Written Testimony

Joint Committee on Cannabis Policy
Commonwealth of Massachusetts
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Academic Policy Paper

Submitted by
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Acknowledgements

This policy brief was developed by Cannabis Community Care and Research Network (CCCRN) a public benefit corporation aiming to advance the science and clinical application of Medical Cannabis. This brief was prepared for the Commonwealth of Massachusetts to provide evidence and recommendations in relation to the safe and regulated roll out of recreational Cannabis. The brief was prepared by Dr. Marion McNabb, Co-Founder and CEO of CCCRN with support from Randal MacCaffrie, Margaret Delia, Kellie Klein, Adam Klock, Elizabeth Kinnard, Sarah Trocchio, and Lindsay Garito.

Medical and Recreational Cannabis Use

Medical use of Cannabis is now widely accepted in the United States with 29 states, the District of Columbia, Guam, and Puerto Rico now allowing its use for a wide range of health conditions.[1] As of 2017, there are an estimated 2.3 million medical Cannabis patients in the United States.[2] The end of the prohibition-era for Cannabis is underway, with several states, including the Commonwealth of Massachusetts, passing laws to legalize adult-use Cannabis.[3] With this important shift, it is important for States to consider balancing both the public health and safety risks with the medical benefits and potential of Cannabis in a free market.

Recreational Cannabis is often not consumed for a specific medical purpose, but rather users may consume it with the goal of getting "high".[4] However, it is important to note that there is considerable overlap between medical and recreational users.[4] Research reveals that "self-medication" is common among recreational users, and some adults may report recreational use prior to consuming it for medical purposes.[4] After a review of four states data, researchers report that 86% of people who report ever using cannabis for medical purposes also use it recreationally.[5] Overall, medical users tend to spend more money per month, are more likely to vaporize and consume edibles, with reported higher amounts (in grams) consumed than recreational users.[5] Additionally, only 12% of cannabis users, from a review of 2 legal and 2 non-legal U.S. states data, consume Cannabis and alcohol simultaneously.[5] In a recent study of 104 individuals with HIV, approximately two thirds of the group endorsed cannabis use for medical indication, while 80% of the study population also used it for recreational purposes.[6]

As more States consider recreational adult-use Cannabis it will be important to be cognizant of not only the public health risks and concerns, but also the potential to reach more medical patients in need of Cannabis therapies.[6]

Current State of the Evidence on Medical Cannabis

The evidence base related to medical Cannabis is growing. In January 2017, *The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research*, was published by the National Academies of Sciences, Engineering, and Medicine, provides the latest evidence available around the medical benefits of cannabis use. The following are the most up to date findings regarding cannabis use available.[7]

There is conclusive or substantial evidence that cannabis or cannabinoids are effective in the treatment of:[7]

- chronic pain in adults
- as an antiemetic in the treatment of chemotherapy induced nausea/vomiting
- improving patient-reported multiple sclerosis spasticity symptoms

There is substantial evidence of a statistical association between cannabis use and:[7]

- increased risk of a motor vehicle crash (MVC)
- the development of schizophrenia or other psychoses

There is moderate evidence of a statistical association between cannabis use and:[7]

- better cognitive performance among individuals with psychotic disorders
- increased incidence of social anxiety disorder
- increased incidence of suicide contemplation

There is limited evidence of a statistical association between cannabis use and:[7]

- the triggering of an acute myocardial infarction
- risk of ischemic stroke or subarachnoid hemorrhage
- risk of prediabetes
- risk of developing chronic obstructive pulmonary disorder (COPD)
- impaired academic achievement and education outcomes
- increased rate of unemployment and / or low income
- impaired social functioning in developmentally appropriate social roles
- increased symptoms of anxiety
- increased severity of posttraumatic stress disorder symptoms
- initiation of tobacco use

There is insufficient or no evidence of statistical association between cannabis use and:[7]

- death due to cannabis overdose

There is moderate evidence to support the *lack* of statistical association between cannabis use and:[7]

- the incidence of lung, head, and neck cancer
- worsening of negative symptoms of schizophrenia among individuals with psychotic disorders

Recreational Adult-Use of Cannabis in Massachusetts

In November 2016, 1.8 million citizens voted for the legalization of Cannabis for adult-use in Massachusetts, while 1.5 million voted against it.[8] In December the law came into effect.[8] On December 30, 2016 Governor Charlie Baker signed legislation that extended

the start date of recreational Cannabis by six months, to July 2018. The administration has been clear that the delay is due to the Legislates desire to thoroughly prepare for launching the new industry and is committed adhering to the will of the voters.[9] In January 2017, a Joint Committee on Cannabis Policy was formed consisting of 17 legislators from the House and Senate to review 90 bills posed to alter the law and gather public opinion.[10] From March – April 2017, the Committed held four public hearings to review the 90 bills that are posed to change the recreational adult-use law. The final hearing is scheduled for April 24, 2017.[10]

This academic policy review was conducted by the Cannabis Community Care and Research Network (CCCRN) in April 2017 to provide the Committee with a review of the evidence-based literature related to the 90 bills posed to alter the recreational adult-use law in the Commonwealth. After reviewing the literature, the CCCRN team developed recommendations for the Joint Committee on Cannabis Policy to consider while making legislative changes.

