Report of the 2020 Virginia Medical Cannabis Work Group

To the Governor of Virginia, the Attorney General, and the Chairs of the House Committee on Health, Welfare, and Institutions and the Senate Committee on Education and Health

As required by Chapter 711, 2020 Virginia Acts of Assembly

December 15, 2020

Daniel Carey, Secretary of Health and Human Resources

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Executive Summary

Virginia initially established a medical cannabis program to provide additional treatment options for patients with intractable epilepsy in the Commonwealth. The program has been expanding since 2015, with significant changes occurring in the 2020 Regular Session of the General Assembly. Virginia law allows for five pharmaceutical processors, one in each health service area established by the Department of Health, with up to 30 dispensing sites to dispense medical cannabis products. Patients can legally obtain a broad range of cannabis oil products that may contain up to 10mg of tetrahydrocannabinol (THC) per dose, with dose not defined by the Code of Virginia. While most states have a list of qualifying conditions, practitioners in Virginia can recommend medical cannabis for a patient based on a diagnosed condition or disease. Currently, four pharmaceutical processors are permitted to cultivate and process cannabis, with three of those four open for dispensing cannabis oil to registered patients. Cannabis dispensing facilities, which will not cultivate or process any cannabis, are expected to become operational in 2021. For a full summary of the program's structure and history, see Appendix I.

The Virginia Medical Cannabis Work Group was established by HB 347, or Chapter 711 of the 2020 Acts of Assembly. The legislation charged the Secretary of Health and Human Resources to:

> "…convene a work group to review the Commonwealth's medical cannabis program and issues of critical importance to the medical cannabis industry and patients, including expansion of the medical cannabis program and the medical use of cannabis flowers. Work group members shall include the Secretary of Health and Human Resources, the Director of the Department of Health Professions, the executive director of the Board of Pharmacy, one member of the House of Delegates, one member of the Senate, three representatives of the medical cannabis industry who are currently licensed as pharmaceutical processors by the Board of Pharmacy, one person with expertise in issues of importance to patients who use medical cannabis for treatment or alleviation of the symptoms of a diagnosed condition or disease, and one member who is a physician who is currently registered with Board of Pharmacy to issue written certifications for use of cannabidiol oil and THC-A oil."

In alignment with the statutory requirements, the work group was comprised of medical cannabis industry representatives, patient experts and advocates, physicians registered to recommend medical cannabis, and representatives from the Virginia House of Delegates, Senate, Department of Health Professions, Board of Pharmacy, and Secretary of Health and Human Resources:

- Dr. Daniel Carey, Secretary of Health and Human Resources
- Catherine "Catie" Finley, Assistant Secretary of Health and Human Resources
- Dr. David Brown, Director of Health Professions
- Caroline Juran, Executive Director of the Board of Pharmacy
- Delegate Glenn Davis, Member of the House of Delegates
- Senator David Marsden, Member of the Senate

- Ngiste Abebe, Director of Public Policy, Columbia Care
- Dr. Sam Caughron, Charlottesville Wellness Center Family Practice, designated by the Medical Society of Virginia (MSV)
- Jack Page, Chief Operating Officer, Dharma Pharmaceuticals
- Sara Payne, Senior Corporate Counsel Jushi, parent company, Dalitso, dba Beyond/Hello
- Jenn Michelle Pedini, Executive Director of Virginia NORML
- Lisa and Hayley Smith, patient representatives
- Joy Strand, Vice President, Green Leaf of Virginia
- Dr. Preston Grice, University of Virginia (*note that Dr. Grice only attended the first meeting and then submitted a statement and narrated powerpoint presentation)*

The work plan and discussion topics were established by consensus under the leadership of the Office of the Secretary of Health and Human Resources. The work group met five times between August and November, 2020. All meetings were open to the public and were held virtually via WebEx due to the COVID-19 public health emergency. For a full summary of the work group's charge, membership, and work plan, see Appendix III.

The most significant program change the workgroup considered was introducing the medical use of flower, or botanical products, into Virginia's medical cannabis program. Currently, Virginia only allows processed products such as oils and concentrates. The work group also discussed a number of policy changes that would likely increase access to medical cannabis. A couple realities became clear through workgroup discussions. First, medical cannabis patients often face significant costs in obtaining their medication, in part because insurance does not cover the products. Additional issues related to patient cost are discussed throughout the report. Second, some patients face barriers to obtaining medication ranging from logistical hurdles to stigma and lack of provider education.

Virginia should continue to explore ways to increase access for patients for whom medical cannabis treatment is beneficial. Virginia should look to remove unnecessary, onerous requirements, while encouraging safe use by patients. Similar to other regulated medical drugs, medical cannabis has both therapeutic benefits and a potential for abuse. Unlike other medications, medical cannabis remains illegal at the federal level. In addition to the legal implications, its federal status has implications for the amount of high-quality research on its positive and negative effects. The report below begins with an overview of cannabis health effects and research. It then summarizes work group discussions on several issues and details potential policy changes.

Medical Cannabis Research and Health Effects

Cannabis has been used since antiquity[1] and there are many published studies examining its effect. However, there is minimal cannabis research that is based on generalizable, placebo controlled, randomized controlled trials. As a result of the research limitations much of the

[1] (Diane P. Cabello, MD, n.d.)

information on cannabis shows association, not causation. It is also largely based on botanical products, which are generally lower in potency and do not mirror the full range of commercially available products. Variance between products and between cannabis plant materials make it difficult to consistently define exposure or dosage. The biggest barrier is the federal research restrictions on cannabis. For further information on the federal restrictions on research, see Appendix IV.

As more states legalize marijuana for both medical and recreational adult use, the number of high quality research trials will likely continue to increase. There is substantial preliminary evidence that cannabis can be used for clinical indications beyond those listed in the next paragraph. In the meantime, most public health experts recommend using systematic reviews of "gold standard" research. One example is the seminal study entitled "The Health Effects of Cannabis and Cannabinoids" published in 2017 by the National Academy of Sciences, Engineering, and Medicine (NASEM).

Dr. Robert Wallace, a member of the authoring committee of the 2017 NASEM report, presented an overview of the report's findings to the work group. He first noted the study's limitations, some of which are listed above. The report found moderate effects of reducing emesis (vomiting) in cancer patients, improving spasticity in multiple sclerosis patients, and reducing chronic pain symptoms.[2] It also found moderate evidence for improving sleep in individuals with certain conditions, and some limited evidence for improving symptoms of anxiety disorders and posttraumatic stress disorder.[3] Childhood epileptic syndromes are also an accepted clinical indication.[4]

In terms of negative effects, cannabis use disorder impacts approximately 10-25% of regular cannabis users[5] and is characterized by dependence and continued use despite interference with important social, occupational, and relational commitments. Cannabis use is also associated with the development of substance use disorder more generally[6], as well as schizophrenia, other psychoses, and suicidal thoughts.[7] Acutely, cannabis impairs cognitive functioning[8] and increases risk of motor vehicle accidents[9]. Cannabis impacts immune function and there is at least one study associating it with seminoma[10]. Respiratory effects are discussed in the section of this report on medical use of flower. The negative effects of cannabis are higher for youth and pregnant women. Adolescent use is associated with impaired academic and employment

[2] Appendix VIII, p. 100, Dr. Wallace presentation
[3] ("The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research." 2017)
[4] Appendix VIII, p. 100, Dr. Wallace presentation
[5] Appendix VIII, p. 95, Dr. Wallace presentation
[6] Appendix VIII, 9. 100, Dr. Wallace presentation
[7] Appendix VIII, p. 99, Dr. Wallace presentation
[8] Appendix VIII, p. 98, Dr. Wallace presentation
[9] Appendix VIII, p. 99, Dr. Wallace presentation
[10] Appendix VIII, p. 96, Dr. Wallace presentation

achievement[11] and increases the likelihood of developing substance use disorder.[12] Use during pregnancy leads to lower birth weight, which is associated with other negative outcomes.[13] Given that cannabis can have both positive and negative health effects, practitioners must weigh both factors when recommending cannabis treatment.

Cannabis Provider Education & Health System Policies

As of December 2020, there are 577 practitioners registered to recommend medical cannabis in Virginia. Increasing the number of participating providers is critical for the growth of the medical cannabis program. Medical cannabis patients should be able to receive medical cannabis in the context of their medical care, and in consultation with their existing medical care team. Receiving the written certification from a primary care physician helps keep those lines of communication open. The work group met with the Medical Society of Virginia (MSV) and the Virginia Hospital and Healthcare Association (VHHA) to better understand barriers to practitioner registration.

MSV conducted a survey of 113 of its members. 95% of respondents were not currently registered to recommend medical cannabis. More than 60% reported concerns with recommending medical cannabis, including its status as a Schedule I drug at the federal level. Nearly 70% believed additional education should be required. Recurring themes from respondents' comments included concern around the lack of product research and the potential for overuse and addiction. 87% believe that additional education would improve physician comfort in discussing medical cannabis with patients. MSV concluded that "respondents would require a plethora of information both about the effects of the product and what coverage (cost) would be like for the patients in order to consider prescribing it." The full results of the survey are found in Appendix V.

Practitioners employed by health systems face additional barriers to recommending medical cannabis. Brent Rawlings from the Virginia Healthcare and Hospital Association (VHHA) explained the primary challenges, which relate to Medicaid and Medicare funding and national accreditation policies. A full summary from VHHA is provided in Appendix V. VHHA is aware of health systems in other states that have established some workarounds to segregate their duties and allow patients to use cannabis in the hospital. Ms. Smith, the group's patient representative, noted that it can be dangerous for some patients to go without their medical cannabis treatment. Workgroup members are also concerned with health systems' prohibiting their practitioners from participating in the medical cannabis program. They are aware of multi-state operators that allow their physicians to recommend medical cannabis in other states, but not in Virginia. VHHA said it would work with its members to see if further information on health system cannabis policies in Virginia and other states is available.

[11] Appendix VIII, p. 98, Dr. Wallace presentation
[12] https://www.samhsa.gov/marijuana
[13] Appendix VIII, p. 97, Dr. Wallace presentation

Medical Use of Flower

As stated previously, Virginia currently allows processed products such as oils and concentrates, but does not allow flower. Many states with medical marijuana programs also allow flower, or botanical products. Botanical products range from dried flower buds to unprocessed plant material made available to patients in pre-approved administration forms. Oil-based products are created through a multi-phase manufacturing process that involves isolating individual constituents of the cannabis plant material such as tetrahydrocannabinol (THC), cannabidiol (CBD), and other cannabinoids.

Among states that allow flower, some permit sale of whole flower and others require it to be ground or homogenized in size. Flower can be smoked, unlike oils and concentrates. Some states that allow flower still prohibit the use by smoking. Other than smoking, all modes of use - including vaporizing, baked goods, capsules, and solutions – can be done with both flower and concentrate products. In states that allow it, flower is generally more popular than concentrates for both medical and recreational. The 2017 Cannabis Industry Annual Report found that flower represented 47% of sales volume.[14] Flower by itself is generally lower in potency than concentrates, though not exclusively so.

Workgroup members presented several considerations around allowing botanical products. The group also heard from a pharmacist and three physician researchers on the established and hypothesized health effects of cannabis, especially as they relate to flower:

- Farzana Kennedy, the pharmacist-in-charge at Dalitso, a multi-state cannabis operator,
- Dr. Sue Sisley, Medical Director for medical cannabis license holders in several states, physician researcher at the Scottsdale Research Institute in Arizona, and
- Dr. Robert Wallace and Dr. Ziva Cooper, members of the authoring committee of the National Academy of Sciences, Engineering, and Medicine report *The Health Effects of Cannabis and Cannabinoids* and professors at University of Iowa and University of California Los Angeles (UCLA).

In addition, the group heard from other states on their approaches to botanical products. See appendices XIII and IX for those presentations. Key considerations around cannabis flower products include:

Dosage control or "self-titration." Inhalation of cannabis products includes both smoking, which requires flower products, and vaporization. Both oil-based and flower products can be inhaled.[15] Inhalation provides a rapid onset of relief that can last as little as two hours. Inhalation allows patients to "self-titrate" or more effectively control their dose. Self-titration is often referred to as "start low, go slow," where patients take small amounts until they experience symptom relief. On the other hand, oral consumption provides a slow onset, sometimes two hours, and a much longer duration of effect. Both botanical and oil products can be used orally.

[14] Appendix VIII, p. 122, Dr. Sisley presentation
[15] Appendix VIII, p. 84, Dr. Cooper presentation

A slow onset can be difficult for patients trying to manage pain. Patients report that flower products give them more control over their dose and mode of delivery than oils.[16] Many veterans prefer flower for treating post-traumatic stress disorder (PTSD).

Practitioners participating in workgroup discussions made varying statements regarding self-titration with flower as opposed to oils. Dr. Sam Caughron, the group's primary physician representative, supported allowing flower in Virginia's medical cannabis program due to the increased flexibility for patients. Dr. Preston Grice stated the importance of ensuring that patients can distinguish between symptom relief and the "buzz" with rapid onset products. Dr. Sisley and Farzana Kennedy said flower products improve patients' ability to "start low and go slow," customizing use to their individualized symptoms.

Dr. Cooper agreed that low-potency flower products are effective for self-titration as compared to high-potency concentrates. However, she said it is not as straight-forward as comparing flower to extracts. Patients' ability to self-titrate depends on a number of factors including potency, chemical content, preparation, route of administration and product consistency.[17]

Product consistency. Most pharmaceutical products have consistent amounts of active ingredients in each dose. For example, consumers know that each tablet in a bottle of Advil has the same amount of ibuprofen. As Dr. Caughron stated, "when you use a botanical, you are never really going to be able to standardize it."[18] Dr. Grice did not support botanical products because they restrict his ability to recommend a specific dosage. "Processors can make some pretty good estimates on the percentage of various cannabinoids in a dried product, especially THC and CBD…however, that doesn't tell me as the prescriber the specific amount of cannabinoid the patient is taking dose per dose."[19] Dr. Sisley believes that the FDA is moving away from the paradigm of fixed dosing, given its recent approval of her medical trial using smoked flower. She believes dosing is challenging with concentrates as well, given the lack of solid data.[20]

Consistency is important in any product. With both botanical and concentrated products, most dispensary products are unable to meet the consistency and purity standards required for research trials.[21] The amount of THC, CBD, and other cannabinoids varies bud-to-bud, plant-to-plant, and batch-to-batch. The medicinal aspects of botanical products are activated by the delivery mechanism. THC is activated during processing with oils.[22] With respect to inhalation delivery, such as a vaporization device, cannabinoids are converted at a consistent rate based on the quantities and ratios present in the plant, as shown through a laboratory analysis. The variances in cannabinoid levels present in botanical products can be reduced using by using established plant genetics, good cultivation and post-harvest handling practices, and accurate product labeling informed by lab analysis.

[16] Appendix VIII, p. 116, Dr. Sisley presentation
[17] Appendix VIII, minutes p. 87
[18] Appendix VIII, minutes p. 87
[19] Appendix VIII, minutes p. 86
[20] Appendix VIII, minutes p. 97
[21] Appendix VIII, minutes p. 88
[22] Appendix VIII, p. 85, Dr. Sisley presentation

A key factor for product consistency and safety is third-party lab testing. Some states allow a certain percentage of variance between the chemical content listed on the label and in the product to accommodate plant-to-plant differences and other challenges. Dr. Sisley noted that testing capability is improving nationwide. During public comment, it was noted that Virginia does not yet have many labs conducting cannabis testing.[23] Virginia should consider the availability of third-party lab testing as it contemplates expansion of the marijuana program.

Smoking. Unlike concentrates, flower can be smoked. Smoking cannabis is strongly associated with respiratory symptoms and chronic bronchitis. However, it has not been associated with Chronic Obstructive Pulmonary Disease (COPD).[24] Studies suggest marijuana smoke is similar to tobacco smoke and contains carcinogens at similar rates.[25] However, there is no consistent evidence of lung and other cancers in cannabis users.[26] Researchers are continuing to look at long-term lung impairment. For example, Colorado's public health department has found daily or near daily marijuana smoking may be associated with bullous lung disease.[27] There is also evidence of acute (short-term) improvement of airway function.[28]

The workgroup members did not have a robust discussion on whether Virginia should allow medical cannabis use by smoking, should the Commonwealth choose to allow botanical products in the medical program. Dr. Sisley highlighted promising results from research trials with flower smoked. However, Dr. Grice stated that there is a lack of support for smoked cannabis in the medical field.

It is a widely accepted hypothesis that vaporizing the plant is better for respiratory effects than smoking.[29] However, there are many unknowns with the health effects of vaping and additives are a potential concern. In 2019, there was an outbreak of cases of acute lung injury from e-cigarettes caused by the contaminant EVALI.

Safety. There is little information available on the long-term health effects of concentrates, including high-potency products. Until recently, all federal research on cannabis health effects was conducted using dried flower from the University of Mississippi. While not necessarily so, flower products are often lower in potency than concentrates. Flower alone can have no more than 30% THC, and concentrates can have up to nearly 100% THC. Current examples of products in Virginia have a combined THC/THC-A concentration of 35% to 82% for some formulations. High potency products may be accidentally over consumed, especially by naïve user. Based partially on the more substantial body of research using flower and high potency of some extracts, Dr. Sisley concluded that flowers are often a safer option for patients.

Allowing flower for medical use would also provide a regulated, safer product for patients already using flower from the illicit market. Many patients prefer botanical products and their

[23] Appendix VII, Public Comment
[24] Appendix VIII, p. 97, Dr. Wallace presentation
[25] (Hall et al., 2019)
[26] Appendix VIII, minutes p. 86
[27] (Colorado, n.d.)
[28] Appendix VIII, Dr. Wallace presentation, slide 97
[29] Appendix VIII, minutes p. 83, Dr. Cooper presentation

only options in Virginia are the illicit market or going without medical cannabis treatment. Similar to product consistency, Virginia's lab testing is a key consideration for product safety.

Opioid Substitution. The group found encouraging but inconclusive data on whether medical cannabis reduces opioid dosage.[30] Similarly, the Colorado Department of Public Health & Environment found mixed evidence on whether marijuana use is associated with decreased opioid use in chronic pain patients or those with a history of opioid addiction treatment.[31] Some chronic pain patients use both medical cannabis and opioids, and promising studies are looking at lower opioid doses among those patients.

Cost. Many workgroup members stated that flower products cost significantly less, because they require less processing. Medical cannabis costs are already a barrier to access due to the lack of insurance coverage. Anecdotally, it appears discussions around flower in other states also involved cost considerations. In Minnesota, which does not allow flower products, most patients reported medical cannabis was not affordable.[32] The average amount spent each month was $316 in 2019.[33] However, a study done by Colorado found that the average price per THC dose was the same for flower and concentrates ($1.35 per dose).[34] Colorado used a THC dose equivalent, instead of weight, to account for product differences. For example, one would consume less concentrate than flower (by weight) in order to achieve the same effect. Some work group members stated it was not appropriate to compare prices in Colorado with what they might be in Virginia, since a number of market forces unique to each state (e.g. supply, market maturity) factor into prices. A work group member provided a study that found a gram of concentrate to be approximately three times as expensive as a gram of flower in six states, including Colorado. However, the information only included information by weight, not by dose.

"Entourage effect." The "entourage effect" refers to an improved therapeutic effect when "all of the components found in marijuana work together" in flower products.[35] Some patient testimonials and studies support the entourage effect and state that "extracts often leave out therapeutically important [compounds] that are needed for the full medical cannabis 'entourage' effect."[36] Several work group members highlighted the importance of keeping the natural balance of flower, since cannabinoids may be stripped out during extraction of oil-based products.[37] However, very few rigorous trials have been done to date examining this hypothesized effect.[38] As. Dr. Cooper described, people are actively conducting studies on the entourage effect, but we don't know very much at this point.[39]

[30] Appendix VIII, p. 89
[31] (Colorado, n.d.)
[32] Appendix VIII, p. 118, Dr. Sisley presentation
[33] https://www.health.state.mn.us/people/cannabis/data/pricereport.html
[34] (University of Colorado, Business Research Division & MPG Consulting, 2019)
[35] Appendix VII, p. 120, Dr. Sisley presentation
[36] Appendix VIII, p. 121, Dr. Sisley presentation
[37] Appendix VIII, minutes p. 119, Dr. Sisley presentation
[38] Appendix VIII, minutes p. 117, Dr. Cooper presentation
[39] Appendix VIII, minutes p. 84, Dr. Cooper presentation

State Oversight and Administration. Given the popularity of flower products, it is likely that introducing them would significantly expand the volume of patients and sales in Virginia's medical cannabis program. The Board of Pharmacy projects they would need to procure a patient registration software system and hire additional full-time employees to address the increased workload. Connecticut's medical cannabis program has three full time employees and eighteen staff dedicating partial time, and still feels understaffed. The Utah Department of Health has six full time employees and part-time help from budget managers, in addition to the Department of Agriculture staff responsible for the processors and growers. Other states also noted that regulation and oversight of flower has unique challenges as compared to oils. For example, Connecticut has received complaints of mold in flower products. It may also be difficult to enforce no smoking laws in homes.

State Approaches. Many of the thirty-six states with medical cannabis programs allow flower products. Some allow flower in all forms, likely due to some of the reasons mentioned above. Virginia also heard from some states that do not allow flower products, or allow flower only in certain forms. For example:

- Louisiana: While the Louisiana legislature did approve some significant changes to the medical marijuana law during their regular session earlier this year, they did not change the prohibition on the use of raw or natural cannabis products. The two producers, which are licensed and regulated by the state agricultural department, are authorized to produce pharmaceutical-grade products in dosage forms approved by the Board of Pharmacy. Louisiana also does not permit smoking of medical cannabis; however, inhalation using metered dose inhalers is allowed. In addition to raw flower products not being permitted by law, the Louisiana Board of Pharmacy has determined they do not meet the definition of a pharmaceutical grade product (21 CFR 111).

