation shall constitute a separate offense.

6300.8 Notwithstanding Subsection 6300.7 of this chapter, the Director may revoke the registration of a dispensary that commits egregious or multiple violations of this chapter; that uses fraud to conceal its annual gross revenue; or that submits false or misleading reports to the Director.

Vermont

Vt. Admin. Code 17-2-3:6. Registered Dispensary

6.1.4 Shall implement and operate a sliding-scale fee system that takes into account a registered patient's ability to pay.

Appendix B

Written comment submitted by medical cannabis businesses

(See Next Page)

The Maryland Medical Dispensary Association (MDMDA) was established in May, 2017 in order to promote the common interests and goals of the Medical Cannabis Dispensaries in Maryland. MDMDA advocates for laws, regulations and public policies that foster a health, professional and secure medical cannabis industry in the State. MDMDA works on the State and local level to advance the interest of licensed dispensaries as well as to provide a forum for the exchange of information in the Medical Cannabis Industry.

Since dispensaries are the face of the cannabis industry for patients, we are very aware that there are patients who struggle to purchase medical cannabis needed to treat their particular conditions. Most dispensaries in Maryland already offer a number of ways to assist these patients in receiving medical cannabis.

Discounts are one way that dispensaries currently help patients afford the cost of medicine. Every dispensary already offers different kinds of discounts, but all dispensaries offer veterans discounts. The amount of this discount can vary from 10-22%, and there are many dispensaries that continue to offer 22% to all veterans in recognition of the 22 veterans who commit suicide each day.

Many dispensaries also offer a compassion discount, called different names by different dispensaries. This discount is applied to those with terminal diagnoses, those struggling financially, minor patients, and more. This discount usually ranges between 10-25%. Some dispensaries offer bulk discounts. For example, one dispensary offers cancer patients RSO at $5 above cost if a patient purchases at least 10. However, as the industry has grown and continues to grow, pricing pressure has significantly increased as the number of out of state corporate owners has increased. Discounts of 20-25% results in the dispensary selling at or below cost due to the small margins, effect of 280E and overhead.

While thinking about the best ways to fund the compassion fund required by HB2, it is important to remember that dispensaries have limited control over price. Growers and processors who manufacture the products set prices when a product is sold to a dispensary. The margin necessary to cover costs varies greatly across the state and depends on factors such as dispensary location, salary and amount of staff. That pressure increases even more on the locally owned independent dispensaries as some vertically integrated growers/processors sell directly to consumers at wholesale prices.

Lastly, we also feel this program could inadvertently lead to diversion. Providing medical cannabis to patients at a cost well below the market rates could create an incentive for patients to resell medical and foster the black market which we are attempting to eliminate.

Thank you for keeping these important points in mind as you continue to give thought to the framework of a compassionate care program.

State Circle Strategies, LLC
Government Relations

Commissioner Brian Lopez, Chair
Executive Director Joy A. Strain, MHA
Maryland Medical Cannabis Commission
849 International Drive Suite 450,
Linthicum, MD 21090

October 30, 2018

Re: § 13-3303.1. Natalie M. LaPrade Medical Cannabis Compassionate Use Fund

FAVORABLE

Dear Chair Lopez and Executive Director Strain,

This letter is written on behalf of Mary and Main Dispensary located in Prince George's county. Mary and Main is 100% African American, Women, Disabled Veteran owned. Mary & Main's mission is to provide safe and premium quality products with exemplary and compassionate services to all medical patients who are suffering from a number of chronic debilitating illness.

In keeping with its mission, Mary & Main supports the establishment of the Compassionate Use Fund.

Medical Cannabis is not covered by health insurance. Since it is not approved by the U.S. Food and Drug Administration as a medicine, private and federal insurance programs will not cover it. Marijuana also remains classified as a Schedule I drug by the U.S. Drug Enforcement Administration, meaning it has been deemed as having no medical use and a high potential for abuse.

The fact remains that medical cannabis has been documented to improve the quality of life of those suffering with anxiety, post-traumatic stress disorder, chronic pain and other health issues. A glaring issue remains: Those who may benefit the most from Maryland's medical cannabis program may not be able to shoulder the costs. Participation in the program is extremely expensive, especially if you're living on Social Security and disability benefits.

Due to the extremely high cost of medical cannabis, we ask that consideration is given to allow dispensaries to receive financial support or reimbursement under the fund for discounts given to the following:

Veterans 22%. There currently is an initiative in the state to give a 22% discount on the price of medical cannabis to veterans, in an effort to address PTSD. PTSD is a leading cause of suicide among veterans. Due to the steep wholesale costs and 280E restrictions on writing off expenses, participation in the 22% program is very costly to dispensaries. Mary & Main would like to offer the discount but assistance (reimbursement) from the fund is needed.

Pediatrics. Ill Children in the program may be considered the most vulnerable and their parents or care takers should not have to decide between medicine or putting food on the table, due to the high cost of medical cannabis. Cost should not prevent these sick patients from accessing medicine. Dispensaries should be reimbursed under the fund for discounts provided to children in need.

Hospice- Those in hospice care benefit greatly from use of medical cannabis. Terminally ill patients should not let the high cost of medical cannabis prevent them from accessing their medicine. Dispensaries should be reimbursed under the fund for discounts provided to those in hospice care.

Low Income Patients-Since buying medical cannabis is an out of pocket expense, low income patients will benefit greatly from any discounts provided. We suggest low income patients must provide proof of eligibility to determine their economic status by some method of documentation (w2 pay stubs, or other qualifying documentation).

Educational Material and Classes- The key to Maryland's medical Cannabis program's growth lies within education. Dispensaries have the most direct access to patients and potential patients and therefore should be aided in their educational outreach efforts. A grant or other finical support should be provided to dispensaries from the fund to aid in educational outreach efforts.

It is our hope that these written comments will help in the development of the Natalie M. LaPrade Medical Cannabis Compassionate Use Fund. We thank you for the opportunity to submit these comments.

Please feel free to contact me if any questions

Respectfully yours,

Bryan Alston
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