Massachusetts Medical Cannabis Background

In 2012, the Commonwealth of Massachusetts passed Question 3, the Medical Cannabis Initiative. Over the last few years, the Department of Public Health and other government agencies have worked to roll out the Medical Cannabis in the Commonwealth, yet challenges remain. As of 2017, only 0.5% of the population registered as a medical Cannabis patient and less than 0.01% of physicians registered as medical Cannabis recommenders.[11,12] As of February 2017, the Department of Public Health reports:[11]

- 34,392 active patients
- 3,006 caregivers
- 183 registered physicians
- 9 registered medical dispensaries are open

In order to qualify to be a medical Cannabis patient in Massachusetts, one must be above the age of 18 and in rare conditions two physicians must diagnose the qualifying patient as “having a debilitating life-limiting illness” (one that does not respond to curative treatments, where reasonable estimates of prognosis suggested death may occur within two years).[13] The current qualifying conditions include:

- Cancer, glaucoma, HIV positive, AIDS, Hepatitis C, amyotrophic lateral sclerosis (ALS), Crohn’s disease, Parkinson’s disease, and multiple sclerosis

However, guidelines state that a physician may prescribe for any other "debilitating condition", which could include substance abuse, nausea, or pain.[14] Despite the great potential medical Cannabis can have on many health conditions, the numbers of those enrolled do not match those who might benefit from medical or recreational Cannabis. Below is a table that describes the potential patient population with health conditions that qualify for medical Cannabis in Massachusetts, according to the latest data or estimations.

Table 1 ***Estimated Cases of Health Conditions that Quality for Medical Cannabis in Massachusetts***

Health Condition	**Rate per 100,000 Population**	**Potential Medical Cases in Massachusetts***
Cancer	170.3 per 100,000[15]	11,495
Glaucoma	N/A	58,588[16]
HIV	261 per 100,000[15]	17,618
Hepatitis C	190.2 per 100,000[17]	12,839
ALS	2.4 per 100,000[18]	162
Crohn's disease	241 per 100,000[19]	16,268
Parkinson's disease	1.6% of people over of the age of 65[20,21]	16,632
Multiple Sclerosis	103 per 100,000[18]	6,953
Opioid Addiction	9,756 per 100,000[22]	658,530
Total Estimated Patients with "unmet need" for Medical Cannabis in Massachusetts		**799,555**

*Population of Massachusetts use to estimate cases: 6.75 million[12]

As seen in the table above, there are an estimated 800,000 patients with medical Cannabis qualifying conditions in the Commonwealth that are not currently accessing Cannabis as a treatment. Despite the great gains made by the Massachusetts Department of Public Health (DPH) in expanding the program, many hurdles to achieving adequate coverage remain.

Key Challenges for Clinicians and Clients with Medical Cannabis in Massachusetts

- In Massachusetts, physicians cannot legally prescribe Cannabis due to the Federal scheduling of it as a class 1 drug.[23] However, in 2013, the U.S. Department of Justice advised US Attorneys not to pursue actions against physicians in states that all medical marijauana.[23] Despite this, the DEA has reportedly visited at least seven Massachusetts doctors in their homes or offices asking to sever ties to medical-Cannabis dispensaries.[23]

- One of the largest barriers to physician's reluctance in Massachusetts to get a license centers on the fear of possible legal repercussions.[14]
- The Massachusetts Medical Society is reluctant to recommend medical cannabis in the State.[14] However, Partners HealthCare allows their physicians to certify patients, and as of 2015 was working on a referral resource for their physicians who might not choose to be certified.[14]
- In the current model, clients access Cannabis Clinicians to obtain a medical card, and usually pay $200 for a visit and $50 for a card with the DPH.[11] This can be prohibitive for patients in need of Cannabis might be unable to work, are low-income, and are unable to travel long distances to reach medical dispensaries.
- High costs of treatment often prohibit those in need of care. Many are covered by Medicare or Medicaid, offering no reimbursement for costs as a medical patient. Additionally, the costs of purchasing Cannabis from a dispensary remains high, causing patients to seek Cannabis from other sources, including the black market.
- The current paradigm and course of treatment for a cannabis patient is challenging and patients are left in the position of self-medicating and experimenting with dosing, edibles and other ways to relieve pain and symptoms.[4]