- New York: New York state law prohibits smoking medical cannabis and does not allow whole flower. Inhalation is allowed through vaporization using a metered dose. Limiting products to a ground (particle size less than 5mm) format, as opposed to larger plant materials, helps ensure that patients are using medical cannabis in that fashion. Raw flower products would allow for greater variability in use, including modifying their dosage and their route of administration. New York regulates medical cannabis similar to the way it regulates other pharmaceutical products, where consistency is required dose-to-dose.

- Utah: Utah requires flower products to be sold in a jar with opaque packaging. Patients are prohibited from transporting flower products outside their home more than 60 days after purchase in order to help mitigate over-purchasing and diversion. Smoking cannabis is prohibited. Edibles must be sold in subcutaneous cubes to help avoid accidental child consumption.

- Connecticut: Connecticut allows flower products but they must be homogenized in small sizes. Individuals under 18 may not have smokable or inhalable products, and must have

two physicians (including the patient's primary care provider) confirm that the palliative use of marijuana is in the minor patient's best interest.[40]

- Florida: In Florida, the route of administration is approved by the physician, as opposed to approving medical cannabis more generally. They also have strict rules around delivery devices and a process to approve every product and label.

Marketing and Hemp-Derived CBD

Currently, Virginia Administrative Code (18VAC110-10 et seq.) limits pharmaceutical processors advertising to a website with basic information such as store location and product list. Representatives from the medical cannabis industry noted that the restrictions limit their ability to educate potential and existing patients and to grow as an industry.

Some consumers do not understand the difference between hemp-derived CBD and medical cannabis. Hemp is cannabis with no more than 0.3 percent THC and a hemp-derived CBD product can also have no more than 0.3 percent THC, whereas medical cannabis has a much higher THC limit at 10 mg per dose. The cultivation of hemp is federally legal, while medical cannabis is legal only at the state level. Hemp-derived CBD is often characterized or marketed as wellness product, whereas medical cannabis has generally accepted therapeutic benefits for certain conditions. Many work group members expressed concern about misleading hemp marketing. Overstating the health benefits of hemp-derived CBD could lead to patients consuming these products in an attempt to address chronic conditions, when medical cannabis may serve them better.

The Virginia Department of Agriculture and Consumer Services (VDACS) regulates hemp-derived extracts that are intended for human consumption in a manner similar to its regulation of food and dietary supplements. In July 2019, Governor Northam directed VDACS to place qualifying industrial hemp processors under food safety inspection in order to address the safety of products that were available and being consumed but were not being regulated by the FDA, due to FDA's current position that hemp extract is not an approved food. Under VDACS's food safety criteria, hemp-derived extracts produced in Virginia must undergo testing to ensure it has no adulterants.

In terms of advertising, the U.S. Food and Drug Administration (FDA) prohibits therapeutic claims on unapproved drug products, and no food or dietary supplements under VDACS's regulation are allowed to present themselves as a drug or include therapeutic claims. That prohibition would have applied to individuals selling hemp-derived CBD in white lab coats, in alignment with a bill introduced by Delegate Davis in the 2020 General Assembly session (HB

[40] https://portal.ct.gov/DCP/Medical-Marijuana-Program/Patients-Under-18

349). Another option that was discussed was requiring hemp-derived CBD to be labeled as "hemp CBD" instead of solely "CBD" to highlight distinctions and mitigate inappropriate marketing (HB 484, 2020 session).

The work group raised concerns about gaps in oversight and enforcement around hemp-derived CBD, especially as it relates to environmental contagions. For example, CBD vapes or inhaled products are regulated as tobacco products under the FDA, but are not regulated by a state agency. Additionally, many hemp products sold in Virginia are imported from out of state. While the same laws apply for all products sold in Virginia, enforcing them on out-of-state products is more challenging and resource intensive.

Insurance and Fees

Insurance does not currently cover much, if any, medical cannabis in Virginia, in part due to its federal illegality. Work group members found that some states prohibit medical cannabis recommendation fees if they are provided as part of a regular visits. In Virginia, examples have been noted of practitioners charging several hundreds of dollars out-of-pocket for a visit to issue a written certification. Doctor fees are in addition to the cost of the medicine itself and the $50 annual patient registration fee. Should Virginia wish to reduce these high costs for patients, it could explore innovative approaches utilized in other states in terms of insurance and fee structures. For example, Virginia could include a reduced-cost option for veterans or individuals who are Medicaid-eligible.

Patient and Practitioner Registration Changes

Similar to many other states, Virginia requires patients and practitioners to register with the Board of Pharmacy (BOP) in order to participate in the medical cannabis program. In order to register, patients must obtain a written certification from a registered practitioner, complete a brief application, pay a $50 fee, and submit a copy of the written certification and proof of age, identity, and residency. Eligible practitioners complete a brief online application, pay a $50 fee, and once approved receive the written certification form to issue to patients. A complete description of the registration processes is in Appendix II of this report.

Some workgroup members proposed two changes to the patient and practitioner registries, as listed below. In addition to fee implications for the Board of Pharmacy, the work group discussed several considerations for each proposed change:

Extending Patient Registration from One to Two Years:
Many work group members supported extending the patient registration from one year to two years. The work group discussed making both the BOP registration and the written certification valid for up to two years. Many medical cannabis patients are disabled or especially vulnerable, making it more difficult to connect with their practitioner and complete the one-time application form. Some patients are juggling multiple appointments with specialists. Dr. Caughron noted that

most medical cannabis patients are dealing with chronic conditions that are unlikely to go away, and agreed with extending the registration timeline. He does try see everyone in his practice at least once a year and see those on narcotics at least every three months. The written certification allows the practitioner to communicate to the dispensary that they have recommended medical cannabis products for the patient, similar to a prescription. Practitioners may specify on the form which types of products they are recommending. There is some precedence in Virginia for mandating prescription renewal timelines, which differ depending on the substance.

The work group briefly discussed eliminating the patient registration requirement. However, several members noted that the registration provides meaningful protection from law enforcement for patients.

Eliminate practitioner registration:
Many workgroup members recommended eliminating the practitioner registration requirement. The goal would be to remove barriers in order to encourage practitioner participation and increase access for patients. In addition to the hassle of the brief registration form and the $50 fee, registration likely exacerbates stigma associated with medical cannabis. Work group members proposed that, instead of BOP sending the issuing form to the practitioner, BOP make the form publicly available for patients to bring to their provider, similar to the Oklahoma model. As discussed earlier in the report, it is important for patients to receive medical cannabis in the context of their other health care, when possible.

Dr. Caughron recommended easing the practitioner registration process. He noted it is likely more so the hassle and less the $50 that is the barrier for physicians. Among the 113 MSV members surveyed, the majority said that physician registration should be required to recommend medicinal cannabis.[41] In addition, of the small number of survey respondents who had registered with the BOP, the majority reported it was easy to register and to maintain their registration. Many states, though not all, require practitioner registration. In states like Utah and Florida, registering practitioners must also take an introductory course.

One potential disadvantage of removing the practitioner registry is that it may be more difficult for patients to identify providers willing to recommend medical cannabis. Currently, the BOP uses the registry to populate its public list of registered practitioners recommending medical cannabis. BOP is in the process of updating that "license look-up" to make it more user-friendly, since identifying a recommending provider is often a challenge for patients. Without the public list, patients would rely on word-of-mouth, advice from dispensaries, communications from the providers, and making phone calls to doctors. As of December 2020, there are 577 practitioners registered with the BOP.

Telehealth

Some members of the work group proposed allowing additional telehealth options for medical cannabis patients. Under current requirements, patients are required to visit with their practitioner and the dispensary at least annually. The annual practitioner visit may be done

[41] Appendix V

through telehealth, as long as it is in accordance with the requirements for Schedule II-V drugs.[42] Under current law, the patient must be in the presence of DEA licensed practitioner or at a DEA licensed facility to conduct the telehealth visit. According to the BOP, while the DEA has issued some waivers during the COVID-19 public health emergency, it has not waived that requirement for any Schedule II-V drug.[43] With child care, mobility, employment, and other concerns, traveling to a facility can be difficult. Those issues are compounded by the challenges faced by many patients with chronic conditions, especially during COVID-19. The DEA has temporarily waived the requirement for practitioners to become DEA-registered in the state where the patient resides, provided the practitioner is DEA-registered in the state where they (the practitioner) reside and are complying with other laws and regulations.

Currently, patients must visit a dispensary at least annually in order to provide the dispensary with a copy of their written certification. Following the visit, the patient may use delivery or conduct telehealth visits by phone or video. Relaxing the annual in-person visit would be difficult under the BOP's current administrative system, since the paper copy is the sole mechanism to validate written certification renewal.

Increasing the Patient Cap

There was some discussion about removing the current cap of 600 medical cannabis patients per practitioner. Practitioners can request a variance from the cap, but the BOP reported that no one has yet applied for a variance. Dr. Sam Caughron noted that increasing the cap might incentive "pill mills," where physicians issue written certification without providing meaningful care. He said 600 is a very high patient count for physicians in normal health care practice, even those in health systems. Others noted that some patients' only option may be a practitioner who specializes in medical cannabis written certifications, given the relatively low number of primary care physicians participating in the program.

Qualifying Conditions List

Virginia is one of few states that does not restrict the conditions for which patients can receive medical cannabis. Thirty-eight of the forty-one states and territories with medical marijuana laws have a qualifying conditions list, though some of those states include a provision giving doctors some additional discretion.[44] Dr. Brown suggested revisiting the qualifying conditions list in light of an approach we heard from Utah. Utah's Compassionate Use Board reviews medical cannabis recommendations for conditions not included on the statutory list. For example, the board must approve all requests related to anxiety, since PTSD is the only approved mental health condition. The board also reviews all medical cannabis recommendations for minors. According to a representative from the Utah Department of Health, the Compassionate Use

[42] Note: If the practitioner chooses to issue the written certification for less than one year, the patient has to visit the practitioner when the written certification expires. Very few providers issue the certifications for less than one year.
[43] Appendix X, minutes p. 177
[44] https://norml.org/laws/medical-laws/

Board has approved the vast majority of applications. In addition, Utah set up a cannabinoid product review board to review research and inform the program.

Dr. Brown suggested establishing a qualifying conditions list so that physicians, nurse practitioners, and physician assistants would have guidance on what conditions medical cannabis could be considered for. Many other work group members supported leaving the qualifying conditions to the discretion of practitioners.

Another Round of Licensing

Current law allows for only five pharmaceutical processors in Virginia, with one in each Health Service Area (HSA). Processors must be vertically-integrated, meaning the processor must cultivate, process and dispense the products. Each processor may dispense products at the processing site and may establish five additional cannabis dispensing facilities in the HSA in which it is permitted as a pharmaceutical processor. Three of the four existing processors began dispensing cannabis oil products in fall 2020. None of the allowable additional cannabis dispensing facilities have opened, but are expected in 2021 once regulations governing the operation of such facilities have been approved.

States use different approaches to manage supply and demand of cannabis, which is important for both patient access and oversupply issues. Some states allow the regulatory body to issue new requests for application based on supply and demand. For example, Connecticut's regulatory body has some statutory license caps, but generally issues new licenses when there are supply shortages. They base their supply analysis on monitoring the dispensaries by tracking how many patients they serve and customer complaints. Other states, like Maryland, have conducted more formal market projection studies. In November 2020, the Virginia Joint Legislative and Audit and Review Committee (JLARC) released a report that addressed medical cannabis market considerations in the context of adult use legalization, though it did not include patient projections specific to the medical cannabis program.[45]

Virginia's medical cannabis market is still growing to meet the current allowances for locations. However, should the state decide to expand the number of pharmaceutical processor licensees, some work group members noted that equity or minority ownership should be taken into account.

Conclusion

Medical cannabis provides an important treatment option for some patients in the Commonwealth and nationwide. It is clear that patients in Virginia face challenges obtaining medical cannabis. Potential barriers include the low number of available dispensaries and participating practitioners, high patient costs, and requirements and processes that may be overly onerous. Cannabis occupies a somewhat unique space in that it can be used both medicinally and recreationally. However, the needs of patients seeking its therapeutic benefits are often very

[45] (JLARC, 2020)

different from consumers seeking marijuana for adult use. Participants in Virginia's medical cannabis program are under the care of at least two clinicians – the recommending practitioner and the pharmacist at the dispensing site. Virginia should continue to examine ways to increase medical access and avoid stigmatizing cannabis patients, while being mindful of cannabis potential for abuse and potentially negative health effects, similar to other medical drugs with negative side effects.

One option for expanding the program is to allow the medical use of flower. As described earlier in the report, the work group heard varying points of view from physicians on botanical products as compared to the oil-based products currently available in Virginia. Federal restrictions on medical cannabis research have resulted in a lack of rigorous clinical trials examining the unique benefits of botanical products. However, it is clear that many medical cannabis patients prefer botanical products and are able to use them to treat their symptoms. Expanding available products would increase patient options and choice, since medical cannabis is used for a variety of conditions. If Virginia decides to allow botanical products, it may wish to explore some of the restrictions on flower used by other states (see page 11). Given the potential harms associated with cannabis, patient education and safety is also critical. Virginia may consider requiring warning labels and efforts to improve practitioner education. High-quality lab testing is foundational to patient safety, and there are some unique considerations for testing botanical products. As such, Virginia should assess the existing capacity of its third-party labs.

In addition to botanical products, the work group examined a number of potential changes to the medical cannabis program. Those changes included increasing provider education and participation, clarifying distinctions between medical cannabis and hemp, relaxing registration requirements, expanding telehealth, and considering additional locations. They also focused on reducing the high cost to patients. Those costs include a $50 annual registration fee, practitioner fees, and the cost of the product, almost all of which are out-of-pocket. The work group heard reports of doctor fees as high as $400 per visits and product costs as high as $20,000 per year. Virginia should continue to examine ways that other states have addressed these high costs, working within federal limitations, including some of the options suggested by the work group.

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List of Appendices

Appendix I - Virginia's Pharmaceutical Processor Program

In Virginia, the medical cannabis program is regulated by the Board of Pharmacy, one of 13 health regulatory boards within the Department of Health Professions. Virginia entered into the medical cannabis field in 2015 when the Virginia General Assembly created an affirmative defense for the possession of cannabidiol (CBD) oil and tetrahydrocannabinolic acid (THC-A) oil, initially to address the treatment of intractable epilepsy. Legislation passed in 2016, and reenacted in 2017, authorized the Board of Pharmacy to issue up to five pharmaceutical processor permits, one in each health service area (HSA) established by the Board of Health. A pharmaceutical processor is authorized to cultivate cannabis plants intended only for producing cannabis oil and dispensing such oil products to board-registered patients. As required in Code, the Board of Pharmacy adopted regulations establishing health, safety, and security requirements for pharmaceutical processors. A Request for Applications (RFA) was released in April 2018 to facilitate a competitive selection process for awarding the five pharmaceutical processor permits. Four of the selected entities awarded conditional approval were subsequently issued a pharmaceutical processor permit. Conditional approval for a fifth entity was rescinded in June 2020 and a RFA is currently open for a pharmaceutical processor permit in HSA I. It is anticipated that the Board of Pharmacy will award conditional approval for an entity to be located in HSA I in the first quarter of 2021.

A pharmaceutical processor operates as a vertically integrated program, cultivating cannabis plants indoors, producing cannabis oil in various formulations, and dispensing these drug formulations to registered patients for treatment or to alleviate the symptoms of any diagnosed condition or disease determined by the practitioner to benefit from such use - an expansion of the original intent to treat intractable epilepsy that was enacted into law in 2018. The pharmaceutical processors operate under the supervision of a pharmacist. Prior to dispensing, an independent laboratory must test a sample from each batch for microbiological contaminants, mycotoxins, heavy metals, pesticide chemical residue, and for purposes of conducting an active ingredient analysis. Only those oils that successfully pass laboratory testing can be registered by the Board of Pharmacy and dispensed to patients.

The prohibition for the oils to contain no more than 5% tetrahydrocannabinol, the psychoactive component of the cannabis plant, was removed in the 2020 General Assembly Session. The formulations are required by the Code of Virginia to contain at least five milligrams of CBD or THC-A and no more than 10 milligrams of THC per dose. The term "dose" is not defined. Current examples of cannabis oil product formulations available include: nasal spray, chewable, suppository, topical gel, oral and vaped oils, wax concentrate, and bubble hash concentrate inhalations. The THC/THC-A combined concentration in the inhalant products range from 35% to 82%, while other formulation types range from 0.25% to 3.5%. The CBD/CBDA combined concentration in the inhalant products range from 0.08% to 4.4% while other formulation types range from 0.0% to 1.1%. In addition to dispensing the cannabis oil products that the pharmaceutical processor produces for its own patients, the processor is also permitted to wholesale distribute cannabis oil products to other permitted pharmaceutical processors. In 2020, legislation legally expanded the number of dispensing sites in the Commonwealth from five to

thirty. The legislation authorizes the Board of Pharmacy to issue permits for up to five cannabis dispensing facilities in each HSA that must be owned in part by the pharmaceutical processor located in that HSA. The cannabis dispensing facilities, which are anticipated to become operational in 2021, will not cultivate nor process any cannabis. These facilities may only dispense cannabis oil products to registered patients. Federally, marijuana is a Schedule I illicit substance. There is no legal ability under State or Federal law to prescribe it. Hence, its derivative, e.g., cannabis oil as defined in the Code of Virginia, cannot be prescribed. Instead, the Code of Virginia authorizes a practitioner to issue a written certification recommending the use of the oil. The term "practitioner" is defined to mean a licensed doctor of medicine or osteopathic medicine, physician assistant or nurse practitioner. The written certification form, required by Code to be developed by the Supreme Court of Virginia in consultation with the Virginia Board of Medicine, initially provided an affirmative defense for the patient, parent, legal guardian or registered agent to possess cannabis oil as defined in the Code of Virginia. In 2020, the Code was changed to legalize the possession of cannabis oil if the patient, parent, legal guardian, or registered agent maintains a valid written certification and Board of Pharmacy registration. Per the Code of Virginia, the practitioner may issue the written certification to be valid for no more than 12 months from the date of issuance.

To issue a written certification, the practitioner must first hold a current active license with the Virginia Board of Medicine, or in the case of nurse practitioners, a license issued jointly by the Virginia Boards of Nursing and Medicine. The practitioner must also obtain registration from the Virginia Board of Pharmacy. A practitioner issuing a written certification for the use of cannabis oil must evaluate the patient, perform an examination, and make a diagnosis. The practitioner may determine the manner and frequency of patient care and evaluation, which may include the use of telemedicine consistent with federal requirements for the prescribing of Schedules II through V controlled substances. These tasks cannot be delegated to another practitioner. The practitioner must be of the opinion that the potential benefits of cannabis oil outweigh the risks associated with its use. The practitioner must query the patient in the Prescription Monitoring Program, which should include an evaluation of whether the patient has a current written certification issued by another practitioner, because a patient may only possess one unexpired written certification at any time. Once an individual receives a written certification recommending the use of cannabis oil, the patient and the parent or legal guardian, if applicable, must register with the Board of Pharmacy. The applicant, when applying for registration, must provide a copy of the written certification, along with proof of identity and residency. To legally possess cannabis oil patients must obtain both the written certification and the board registration. These documents must be shown in order to obtain dispensed oils. Patients may not obtain these oils from any location other than a permitted pharmaceutical processor or cannabis dispensing facility, and may receive no more than a ninety day supply at a time. Patients or their registered agent must currently present the written certification in-person at the pharmaceutical processor or cannabis dispensing facility annually after obtaining a newly issued written certification. Subsequent dispensations may then be delivered to the patient's residence by a delivery agent of the pharmaceutical processor or cannabis dispensing facility. The allowance for a "registered agent" to obtain the oils on behalf of a patient became effective in 2019, following the passage of emergency regulations on this subject. Prior to 2020, only a patient residing in the

Commonwealth was eligible for a patient registration. Legislation passed during the 2020 General Assembly Session expanded eligibility to persons temporarily residing in the Commonwealth.

Appendix II – Medical Cannabis Registration Processes

Process for Obtaining Patient Registration for Cannabis Oil

The process to obtain patient registration for cannabis oil in Virginia is a two-pronged requirement: 1) obtain a written certification from a registered practitioner; 2) apply for a patient registration from the Board of Pharmacy.

Identifying a Registered Practitioner

Patients may identify a registered practitioner authorized to issue a written certification by using the Department of Health Professions' online License Lookup. For "Occupation", select *Registered Practitioner of Cannabis Oil*; for "State", select *Virginia;* then enter a zip code or a practitioner's name prior to clicking on "Search". Currently there are over 500 registered practitioners for cannabis oil located throughout Virginia. A registered practitioner may be a licensed physician, nurse practitioner, or physician assistant.

Applying for Patient Registration from the Board of Pharmacy

Once a registered practitioner has evaluated the patient and issued a written certification, the patient must submit the online application for a patient registration from the Virginia Board of Pharmacy. Patients may access the Frequently Asked Questions and How to Register with the Board as a Patient, Parent or Legal Guardian document for assistance in navigating the application process. The patient is required to create a User ID and Password to begin the initial application. After completing the brief application and submitting the $50 application fee online, the patient must fax, mail or email proof of identity, residency, and age, along with a copy of the written certification to the Board. A valid Virginia Driver's License will fulfill the requirements for proof of age, identity, and residency. A copy of a birth certificate, other government-issued identification card, or tax receipt may be acceptable alternative documents. The Board is currently promulgating emergency regulations to address the recent statutory change authorizing patients who are temporarily residing in Virginia to obtain a patient registration for cannabis oil.

The patient registration is valid for 12 months from the date of issuance and may be renewed annually. The written certification is valid for no more than 12 months from the date of issuance, with the time being determined by the registered practitioner. For renewal of the patient registration, the patient must attest online to having a current written certification and pay the $50 renewal fee. Because the Board has provided two expiration date extensions due to the delay in cannabis oil product availability, to date, no patient has had to pay a renewal fee.

All efforts are being made to process new patient registration applications within 30 days of receipt of a complete application; applications are processed in the order in which they are received. After processing, the patient will receive an email indicating that the registration has been issued or if the application is incomplete, that additional information is required prior to approval. The registration card is then mailed to the patient's address of record. The Board is currently exploring a new patient registration software system to streamline the issuance of the written certification and patient registration application process.

Process for Registering with the Board of Pharmacy as a Registered Practitioner for Cannabis Oil

A practitioner of medicine or osteopathy, or a physician assistant licensed by the Virginia Board of Medicine, or a nurse practitioner jointly licensed by the Virginia Board of Medicine and the Virginia Board of Nursing, may apply to the Board of Pharmacy to be a registered practitioner for cannabis oil. The practitioner must complete the brief online application and pay the $50 application fee. Once the application is processed, the practitioner will be emailed the written certification form and can then begin providing this service to patients. The practitioner may renew the registration annually online and pay the $50 renewal fee. Patients may identify a registered practitioner authorized to issue a written certification by using the Department of Health Professions' online License Lookup.

Appendix III – Virginia Medical Cannabis Work Group

Virginia Medical Cannabis Work Group
As Required by 2020 Acts of Assembly Chapter 711

Work Plan
Approved by the work group 9/2/20

Work Group Charge:

"That the Secretary of Health and Human Resources shall convene a work group to review the Commonwealth's medical cannabis program and issues of critical importance to the medical cannabis industry and patients, including expansion of the medical cannabis program and the medical use of cannabis flowers. Work group members shall include the Secretary of Health and Human Resources, the Director of the Department of Health Professions, the executive director of the Board of Pharmacy, one member of the House of Delegates, one member of the Senate, three representatives of the medical cannabis industry who are currently licensed as pharmaceutical processors by the Board of Pharmacy, one person with expertise in issues of importance to patients who use medical cannabis for treatment or alleviation of the symptoms of a diagnosed condition or disease, and one member who is a physician who is currently registered with Board of Pharmacy to issue written certifications for use of cannabidiol oil and THC-A oil. The work group shall report its findings and recommendations, including any legislative recommendations, to the Governor, the Attorney General, and the Chairmen of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health no later than October 1, 2020."

Membership:

- Dr. Daniel Carey, Secretary of Health and Human Resources
- Catie Finley, Assistant Secretary of Health and Human Resources su
- Dr. David Brown, Director of Health Professions
- Caroline Juran, Executive Director of the Board of Pharmacy
- Delegate Glenn Davis, Member of the House of Delegates
- Senator David Marsden, Member of the Senate
- Ngiste Abebe, Director of Public Policy, Columbia Care
- Jack Page, Chief Operating Officer, Dharma Pharmaceuticals
- Sara Payne, Senior Corporate Counsel Jushi, parent company, Dalitso, dba Beyond/Hello
- Joy Strand, Vice President, Green Leaf of Virginia
- Lisa and Hayley Smith, patient representatives
- Jenn Michelle Pedini, Executive Director of Virginia NORML
- Dr. Sam Caughron, Charlottesville Wellness Center Family Practice

- Dr. Preston Grice, University of Virginia (*note that Dr. Grice only attended the first meeting, and then submitted a statement and narrated power point presentation)*

Agenda:

I. Overview of the medical cannabis in the Commonwealth and in other states (DHP covered in first meeting)

II. Operational Considerations of Expansion
   a. Consumer Education: What, if any, improvements are needed so that CBD consumers know what they buying?
      i. Is there sufficient distinction in the market between hemp derived CBD and medical cannabis CBD products? If not, what changes are needed?
      ii. Is there sufficient information available to consumers on appropriate dosage, especially given the varying nature of biological products?
      iii. Would changes to medical cannabis marketing restrictions lead to increased patient education? If so, what changes are suggested and/or recommended?
   b. Patient Access: What, if any, changes are needed in terms of ensuring adequate patient access and participation?
      i. How can medical cannabis processors and dispensaries be more open, welcoming, and accessible to patients?
      ii. What, if any, are barriers to access for low-income and rural individuals, especially relating to affordability and transportation
      iii. Similar to (a)(iii), what changes should be made to the marketing restrictions in order to allow for community outreach?
   c. Provider Participation: What actions needed to increase the number of registered practitioners?
      i. Are there any regulatory, legislative, or educational barriers?
      ii. What approaches are other states using to allow medical cannabis in hospitals despite federal funding prohibitions?
   d. Banking: What state-level changes would increase medical cannabis banking options?
   e. Potential Future Licensing Rounds: How might Virginia encourage involvement from minority-owned businesses?
   f. State Agency Structure: What, if any, changes should be made to the state oversight structure as the industry expands?
      i. Are there revenue projections (and an associated timeline) for the expansion of the medical cannabis industry?
      ii. What have other states done with any revenue stream (e.g. has it gone to the state treasury or to a specified purpose)?
      iii. What mechanisms do other states use to "capture" the revenue and what might that mechanism look like in Virginia?

III. Medical use of cannabis flowers: What are the health benefits and negative effects/risks?
   a. Literature review
   b. Review of other states
      i. What do they allow?
      ii. What is the price point compared to non-flower products?

Schedule:

Note: Deadline for the work group's report is now November 30, 2020

- First Work Group Meeting – Monday, August 3rd from 3-5pm
- Second Work Group Meeting – Wednesday, September 2nd from 9:30-11:30am
- Third Work Group Meeting – Wednesday, September 30th from 9:30-11:30am
- Final Work Group Meeting – Friday, October 30th from 9:30-11:30am
- *A fifth meeting was later added on Wednesday, November 18th from 11am-1pm*
- Submit Report – Wednesday, November 30th

Appendix IV - Limitations on Marijuana Research

Under the Controlled Substances Act, cannabis, excluding hemp, is classified as a Schedule I controlled substance which means it has no acceptable medical use and has a high potential for abuse. A Drug Enforcement Administration (DEA) registration is required to perform research on a Schedule I substance. Researchers have indicated that obtaining or modifying a DEA registration for this purpose can be difficult and time-consuming. An additional registration as a manufacturer may be required for research protocols wherein a particular dosage form must first be created.

While DEA indicated in August 2019 that it would review additional grower applications, there is currently only one entity, the University of Mississippi, registered by DEA to cultivate cannabis for research purposes under a grant with the National Institute on Drug Abuse (NIDA). A single domestic source of cannabis limits formulations for research and the University does not appear to have the capacity to provide cannabis for commercial development. Additionally, federal law does not allow researchers supported by NIDA or other federal agencies to obtain cannabis from state dispensaries for research purposes. While there have been efforts to research these products, including by some state universities, there appears to be a lack of research on these formulations and their health effects.

As more states legalize marijuana for both medical and recreational adult use, the number of high quality research trials is on the rise. When it comes to the therapeutic benefits of cannabis, there is substantial preliminary evidence that the plant can be used for additional clinical purposes. In the meantime, most public health experts recommend using systematic reviews of “gold standard” research. One example is the seminal study entitled “The Health Effects of Cannabis and Cannabinoids” published in 2017 by the National Academy of Sciences, Engineering, and Medicine (NASEM).

Appendix V – Medical Society of Virginia (MSV) Survey & Virginia Hospital and Healthcare Association (VHHA) Overview

MSV November 2020 Survey

Summary of Findings:

The Medical Society of Virginia (MSV) conducted a survey made up for 14 questions with the purpose of enhancing our understanding on opinions around medical cannabis. The survey was sent out to physicians and physicians assistants within the MSV membership. The survey was live for 7 days and 113 responses were registered. After reviewing the data, we can conclude that respondents would require a plethora of information both about the effects of the product and what coverage (cost) would be like for the patient in order to consider prescribing it. Additionally, respondents are concerned that cannabis remains a Schedule 1 drug at the federal level.

Recurring Themes from Respondent's Comments*:

- Concern around lack of product research and sufficient evidence (top concern)
- Concern around medical cannabis prescribing abuse as seen with opiates
- Concern for overuse and addiction
- Concern about the quality of product, and where it would come from (pharmaceuticals, farmers/growers directly, etc.)
- Concern around how the product will be administered (smoking, ingested in form of an edible, syrup, etc.)
- Insufficient data on adverse effects, both short and long term
- Sellout for legalizing recreational marijuana and using doctors as the middle man

Summary of Question Results:

Q1: 63.72% of respondents have concerns with recommending medicinal cannabis

Q2: 69.9% of respondents believe additional education should be required

- Suggested education: CME course of at least 3 hours, online certifications involving pharmacists

Q3: 75.8% of respondents have not explored the potential of recommending medicinal cannabis

Q4: 94.6% of respondents are not currently registered to recommend medicinal cannabis

Q5: Out of those respondents registered to recommend, the majority say it is easy to register

Q6: Out of those respondents registered, the majority say it easy to maintain that registration

Q7: 55.5% of respondents agree that physician registration should be required to recommend medicinal cannabis

Q8: 36.1% of respondents find it uncomfortable talking with patients about medicinal cannabis as a treatment option, while 31.5% find it comfortable. 32.4% of respondents are neutral

Q9: 87.04% of respondents believe additional education would improve physician comfort talking with patients about medicinal cannabis as a treatment option

Q10: 61.1% of respondents feel their comfort level in recommending medicinal cannabis would differ depending on whether the patient is a new patient or an established patient

Q11: 83.02% of respondents do **not** believe physicians should be limited in the number of patients to whom they recommend medical cannabis

- Suggested limit: if limited, it will depend on specialty and percent of practice volume

Q12: 54.72% of respondent do not have concerns about medical cannabis treatment costs for patients while 45.28% do have concerns.

- Of those concerned with treatment costs, the concern is not isolated to medical cannabis but rather to all drug prices

Q13: 98% of respondents are not aware of any options to allow insurance reimbursement for medicinal cannabis, meaning there is a general lack of knowledge around insurance coverage and medical cannabis

Q14: 75.79% see lack of knowledge and education around the product a concern while 67.37% of respondents see the product's qualification of a Schedule 1 drug as a challenge.

VHHA Overview of Medical Cannabis Policies November 2020

Legislation in the 2020 General Assembly (HB 347) directed the Secretary of Health and Human Resources to convene a work group to review the Commonwealth's medical cannabis program and issues of critical importance to the medical cannabis industry and patients, including expansion of the medical cannabis program and the medical use of cannabis flowers. The work group is to report its findings and recommendations, including any legislative recommendations, to the Governor, the Attorney General, and the Chairmen of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health no later than October 1, 2020.

On September 2, 2020, VHHA participated in a meeting of the work group to discuss barriers to expanding the use of medical cannabis in the Commonwealth, including potential legal and regulatory barriers. Below is a summary of information presented to the work group.

Considerations for Hospital Policies Regarding Medical Marijuana

I. Marijuana as an Illegal Substance under Federal Law

The Controlled Substances Act, 21 U.S.C. § 801 et seq., classifies marijuana as a Schedule I drug, which has no currently accepted medical use. Accordingly, providers are not authorized under federal law to prescribe, administer, or dispense it. The CSA provides for criminal penalties for the possession, manufacture, and distribution of marijuana and other Schedule I drugs. 21 U.S.C. Part D.

II. Federal Classification Places Hospital Federal Funding at Risk

a. Conditions of Participation (CoPs)

i. Hospital participation in Medicare and Medicaid and receipt of payment provided to beneficiaries enrolled in those programs requires compliance with various "conditions of participation."
ii. The CoP at 42 C.F.R. § 482.11(a) requires the hospital to act "in compliance with applicable Federal laws related to the safety and health of patients." 42 C.F.R. § 482.11(a).
iii. Failure to meet CoPs can result in a termination of the hospital's participation agreement.

III. Accrediting Bodies Have Requirements for Medication Safety
a. The Joint Commission Standard MM.03.01.05 requires that "The hospital safely controls medication brought into the hospital by patients, their families, or licensed independent practitioners.
i. The hospital must define when medications brought into the hospital by patients, their families, or licensed independent practitioners can be administered.
ii. Before use or administration of a medication brought into the hospital by a patient, his or her, family, or a licensed independent practitioner, the hospital identifies the medication and visually evaluates the medication's integrity.
iii. The hospital informs the prescriber and patient if the medication brought into the hospital by patients, their families, or licensed independent practitioner is not permitted.
b. Practical challenges involved in complying with this include:
i. How is the product identified if not through FDA/DEA registration?
ii. How does the institution verify integrity?
iii. How is the drug "permitted" if it is illegal under federal law?
iv. If use is permitted, how do hospital clinicians monitor for drug interactions?

IV. Some Hospitals in State that Permit Use of Medical Marijuana Have Developed Related Policies
a. Under no circumstances is the medical cannabis supplied by the hospital.
b. Medical cannabis is administered by the patient or registered designated caregiver per labeled instructions by the dispensary.
c. Medical cannabis will not be left unsecured at any time (stored securely in safe or other locked storage in patient's room).
d. Nurses and other health care professionals for the hospital will not retrieve medical cannabis from storage or administer/observe administration of medical cannabis.
e. Some policies do allow the medical cannabis to be included in the hospital-based medication reconciliation policies and procedures.
i. Hospital health care professionals may not change the dose or frequency.
ii. Medical cannabis regarded as a continuation of therapy order with in the electronic medical record.

Appendix VI – Meeting One

Virginia Medical Cannabis Work Group
Meeting One
August 3, 2020
3:00-5:00pm

Agenda

1. Public Meeting/FOIA Overview – TBD *5 min*

2. Introductions – facilitated by Dan Carey, Secretary of Health and Human Resources *10 min*

3. Virginia Medical Cannabis Program Overview – Caroline Juran, Executive Director, Virginia Board of Pharmacy and Annette Kelley, Deputy Executive Director, Virginia Board of Pharmacy *30 min*

4. Work Group Charge and Proposed Work Group Agenda – Catie Finley, Assistant Secretary of Health and Human Resources *10 min*

6. Group Discussion & Finalize Work Plan – All *40 min*

7. Public Comment (2 min per person) *25 min*

8. Adjournment

Meeting Minutes

The meeting adjourned at 3pm on August 3, 2020. All participation was virtual, there was no central physical location.

James E. Rutkowski, Assistant Attorney General, did an overview of the Freedom of Information Act (FOIA) as it applies to public records and public meetings.

Secretary Carey thanked everyone for participating in the group and asked the workgroup members to introduce themselves:

- Daniel Carey, Secretary of Health and Human Resources
- Catherine "Catie" Finley, Assistant Secretary of Health and Human Resources (HHR lead for this work group)
- Dr. David Brown, Director of the Department of Health Professions
- Caroline Juran, Executive Director of the Board of Pharmacy
- Delegate Glenn Davis, Virginia House of Delegates 84th District

- Senator Dave Marsden, Virginia Senate District 37 (noted that he has been working towards a Virginia medical cannabis program for the past 6 years and is excited to plan the future of this new industry to help those who are in pain and discomfort across the Commonwealth)
- Ngiste Abebe, Director of Public Policy for Columbia Care
- Jack Page, COO for Dharma Pharmaceuticals in Bristol Virginia
- Joy Strand, Executive Vice President, Green Leaf Medical
- Lisa and Haley Smith, patient representatives
- Jenn Michelle Pedini, Development Director for National NORML and the Executive Director of the state affiliate Virginia NORML
- Dr. Sam Caughron, in Family Practice in Charlottesville, VA
- Dr. Preston Grice, UVA Dept of Physical Medicine and Rehabilitation
- Sara Payne, Jushi Corporate Counsel, (Dalitso's parent company)

Secretary Carey made opening remarks. He noted the talent in the group including the lived experience of patients and families, the business community, the medical community, the policy community, and the legislators – Del. Davis and Sen. Marsden. He reviewed the charge of the workgroup established by HB 347, including issues surrounding expansion of the medical cannabis program and the medical use of cannabis flowers. His goal for the workgroup is to promote Virginian's health and to use an equity lens.

Caroline Juran, Executive Director the Board of Pharmacy, presented on the history and status of Virginia's Medical Cannabis program (see slides).

Annette Kelley, Deputy Executive Director of the Board of Pharmacy, gave an overview of medical cannabis program in other states (see slides).

The Board of Pharmacy (**Ms. Juran and Ms. Kelley**) clarified that the newly allowable five dispensary sites in each Health Services Area (HSA) must be "vertically integrated" in the sense that they must be owned by the processor in that HSA, but do not have to be located on the same physical location as the processor's main location.

- **Sen. Marsden** noted that requiring the processors' dispensaries to be within their designated HSA helps ensure product access in rural areas.
- **Del. Davis** noted that if dispensaries are not vertically integrated (in terms of ownership), dispensaries that are not affiliated with a processing site would have a business disadvantage, because the processor-owned dispensaries will always have lower costs.

In answer to a question from Dr. Caughron, **Ms. Juran** explained that industrial hemp cannot legally have more than 0.3% THC and is regulated by the Virginia Department of Agriculture and Consumer Services (VDACS). That differs from medical cannabis, which is designed specifically for patient conditions and has a higher level of THC.

- **Del. Davis** noted that there is a lot of confusion between the two products and it would be great for this group to look at that issue as more medical cannabis becomes available.

- **Dr. Caughron** said that consumers need to be able to understand what is "apples and oranges" in terms of what they are getting with a product and with dosage, especially given that it is a biological product and each plant produces slightly different cannabidiol oil. We should be the "voice of reason" in Virginia, and he hopes this group can provided the necessary clarity.
- **Sen. Marsden** reminded the group that VDACS is working on regulations that will require testing and standards for the hemp CBD products being sold in grocery stores (including for out-of-state products sold in Virginia). There is confusion and it will take a little bit to sort out. His understanding is that CBD oil is CBD oil regardless of whether it comes from hemp or from a marijuana plant, but that the level of THC is not allowed in hemp products (as Ms. Juran mentioned).

Asst. Sec. Finley outlined the scope of this work group as distinct from the Marijuana Legalization Work Group established by SB 2/HB 972 and the JLARC study established by SJ67/HJ130. She began going through the draft work plan.

Ms. Abebe pointed out that, for operational consideration, it's not just about new licenses, but also ensuring we have adequate patient access, participation, outreach and education. In terms of equity, the cost of participating can be cost prohibitive for patients who really need this medication. That includes how to make a space that is open and welcoming. It also includes having effective communications, community outreach, and paid education content, and the current ad ban is restrictive and makes those efforts difficult.

- **Ms. Payne** noted that it is nearly impossible to provide information about product distinctions and to communicate more broadly, and having a plan to do that would add value.
- **Del. Davis** noted that CBD is often used as a marketing term, and we should look at limiting or clarifying the use of the term CBD. He would like to invite the marketing people from the hemp CBD industry to provide their perspective.
- **Mx. Pedini** noted that we should include VDACS in that discussion.

Senator Marsden said that we should keep in mind that many, including those who spoke in subcommittee this past session, have an interest in encouraging equity ownership minority involvement if the number of licenses expands.

- **Mx. Pedini** agrees, but think equity is equally, if not more, important in the context of patient access, and there are significant barriers to patient entry in the current program.

Dr. Grice noted that a lot of the expansion considerations come down to marketing. If you have a new line of products you need to be able to present it to physicians who are going to be prescribing it, and in Virginia doctors don't have enough education to understand the product. He thinks having access to the producers via open forum, etc. would be beneficial. He would love to see their product list.

Asst. Sec. Finley moved to the "medical use of cannabis flowers" piece of the work plan. Do we agree that the right question is "what are the benefits and risks of expanding to cannabis flowers from a health perspective"? How are we going to go about exploring that question?

- **Dr. Grice** noted that there are a lot of great articles from early 2000's that look at a variety of issues around buds, especially looking at smoking as opposed to baked goods, vaping, etc. There is a lot more paraphernalia than there used to be, such as vaping pens (user friendly and concealable), oil, and dabs.
- **Del. Davis** said it would helpful to look at how we can allow the inhalation piece and not cross into the smoking piece (i.e. where is that "line").
- **Ms. Abebe** has a number of outside experts with whom she connect the group. Adding flower is not just about smoking. There are a number of different cannabinoid processes and ways of consuming it. Veterans have talked about how different products are used to treat different types of illnesses, and many patients have had better alternatives with some of the botanical options.

Sen. Marsden reiterated that he really wants to spend time on the barriers and the deficiencies in regulation and code that limit authorization and permission. This is a tipping point for the industry and there may need things we need to fix.

- **Ms. Juran** noted that there is a general lack of education among practitioners, and other states have said a lot of education was needed for the practitioners in the beginning. Hospital physicians often do not allow use of these oils within their facility because they believe they could lose their federal funding, especially Medicaid and Medicare. She has heard of some hospitals in other states that allow a family member to sign a waiver and bring it into the facility, but Virginia has generally said they are not ready to do that.
- **Mx. Pedini** stated that the major health systems sent letters to their practitioners directing them not to participate in the program, including multi-state operators that allow it in other states, such as Bon Secours. That leaves patients with practitioners who specialize in medical cannabis, who often have a self-pay model so there is not really a low-cost option.
- **Dr. Caughron** suggested tapping into MSV about how to educate practitioners.
- **Dr. Grice** noted that UVA is currently at a "stalemate" and has not articulated a position.
- **Sen. Marsden** noted this product is an anomaly because the pharmacists, as opposed to the doctors, are generally the experts.

Del. Davis asked the industry representatives if they are still experiencing challenges with banking, since there may be some ways to resolve that.

- **Ms. Strand** said it has been very difficult for Green Leaf to find a banking vendor in Virginia. Banking is a challenge in every state, and in MD there is one state-sponsored bank that is dealing with cannabis and they have been extremely helpful. The cannabis business is a cash based business and needs a place to securely deposit its cash. She has not been able to identify a bank that deals with cannabis in VA.

- **Mr. Page** said Dharma does a have a local charter bank in southwest Virginia that is accepting their money, and he will share that information.
- **Ms. Abebe** said that Louisiana just passed some banking reforms at the state level. Existing processors have generally been able to find banking solutions, but those solutions are not easily available for all potential business operations. They often pay high bank fees. It will never be a perfect system as long as the substance remains a scheduled drug at the federal level, but there is room for improvement even at the state level.
- **Ms. Payne** agreed with Ms. Abebe.

In terms of looking at operational and fiscal considerations for the state, **Ms. Juran** said it would be wise to determine whether this model can continue to be regulated solely by the Board of Pharmacy. Considerations are both the sheer volume as the program expands and the inability of DHP to feed revenues to the general fund. The Board of Pharmacy has always informally believed that, if the program continues to expand, the Commonwealth should consider establishing a structure to capture potential revenue.