Massachusetts Overview

Massachusetts has a population of 6.75 million people, with 9.6% of the population living 100%, and 22% living 200% below the poverty line.[12,24] While poverty remains a challenge in the Commonwealth, Massachusetts is a historic leader in ensuring residents have access to quality healthcare and universal health coverage (UHC). As of 2017, only 3.5% of residents in Massachusetts lacked health insurance, making Massachusetts an innovator and healthcare leader in the nation.[25]

Massachusetts has long been known as a global leader in healthcare and education. This is evident in the fact that in February 2017, Massachusetts was named in the U.S. News and World Report ranking as the #1 best state in the nation overall, number one in education and number two in healthcare.[26] Despite great gains, the State still faces significant health challenges affecting the health of its citizens, economic stability, and crime rates.

Massachusetts Opioid Epidemic

The Commonwealth of Massachusetts is facing a serious opioid addiction epidemic, with rates of visits to the emergency room twice as high as the national average; between 2007 and 2014, all opioid related hospital discharges increased by 84%.[27] In 2016 alone, the Department of Public Health (DPH) reported 1,465 confirmed opioid related deaths, with an additional 469-452 deaths suspected to be overdoses.[28]

According to the latest Federal report published April 2017, Massachusetts had the highest rate of opioid related visits to the hospital emergency room, as compared to 30 states included in the report.[29,30] There were more than 450 visits per 100,000 population (around 30,375 persons) to the emergency department in Massachusetts, much higher than the second state of Maryland with 300 visits per 100,000 population. The majority of the visits were associated with fentanyl use, a synthetic opioid.[29] Residents in the Berkshires, Fall River, Metro South, New Bedford, and East Merrimack regions had the highest rates of opioid–related hospital discharges.[27] The financial burden related to opioid intakes and discharges is also significant. In 2014 alone, MassHealth paid for 42% of opioid related discharges and Medicare covered an additional 24%.[27]

Substance Abuse Programs in Massachusetts

According to the DPH, in 2014 there were 107,358 persons admitted to substance abuse programs.[31] The most affected population is white (81%), male (68%) and never married (73%). Nearly half of those admitted into substance abuse programs had a high school education (48%) and were not homeless (84%).[31] Overall 50% did not report past-year needle use, and the majority (56%) had not had prior mental health treatment.[31]

The ages of those admitted vary widely; admissions were aged 18-25 (21%), 26-30 (21%), 31-40 (26%), 41-50 (19%) and 50 and older (12%).[31] Heroin (53%) was the top reason for admission, followed by alcohol (32%), other opioids (6%), crack/cocaine (3%), and Cannabis (4%).[31]

Medical Cannabis and the Impact on the Opioid Epidemic

The scientific evidence related the effect of Cannabis for the treatment of opioid addiction and chronic pain is well established.[32] Several studies have documented a range of 31% - 80% of medical patients reporting successfully substituting cannabis for opioids and other prescription medications.[32–37] Three separate but recent studies also show that states with medical Cannabis laws have also seen from 13% - 35% significant reduction in opioid overdose deaths compared to states without.[38–40]

Due to increasing evidence that Cannabis can have an impact on opioid addiction and recovery, in September 2016, the CDC published new guidelines for opioid addition and recovery treatment programs calling for clinicians to stop Cannabis (THC) drug testing as a requirement for their treatment. The guidelines also urge doctors not to drop patients who test positive for THC.[41]

The cost savings related to integrating medical cannabis is also compelling. A recent study reviewed Medicare Part D prescriptions enrollees from 2010 to 2013 and found that prescription drug use fell significantly for those medications that Cannabis could serve as a clinical alternative. Additionally, national reductions in Medicare spending when States implemented medical Cannabis laws were estimated to be $165.2 million per year in 2013.[42] These findings suggest that State and private insurance companies could save the hundreds of millions of dollars that they would normally payout to cover thousands of these prescription medications.[43]

Understanding this compelling evidence, Massachusetts Senator Elizabeth Warren wrote a letter in February 2016 to the director of the U.S. Centers for Disease Control and Prevention (CDC), Dr. Thomas Friedan, calling for additional research surrounding the role legal Cannabis can play on the opioid epidemic.[44] The Commonwealth of Massachusetts can lead the U.S. in designing a nimble, yet rigorous, research and medical care integration agenda for recreational Cannabis.