- **Dr. Brown** agreed and added that, if we see medical cannabis expansion as a step towards legal recreational cannabis, those are two very different models and it would behoove us to have a smooth transition.
- **Mx. Pedini** noted that there are items in the larger marijuana legalization work group and JLARC study that we should be able to learn from.

Asst. Sec. Finley asked if the workgroup is in agreement re: the agenda for the next meeting: a discussion with VDACS and the CBD industry about product distinction and related issues discussed earlier, meeting with MSV and VHHA representatives re: provider education and other barriers to expansion, and having some time devoted to a review of the literature.

- **Sen. Marsden** agreed. He added that he wants a good medical cannabis program established before legalization of recreational marijuana, so that people first establish a relationship with their doctor, a knowledgeable pharmacist, and a well-run, regulated company. When Colorado legalized recreational use, he believes that medical cannabis program participation dropped from 230,000 to 185,000 people, so it is very important that get medical model up and running.
- **Ms. Abebe** agreed with Sen. Marsden, and would like to look at what more mature state programs like Oklahoma have done to make patient registration affordable and expand to flowers. She reminded the group that the list of states that allow flower for medical cannabis use on slide 7 of DHP's presentation is not comprehensive. Other examples include Louisiana (passed earlier this year), New York, and a bill that has passed one house in the West Virginia legislature. Flowers are a critical piece of patient care.
- **Del. Davis** asked to invite the "C-level" folks from the health care systems, especially to flesh out Jenn Michelle's earlier comment about allowing certain medical cannabis use in hospitals in other states.

- **Dr. Caughron** noted that we should also be drawing on the resources from other countries, like Israel.

Asst. Sec. Finley proposed a roll call vote. Do participants agree with the agenda for the second meeting and agreed to hold the dates listed on the draft work place, including September 2nd? The work group agreed unanimously.

There was one speaker during the public comment period. **Thomas Malone** is the founder and CEO of Arena Group Consulting, the largest Virginia registered hemp dealer and probably one of the top three biggest hemp dealers on the east coast. Their expertise is in supply chain operation and they do it with CBD oil. There are a lot of questions and confusion about CBD and he is happy to be part of the conversation.

The meeting adjourned at 5pm.

Virginia Department of Health Professions

Virginia Board of Pharmacy

Medical Cannabis Workgroup

August 3, 2020

Caroline D. Juran, RPh
Executive Director, Board of Pharmacy

Virginia Department of Health Professions

Department of Health Profession

- Mission: To ensure safe and competent patient care by licensing health professionals, enforcing standards of practice, and providing information to health care practitioners and the public.
- 13 health regulatory boards, Board of Health Professions, Prescription Monitoring Program, Health Practitioners' Monitoring program, Healthcare Workforce Data Center
- Regulates healthcare practitioners over 60 professions

Department of Health Profession

- Non-General Fund agency
- Must cover expenses through licensing fees
- Monetary penalties must be transferred to State Literary Fund within DOE

Board Members

Kristopher S. Ratliff, *Chairman*

Cheryl H. Nelson, *Vice Chairman*

Glenn Bolyard

Melvin L. Boone, Sr., *Citizen*

James L. Jenkins, Jr., *Citizen*

Ryan K. Logan

William Lee

Patricia Richards-Spruill

Rebecca Thornbury

Cynthia Warriner

Pharmaceutical Processor Laws

2015

- Authorized physician to issue written certification providing affirmative defense for possessing CBD oil and THC-A oil

2016

- Directed BOP to oversee CBD oil and THC-A oil production and dispensing by up to 5 pharmaceutical processors for treatment of intractable epilepsy

Virginia Department of Health Professions

Pharmaceutical Processor Laws

2017

- Reenacted legislation, as required by 2016 bill.
- August 2017: Emergency regulations became effective; establish health, safety and security requirements for processors

2018

- Expanded program to allow physician to issue certification for the use of CBD oil or THC-A oil for the treatment of any diagnosed condition or disease

Pharmaceutical Processor Laws

2019

- Expanded authority to physician assistants and nurse practitioners to issue written certifications
- Created authority for BOP to register a “registered agent” who may be designated by a patient to receive CBD or THC-A oil on his/her behalf
- Allows processors to wholesale distribute oil products between processors

Virginia Department of Health Professions

Pharmaceutical Processor Laws

2020

- Removes affirmative defense
- Replaces “cannabidiol” and “THC-A oil” terms with “cannabis oil”; removes 5% THC cap, but retains THC cap/dose
- Authorizes use of telemedicine consistent with federal requirements for Rx drugs
- Allows persons temporarily residing in Virginia to obtain patient registration
- Authorizes up to 5 cannabis dispensing facility permits per HSA

§54.1-3408.3

- "Cannabis oil" means:
  - any formulation of processed Cannabis plant extract, which may include oil from industrial hemp extract acquired by processer, or a dilution of the resin of the Cannabis plant
  - that contains at least 5 mg of CBD or THC-A and
  - no more than 10 mg of delta-9-tetrahydrocannabinol per dose.

§54.1-3408.3

- "Cannabis oil" does not include industrial hemp, as defined in § 3.2-4112, that is grown, dealt, or processed in compliance with state or federal law, unless it has been acquired and formulated with cannabis plant extract by a pharmaceutical processor.

Pharmaceutical Processor

- Facility permitted by Board of Pharmacy
- Vertical operation:
  - Indoor cultivation of Cannabis plants;
  - Production of cannabis oil;
  - Dispensing of oils by pharmacist to registered patients

Pharmaceutical Processor, cont.

- Operates under supervision of a pharmacist.
- Board quarterly inspections required.
- Oils independently laboratory tested prior to dispensing.
- Lab results available upon request to patients, parents/guardians, practitioners.
- Products must be registered by BOP

Pharmaceutical Processors

- HSA I = vacant
- HSA II = Dalitso LLC, Manassas
- HSA III = Dharma Pharmaceuticals, Bristol
- HSA IV = Green Leaf Medical of Virginia LLC, Richmond
- HSA V = Columbia Care Eastern Virginia LLC, Portsmouth

Lab Testing of Oil Products

- Microbiological: microorganisms
- Mycotoxin: fungus, mold
- Heavy metal: Arsenic, Cadmium, Lead
- Pesticide chemical residue: no chemicals/petroleum based solvents
- Residual solvent test: organic volatile chemicals
- Active ingredient analysis (CBD, CBDA, THC, THC-A)
- Expiration date based on stability test

Availability of Oil Products

- Approximately 3-6 months to cultivate and produce oils
- Processor anticipates availability of oils in August
- Patients may access any of the pharmaceutical processor sites

Practitioner Requirements

Practitioner Requirements
18VAC110-60-30

- Conduct an assessment and evaluation of the patient to develop a treatment plan; obtain patient's medical history, prescription history, current medical condition
- Diagnose the patient;
- Be of the opinion that the potential benefits of cannabidiol oil or THC-A oil would likely outweigh the health risks of such use to the qualifying patient;

Practitioner Requirements, cont.

- Explain proper administration, potential risks and benefits, prior to issuing the written certification;
- Be available or ensure that another practitioner is available to provide follow-up care and treatment to determine efficacy of CBD oil or THC-A oil for treating the diagnosed condition or disease;
- Access to the Virginia Prescription Monitoring Program;

Practitioner Requirements, cont.

- Practitioner shall not delegate responsibility of diagnosing a patient or determining whether a patient should be issued a certification.
- Cannot issue more than 600 certifications at any given time. Can petition Boards of Pharmacy & Medicine for increase.

Practitioner Prohibitions

Virginia Department of Health Professions

Prohibited Practices of Practitioner, 18VAC110-60-40

- Directly or indirectly accept, solicit, or receive anything of value from any person associated with a pharmaceutical processor or provider of paraphernalia;
- Offer a discount or any other thing of value to a qualifying patient, parent or guardian based on the patient's agreement or decision to use a particular pharmaceutical processor or cannabidiol oil or THC-A oil product;

Virginia Department of Health Professions

Prohibited Practices of Practitioner, 18VAC110-60-40

- Examine a qualifying patient for purposes of diagnosing the condition or disease at a location where cannabis oil is dispensed or produced;
- A practitioner, and such practitioner's co-worker, employee, spouse, parent or child, shall not have a direct or indirect financial interest in a pharmaceutical processor or any other entity that may benefit from a qualifying patient's acquisition, purchase or use of cannabis oil

Virginia Department of Health Professions

Prohibited Practices of Practitioner, 18VAC110-60-40

- A practitioner shall not issue a certification for himself or for family members, employees or co-workers
- A practitioner shall not provide product samples containing cannabis oil other than those approved by the United States Food and Drug Administration.

Board Registrations

Registrations

- Online applications
- Patient & Practitioner = $50 initial and annual fee
- Parent/Legal Guardian = $25 initial and annual fee
- Registered Agent = $25 initial and annual fee

Registrations as of 7/24/2020

- Registered Practitioners: 423
- Registered Patients: 3814
- Registered Parents/Guardians: 50
- Registered Agents: 6

Virginia Department of Health Professions

Contact Information

Department of Health Professions
Virginia Board of Pharmacy
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, VA 23233
(804) 367-4456

cbd@dhp.virginia.gov – CBD, pharmaceutical processor – related questions

pharmbd@dhp.virginia.gov - General board questions

Virginia Department of Health Professions

Virginia Board of Pharmacy

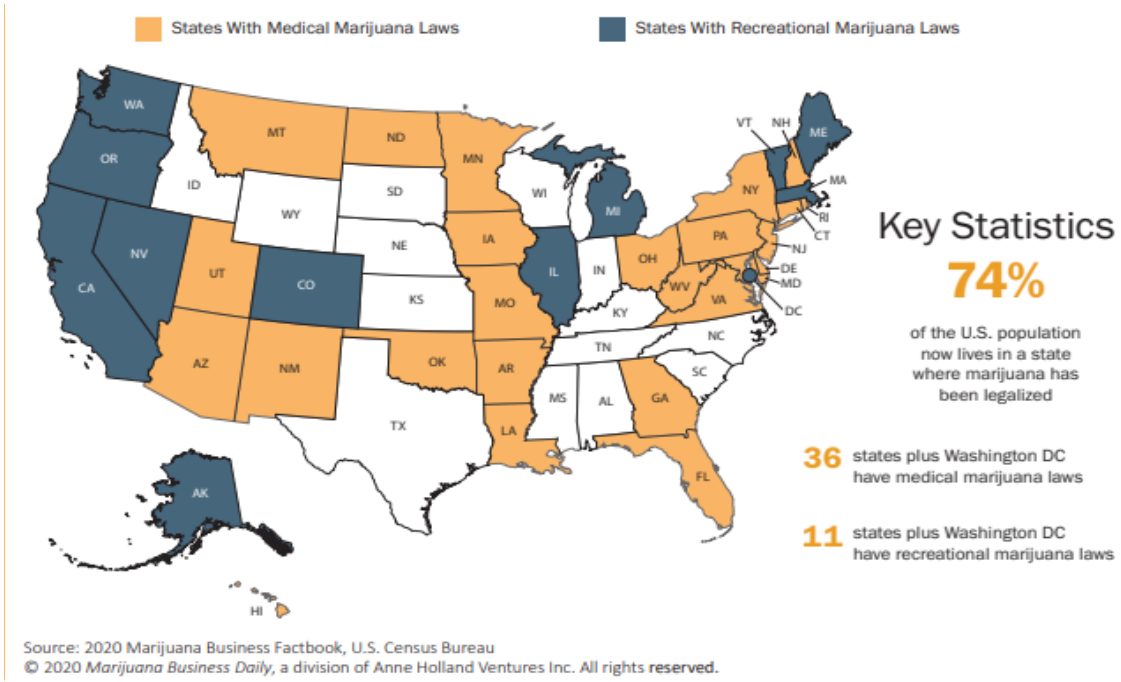
Medical Cannabis Workgroup

August 3, 2020

Annette S. Kelley, M.S.; C.S.A.C.

Deputy Executive Director, Board of Pharmacy

Medical/Recreational by State



Source: 2020 Marijuana Business Factbook, U.S. Census Bureau

Program Design

- Only 9 states have a true vertical program; majority have a combination of cultivators, processors and dispensers that may operate independent of each other
- Most states maintain regulatory oversight of their medical marijuana program within a health services related state agency. 14 states have an identified “Commission” or “Department” to focus on the program.

Program Design

- Extreme variability across states
  - Alternative Treatment Centers
  - Compassion centers
  - For profit and not for profit
  - Cultivator, processor, dispenser separated and some with a combination of these
  - States with 100s of dispensaries and states with only a handful

Fees

- Varies greatly across states
- Initial, License, Renewal
  - 29 states charge a fee for all three categories
- Difficult to compare total fee amount per state as states vary in fees charged
  - $0-$200,000

State Tax Requirements

- 26 states charge a tax for medical marijuana
  - CO-2.9%; WA-37% excise tax
- All recreational marijuana states charge tax except Vermont
  - ME-10%; WA-37% + 9.6% at point of sale
- No tax on medical marijuana:
  - CT, DE, FL, MD, MA, MN, NH, OR, UT, VT, VA

Formulations/Restrictions

- Flower: FL, HI, NJ, ND, CT (baked goods), OH (plant material), UT (unprocessed flower in a blister pack)
- No flower: LA, GA, NY, VA, WV

Formulations/Restrictions

- Edibles not allowed:
  - CT (allow baked goods), GA, HI, IL (limited), IA, NY, ND, NJ (allow for minors), PA, UT, WV
- Vape products not allowed:
  - GA, LA
- Tinctures not allowed:
  - NJ
- Products cannot be attractive to children:
  - AK, AZ, CO, CT, FL, LA, MA, HI, OH, UT, VA, WA, WV

Patient Services

- Patient Registry
  - Required in all but 4 states
    - Voluntary in CA, ME, WA; No registry in LA
- Practitioner Statement/Certification
  - Required in all states
- Caregivers
  - All states allow

Patient Services

- Qualifying conditions
  - 3 states have no restrictions for use of medical marijuana (DC, OK, VA)
  - 14 states have a list and a “physician discretion” clause
  - 20 states have a specific list of conditions/ diseases
- Patient registration fees
  - All states except ME & LA
  - MT-$5; MN & OR-$200

Registered Patients as % of State Population

% of Population	State(s)
7.51	OK
4.0-4.9	ME, NM
3.0-3.9	MT, AZ
2.0-2.9	MI, PA, HI
1.0-1.9	AR, RI, MD, FL, CO, DE, CT, MA
.50-.99	IL, DC, NJ, OH, VT, MO, NH, NY, OR, WA
.03-.49	NV, ND, MN, IA, GA, LA, UT, VA

Appendix VII – Meeting Two

Virginia Medical Cannabis Work Group
Meeting Two
September 2, 2020
9:30-11:30am

Agenda

1. Finalize Work Plan – All *15 min*

2. Conversation with Industrial Hemp Industry re: Product Distinction *45 min*
   Presentation from Virginia Department of Agriculture and Consumer Services (VDACS)
   Open Discussion with Industrial Hemp Representatives

3. Conversation with Medical Community re: Potential Barriers to Expansion
   Open Discussion with members of the Virginia Hospital and Healthcare Association and members of the Medical Society of Virginia *45 min*

4. Public Comment

5. Adjournment

Meeting Minutes

The meeting adjourned at 11am. All workgroup members were present at the start of the meeting, except for Dr. Grice who was not able to attend.

Assistant Secretary Finley: In the last meeting, the group requested to speak with representatives from the hospital and practitioner community explore the barriers to expanding the number of participants in the Virginia Medical Cannabis Program.

Brent Rawlings from the Virginia Hospital and Healthcare Association (VHHA) provided the regulatory backdrop. He has also had a number of conversations with peer hospital associations in other states to better understand how they manage this issue. The regulatory and similar considerations are primarily:

- Marijuana is a Schedule I drug under the Controlled Substances Act, so federal law prohibits prescribing, administering, and dispensing the product. Medicaid and Medicare recipients must agree to "conditions of participation." That includes 42 CFR 482 11A, which requires every hospital to act in compliance with applicable federal laws related to the safety and health of patients, which includes the CSA as well as certain Federal and Drug Administration (FDA) and Drug Enforcement Administration (DEA) requirements. Many hospitals receive the majority of payers from Medicaid and Medicare.
- While the CSA is the biggest factor, hospitals national accreditation is also a factor. The Joint Commission is the largest accreditation body. It sets the broad standard that the

hospital safely controls medication brought into the hospital by patients or licensed independent practitioners. As such, hospitals must identify, visually evaluate, and inform patients about medications. This again goes back to the CSA, because hospitals must figure out how to identify and determine the integrity of a product that is not FDA registered.

All that said, there are other states that have also liberalized their marijuana policies where some health systems have developed policies and procedures that allow them to "straddle the fence" with federal and state laws. They have put in place guardrails and practice that allow them to segregate their duties from the patient/provider desire to continue to use those substances when they are admitted to the hospital.

Dr. Caughron asked for copies of those "go-arounds" that other hospitals or states have implemented and Brent said he could share a couple template policies from other state associations.

Del. Davis also asked for those policies that allow other hospitals/states to allow the product while complying with federal law. He is interested in any state-level hurdles so they can get the necessary legislation passed and any hospital-level policies so he can make the necessary calls.

Ms. Smith – Her daughter Haley was at VCU in 2017 and had not been giving her CBD since she did not have the necessary permissions. Her neurology team advised her to start administering it and received the necessary approvals (bottle was perfectly labeled). On the discharge papers the hospital staff said Haley was using CBD because she was part of a medical study, so maybe the processors could set up a kind of research study. She also knows a family in DC that had no trouble administering the medication in the hospital. For some kids, it is more dangerous to have medication taken away from them than to use it while in the hospital, and that is what her neurology team thought at the time.

Mx. Pedini: Using in hospital is an issue, but the bigger concern is letters going out from health systems telling physicians not to participate in the program (not to register with DHP to issue written certifications). This workgroup is seeking clarification on health systems that are multi-state operators that are not prohibiting participation in other states but are doing so here. Del. Davis seconded that question about the difference between other states and here.

Dr. Caughron: Are you referring to Sentara? Mx. Pedini: They are just one of many.

Mr. Rawlings: The hurdle is the federal law, as healthcare providers try to be amenable to the level of access and still comply with medical law. VHHA can provide some policies from other states, but they as an association have not taken any position on this. Their members are situated differently and range from multi-state operators to in-state and/or small, independent providers. Another thing they can offer is to get a better understanding of exactly where their members are, since this is new in Virginia and folks are at different stages in terms of trying to adapt their operations.

Del. Davis understands the challenge for in-state operators but wants to understand the differences between our state and other states for the multi-state operators. If it is because of

regulations or laws then he would like to try to address it, and then hopefully the multi-state operators can mentor the smaller, in-state operators. He would think they could build this out quickly.

In response to a question from Dylan Bishop, Counsel for CannabizVA, **Mr. Rawlings** said they do not have a lay of the lay in terms of medical cannabis policies, but can do a survey and look into Del. Davis's question re: multi-state operators.

Assistant Secretary Finley introduced Clark Barrineau from the Medical Society of Virginia (MSV). MSV has also offered to do a survey one of the goals of today is to establish the right questions for MSV and VHHA to ask their members, so we can have a lay of the land.

Mr. Barrineau: What questions do you need as far as education and adoption? From a few member conversations and some basic research, it seems that the main barriers to physician participation are stigma and education surrounding medical marijuana. In Delaware, 35% of primary care physicians (PCPs) were very unlikely or unwilling to authorize patients to use medical marijuana or similar products. The fact that it is a Schedule I drug also gives people pause as to what they can do. MSV's policy related to medical marijuana is: support downcoding it from Schedule 1, increase research, and support the rights of physicians to prescribe it where it is legal. He is happy to pose questions to their 10,000+ members of MSV.

- **Ms. Abebe** appreciates the opportunity and would like to know:
    - How hard or easy is it for practitioners to navigate the registration process? They have had to do education materials to help patients navigate the website and the process. So, for providers who are interested, how accessible do they find it to register and maintain that registration?
    - Some policies in other states allow written certifications being renewed as part of a regular appointment (not just related to medical marijuana) to be covered by insurance. She knows that can be tricky with the CSA but would love it to add the insurance coverage element in some way. The more patients that can have this conversation with their PCPs, in the context of their overall healthcare, the better. Fear of stigma presents a challenge. Currently (without insurance), it can be unaffordable with $100-200 coming entirely out-of-pocket for the appointment + $50 for DHP patient registration + $20 per caregiver registration. Then, medications at the dispensary are expensive because they can only sell processed products. Are there innovative solutions to promoting access to healthcare and positive patient outcomes without compromising Medicaid?
    - Is the patient limit (600 people) a concern for providers?

- **Dr. Caughron:** The main issue for him is with new patients seeking CBD oil (as opposed to existing patients, because you wonder whether they are getting at it with a healthcare goal. The issues of healthcare access is one of the most serious problems we are dealing with at the state and national level.

The certification makes it extremely difficult, and until the national law is changed it makes it a problem for them to prescribe. All they can do is recommend but giving some folks access to the product is just good medical care as he sees it.

Mr. Barrineau summarized the survey question topics: stigma, need for more education, accessibility to register and maintain registration, comfortability in talking about patients, issues around insurance reimbursement, issues around equity and cost to patient, questions around existing vs. new patients, and patient limits.

- Mx. Pedini: How do your members feel about the required registration for practitioners?
- Mr Barrineau: Do we want to invite the Virginia Association of Health Plans to join the conversation re: the insurance piece?
- Del. Davis: For insurance questions, he thinks it would be whether they are willing to put it in a formulary (which they should) and whether there is a PBM problem because of pricing scenarios. He thinks they should bring in AHP, but first need to solve problem around physicians.
- Dr. Caughron: I don't see how we can do that, since registration/written certifications is a hurdle and he doesn't know a lot of physicians who are crazy about doing it at all. He feels like he should be able to provide recommendation without those hurdles, but that is part of the larger marijuana issue.