Current Bills related to Adult-Use Cannabis Roll Out in The Commonwealth of Massachusetts

The following section details the current bills being reviewed by the Joint Committee on Cannabis Policy in the Commonwealth, and provides evidence-based recommendations prepared by the Cannabis Community Care and Research Network.

Advancing the Research Agenda

Bills H3181, S1072: An Act Relative to Cannabis research, data collection, and best practices

1. Consider revising these bills to promote a balanced research agenda highlighting the medical benefits and potential risks based on the National Academies of Science, Engineering, and Medicine report published in January 2017.
2. Support the development of a Center of Excellence in Massachusetts for Cannabis Care and Research that promotes a balanced public health and clinical research agenda. CCCRN is happy to provide the State with a more detailed proposal if interested.
3. Consider explicitly integrating opioid addiction and other conditions with proven potential therapeutic value into research agenda to advance the science related to the potential role of Cannabis.

Piloting Models of Integrated Care

Bill H1050: An Act Relative to a Medical Cannabis Pilot Program

1. We support this bill and the Committee could consider funding to establish a research agenda and pilot program for integrating Cannabis therapies into the care for Veterans with Opioid Addiction in Massachusetts.
2. Consider extending research and program implementation to include post-traumatic stress disorder (PTSD) and other qualifying medical conditions to develop a comprehensive program addressing multiple health outcomes, translating research into action.

Funding the Medical and Recreational Cannabis Research Agenda

Bill H3200: An Act Establishing a Commission to study the impact of Cannabis legalization on public safety and the well-being of children in the commonwealth

1. Consider developing an innovative public fund for research that balances health benefits and risk mitigation for medical and adult-use Cannabis. This fund could be governed by a community advisory board, drawing funding from State, Private Sector, Cannabis Industry, Private Foundations, and other interested groups or Individuals. This recommendation was also noted in the Health Effects of Cannabis and Cannabinoids Report released January 2017. A fully detailed proposal can be submitted by CCCRN if the Committee is interested.[45]

Evidence Summary

- As mentioned above, the scientific evidence-base for Cannabis and its potential to impact the opioid epidemic is growing and very compelling.
- Researchers face serious challenges in accessing funding and quality Cannabis samples for rigorous trials due to the scheduling of Cannabis as a class 1 drug.[45]
- The Commonwealth of Massachusetts is a long-time leader in healthcare innovations and has some of the best minds in the world.
- Public health prevention and risk mitigation frameworks have been published based on the experience of Colorado and can be leveraged to ensure the public's safety is upheld.[46]
- A diverse network of funders is needed to support cannabis and cannabinoid research that explores the beneficial and harmful effects of Cannabis use.[45]
- The increase in state-level legalization for medicinal and recreational purposes may spur funding more high-quality studies.[4]

Youth Cannabis Use, Prevention, and Education

S1071: An Act relative to youth Cannabis use, prevention, and education
H3180: An Act relative to youth Cannabis use prevention, and education
H2382: An Act to prevent adolescent substance use
H3504: An Act to Increase addiction treatment services
H3175: An Act to protect children from the use of alcohol and Cannabis

1. We support passing these bills. However, the Committee can consider designing education campaigns that de-stigmatize Cannabis, and adopt approaches that educate youth that recreational Cannabis use is meant for adults. Campaigns that promote the medical benefits of Cannabis and CBD, while advising on the necessary steps to prevent abuse and addiction might prove valuable.

H3166: An Act dedicating one-percent of the recreational Cannabis excise tax to youth substance use prevention
H3167: An Act funding youth substance abuse prevention through a fee on licensed Cannabis establishments

1. We recommend the Commonwealth leverage additional funding sources for research, in addition to taxes, that will contribute to the evidence-base as well as broaden the topics of research to explore the medicinal value of Cannabis. One example would be to create a public fund for research, as mentioned above.

Evidence Summary

- In 2016, the Monitoring the Future (MTF) Survey found that Cannabis use among 8th and 10th graders has declined, resulting in the lowest level of Cannabis use amongst 8th and 10th graders in more than two decades. The survey found that disapproval of Cannabis remains high in 12th graders, with 69% of the 12th graders surveyed saying they "disapprove of smoking Cannabis regularly".[47]
- According to a CDC review of national data from 2002-2014, found Cannabis use increased among persons aged 18 years and over, but not among those aged 12-17 years.[48]
- Colorado has not shown an increase in youth use or abuse of Cannabis and levels of perceived risk among youth remains static despite legalization.[49]
- State surveys in Colorado, Washington, Oregon, and Alaska show after legalization the number of students in grades 6-12 who used or ever used Cannabis, stayed stable or decreased slightly, while alcohol abuse remained high.[49]
- A study conducted by Columbia University showed no association with increased teen use as a result of medical Cannabis laws.[50]
- A study published in Lancet Psychiatry also found no evidence for an increase in adolescent use of Cannabis within the first or second year after passing medical Cannabis laws.[51]
- Although some studies found frequent Cannabis use can impact cognitive development, a 2016 review of four states with legal Cannabis show no changes in standardized testing performance of 8-10th graders.[52]

Recommendations

- Latest evidence recommends developing targeted prevention strategies to reduce youth initiation, prevent Cannabis dependence, and prevent adverse health effects.[48]
- In a September 2016, CDC authored review of national estimates of Cannabis use from 2002 – 2014 called for states to modify state-level surveys and develop more timely and comprehensive surveillance systems as a way to improve data collection methods.[48]

Medical Use

H2385: An Act to protect patients approved by physicians and certified by the department of public health to access medical Cannabis
H2386: An Act relative to medical Cannabis pediatric patient protections

1. We support passing these bills

H3202: An Act Affecting Municipal Rights Regarding Medical Cannabis

1. We do not support this bill as the health benefits associate with Cannabis are evidenced-based; denying treatment with Cannabis or cannabinoids would be discrimination due to having a medical condition.

Cannabis Laboratory Testing

Currently, States design their own protocols and standards for laboratory testing of Cannabis products in the United States.[53] The lack of standardized protocols for lab testing can cause the Cannabis industry to faces challenges in obtaining accurate readings on products, which can cause public health harm. Additionally, the costs associated with testing Cannabis products can be quite high, with results often unreliable among testing facilities. The Association of Public Health Laboratories has published guidance for States developing new and assessing existing testing programs that can be leveraged.[53] By improving the overall quality of products, both medical and recreational clients will benefit in Massachusetts.

Recommendation

1. Assure standardized laboratory testing protocols are available that can serve as a model for other States or the national to follow for testing of Cannabis products.

Evidence: Lab Testing

- In 2014, an investigation in Colorado found that the THC content of retail edibles differed significantly from the amounts claimed on product labels.[4] One study in Washington found that 83% of edibles tested differed from labeled amounts by over 10% with more than one half of the products containing much less THC and one quarter had more.[4]

- Issues relating to the quality control of products is largely due to the lack of standardization in the Cannabis industry, and thus are governed at the State-level.[4]
- THC exists in both an acid and a neutral form, both of which have been found to be therapeutically relevant.[54] Methodologies for cannabinoid analysis should detect and quantify both forms of THC, with the most successful methodology being non-gas forms of chromatography.[54]
- A retention sample archive, samples representing each tested lot of cannabis product, will aid the state of Massachusetts in numerous ways.[55] The purpose of keeping retention samples is to support or verify cannabis product shelf life, quality, microbial, physical and chemical attributes. Retention samples also enable effective management of lab result discrepancies, incidents of patient complaints (adverse events) and other product quality investigations as well as law enforcement investigations into the origin of an unlabeled cannabis product.

Evidence: Consumer Safety

- Testing for mold, fungus, bacteria, and other microbial organisms should be required to ensure safety and quality.[56]
- The American Association for Laboratory Accreditation (A2LA) has partnered with Americans for Safe Access (ASA) to provide a cannabis specific laboratory accreditation. Specific testing includes cannabinoid testing and content, pesticides/fungicides/plant growth regulators, residual solvents, and microbiological contaminants (mold, insects, bacteria).[57]

Patient Coverage of Medical Cannabis Costs

The barrier to entry for a medical Cannabis patient in Massachusetts is high. As medical Cannabis is not covered under insurance schemes, and patients are often out of work due to illness they often cannot afford to access the quantity and quality of Cannabis necessary to treat their conditions.[58]

Recommendation:

1. Consider innovative insurance mechanisms to cover patient costs for accessing medical Cannabis to ensure equity and access to care

Evidence: Insurance

- Some have suggested that patients who want to use cannabis for pain and other chronic symptoms may pay as much as $1000 per month for their medication.[58] We can increase the number of patients through the roll out of safe and regulated recreational to improve access to Cannabis therapies.
- MassHealth/Medicaid have a waiver program that employers could be leveraged to cover medical Cannabis costs for employees, however as this is a jointly funded venture with Federal and State levels, this may be a challenge.