Assistant Secretary Finley: How do you sort through the differences in the academic literature? I read through the summary of the 2017 National Academy of Sciences study on marijuana and it seemed like there were areas with conflicting and insufficient research.

- **Dr. Caughron**: The American College of Occupational and Environmental Medicine (ACOEM) is doing a report on this. There are a number of consensus reports that are being worked on, but are not yet available in medical community. They don't have a good handle on the topic because the all necessary studies have not been done. They do have evidence in some areas, for example, it is a no-brainer for childhood and congenital seizures. For many other things, there is anecdotal information but the necessary studies to convince practitioners are the in the process of coming out. Much more research – beyond just cannabidiol – is needed. Part of why he got involved is to encourage us to proceed in a more forthright manner.

Ms. Juran reminded everyone that the Department of Health Professions is non-general fund agency, so licensure and registration fees are the only way to cover their cost. That is part of the reason for the registration process and fee.

Ms. Payne (via chat): Would it be helpful to have doctors in other states who have more experience with integrating medical cannabis into their conventional practice come to Virginia and give a few talks or continuing medical education courses (CMEs)?

- Mr. Barrineau: Yes, they are happy to offer that for their members through their existing webinars and CMEs (CME credits get more participants). People have a lot of questions and the longer they have to promote the opportunity, the more buy-in for attendance.

- Ms. Juran and Dr. Caughron noted there have already been some educational opportunities like that. Mr. Barrineau pointed out that doing it multiple times is always a good idea and they are happy to facilitate. Ms. Juran agreed with that recommendation.

Del. Davis: What are other states doing in terms of registration fees? Is the cost similar and what have been the impacts? We need more doctors - if you can prescribe opioids you should be able to prescribe marijuana.

- Ms. Smith: From patient perspective, Massachusetts recently removed the registration fee. She noted the fee increases the stigma of the medication.
- Ms. Abebe: In New York, I believe they eliminated the fee until they hit the projected patient registration numbers (based on disease rates). In Oklahoma, the fees are reduced for Medicaid-eligible and veterans.
- Mx. Pedini: We should look at Oklahoma process, which accounts for patients who can't afford the medicine. Practitioners are not required to register and it has a very user friendly website that explains the process.
- Ms. Juran: She will look at other states and innovative approaches, but believes the vast majority of states do have a registration process with a similar fee process in place.
- Another workgroup members agreed that Virginia is in line with most other states, since the overhead costs of administering the program are significant. A few states have waived the fee later in the program once things are established, and some are looking toward a hybrid model with a low-income or distressed patient qualifier for a reduced fee. As Ngiste mentioned, the products are expensive and not covered by insurance, so most dispensaries she is aware of have discount programs for either low-income or veteran participants. It needs to be a healthy balance between patient access and the costs of running the program.
- Dr. Caughron wants to see registration process go away, since it creates a bureaucratic nightmare, but it will have to be this way until the national law is changed.
- Ms. Juran: Another approach is to look at shifting the regulatory fees amongst the registrants (regulatory process), e.g. increasing the fees for processors but reducing them for practitioners and/or patients.

Assistant Secretary Finley: In our last meeting, the work group requested to talk to industrial hemp industry. The goal is two-fold: 1) broader issue of product distinctions within the industry (e.g. Dr. Caughron mentioned dosage and fact that get something different from each biological product); 2) differentiating medical cannabis from hemp-derived CBD, including the two bills that Delegate Davis wanted to discuss. Dylan Bishop from CannabizVA and Graham Redfern from the Industrial Hemp Coalition joined the meeting today to discuss these issues.

Lisa Ramsey (VDACS Office of Dairy and Foods, Food Safety Program) and Erin Williams (VDACS Office of Policy, Planning, and Research, Industrial Hemp Program) first presented on the current legal and regulatory landscape with industrial hemp products. See both slides and notes below:

- Erin uses hemp and industrial hemp interchangeably. It is cannabis with no more than 0.3% THC, and extract is the broad term that applies to the cannabinoids that are extracted from the hemp plant which includes both CBD (or cannbididiol).
- Processors need to register with VDACS. Pre 2020, their laws and regulation were such that their food safety program could not inspect hemp processors who were producing hemp-derived extract for consumer consumption. In July 2019, Governor Northam directed VDACS to place qualifying industrial hemp processors under food safety inspection and in 2020 the Virginia Food and Drink Law was amended to address industrial hemp derived extracts for human consumption.
- See slide re: size of program. 17 processors currently under food safety inspection and in operation.
- Food is a broad term for products that are ingested orally, and includes dietary supplements. Any additive must be an approved food additive from an approved source. Approved food additives are either approved by the FDA or receive a notification that it is a generally recognized as safe (GRAS). Sources are approved by VDACS, FDA or a comparable program in other states.
- Virginia Food and Drink Law & Regulations closely mirror federal regulations. In order to address the safety of products that were under consumption but were not being regulated by the FDA, Governor Northam directed VDACS to put the hemp processors under food safety inspection. From that, VDACs established criteria/guidance: compliance with 21 CFR part 117, produced from hemp grown in compliance with federal/state law, no more than 0.3% THC, specific standards for heavy metals, mycotoxins, microbiologicals, residual solvents, and pesticides (closely mirror Board of Pharmacy (BOP) regulations for pharmaceutical processors as they existed at that time).
- In 2020 General Assembly session, SB 918 and HB 1430 formalized the authority to inspect registered hemp processors (see slides). The legislation directed VDACS to promulgate regulations and those will be posted to Town Hall soon and include a public comment period.

Dylan, CannabizVA represents business folks on the industrial hemp side of the market and those looking to expand opportunities on the pharmaceutical side of the market. They are only interested in use within Virginia law and regulations (not currently adult use). He brought to the meeting Sterling Edmunds from Golden Piedmont and David Derian from Botanaway.

- There is no distinction between hemp derived CBD and marijuana derived CBD. The only difference in the products would be the THC content, which is a function of the plant genetics, how it has been grown, and processing. However, in terms of the chemistry – CBD is CBD regardless of the type of plant it is derived from. In terms of Del. Davis's bills from last session, he thinks they are redundant and create confusion since CBD is the same in both products. As an organization, they are in favor of VDACS implementing reasonable testing and labeling requirements on hemp products intended for human consumption. (That clears out bad actors and bolsters confidence in the product.) He is happy to work with Del Davis on additional legislation.

- **Del. Davis**: While the CBD is the same in both products, from a business perspective CBD is now a marketing tool, whereas in healthcare it is a product. There is a lot of confusion and his bill would highlight for consumers what they are getting, since hemp-derived CBD is different than what you get through your doctor.

  The other piece of legislation said you can't wear a white lab coat, pretend you are a doctor, and sell hemp CBD. It is probably only a small population that are doing that, but having a "medical" person pushing CBD further the confusion and we should keep out bad actors trying to take advantage of a "hot topic" term.
- **Mr. Bishop** thinks the FDA has certain restrictions on adverting the value of supplements. (David Derian is an expert in that, but was having audio trouble and not able to speak.)
- **Dr. Caughron**: CBD is composed of a number of products, so it is like wine in that the products differ.
- **Mx. Pedini:** The FDA says you cannot make health claims on a product and has expanded what it considered health claims to include patient testimonials, but it has also been clear that is not the focus of their work and they rely on others to draw their attention to bad actors. Health claims are different than someone in a white lab coat. CBD is the same regardless of the plant, but there is still confusion about these products. Dr. Michelle Peace from VCU did a study and found these products do contain contaminants. VDACS has testing requirements, but no lab in the state can conduct environmental and potency testing to bring the medical products to market. Does the hemp industry have access to labs and, if not, how are those coming to market? What happens if the products are sold not as a food but as a vape, how is that regulated? She is concerned about environmental contagions that may be heated and inhaled.
    - Ms. Williams, VDACS: The regulations and process that she went over is specific to hemp extract that is intended for human, oral consumption, so products that are inhaled or topical are out of the jurisdiction of VDACS. They are treating them like other foods they regulate.
    - Ms. Ramsey, VDACS: They are regulated under 21 CFR 117. Dietary supplements are also a food and have an extra layer of regulation under 21 CFR 111. No foods are allowed to include adulterants and within the hemp regulations they approved certain requirements to not include certain bacteria, mycotoxins, residual solvents that can be associated with hemp, so they are not allowed to have contaminants.

      In terms of what Del. Davis talked about, the only products that could have white lab coats would be products that are not under their supervision. They seek out those who are not registering with VDACS when they can. They are not allowed to present themselves as a drug on the label, flyer, or internet (all are considered labeling). As dietary supplements, they can have information on the label but it must be truthful and they cannot state that the product is intended for as preventing, treating, or diagnosing a disease. They cannot advertise that CBD will

do some of the things that the scientific community and anecdotal evidence has said it can do.

- **Ms. Abebe**: We are discussing this topic because there is a concern that the pharmaceutical processors are unable to sufficiently educate and spread the word about their program. While CBD is the same in both industrial hemp and pharmaceutical products, the development is different, the amount of THC is important, and the pharmacist involvement differentiates the product. Under Virginia code, the pharmaceutical processors can only put their address and operating hours on their website whereas CBD can advertise; while there are federal limits, there are no stark limitations in Virginia code for the hemp processors. The medical cannabis industry does not want to be reckless, but are severely limited in their ability to run a business and provide a medical recourse for patients. The advertising limits are different and it is important that patients can differentiate between the products. It is similar to advertising Tylenol differently than Tylenol with codeine that you need to go to the doctor for.
- **Mr. Bishop**: Is the concern that hemp processors can advertise too much, or that pharmaceutical processors can't advertise enough, or somewhere in between? The code that restricts medical cannabis marketing came out of concern re: the psychotropic effects, because they can lean on a near-monopoly for their consumer base, and because you have to go through a doctor that will explain the product differences. Those factors are not the same on the industrial hemp side.
- **Del. Davis:** They do have a near monopoly, but the issue is that CBD is being used as a marketing term and no one has a monopoly on CBD. Some folks view it as the difference between Zyrtec and prescription Zyrtec, but that is not the case here since I cannot use my insurance. There must be some kind of branding that gets rid of the confusion between the two products, since we cannot educate everyone. We do not want to remove the ability of hemp industry to compete, but they should be able to do it without misrepresenting their product.
- **Mr. Bishop**: At the end of the day the products are distinct but also substantially similar…
    - **Ms. Abebe**: They are relying on the same chemical compound but they are very different, e.g. cannot help with epileptic seizures, etc. It is important to not blur the line and that statement is why this discussion is important. People do not understand there is another program they can be participating in with their doctor, a pharmacists, and a higher concentration of medically relevant chemicals that can help them manage their disease state. CBD is just a wellness product or another natural herb. Another work group member agreed with Ngiste that there is confusion and we need to be clear.
        - Senator Marsden's representative (Matthew Rogers) agreed. He got into this to help kids with severe conditions, and we should not be leading folks to think that CBD can treat their chronic conditions. If businesses are not behaving appropriately, the legislature should step in.

- **Mr. Bishop**: These products are not advertised as medical therapies and there are FDA regulations that ensure that. He was not in any way asserting that hemp products are medical products, but saying that in some instances the active component CBD in over the counter products are substantially similar to the compounds that you may get from a pharmaceutical processor. Second, we are acting as if these are poison pills that folks are selling. He would like others to weigh in on the extremely high level of testing that must be done before an industrial hemp product can be sold as a product for human consumption. Many of those regulations were copied and pasted from the BOP regulations for pharmaceutical processors.
- **Sterling Edmunds, CEO Golden Piedmont** (large CBD company): They have PhDs and chemists and test the soil for the contaminants that Ms. Ramsey mentioned. They are not having trouble finding labs (he thinks because the pesticide requirement for them is different). They track their process from dirt to seed to plant to and until it is turned to distillate, etc. to sell. A lot of CBD that is sold in Virginia is coming from elsewhere, but if you are in VA and producing CBD for food-made purposes you have to comply with the requirements. What they do it close to the BOP regulations, with the main difference being that they grow outside.
- **Mr. Bishop:** They have worked with VDACS to clear out bad actors in terms of testing and labeling requirements that are selling vape or one-off products in convenience stores. That is not the Virginia hemp industry and they do not want to be confused with them.
- **Del. Davis** said he is not confusing that and respects what Sterling and others do, but consumers are still confused and it comes down to labeling. Using "hemp-derived CBD" is accurate and is still beneficial, so is there a problem with requiring that hemp-derived CBD be included on those products?
    - Ms. Ramsey: Virginia would be the only state doing that. Gas station products are generally not from Virginia, so including that on Virginia products would not impact the products he is looking to have an impact on.
    - Del. Davis: They can mandate those requirements regardless of where it comes from.
    - Ms: Ramsey: It would be hard to regulate.
    - Mr. Bishop: It would be hard to enforce. He does not think they would have a huge problem but would have to check with his members on that or similar alternatives.
    - Ms. Juran: Does VDACS have jurisdiction to cover out-of-state products? Any pharmacy shipping from out of state they have to register with BOP as an out-of-state pharmacy and comply with the same regulations.
    - Ms. Ramsey: I don't know how we would do that, especially since we are regulating it as food.
    - Del. Davis: The Administration thinks they can do that with masks from other states and would think the same process can be utilized for this.
    - Ms. Williams: The VDACS regulations pertain to hemp-derived extract for human consumption, and that applies to both Virginia manufactured and out-of-state products at Virginia retail stories. In terms of enforcement, the reality is that

it might look different because of resources. However, the expectation and the law/regulations is that they are all held to the same standard.

- **Mx. Pedini**: Regarding hemp flower and CBD vapes, who oversees those products especially with lab testing? They are advertising themselves as CBD dispensaries.
    - Mr. Bishop: Remember that hemp is not a controlled substance. In terms of vaped products, federally they are deemed a tobacco product and regulated by the FDA. At the state level, it is only the Department of Tax after the tax was passed on liquid nicotine. The BOP did enact regulations after bad respiratory effects from illicit THC vaping products with vitamin E acetate. CannabizVA would support legislation preventing the use of vitamin E acetate.
    - Mx. Pedini's concern is not just vitamin E acetate, but contaminant testing in hemp flower and CBD vapes. Where does that regulatory oversight lie? Also, if they have access to environmental testing that is a disparity, since right now medical cannabis products can't get to market because they can't find labs. In the meantime, industrial hemp products are advertising themselves as medical products.
    - Assistant Secretary Finley reminded the group that, while there is some crossover and connection here, the charge of the work group is to talk about the medical cannabis program specifically.
    - Dr. Caughron: It would be helpful to get consistent, quality labs to be able to do the testing.
        - Mx. Pedini said they did legislate that this past year.
    - Ms Williams: The regulations that VDACS is developing for hemp extract for oral consumption do establish criteria for labs to conduct the batch testing of the product. To address the question re: vapes or inhaled products, there is not a Virginia state agency that has regulatory oversight over inhaled or topical products. VDACS is addressing the products that are for oral consumption under the food laws they have jurisdiction over.
    - Mr. Bishop: Rebecca Hobden runs East Coast Analytics, a testing lab here in Christiansburg VA, and she can talk about the testing details with both pharmaceutical processors and industrial hemp processors.
- **Graham Redfern, Director for the Virginia Industrial Hemp Coalition**: Hearing this discussion, they represent the farmers and not the medical side but there seems to be a massive difference between the medical and industrial hemp side. The distinction is between what is grown at the plant level. Medical cannabis is not hemp. If you distinguish between the products, you have medical cannabis for patients and industrial hemp under .3% THC as an agricultural product that produces wellness and dietary supplements. They cannot put on a label that don't have cannibidiol or it comes from hemp – the distinction is that it is less than .3% THC. 95% of stuff on the CBD market right now comes from out of state and out of country, and there are things to figure out there. However, the medicinal side is medicine and what farmers are growing is federally legal and a VDACS approved product. There is a big distinction there and he thinks there is a future in this for everyone.

Assistant Secretary Finley did a roll call vote on the materials that had been emailed out, including the revised draft work plan. It was a unanimous approval, except that Senator Marsden was not in attendance.

Mr. Bishop brought up HB 1460 that would allow pharmaceutical processors to purchase industrial hemp products from VA processors.

- **Ms. Juran** said that bill went into effect July 1st and will be taking action on emergency regulations. They will discuss on September 9th and that sets them up to be approved around January 2021. The agenda packet should be posted later today. Re: pesticide testing, those requirements have been in regulation since 2017, but they have heard they are cost prohibitive and have worked closely with VDACS to consider draft language at the September 9th meeting.

Assistant Secretary Finley: The next meeting is September 30th. We will discuss the use of medical flowers, so please send suggestions for presenters. Dr. Grice will also put together a video.

Public Comment:

Rebecca Hobden, who runs a testing lab ECC test lab in Blacksburg, has been working with hemp industry and do all the testing they talked about. They started with potency and now also do heavy metals, pesticides, mycotixons, turpenes, microbials, etc. There are not a lot of labs like hers, but they are coming. They have run into things that are making it difficult to move industry forward. A lot of other state have a full list of pesticides, whereas BOP/VDACS applies everything on EPA list. That is twice as many as other states, many of which are not relevant to this industry. Her lab took the Oregon list and put it into place because they knew it had been well-researched. As a small business, she encourages Virginia to start sooner rather than later on adjusting the list.

Michelle Peace runs a research lab at VCU where they have been monitoring what is happening in other states as they develop their medical or adult use cannabis industries. She is also the cofounder of Cardinal Laboratories in Richmond, VA. She agrees with everything Becky said re: pesticides list, which is a cost-prohibitive barrier to labs. This conversation is predicated on the assumption that we have products testing in a third party, QA laboratory. They are building, but are experiencing barriers and Virginia needs to support third party labs. They already have enough hurdles with accreditation and proficiency testing. You need labs to clear out bad actors. They are happy to talk with anyone in the industry.

Thomas Malone, GMU for business and UVA law, is interested to see the tug and pull between the industrial hemp and medical cannabis industry. There is some overlap among consumer base and interest. CBD cannot be used to prevent, treat or cure medical conditions, though in practice that is what people are doing, so there is a friction there with people who are going through the CBD. He represents Arena Group hemp farm in Virginia, which will be going through appropriate channel with VDACS and are happy to provide clarity of their own.

Lisa Davis works with Michelle Peace at Cardinal Labs and seconds everything Becky and Michelle said. In terms of adulterants, to think that doesn't happen in this industry is naïve and they are already seeing that in CBD, including labels that don't include what is in the product. Is there an adverse reporting system in place in Virginia? They have received reports of psychotic episodes with over the counter products. What do physicians do if there is an adverse reaction, where would you report that?

After public comment, **Ms. Juran** reminded the group that SB 976 also required them to establish standards for labs. Those are also in the draft emergency regulation in the Board agenda packet posted later today. There are in-person, virtual, and written mechanisms for comment.

- **Ms. Davis** hopes that the solution is immediate because her daughter and patients are waiting. Ms. Juran responded that their reaction and participation is critical.

The meeting adjourned at about 11:45am.

Comments in the WebEx Chat:

From Elly Tucker to All Panelists: Could you use the names of groups instead of initials?
From Elly Tucker to All Panelists: VHHA??
From Elly Tucker to All Panelists: HP?? Health practitioner??
09:51:19 AM from Lisa Smith to All Participants: I think it is Virginia Hospital and Healthcare Association.
From Elly Tucker to All Panelists: I am concerned about injustice surrounding who can afford the costs of access. Those who can afford the visits get it? Those who can't won't?
From Elly Tucker to All Panelists: PDM??
From Elly Tucker to All Panelists: NAS??
From Elly Tucker to All Panelists: Thank you.

From Michelle Peace to All Panelists: Even though "adulterants" are not allowed, it doesn't mean that other kinds of adulterants are not being added...
From Michelle Peace to All Panelists: We have found over-the-counter cough syrup and melatonin in some CBD products
From Michelle Peace to All Panelists: 3rd party testing is an imperative to eliminate bad actors in the industry - the oversight will deter those actors, even if those 3rd party tests don't test for all other kinds of adulterants

From Rebecca Hobden to All Panelists: Hi. I am an analytical testing lab in Virginia that tests for hemp processors. I can speak to some of the questions on testing.

From Michelle Peace to All Panelists: E-cigarettes are only regulated by the FDA as nicotine dellivery products
From Michelle Peace to All Panelists: They will not oversee CBD/THC vapes
From Michelle Peace to All Panelists: As someone who has reviewed that data and been in these conversations re: EVALI, the issue is larger than VitE and VEA - those 2 additives are symbolic of a bigger issue

From Michelle Peace to All Panelists: I have consulted other states re: the other additives that should be cosidered to restrict as chemicals in vapes

From Rebecca Hobden to All Panelists: If anyone hs questions about testing, feel free to email or call: 540-682-3765 or becky@ecctestlab.com

HEMP-DERIVED EXTRACTS INTENDED FOR HUMAN CONSUMPTION

PRODUCTION STANDARDS

VIRGINIA DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES (VDACS)
Erin Williams – VDACS Office of Policy, Planning, and Research, Industrial Hemp Program
Lisa Ramsey – VDACS Office of Dairy and Foods, Food Safety Program

HEMP AND HEMP-DERIVED EXTRACTS IN VIRGINIA

- Virginia Industrial Hemp Law
- Virginia Food and Drink Law
- Federal Food, Drug, and Cosmetic Act

HEMP AND HEMP-DERIVED EXTRACTS IN VIRGINIA

- **2015**: Virginia Industrial Hemp Law enacted. Established industrial hemp research program.
- **2018**: Virginia Industrial Hemp Law amended to, in part, establish an industrial hemp processor registration.
- **2019**: Virginia Industrial Hemp Law amended to, in part, allow commercial production of hemp and distinguish hemp-derived oil from VA's Drug Control Act "cannabidiol oil," which is produced by a "pharmaceutical processor" and regulated by Virginia's Board of Pharmacy.
- **May 2019**: VDACS advises Industrial Hemp Processors that Food Safety Program is not able to inspect them.
- **July 2019**: Governor directs VDACS to place qualifying Industrial Hemp Processors under Food Safety inspection.
- **2020**: Virginia Food and Drink Law amended to address Industrial Hemp-Derived Extracts Intended for Human Consumption.