- Leveraging the MassHealth waiver program to have employers cover medical cannabis costs has the potential to have cost-savings for State. Further investigation into potential possibilities is warranted.

Labeling of Cannabis and Cannabis Products

H1059: An Act requiring certain labeling on packages contracting Cannabis or Cannabis products
S1077: An Act relative to Cannabis product packaging and labeling
H3182: An Act relative to Cannabis product packaging and labeling

1. We support passing these bills but also recommend that the labeling include the CBD% in addition to the THC value on labels. Additionally, consider labeling 'lessons learned' and best labeling practices currently in use in FDA regulated industries.

Evidence: Labeling

- The American Herbal Products Association produced Best Practices and recommendations for labeling Cannabis and Hemp products that can be leveraged.[59]
- Edible labeling in Colorado and Washington have requirements to address: delayed activation time, accidental ingestion, and proper dosing. Focus groups with 94 adult consumers and consumers of edibles revealed more improvements are needed in labeling to prevent unintentional ingestion and help ensure proper dosing and safe consumption.[60]
- Labeling varies greatly state to state. CO, WA, and OR require a universal symbol to be on edibles. OR and WA require the use of pesticides be disclosed on the label. CO and OR require a nutrition facts panel. AK and OR require amount of THC in a serving or single edible be disclosed. AK, CO, WA, and OR prohibit labeling that appeals to youth.[61]
- Development of a Massachusetts State labeling guidance would assist vendors to comply with content and format requirements of labeling for legal cannabis products under the anticipated State's labeling regulations. Massachusetts may find value in an existing guidance developed by the FDA to provide recommendations for developing labeling for new prescription drugs and revising labeling for already approved prescription drugs. This guidance includes implementation of industry labeling for prescription drugs and biologics as well as implementation recommendations to meet labeling content and format requirements of the Physician Labeling Rule.[62]

Evidence: Cannabis Vendor Facility Compliance

- Budding legalized cannabis industry brings with it public safety concerns that need to be addressed by Massachusetts. FDA Current Good Manufacturing Practices (cGMP) is

the standard for finished pharmaceutical products, dietary supplements and medical devices. The Current Good Manufacturing Practice (cGMP) regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacture, processing, packing and sale of a drug product.[55]

- Massachusetts might anticipate that at some point in the future the federal government will require legalized cannabis to be compliant with cGMP regulations as there will be an emphasis on safety, quality and effectiveness and the federal government will attempt to apply a national standard to state legalized cannabis efforts.

Recommendation:

- The most proactive approach to cannabis patient safety that MA could implement would be adoption of requirements that parallel cGMP regulations from the inception of Massachusetts' legalized cannabis program.
- In order to assess all equipment, computerized systems, facility areas, utilities, etc. for applicability and compliance to the regulations the State puts forth, Massachusetts could utilize compliance applicability and compliance assessment forms.
    - A Compliance Applicability Assessment form provides the following benefits:
        - Ensures that there are no unnecessary expectations for compliance, e.g. equipment which has no direct impact on the cannabis product quality, testing, etc. or internal operational function which have no impact on the end product.
        - Defines the scope of equipment/systems/facility that must comply with regulations.
    - A Compliance assessment form provides the following benefits:
        - Implementation of a Compliance Assessment form will provide both the cannabis facility and the regulatory agency a roadmap to compliance and auditing.
        - Enables the regulatory agency to prompt facilities to pre-populate audit forms with evidence of facility conformance to regulations, which becomes a starting point for the auditing process.
        - Based upon the evidence of compliance provided by the facilities, the Department can determine whether an onsite audit is necessary or plan the focus of the audit prior to arriving at the facility.
        - Provides real-time reporting on the level of compliance with any or all portions of the regulations by all regulated entities.
    - The objective of the assessment forms is to make the expectation of compliance as evident as possible while leaving the level of actual compliance as transparent as possible. The pre-audit and audit processes can be automated and incorporated directly into the seed to sale software solution. By adopting this practice, Massachusetts can set the "gold standard" for managing and auditing automated Compliance as a Services (CaaS) through its seed to sale software solution for the legalized cannabis industry.

Evidence: Seed to Sale Software Compliance

- Similar to those seed to sale software regulations under consideration by Massachusetts, Electronic Records and Electronic Signature regulations have evolved within the FDA regulated drug and device industries. These software regulations provide insight into, and avoidance of, many pitfalls that may be eluded by Massachusetts from the inception of its legalized cannabis program. When the manufacture or sale of FDA regulated products relies on computerized systems, these systems must be in compliance with Title 21 CFR Part 11 of the Code of Federal Regulations (commonly referred to as Part 11 regulations).[55] Part 11 regulations deal with the Food and Drug Administration (FDA) guidelines on electronic records and electronic signatures in the United states. Part 11 defines the criteria under which electronic records and electronic signatures are considered trustworthy, reliable and equivalent to paper records. Massachusetts should require that all seed-to-sale software vendors conducting business in the state should be held to standards that parallel the FDA Part 11 standards.

Edibles and Potency

Edibles

S1061 An Act relative to edible Cannabis products

1. While we understand that the bill is aimed at preventing youth from consuming edibles, we suggest that geometric shape be excluded as medications often come in forms that are in a geometric shape and there is no evidence that geometric shapes will cause more young people to consume.

H3193: An Act banning the manufacture and sale of edibles

H3169: An Act limiting the sale of certain edible products in the Commonwealth

1. We do not support this bill. Instead we recommend the committee uses the same standards, including Good Manufacturing Processes, for medical edibles in the recreational edible market.

H3171: An Act regulating certain edible products

1. We support this bill but also recommend that the labeling of the edibles also include the CBD value in addition to THC.

H3177: An Act further regulating the manufacture and sale of certain commercial Cannabis products

1. We do not support this bill passing as it would prohibit a valuable form of ingestion that, while needs further study, would prevent patients or adult-recreation users who cannot smoke full flower or vaping access to alternative ways of ingesting Cannabis or CBD

only products.

S1066: An Act further regulating the manufacture and sale of certain commercial Cannabis products.

1. We do not support this bill as it would prohibit many who need potential medical benefits and push patients to access Cannabis products through a retail market. For example, some patients in need might not be able to smoke Cannabis and can only use tincture or eat edibles.

Cannabis Potency

H3162: An Act relative to the THC level in edible products

1. We do not support this bill. Typically, THC is measured in milligrams and not in potency. CCCRN recommends that potency be a standard of measure.

H3183: An Act relative to Cannabis potency
S1073: An Act relative to Cannabis potency

1. We support these bills. The study of the potency of THC is of great importance. However, the Cannabis plant does not produce standard levels of potent strains, due to the variety of ways it is cultivated. Therefore, it is counter-productive to use potency as an indicator or measure. Rather, THC levels have become the norm for standardization. Additionally, when the inquiry occurs, the Committee could also consider including the CBD% profile in addition to the THC content.

Recommendations:

- Develop educational materials that describe the effects of edibles, including delayed effects, and other key issues and include these in public awareness campaigns.[4]
- Ensure educational campaigns are balanced, not only targeted at prevention, but also highlight that Cannabis has both medical and psychoactive properties. A balanced, adult-use focus for educational campaigns may serve the Commonwealth well.

Evidence: Edibles and Potency

- Edibles are an increasingly common preferred method of ingesting Cannabis. In Colorado in 2014, edibles were around 45% of the total product sales.[4]
- Edibles are more prevalent in states that have legalized medical Cannabis use, particularly in States with medical use in place for longer and those with more dispensaries per capita.[4]
- One advantage of edibles is the longer duration of action and can have less intoxicating effects than smoking Cannanbis.[4]
- A nationally representative sample found that 30% of respondents who had ever used Cannabis reported consuming it in edible or beverage form.[4]

- Anecdotal reports attribute increase interest in edibles as they are discreet and more convenient way to consume, which is helpful in work places where Cannabis is still prohibited.[4]
- Additionally, edibles can increase acceptance of use, as patients still report high perception of stigma associated with Cannabis, and may favor edibles as they are easier to transport.[4]
- A strong predictor in the decision to choose edibles may be related to the perception that edibles avoid harmful toxins caused by smoking Cannabis.[4]
- Eating Cannabis-infused edibles appears to not affect pulmonary function or increase cancer risk. Therefore, this route of administration, as opposed to smoking Cannabis, is preferable for patients with medical conditions such as cancer.[4]
- Despite evidence of increased pediatric hospital visits and calls to poison centers, overall these rates are relatively low, even in decriminalized states.[4]