AS OF AUGUST 31, 2020

- 1,227 Registered Industrial Hemp Growers
- 355 Registered Industrial Hemp Processors
  - 17 currently under Food Safety inspection and in operation

FOOD SAFETY

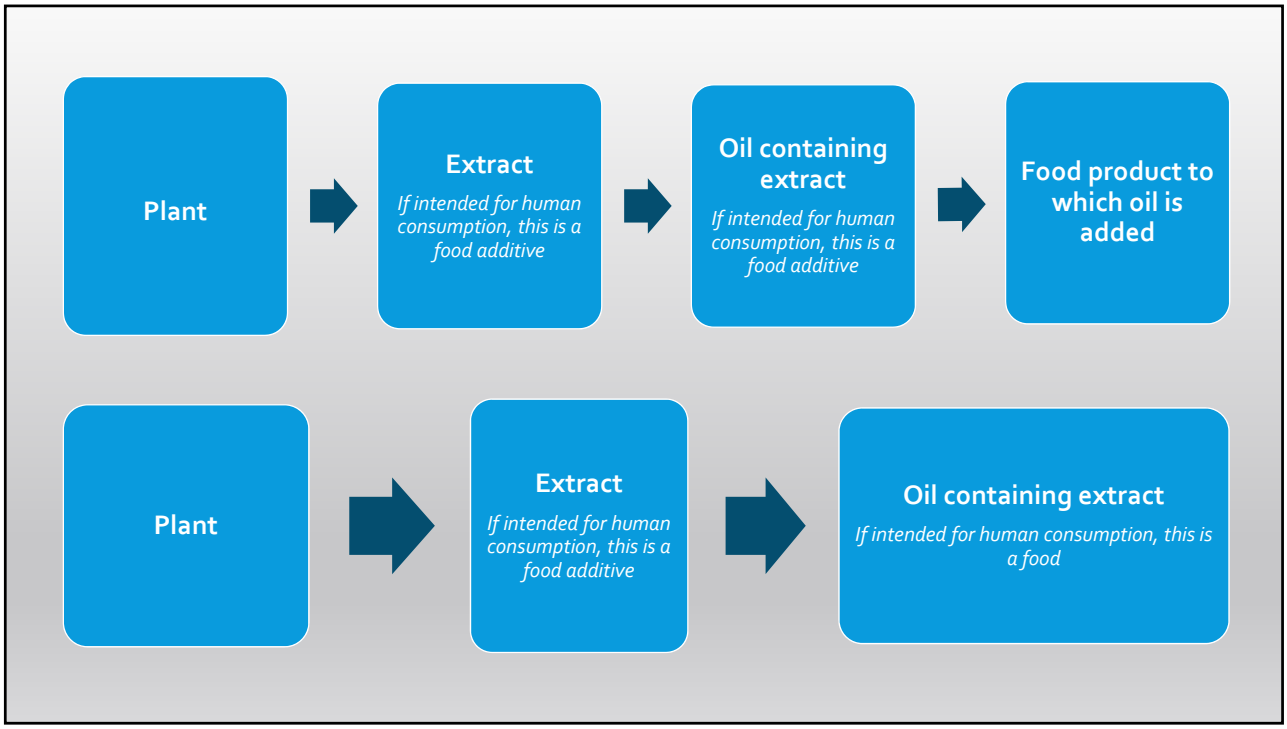
FEDERAL FOOD, DRUG, AND COSMETIC ACT
VIRGINIA FOOD AND DRINK LAW

- Food is a substance intended for human consumption that is orally ingested
- Any substance intentionally added to food must be an approved food additive from an approved source

FOOD SAFETY-RELATED LAWS AND REGULATIONS

FEDERAL FOOD, DRUG, AND COSMETIC ACT
VIRGINIA FOOD AND DRINK LAW

- Approved food additive
  - Approved by FDA, or
  - Generally Recognized As Safe (GRAS)
    - Hulled hemp seeds, hemp seed protein, hemp seed oil
- Approved source
  - Under inspection (by VDACS, FDA, or food program in another state)



FOOD SAFETY-RELATED LAWS AND REGULATIONS ADMINISTERED BY VDACS

- Virginia Food and Drink Law
- Regulations adopted thereunder, including:
  - "Regulations Pertaining to Food for Human Consumption"

GOVERNOR'S DIRECTIVE TO VDACS

- While waiting for FDA action or related state legislation, VDACS should:
  - Treat hemp-derived extracts intended for human consumption as approved food additives
  - Place qualifying Registered Industrial Hemp Processors under food safety inspection so that inspected and approved processors may manufacture a hemp-derived extract intended for human consumption

FOOD SAFETY INSPECTION FOR REGISTERED INDUSTRIAL HEMP PROCESSORS PRODUCING A HEMP-DERIVED EXTRACT INTENDED FOR HUMAN CONSUMPTION

- Good Manufacturing Practices requirements
- Extract must be produced from hemp grown in compliance with federal or state law
- Extract shall have no more than 0.3% THC
- Specific standards for heavy metals, mycotoxins, microbiologicals, residual solvents, and pesticides

Microbiologicals	
A hemp-derived extract intended for human consumption shall satisfy the standards set forth in Section 1111 of the United States Pharmacopeia.	
Mycotoxins	
Aflatoxin B1	<20 ug/kg of Substance
Aflatoxin B2	<20 ug/kg of Substance
Aflatoxin G1	<20 ug/kg of Substance
Aflatoxin G2	<20 ug/kg of Substance
Ochratoxin A	<20 ug/kg of Substance
Heavy Metals	
Arsenic	<10 parts per million (ppm)
Cadmium	<4.1 ppm
Lead	<10 ppm
Mercury	<2 ppm
Residual Solvents	
A hemp-derived extract intended for human consumption shall meet the standards and limits recommended by the American Herbal Pharmacopoeia for Cannabis Inflorescence.	

2020 VIRGINIA GENERAL ASSEMBLY
SENATE BILL 918 / HOUSE BILL 1430

Industrial hemp extract that is intended for human consumption:

- Is a food and is subject to VA's Food and Drink Law;
- Must be produced from industrial hemp grown in compliance with applicable law; and
- May not exceed a Total THC concentration of 0.3 percent.

A manufacturer of an industrial hemp extract or food containing an industrial hemp extract is an approved source if the manufacturer operates:

- Under inspection by the responsible food regulatory agency; and
- In compliance with law that pertains to industrial hemp extracts in the location in which such is manufactured.

2020 VIRGINIA GENERAL ASSEMBLY
SENATE BILL 918 / HOUSE BILL 1430

Board of Agriculture and Consumer Services shall adopt regulations:

- Identifying contaminants and establishing tolerances
- Establishing labeling requirements
- Establishing batch testing requirements and requiring batch testing be conducted by an independent testing laboratory that meets criteria established by the Board

VIRGINIA REGULATION FOR INDUSTRIAL HEMP-DERIVED EXTRACTS INTENDED FOR HUMAN CONSUMPTION

Board of Agriculture and Consumer Services proposed a draft regulation prepared by VDACS staff at its meeting on July 21, 2020.

Proposed regulation will undergo a 60-day public comment period, after which VDACS staff will present a draft final regulation to the Board at a subsequent meeting.

Use the Virginia Regulatory Town Hall to track the progress of the regulation and the Board's upcoming meetings as well as to comment on the proposed regulation.

https://townhall.virginia.gov

VIRGINIA DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES

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Appendix VIII – Meeting Three

Virginia Medical Cannabis Work Group
Meeting Three
September 30, 2020
9:30-11:30am

Agenda

Welcome & Approve Meeting Two Minutes *5 min*

Presentations related to the Health Effects of the Use of Medical Cannabis Flowers

- Farzana Kennedy, Pharmacist in Charge, Dalitso *10 min*
- Robert B. Wallace, MD, MSc, Irene Ensminger Stecher Emeritus Professor of Epidemiology and Internal Medicine (Iowa City, IA) and Ziva D. Cooper, PhD, Director, UCLA Cannabis Research Initiative & Associate Professor, Jane & Terry Semel Institute for Neuroscience & Human Behavior, Dept of Psychiatry and Biobehavioral Sciences, UCLA *20 min*
- Dr. Sue Sisley, President & Co-Founder, Field to Healed Scottsdale Research Institute Foundation *10 min*

Question & Answer and Open Discussion with Presenters & Workgroup Members *45-60 min*

Public Comment *15 min*

Adjournment

Meeting Minutes

Assistant Secretary of Health and Human Resources Catie Finley called the meeting to order at 9:35am. She took attendance:

Meeting Attendees:

Caroline Juran (Board of Pharmacy)
Senator David Marsden
Ngiste Abebe (Columbia Care)
Jack Page (Dharma)
Sara Payne (Dalitso)
Joy Strand (GreenLeaf)
Lisa and Haley Smith
Jenn Michelle Pedini (Virginia NORML)
Dr. Sam Caughron

Del. Glenn Davis
Secretary Daniel Carey

Sara Payne introduced Farzana Kennedy, President of Dalitso, to give info on botanical products from a pharmacist's perspective. She is a licensed compounding pharmacist licensed and Managing Partner at Dalitso.

Guest Speaker: Farzana Kennedy

The cannabis plant has been used a medicine for thousands of years. It provides hundreds of different cannabis compounds with a range of health benefits. Her presentation will focus on botanical or flower products, which have:

- Great product efficacy,
- Improved ability to properly dose a patient (titration),
- Increased benefit of entourage effect,
- Reduced patient cost.

In terms of product efficacy and titration, vaporization - as opposed to other forms of inhalation such as those that involve combustion - is particularly effective because the patient feels almost immediate effects. For pain, they get immediate relief. She can work with them to combine those with products that are longer acting and there are less issues. Regarding patient choice, botanical products are more desirable. They are more pure. Not every product works for every patient, so patients and practitioners should have maximum choice.

The cannabis plant has over 400 chemical entities, including more than 60 cannabinoid compounds, and with botanical compounds they work in concert producing an "entourage effect." Because many naturally occurring compounds are stripped during processing, oil based products do not provide the full spectrum of entourage effect. Many patients report health benefits of the entourage effect and she sees it is in her practice.

Oil products require significant processing at cost, which unfortunately is passed along to patients. Botanical products can often be produced at a fraction of the cost. Given that it is not covered by insurance, botanical products will allow access to medical cannabis to more Virginians. It will help steer folks who are self-medicating in the illicit market and provide them access to safe products through a qualified health care professional. As a clinician, it is important to consider all patients and all treatment options by allowing botanical products. Virginia would improve patient access to the program while expanding tools available to health care professionals, so patients can achieve maximum benefits with the lowest consumption and with regulated products. This is a public health and safety issue. If they are too expensive and not effective, patients will either forego treatment or get relief from the unregulated market and from opioids.

Farzana shared a story of a patient with unpredictable and often constant pain throughout her body that makes everyday tasks almost impossible. She has trouble standing or walking for long periods of time and often involuntarily cringes due to sharp pain. She was properly diagnosed with lupus after 3 years. She struggled to have a normal student experience. Botanical products were the only form that let her get up in the morning and attend a class.

Asst. Sec. Finley introduced the next two presenters, who participated on the Committee for National Academy of Science, Engineering, and Medicine (NASEM) 2017 report entitled *The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research.* The presenters were Robert B. Wallace, MD, MSc, Irene Ensminger Stecher Emeritus Professor of Epidemiology and Internal Medicine (Iowa City, IA) and Ziva D. Cooper, PhD, Director, UCLA Cannabis Research Initiative & Associate Professor, Jane & Terry Semel Institute for Neuroscience & Human Behavior, Dept of Psychiatry and Biobehavioral Sciences, UCLA.

Guest Speaker: Dr. Robert Wallace

Dr. Wallace gave an overview of the NASEM 2017 report on the health effects of cannabis. The paper copy is nearly 500 pages and you can download it for free, but in summary (see slides as well):

- It is a systematic review of many hundreds of abstracts and papers.
- Focuses on smoking cannabis and disease outcomes, less on the more modern agents that are derived from the cannabis plant.
- Population utilization issues not a major focus.
- Except in selected areas, therapeutic effects not evaluated.
- New findings since the report.
- Studies across the developed world.

See the cautions in interpreting studies in the slides (below).

10-25% of regular cannabis users have Cannabis Dependence or Cannabis Use Disorder, who may have different health outcomes than the rest of the population. He believes they should be treated differently in terms of how you look at the health outcomes of cannabis use, but that is often not considered in the studies.

Disease and Functional Outcomes:

- Cancer in Adults – little evidence of harm, including in cancers that are often associated with tobacco smoking (lung & head/neck cancer/kidney, one study positive for testicular cancer, a few positive studies in kids but not enough, otherwise insufficient so evidence that smoking cannabis leads to cancer
    - The same is true (insufficient evidence) for heart attack, stroke or Type 2 diabetes.
- Using cannabis during pregnancy is linked to low birth weight, which in itself can lead to a number of problems in a child

    - Since then, maternal prenatal smoking has been associated with abnormalities as children grew up, and can say a little but not a lot of evidence one way or the other.
- Respiratory – long term cannabis smoking strongly associated with respiratory symptoms and chronic bronchitic episodes but not COPD or emphysema; acute but not chronic use improves airways and vital capacity in some people; cessation associated with improved respiratory symptoms
- Immune function – cannabis with all the chemicals that were mentioned does perturb the immune system, but found no measurable effect on health one way of the other.
- Psychosocial – first bullet is moderate, second bullet reasonably well established
- Injury and death
    - Has been established over a number of years – acute use prior to driving increases risk of motor vehicle accident
    - In states when cannabis legal, increased risk of unintentional injuries in children
    - Unclear if cannabis is associated with increased occupational injury or all-cause mortality
- Mental illness
    - Substantial association with development of schizophrenia and other psychoses
    - Heavy users more likely to have suicidal thoughts
    - Use does *not* appear to increase the development of depression, anxiety, and PTSD
- Other behaviors
    - Limited evidence of cannabis use associated with starting tobacco
    - However moderate for cannabis use and the development of other SUD such as with tobacco, alcohol or illicit substances
    - The literature is not as good as should be put forensic studies that are around show that cannabis levels occur with other substances when death for ED visits and other kinds of studies
- Therapeutic-Moderate Effects
    - Anti-vomiting effect in cancer
    - Reduction in chronic pain symptoms
    - After finished study, trials started to appear for certain childhood epileptic syndromes and that is now licensed indication
- At time (2016) inadequate evidence for other clinic indications

Guest Speaker: Dr. Ziva Cooper

Although she was on NASEM Report Committee, the area she is covering today was not explicitly covered in report. The remarks below accompanied her slides, "Cannabis: Constituents, Modes of Use, & Health Impact."

What is Cannabis?

Cannabis plant has phytocannabinoids (over 140 chemicals, still learning more, unique to plant). The most well-known are CBD and THC.

- THC has been studied the most and causes the intoxicating effects. It is responsible for the cognitive effects and abuse potential.
- We also know there are some therapeutic uses.
    - FDA approved synthetic THC in the 1980s for increasing appetite and decreasing nausea.
    - We also know based on NASEM report that there is substantial evidence support THC's ability to help reduce pain.
    - CBD: 1 in 5 using, but don't know that much about the therapeutic effects.
        - People are interested in it because it is not intoxicating.
        - Studies in animals do show therapeutic effects.
        - There are definitely anti-seizure effects. FDA approved Epidiolex for certain seizures, which is 98% CBD.
        - In terms of pain reduction, there are very few studies in humans where CBD is compared to a placebo (usually CBD and THC given together).
        - More cannibinoids will probably emerge but right now only animal studies.
        - Also have terpenes that are not unique to cannabis plant but are also thought to have therapeutic effect.
- Do these work together to maximize therapeutic potential and minimize adverse effect, the "entourage effect"?
    - To date very little rigorous studies done looking at this hypothesized effect
    - We know most about interaction between THC and CBD, and some studies show CBD has some ability to decrease adverse effects of THC
    - But re: the other cannabinoids either given alone or together, we know very little re: whether they need to work together the maximize therapeutic effects and minimizes harm
        - People are actively working on those studies now

<u>Modes of use</u>

- Smoking (botanical only, cannot smoke the extract)
- Vaporizing (both botanical and extract)
- Candy, baked goods, capsules/solutions (both botanical and extract)
- Others not covered here e.g. topicals

<u>Modes of Use: Impact on Pain Relief</u>

- With inhaled (in this study means smoked, but they think similar to vaporizing), patients sees very sharp increase in pain relief (and therefore patients can better control how much pain relief they can get).
    - Short-acting, can dose at 120 minutes
    - Easy to titrate, rapid short effect
- With oral, patient experiences slow onset, longer duration.
    - Don't feel effect until about an hour or two after use the medication, hard if dealing with pain
    - From graph: note the peak pain relief level is the same for both modes of use.

Modes of Use: Impact on Intoxication

- 20mg (same dose) used in each scenario
- Intoxication or adverse effect spikes higher and quicker for in inhaled (smoked/vaporized) than for oral consumption, where effect is longer and more gradual.
- Reminder: Aside from smoking, extracts can be used for oral administration as well as inhaled (vaporized)

Respiratory risks:

- The respiratory risks are especially important for those seeking cannabis for symptoms associated with diseases that are contra-indicated for smoking, vaporizing.
- Marijuana smoking is associated with respiratory symptoms and chronic bronchitis, but not COPD or lung cancer (long term effects, large samples).
- We know very little about vaporizing even though it is emerging as one of the primary modes of use. One study shows improvement in cannabis smokers who shifted to vaporizing plant products.
- For extracts, we know very little. In 2019, there was a sudden rash of cases where e-cigarette and vaporizing caused acute long injury that was associated with a contaminate (EVALI).
- It is a widely agreed upon hypothesis that vaporizing plant and extract is better for respiratory health than smoking, except that we often do not know what additives are included.

Summary

- Do cannabis constituents work together for improved efficacy/safety profile? We don't know very much at this point.
    - The flower has a variety of cannabis constituents that also vary between flowers. Extracts might be stripped of some of these constituent chemicals but are ways to maintain those constituents.
- Modes are same are pretty much the same except for smoking.
    - Keep in mind the only evidence we have that vaping has better respiratory profile than smoking is from vaporizing flower (at this point).
- Oral and inhaled use have different time courses impacting both therapeutic and negative outcomes, and that is the same for both plant products as well as extract.
- Potential for reduced respiratory risks associated with vaporizing plant as compared to smoking; long term effects unknown

Guest Speaker: Dr. Sue Sisley

- Dr. Sisley is a practicing physician in internal medicine psychiatry based in Arizona. Her recent work is focused around cannabis, specifically flower.
- She works at the Scottsdale Research Institute, which does FDA-approved randomized controlled trials evaluating safety/efficacy of smoked and vaporized cannabis flower.

    - Focused on treating chronic and breakthrough pain, PTSD, and looking at flower as a substitute for opioids.
- Why dry bud/raw flower?
    - Least expensive for patients (don't have to process into oils, which is costly)
    - Still most popular in legal states representing more than 50% of sales
    - If can get through the entire FDA drug development process, it will set precedents for other botanical medicine to become FDA approved
    - If flower on market with FDA indication, it will force insurance to pay for it
- A trial two years ago in Montreal in patients with advanced cancer compared inhaled (smoked) flower to fentanyl.
    - Time of onset of smoked flower was only 5 minutes where fentanyl tablets could take 1-3 hours to kick in.
    - This shows that flower is not just recreational, because it can compete with fentanyl.
- Dr. Sisley has a DEA Schedule I license which allows her to purchase flower from the federal government (NIDA).
    - That is the study drug for every randomized control trial in the U.S. for the last 50 years for academic studies, except for pharmaceutical company studies.
    - When people try to say extracts are safer, there is not really data to support that.
    - It was only last year that NIDA began providing extracts and oils to scientific investigators.
    - The only product licensed by the DEA for academic studies comes from the University of Mississippi.
- Flower allows patients to titrate their dose effectively, unlike concentrates.
    - Patients start with a couple inhalations, wait 10 min, continue until it has an effect on pain or PTSD.
    - Data on extracts is limited because NIDA has not been providing that as a study drug.
    - Value of dried flower in acid form is not well studied in controlled trials, but patients have been successfully blending it into smoothies, etc. It has not been heated so the psychoactive component is not active, but still has therapeutic benefits. You can't do that with oils since the THC is activated during processing.
- Flower lowers costs. In Minnesota and New York, flower was bankrupting patients.
- There is a possibility that terpenes and other plant molecules get stripped out during extraction and may be related to entourage effects.
- Only 2-3 states with full medical cannabis programs do not provide access to flower. The vast majority of patients have already been benefiting from flowers. Providing solely oils and extracts forces them to either switch products (or risk side effects) or to stay in the unregulated market.
- According to Arizona Poison Control Center data, only 100 of 65,000 calls are related to cannabis and all of them are related to extracts.

- You lost the natural balance of real flower by extracting into hyper potent concentrates. You cause a lot more adverse events, which you rarely see with smoking flower. Vape pens can be 80-90% THC concentration.

Written Statement from Dr. Preston Grice (work group member) re: botanical products:

"A few comments about the sales and use of unprocessed cannabis (flowers, buds, leaves, stems, etc.) This DOES NOT include oils, concentrates, tinctures, etc. I consider these 'processed.'

Honestly, I am opposed to the sales and use of unprocessed cannabis, in particular flowers. Now, I do completely acknowledge the versatility and economics of using unprocessed cannabis. It can be used in multiple dosing formats to principally include inhalation and ingestion. Also, it is easier to produce and package for sale than processed products

HOWEVER, the issue I have is dosing strength (mg, ml, g, etc.) per individual dose of product. Can a specific dosing strength per individual unprocessed product (flower in particular) be consistently determined? This is also the issue that several of my colleagues would have with prescribing and dosing unprocessed cannabis.

When I prescribe a patient a pharmaceutical product, I know what the specific dose of the active ingredient is in that medication. It is assumed to be consistent lot to lot, pill to pill, dose to dose, etc. as based on standards established by multiple regulatory organizations.