Challenges with Edibles

- The lack of standards for dosing and potency of Cannabis edibles also still remains a public health concern.[49]
- Despite evidence of the value of CBD in edibles, few manufacturers report CBD content in their products.[4,56]
- To date, little attention has been paid to the dosing levels, information for new users, and regulations to ensure safety and the potential contamination of edibles.[49]
- The delayed effects and lack of awareness among clients leads to the often unintentional ingestion of greater than intended amounts.[4]
- Edible products, due to the lack of consistency and delayed intoxication, make edible products responsible for the majority of healthcare visits related to Cannabis and likely due to the failure of users to appreciate the delayed effects.[4]
- Some authors argue that the maximum recommended dose is 10 mg/serving and Colorado only allows a 100 mg limit on Cannabis products.[4]
- The increased number of accidental ingestion of edibles among children have increased, since legalization, rates of these visits have gone from 1.2 per 100,000 since legalization to 2.3 per 100,000 two years' post-legalization.[63]
- In Colorado, surveillance systems and additional questions have been added to health state surveys, as well as comprehensive public health education campaigns have been launched.[49]
- The Cannabis industry has taken steps towards ensuring the safety of products through educational campaigns, including educating new users on the delayed effects of edibles and appropriate dosing.[49]
- Recent research out of the state of Washington reviewed what types of foods and packaging are most attractive to children in order to provide further information about

how to better design programs that address not only the potency of edibles in addition to labeling.[64]

These and other research findings can be used to create logical and evidence-based guidance for the development and sale of edibles in Massachusetts.

Recreational Market Regulatory Oversight

H2384: An act increasing the legal age for Cannabis consumption from 21-25

- We do not support this bill

H2382: An Act regarding the authority of the Alcoholic Beverages Control Commission over the business of Cannabis establishments

- We do not support this bill

Evidence: Regulatory Oversight

- Cannabis is an entirely different substance than tobacco and alcohol and thus, requires a unique regulatory framework. Cannabis regulations will influence prices, revenue collection, product safety, consumer information, sales to minors, and distribution in other states.[66]
- If regulations make the legal Cannabis market too expensive, patients will turn to lower quality products of the illegal market.[66]
- Giving authority to the Alcoholic Beverages Control Commission (ABCC) may have serious consequences for the patient community in MA and ignores the lessons learned from other states.[67]
- The Department of Public Health, not ABCC, keeps the interests and rights of patients at the forefront. ABCC is not set up to protect patient privacy, offer advice, to answer patient questions about their medicine, or to regulate a medication.[67]
- Evidence shows legal cannabis sales infringe on the sales of alcohol. The alcohol lobby is strong in Massachusetts, putting cannabis at a disadvantage. Cannabis tax revenue in Colorado for 2016 was projected to be at least four times the revenue of alcohol, which could lead to unfair regulations for cannabis.[67]

Tax

H3170: An Act establishing a tax rate for Cannabis equal to the tax rate for tobacco
H3186: An Act relative to the Cannabis tax rate

- We do not support these bills

Evidence: Tax

- Colorado, Washington, and Oregon initially placed high tax rates (above 30%) on cannabis and found that a high tax rate did not sufficiently reduce the black market. More recent ballot proposals across the country propose rates between 10-25%. Tax rates on final retail sales have proven the most workable form of taxation. To date, other states have found that taxing the retail or wholesale price is most efficient.[68]
- While tobacco and Cannabis are both plants that are dried and processed for ingestion, lumping cannabis into the same category as tobacco is a flawed design when it comes to taxation. Tobacco has no demonstrated medicinal value and is in fact a known carcinogen, while cannabis is currently legal in the state of Massachusetts as a medicinal product.
- Tobacco products are highly taxed. Much of the reasoning behind the tax rate is related to moral objections, calling such taxes a "sin" tax, and to efforts to reduce tobacco use due to its status as a known carcinogen. The assumption is that, by taxing tobacco at such high rates, it will deter consumers from purchasing tobacco products.[68]
- Cannabis use should not come with moral assumptions and taxes that tobacco does. Taxing cannabis the same as tobacco could have adverse effects, such as inflating the price, possibly to the point of locking low income adults out of the market, especially those who are self-medicating a physical or mental condition.[68]

Expungement

S1063: An Act relative to expungement for repealed crimes

- We recommend passing Although this bill addresses the issue, we believe a more comprehensive approach is necessary calling for a retroactive dismissal of convictions in addition to the sealing of criminal records. Developing a comprehensive re-integration program can help these citizens access jobs and improve their lives post-incarceration.

Evidence Summary

- Cannabis convictions can lead to devastating consequences. According to the Supreme Judicial Court, low-level drug offenders may be subject to the following: deportation, disqualification for employment, disqualification for professional licensure, loss of access to public housing and government benefits, probation fees, and prison sentences for subsequent offenses.[69]
- Those who committed acts violating the laws regarding recreational use of Cannabis have likely "paid their debt to society", and therefore expunging their records would have little to no effect on past violations but would instead provide expanded future opportunities.[69]
- The expungement legislation should also pass as a part of the racial justice platform; people of color are arrested at higher rates than white people, despite similar rates of Cannabis use and sales.[69]

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