Can that be guaranteed "flower to flower"?

Producers and processors can make some pretty good estimates of the percentage of various cannabinoids in a dried product, especially THC and CBD, based on the various strains being grown and used as well as thru testing. However, doesn't tell me as the prescriber the specific amount of cannabinoid the patient is taking dose per dose. I am not talking about pharmacokinetics, bioavailability, metabolism, etc. I am talking purely about the amount of "medication" in each dose of medication.

Please note I have absolutely no issues with processed cannabis products (concentrates, oils, extracts, tinctures, edibles, etc.) as long as the amount of active ingredient (THC and CBD in particular) are known dose per dose or at least in the entire amount of product (i.e. the total amount of THC in a 100 g chocolate bar).

Also, one of my objections to unprocessed cannabis is 'smoking.' Again I realize the pro's (and cons) of smoking cannabis. If unprocessed cannabis is to 'pyrolized' (heated / burned) my preference is thru vaporization.

So, that is my opinion and views on unprocessed cannabis, in particular flowers / buds."

Discussion and Q&A:

Dr. Sisley responded to Dr. Grice's statement. Dosing of oils and extracts is much more complicated than dosing flowers. After years of negotiating with the FDA to get approval, they have now agreed that patient self-titration (start low, go slow) can be part of their study in recognition of the fact that it is a viable, safer way of delivering. There is no dosing data on oils, especially when dealing with high potency extracts.

Dr. Cooper agrees that we have high potency products that are difficult to control in terms of titration and adverse effects. Flower has the potential to titrate better if we compare a low-strength botanical to a high-strength extract. However, it depends on what flower and what extracts we are talking about. Botanical in raw form can be high THC/low CBD or the reverse and same with extracts, which can have almost 100% THC and almost no CBD. It depends on what type of chemicals and preparation we are talking about. What are the chemicals in the cannabis plant, and of course the raw materials should be consistent crop-to-crop, preparation-to-preparation, and batch-to-batch. It is really about the chemicals in both products that is the crux of the conversation when we are talking about the therapeutic benefits and the harms.

Senator Marsden: For the potential of time release products, is an analog over-the-counter antacids for both immediate and long-term relief (and now some that do both)? What is the potential for time release products where the dosage could be controlled through flowers, oils, etc. for pain relief?

- Dr. Cooper: As they both showed, when you take either flower or extract orally the effect is super slow. There is also new technology to help absorption and make onset faster. If patient wants control, inhalation is the best method right now, although not necessarily clinically useful for a lot of patients

Dr. Caughron: With botanicals, having a lab that can tell you what you are getting seems to be a foundation for what you are talking about. How do we know that the labs are going to be what we need in terms of being consistent and meaningful, especially since you may have multiple labs?

- Dr. Sisley is on Nevada Lab Testing Commission and they have been actively trying to establish guidelines and organize proficiency standards e.g. SOPs. It is important for patients to know the medicine's content. Some states are more exemplary than others in terms of transparency and accuracy. Lab testing is getting better every year.
- Dr. Caughron: When you use a botanical you are never really going to be able to standardize it. The testing wants to go to the "rifle shot" (pick off single drug that is most useful) and that is not going to cut it with botanicals – it is apples and oranges. We need to make sure that is clear.
- Dr. Sisley: She also had a tough time embracing the idea of the botanical ever being regulated medicine at first. However, through randomized control trials on real, natural, dried flower there are ways to use it safely and harness its potential and even the FDA is changing the paradigm of fixed dosing.

Del. Davis: Is there a place for each product (inhaled and oral)? For example, how there is quick-acting and time-release Adderall? Can you use inhalation and then follow up with oral?

- Dr. Sisley: In the veterans they treat, they commonly employ an array of formulations/ For example, they vaporize dried flower during day to get acute relief and use oil at bedtime to sleep overnight (pain, PTSD). That is common and that is why we want them on the shelf.

Secretary Carey: We are concerned about what the research environment is likely to be in the future. One slide showed the dried flower that has been used for studies for 50 years. As we consider the evidence we have to assess safety, is the research environment loosening up to study the variety of products that are already on the market in many states, so that we have better clinical trials of safety and efficacy?

- Dr. Cooper: She is completely immersed with them at UCLA and works a lot with FDA to try to get them to look at. To date, there have been no randomized control trials of the products that folks can get in their dispensary, because the products that they use for research have to be meet FDA standards – stable, consistent batch to batch, no impurities, etc. For products at dispensaries to meet those standards costs a lot of money, so they try to approximate those products.

  In the last five years, there has been a boom in interest for pharmaceutical cannabis. The work doesn't only include product from NIDA, which has shown some therapeutic effects, but are starting to see new formation and new products. The FDA trying to guide people who want to study the raw botanical form, but it is burgeoning in this area. Over the next 10 years the research will be more voluminous as to whether it support the therapeutic hypotheses or not.

- Dr. Sisley asked Virginia to join their lawsuit (third petition at federal level) to try to end the monopoly at the University of Mississippi and allow states like Virginia to be able to supply their own medicine for clinical trials. They have not made any headway through Congress and the DEA. Their amicus brief at the 9th circuit is getting traction.

- Secretary Carey summarized that there are advantages to having the one cannabis plant because it is predictably clean, but there are also negatives. He can't commit the Governor or Attorney General to a position but happy to review her materials. He also heard optimism about high quality, academic-based research in the coming years, even if it is not until after 2025.

    - Dr. Sisley: In the meantime, we are stuck importing drugs from foreign countries, even for FDA-approved trials.

Ms. Abebe: In terms of making a policy recommendation on allowing flower, she is hearing:

- There is a benefit of patient choice and access - different formats for different types of pain, in consultation with their health care provider.

- Laws would need to be adapted – ensuring labs have capacity for botanical products as well as allowing dispensaries to sell devices, just the products themselves, if talking about vaporizers, etc. for botanical products.
- Cost point issue – options for reimbursement are limited so it is important to provide affordable options. Right now, you can obtain opioids for a fraction of the cost and those are the choices patients are facing for treatment.
- Dr. Sisley added that being able to sell and access devices are key, since patients should be able to discuss their options with the patient liaisons. The FDA has approved those devices for use in their clinical trials so they are not just paraphernalia (bongs, vaporizers).

Asst. Sec. Finley: What do we know about how often patients are substituting marijuana for opioids?

- Dr. Cooper: There are several reports or smaller survey studies, based on self-report data of people using cannabis for chronic pain, that demonstrate that a good percentage are able to reduce their opioid use when using cannabis products, which is encouraging. However, there are other studies – including a four-year longitudinal study from Australia – that did not show this effect.

  So, there is conflict in data with respect to self-report and just observing patients over time. Her group is trying to figure out if it actually reduces opioid doses needed to achieve pain relief (published 2018). They did find that marijuana smoked was able to reduce opioid dose needed to achieve pain relief in a very controlled situation. That would have to be taken to a clinical study. They are now looking at other constituents (terpenes, etc.) to see if they can decrease the need for opioid for pain relief.

  There is also a lot of evidence in the literature that people are using medical cannabis to deal with their OUD. People are using cannabis and reporting that is helping with OUD withdrawal and use more generally. However, there are scarce randomized controlled trials in this area. There is one study with very high cannabidiol, though that is not typically what is available in dispensaries. So she would say there is "encouraging data to that effect."

- Dr. Sisley also partnered with the University of Michigan to publish some papers re: opioid substitution, as well as a variety of other substances including benzodiazepines and sleep aids, that are in peer reviewed journal.

- Dr. Caughron – His experience is that they use both marijuana and narcotics, so it is not that they switch for pain relief. It ends up being a little bit of each to relieve the discomfort. Discomfort is also be more than just pain, it can also deal with psychosocial issues e.g. chronic depression (that often accompanies chronic pain). It is usually both, not one or the other.

- Dr. Sisley agreed but said that reducing opioid dependence using cannabis it is definitely a much safer alternative. Cannabis and opioids can be administered together safely.

- Dr. Cooper: The reports that Dr. Sisley is talking about really point to the need for doing rigorous studies. The patient reports are really encouraging, and it takes a lot of research and funding to determine, compared to a placebo, whether cannabis reduces opioid doses and the adverse effects of opioids and benzos.

- Ms. Abebe: Columbia Care was part of a pilot study (that later received a NIDA grant) where their hard pressed tablet reduced opioid use for pain management in about two thirds of the patients.

    - Patient options for a higher quality of life.
    - There is a lot of research that needs to be done in cannabis, but we know enough to know about basic safety parameters.
    - For policy, there are a lot of benefits that continue to be presented here. All patients participating under the supervision of a doctor and a pharmacist, at a minimum.
    - How do you educate providers about these options?

Dr. Wallace: Don't forget that the report and other sources have shown some potentially very serious adverse effects. He went over them but they include low birthweight, child development and behavioral problems, promotion of adult mental illness, auto crashes, etc. That leads to a couple things:

- It is important that people who are given these drugs understand what the risks might be. That requires patient counseling and must not be forgotten.
- As long as the state is going to be facilitating some of these drugs, it is important to do public health surveillance of those negative effects in selected clinical settings, so that as products roll out we know they are not causing a whole other set of problems.

Del. Davis: There has been a lot of research done outside the U.S, including Israel. Can we look at those studies to provide us the guidance we are looking for?

- Dr. Wallace: Their report does take a global approach and he agrees that is very useful.
- Dr. Cooper: As far as research is concerned, they draw from whatever they have in peer reviewed literature (e.g. study from Australia she mentioned). They always try to integrate what is being done in other countries, since that is definitely important.
- Dr. Sisley: The only time you can't use international data is for FDA drug development trials, though definitely use and cite in their study designs and to bolster their data. It is just that any of those studies would have to be replicated if they were seeking FDA approval eventually.

Sara Payne re: looking at the risks: She agrees we don't have as much clinical study as we would all like to have. However, there are real barriers at the federal level that are political in nature and

a state government that has made a decision to have a medical cannabis program. Given that is the reality, we shouldn't deny patients medicine in a situation where we know a lot of pharmaceutical products have side effects. Most drugs for critically ill people do carry some side effects and we do need to keep that in perspective.

- Mx. Pedini agrees with those comments. Virginia has a regulated medical program and the task of the workgroup is to bring flower to market. Patients are already purchasing this product from the illicit market, and we have the opportunity to provide them a safe product. The health impacts that remain by driving folks to the illicit market are incredibly important.
- Ms. Smith: While she does not know the long-term effect of cannabis, she does know the effect of uncontrollable seizures in her daughter. Cannabis gave her a 40% reduction in seizures with no negative side effects. When we first started talking about this in Virginia, it was just for epilepsy, which does respond well to tinctures and the extracts. When we added other conditions, we made no way for them to access the relevant medications. We should move forward with looking at adding flower to help all the other conditions on the patient list.

Asst. Sec. Finley agreed with the narrow of scope of the workgroup. She noted that Pennsylvania allows flower but not smoking (though she is not clear on how that is enforced). She thinks some of these broader health effects are relevant, because there are some states that allow a variety of things on the spectrum of having flower (no flower, to partial flower, to full flower). She is trying to understand the science behind those decisions. Also, how much are people coming out of the black market vs. how much are they new users? Generally she thinks it can be a mixture, but is open to other thoughts on the consumer effects. In other words, how much are people coming from the black market and how much is the policy encouraging use?

Dr. Sisley: She has been trying to show them the safety of flower as medicine and they did add it in Pennsylvania. It is clear there are no severe long-term consequences from smoking, so even if folks in PA are violating the law and smoking it, that is not cause for alarm. We don't see documented evidence of COPD, lung malignancies, etc. from 30 years of NIDA trials.

Senator Marsden: It is has been a pleasure to work with Secretary Carey and the rest of the cabinet including the Board of Pharmacy and Department of Health Professions. He is glad we are looking at science. It was very clear to him when he started this process 6 years ago that kids with intractable epilepsy needed to have access to CBD oil. The Administration and experts are now beginning to sort through the conflicting data and confusion around medical marijuana. It has also been his goal to get a robust medical marijuana program in Virginia. He wants to make is safe, accessible, and to get the cost down. He is leaning in the direction of supporting expanding to flower. What does Secretary Carey think? Could he discuss and reach out to Senator Marsden if he has hesitancies? He doesn't want to get too far ahead and wants to work together with the Administration and the scientific community. He is hopeful that we can get the costs down and get it to the right people, with the hope that it will eventually be covered by

insurance. He wants a program that is fully actualized, evidence-based, provider reliant, affordable, and easy to access, before we start talking about recreational legalization.

- Secretary Carey: We are focused on putting together an accurate report and then will work with policy re: 2021 session priorities. We will certainly reach out as we formalize all the nuances and look forward to working together.

Del. Davis thanked everyone for their time and thought today was valuable. Del. Davis's position is that, unless someone can tell him that the impact of flower is worse than the impact of opioids, we need to move forward. What he is looking for here is someone to tell him to slow this down. He also wants to take this all in and very much values the Secretary's comments, as well as that of other medical professionals.

Asst. Sec. Finley noted that the next meeting will be on September 30th from 9:30-11:30am and her plan is to have that be mostly open discussion. If work group members would like to suggest another presenter on a specific topic, they are welcome to reach out.

The minutes from the last meeting on September 2nd were approved.

Public Comment:

Elly Tucker, medical cannabis patient with anxiety and anorexia, said it is important to get THC in her system as quickly as possible. She is therefore in full support of including flower. She may have died of anorexia if it weren't for cannabis.

Tamara Netzel, multiple sclerosis patient, said medical cannabis is not a one size fits all. Her MS symptoms are different each day, and are different that other patients'. She needs both flower and oil to have control over her symptoms.

Lloyd Sawyer, combat veteran medically retired from, said medical cannabis is very effective as opposed to the army's high dosages of anti-inflammatories. He found the botanical form provided him with a much more rapid relief, while edibles provided more long-term relief. He has PTSD and multiple back injuries from combat, so he can't take opioids and high doses of anti-inflammatories because of complications. He would like to grow his own to cut down on costs.

Sara O-Hanlon would like additional dispensary locations and the ability to consult via telemedicine. Customized formulations are important for folks with different seizure types. Her son suffers from multiple seizures in the same time period and flower can break the cycle of those clusters.

The meeting adjourned at 11:45am.

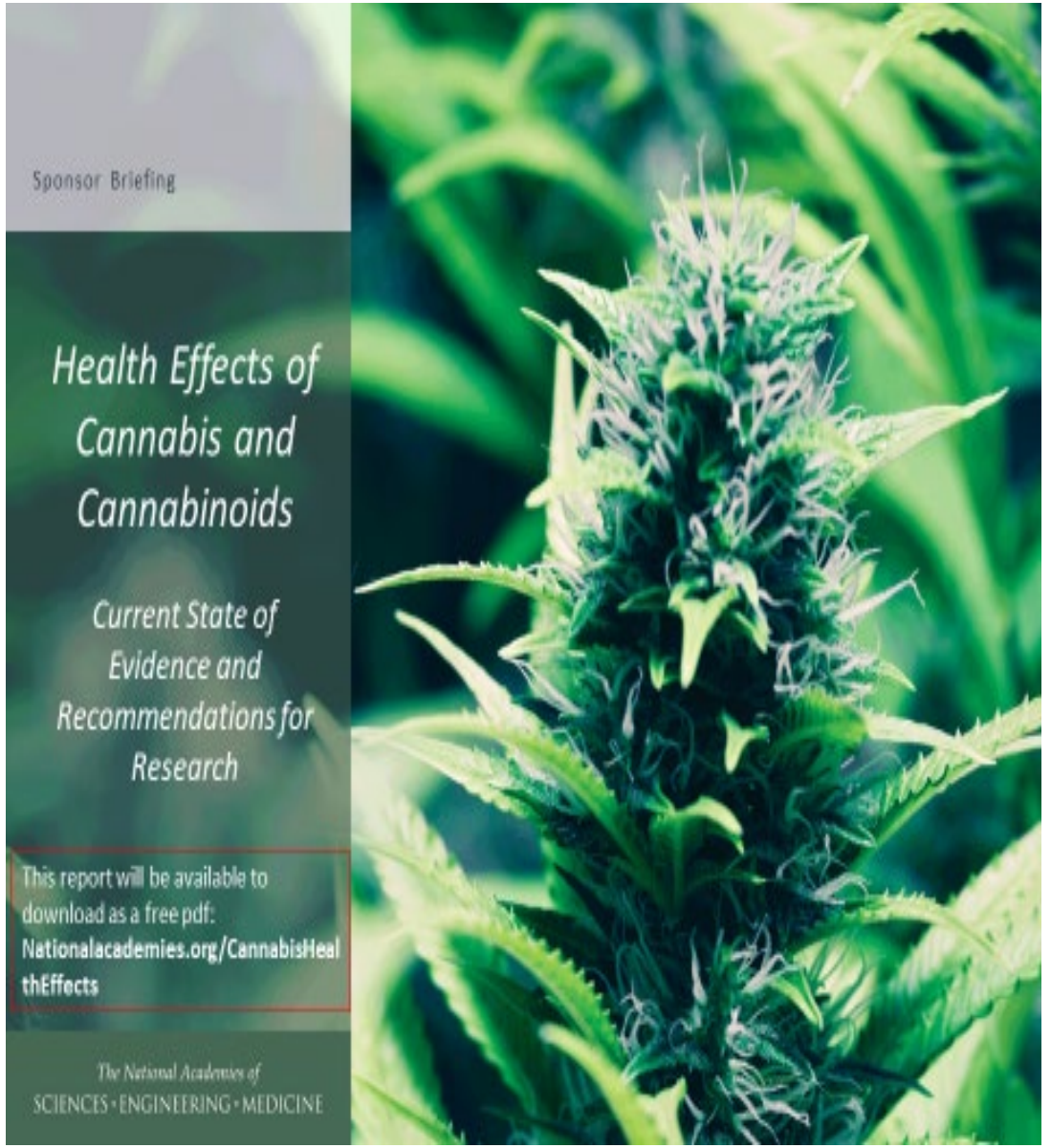
The National Academies of Sciences, Engineering and Medicine Report, 2017…..

….And Beyond:

Robert B. Wallace, MD, MSc

Depts of Epidemiology and Medicine

University of Iowa



Methods and Cautions in the Report

Methods

- Modified, extensive systematic literature review
- Focus on smoking cannabis and disease outcomes
- Population utilization issues not a major topic
- Except in selected areas, therapeutic effects not evaluated
- New findings since the report
- Studies across the developed world

Cautions in Interpreting Studies

- Literature often incomplete
- Varied populations and years studied
- Possible problems in validity of self-report of cannabis use, and quantifying dose
- Variation in content of smoked substances
- Varied definitions of “use”
- Co-existing substance use disorder….

An Important Confounder: Substance Use Disorder: Cannabis and Otherwise

- A non-trivial proportion of *regular* cannabis users (10-25%) and have Cannabis Dependence or Cannabis Use Disorder (DSM-5)
  - -Use starts earlier in childhood
  - -Greater amount of cannabis use overall
  - -Many have associated mental illness (with higher morbidity and mortality rates) and *higher rates of physical illnesses*
  - -Other substance use more frequent (the “polydrug” problem)
  - -Often not considered in epidemiological studies

Diseases and Functional Outcomes

Cancer in Adults

- Little evidence of harm (lung & head/neck cancer/kidney)
- One study: positive for seminoma
- A few single positive studies need follow-up
- Otherwise “insufficient evidence”

Cardio-Metabolic Disease

Unclear evidence of heart attack, stroke or Type 2 diabetes in adults

Diseases and Functional Outcomes

Prenatal, Perinatal, Neonatal Outcomes

- Using cannabis during pregnancy linked to low birth weight
- More recent evidence that maternal prenatal smoking associated with child's behavioral problems

Respiratory Diseases

- Long-term cannabis smoking is strongly associated respiratory symptoms and chronic bronchitis episodes, but not COPD
- Acute but not chronic use improves airway function and vital capacity
- Cessation associated with improved respiratory symptoms

Diseases and Functional Outcomes

Immune Function

- Cannabis affects immune function in several ways
- Very little evidence of effect on immune competence
- Small amount of evidence of a possible anti-inflammatory effect

Psychosocial Function

- Recent use impairs cognitive domains of learning, memory and attention
- Use during adolescence associated with impairment in subsequent academic achievement, education, employment and income

Diseases and Functions

Injury and Death

- Use prior to driving associated with increased risk of motor vehicle accidents
- In states where cannabis is legal, increased risk of unintentional overdose injuries in children
- *Unclear* if cannabis is associated with increased occupational injury or all-cause mortality

Mental Illness

- Substantial association with development of schizophrenia and other psychoses
- Heavy users more likely to have suicidal thoughts
- Use does *not* appear to increase the development of depression, anxiety and PTSD

Diseases and Functions

Other Behaviors

- Limited evidence of cannabis use associated with starting tobacco
- Moderate evidence for use and the development of substance use disorders, including tobacco, alcohol and illicit substances
- Forensic studies show cannabis levels with other (licit and illicit) substances

Therapeutics--Moderate effects:

- Anti-emetic in cancer care
- Reduction in chronic pain symptoms
- Improves spasticity in multiple sclerosis patients
- Cannabidiol—FDA approved for treatment of epileptic syndromes
- *Inadequate evidence for other clinical indications*

Thanks

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Thanks also to a great NASEM Staff for Their Work on this Study!

Health Effects of Cannabis and Cannabinoids

Committee on the Health Effects of Marijuana: An Evidence Review and Research Agenda

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Health Effects of Cannabis and Cannabinoids

Committee on the Health Effects of Marijuana: An Evidence Review and Research Agenda

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Cannabis:
Constituents, modes of use, and health impact

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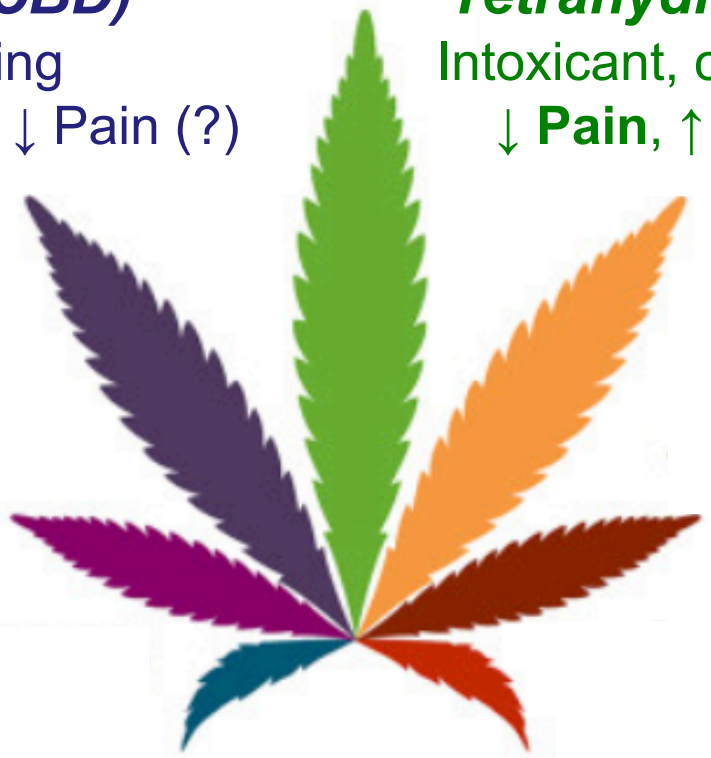
What is Cannabis?

Cannabis *(Plant)*
Phytocannabinoids *(Unique Constituents >140)*

Cannabidiol (CBD)
Non-intoxicating
Anti-seizure effects, ↓ Pain (?)

Tetrahydrocannabinol (THC)
Intoxicant, cognitive effects, abuse
↓ **Pain**, ↑ **Appetite,** ↓ **Nausea**



Cannabinol (CBN)
Drowsiness, some psychoactive effects

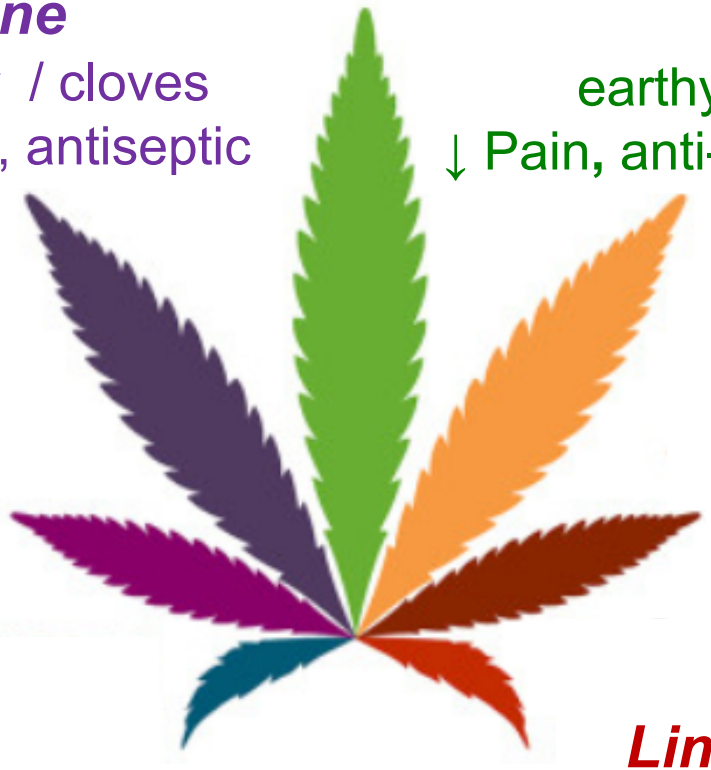
Cannabidivarin (CBDV)
Non-intoxicating, anti-nausea (?), anti-seizure (?)

Cannabigerol (CBG)
Non-intoxicating, pain (?), antidepressant (?)

Cannabis *(Plant)*
Terpenes *(Common Constituents)*

B-Caryophyllene
woody / spicy / pepper / cloves
↓ Pain, anti-inflammatory, antiseptic

Myrcene
earthy / herbal / thyme
↓ Pain, anti-inflammatory, relaxing



Limonene
citrus / lemons
stress relief, elevated mood, antiseptic, anti-inflammatory

Pinene
pine / sage / trees
alertness, energy, anti-inflammatory

Linalool
floral / citrus / lavender
sedation, anxiety, antidepressant

Modes of Use

Many cannabis products from flower and extract

Smoked (Inhaled)

Joint

Blunt

Vaporized (Inhaled)

Vaporizer

Vap-pen

Eaten

Candy

Baked Goods

Capsules / Solution

Modes of Use

Many cannabis products from flower ~~and extract~~

Smoked (Inhaled)

Joint

Blunt

Vaporized (Inhaled)

Vaporizer

Vap-pen

Eaten

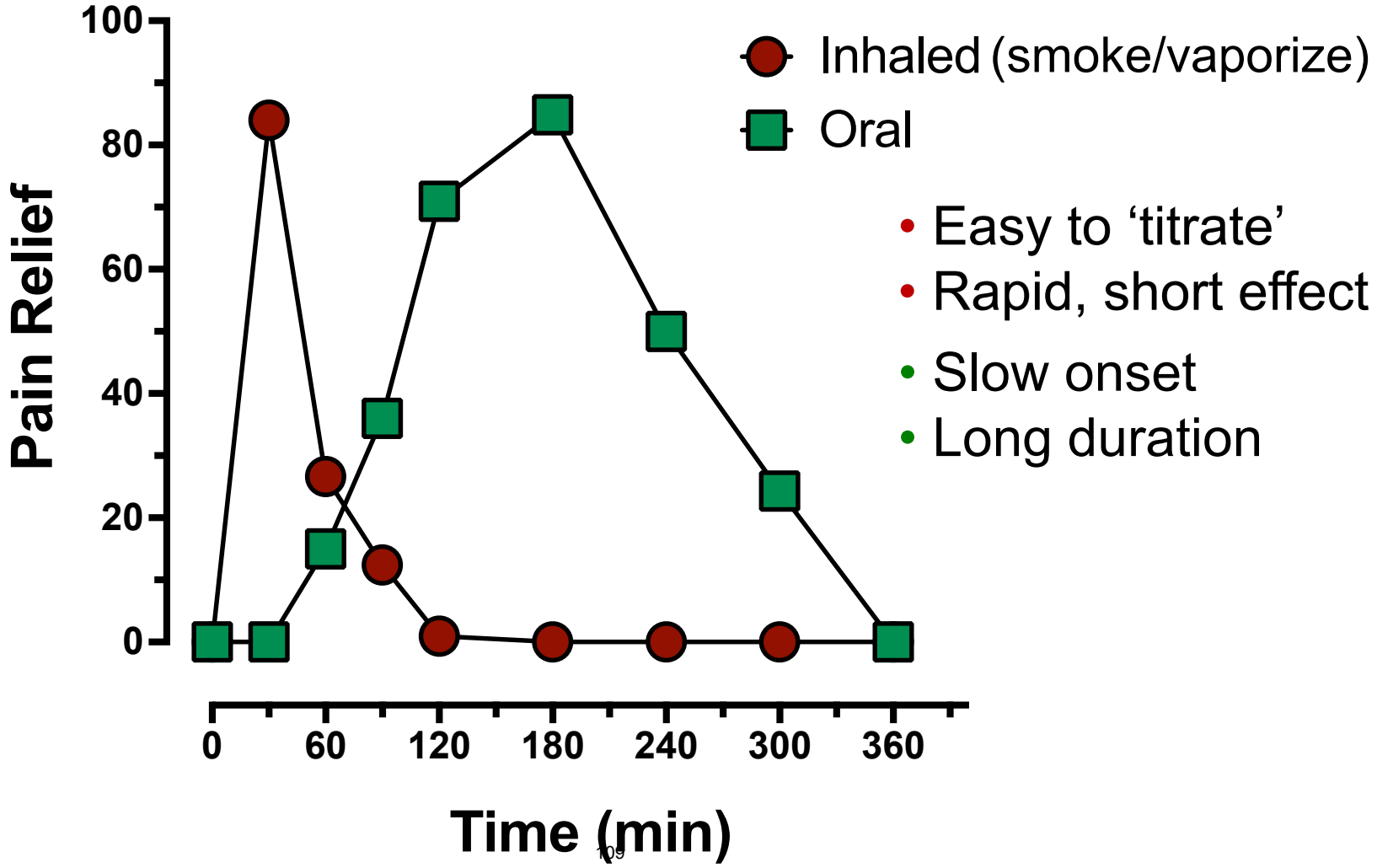
Candy

Baked Goods

Capsules / Solution

Modes of Use

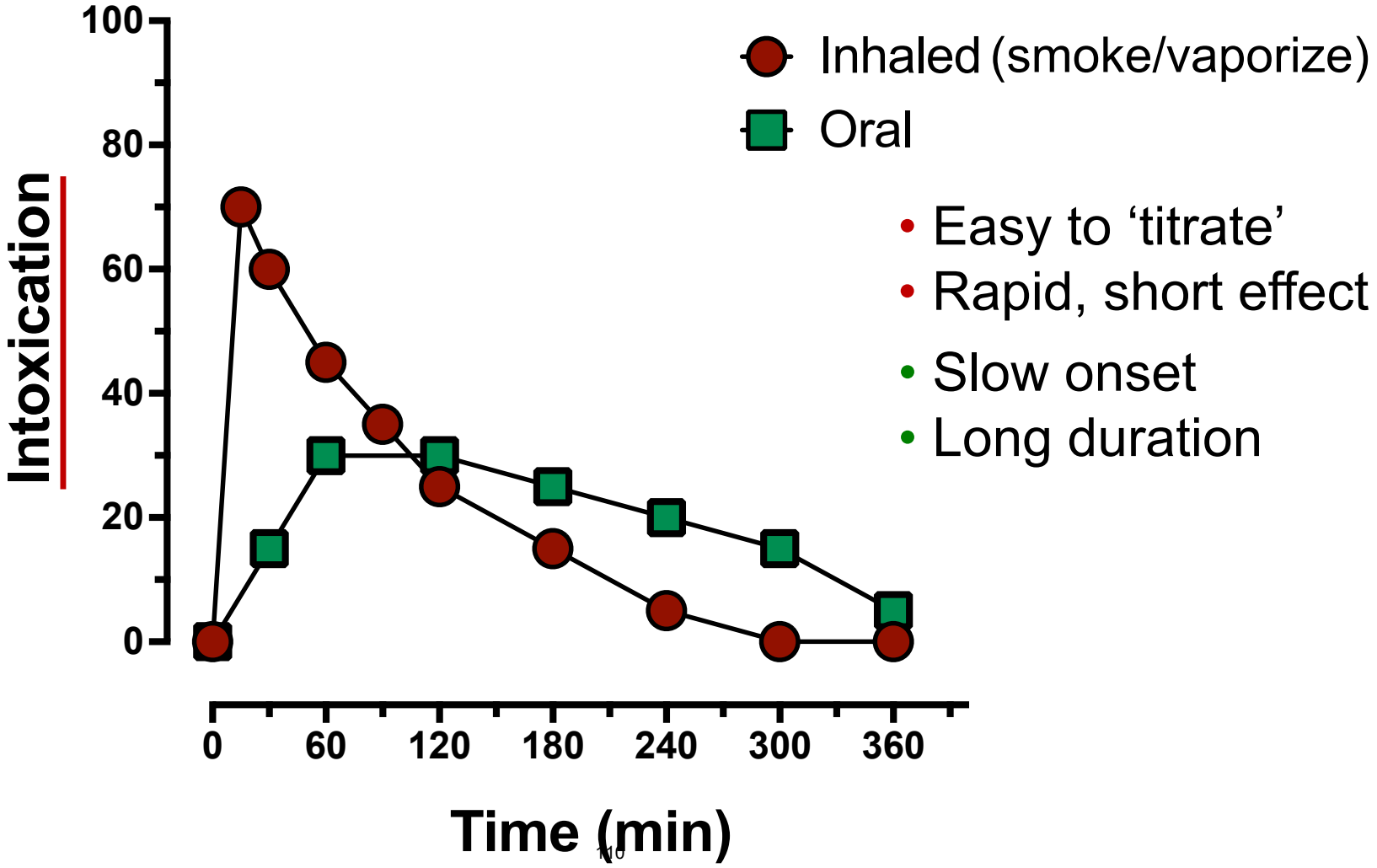
Impact on Health Outcomes: **Pain Relief**



Adapted from Cooper et al., 2013

Modes of Use

Impact on Health Outcomes: **Intoxication**



Adapted from Cooper et al., 2013

Respiratory Risks
Smoking versus Vaporizing

- **Smoking:** Association with respiratory symptoms, chronic bronchitis, not COPD or lung cancer (long term effects)
- **Vaporizing flower:** Improvements in respiratory symptoms when switching from smoking (1 month)
- **Vaporizing extract:** EVALI associated with contaminate, 68 deaths, > 2700 affected
- **Vaporizing plant / extract**: Long term effect are unknown

Van Dam & Earleywine,2010; NASEM, 2017; Heinzerling et al., 2020

Summary

- Do **cannabis constituents work together** for improved efficacy / safety profile?
- Modes of use for flower and extract are same except for **smoking**
- Oral and inhaled use have **different time courses** impacting both therapeutic and negative outcomes
- Potential for **reduced respiratory risks** associated with vaporizing plant compared to smoking; long term effects unknown

The Case for Dry, Natural Flower in VA

SUE SISLEY, MD

PRINCIPLE INVESTIGATOR, SRI

Dry Flower Benefits

- Research has shown Cannabis in its natural, flower form is an effective treatment (1000's of controlled trials published in peer- reviewed journals)

- Flower allows patients to better titrate their dosages to best fit their precise personal needs.

Dozens of studies demonstrate the medical benefits of cannabis in its natural flower form.

In contrast, oils/liquids available under more limited MMJ programs have NOT been adequately tested.

There is NO good reason to deny a sick patient access to a product that has been studied/proven to alleviate a variety of medical conditions.

Benefits of Dry Flower, cont.

- Eating dried flower allows some patients to relieve their symptoms without becoming intoxicated since cannabinoids remain in ACID form if unheated.

Robin Schneider, medical marijuana patient and executive director of the National Patients Rights Association, explains:

- *Allowing medical marijuana patients to access and use marijuana flower, in addition to pills and oils derived from the plant, is a key component to workable medical marijuana laws. Raw marijuana flowers do not need to be produced into oils or liquids in order to be therapeutic. In fact, consuming raw or juiced fresh marijuana flowers is an incredibly effective way for patients to introduce THCA, a precursor to THC that has anti-inflammatory/neuroprotective effects, into their bodies. THCA degrades and loses its benefits if it is frozen or stored too long, so oils and liquids can be far less effective at delivering this important cannabinoid. For patients who need immediate relief, vaporizing dried marijuana flower allows them to more easily control their dosage than vaporizing oils derived from marijuana doses. This allows patients to consume enough medical marijuana to relieve their symptoms without becoming intoxicated.*

Dried flower is the most affordable option for patients.

Seriously ill patients frequently face tremendous medical costs, but often have no income/rely on government disability benefits. Government-issued and private medical insurance will NOT cover the cost of medical cannabis, forcing patients to pay the full price for their treatment.

Dried flower is the most affordable option for patients.

Cannabis in its natural, flower form is significantly less expensive than products that have been processed, and access to it would ease the financial burden on patients. The two states with operational programs that did not allow flower — Minnesota and New York — have had exorbitant prices, resulting in many families paying > 100's of dollars each month.[1] (Following regulatory changes in late 2017, New York is now allowing flower. Minnesota is likely to follow in Fall 2020).

1 "Early Results of Office of Medical Cannabis Surveys," Minnesota Health Department, May 2016. (Most patients reported medical cannabis is not affordable, with 35% saying the cost was "very prohibitive" — a 7 out of 7 for its lack of affordability. One parent wrote, "Our son has life threatening seizures and we are spending > $1000 per month not including travel costs and caregiver expenses.")

Dried flower is the most affordable option for patients.

"Assessing New York's Medical Marijuana Program: Problems of Patient Access and Affordability,"

Drug Policy Alliance. (77% of patients and caregivers who bought cannabis from a dispensary said they couldn't afford the monthly costs; 79% reported monthly costs of $400 or more.

The Entourage Effect:

Researchers agree that whole plant marijuana allows for a greater therapeutic effect than any single compound

As reported by CNN's Dr. Sanjay Gupta, marijuana contains > 480 natural components, including cannabinoids and terpenes. "[A]ll these components of the cannabis plant likely exert some therapeutic effect, more than any single compound alone. ... Unlike other RX drugs that may work well as single compounds, synthesized in a lab, cannabis may offer its most profound benefit as a whole plant, if we let the entourage effect blossom."[1]

While some of these components have been isolated, like CBD and THC, many others have not. Israeli researcher Raphael Mechoulam and his colleagues believe using whole plant marijuana allows all of the components found in marijuana to work together, resulting in a greater therapeutic effect than any single compound accomplishes on its own.

Most liquid cannabis does not contain the VAST terpene profile found in raw, whole plant marijuana, which could weaken the potential therapeutic effect.

1 http://www.cnn.com/2014/03/11/health/gupta-marijuana-entourage/index.html

As medical cannabis expert Sunil Kumar Aggarwal, MD, Ph.D., explains, dry flower is more effective than processed medical cannabis:

“Extracts often LEAVE OUT therapeutically important terpenoids-flavenoids that are needed for the full medical cannabis “entourage” effect produced by whole plant botanical material.

Concentrates/Oils/Extracts may also be TOO POTENT for some patients to tolerate, compared to the whole plant botanical material (due to a concentration effect and because the terpenoids that strongly modulate the effects of the cannabinoids may be reduced or absent from the extract),

and may NOT be effective for all patients NOR allow for careful dose titration.”

Better for VA Small Businesses:

”...[C]annabis flower is the single largest source of revenue for dispensaries, representing **47%** of total sales volume.”

Cannabis Industry Annual Report: 2017 Legal Marijuana Outlook
New Frontier, July 2017

Common Practice:

Of the 33+ states that have medical marijuana laws, only 3 restrict patients to pills, oils, and other products derived from cannabis, but do not permit the actual FLOWERING plant itself.

http://www.northcountrynow.com/news/new-medical-marijuana-products-approved-department-health-st-lawrence-county-and-state-0224074

Sick patients NEED ACCESS TO OPTIONS .

Let's bring 1 more medical cannabis delivery option to debilitated patients of VIRGINIA.

This approach employs Compassion supported by Science.

Thank You

Contact: Scottsdale Research Institute

Dr. Sue Sisley, MD

Cell: (480) 326-6023

SSisleyMD@gmail.com

Appendix IX – Meeting Four

Virginia Medical Cannabis Work Group
Meeting Four
October 30, 2020
9:30-11:30am

Agenda

Welcome & Approve Meeting Three Minutes

Overview of Two State Medical Cannabis Programs

Lila McKinley, Staff Attorney, Connecticut Department of Consumer Protection and Rodrick Marriott, Director, Drug Control Division, Connecticut Department of Consumer Protection

Rich Oborn, Director, Center for Medical Cannabis, Utah Department of Health, and a representative from the Utah Department of Agriculture and Forestry (UDAF rep tentative)

Open Discussion – Work Group Members

Public Comment

Adjournment

Meeting Minutes

Assistant Secretary Catie Finley called the meeting to order and called roll at 9:35am. The work group members in attendance were:

Catie Finley, Assistant Secretary of Health and Human Resources
Senator David Marsden
Delegate Glenn Davis
Lisa Smith
Jenn Michelle Pedini (Virginia NORML)
Ngiste Abebe (Columbia Care)
Jack Page (Dharma)
Sara Payne (Dalitso)
Joy Strand (Green Leaf)
Dr. Sam Caughron
Dr. David Brown (Department of Health Professions)
Caroline Juran (Board of Pharmacy)

The minutes from the last meeting on September 30th were approved.

Guest Speakers: Connecticut's Medical Cannabis Program

Rodrick Marriott is the Director of the Drug Control Division at the Connecticut Department of Consumer Protection and is pharmacist by trade. Lila McKinley is a staff attorney at the Department and assists with the legislative, regulatory, policy, and enforcement aspects of the medical cannabis program.

Connecticut has four medical cannabis producers (manufacturing and processing) and 18 dispensaries. Products can come in a variety of different forms from concentrate to flower to suppositories. Rod has a staff of drug control agents, all pharmacists, for enforcement and six-eight employees for processing patient application. Physicians and APRNs are the gatekeeper in terms of weighing the benefits and risk of cannabis treatment for the patient. The practitioners provide a certification. The patients must register annually and then work with the pharmacist and the dispensary to select the product that is best for them.

Connecticut allows for co-ownership, but vertical integration is not required. They award licenses as needed on a supply and demand basis of patients. Their application process is fairly lengthy.

Connecticut allows raw flower, edibles, sublinguals, capsules, suppositories etc. It is geared toward a medical program - the regulations have a specific list and do not allow confections and anything else that appeals to children. The Commissioner also has discretion to approve new products. It must be homogenized in size (not too large) so patients can select their dose, though that is challenging in a combustible product.

One staff attorney works on the program (splits time), They started with a budgetary allocation, but a year into passage the budget was swept and all licensing fees now go to a general fund. Their agency budget is pretty small. They have three full-time employees (FTE) dedicated solely to their medical marijuana program and many who split time. They have one staff attorney, eight administration staff – three FTE plus five who split time. They have 13 drug control agents, but they also handle pharmacy investigations, and one enforcement attorney. They feel understaffed for the program. They also have one staff member responsible for the Board of Physicians to look at potential new conditions or allotments. The three FTE are a program manager, processing technician, and outreach and education, though they all pitch in with patient registrations.

There are 47,000 registrations in the state and they are under 2 week processing time

Senator Marsden: Do you all have the ability to expand licenses based on demonstrated need?

- They can add producers and dispensaries as they determine need through an RFA process (400 pages, 70 applications for 9 slots in the last round). The Commissioner's authority to do so is written into their code.

How have you handled minority involvement?

- There is nothing written into their statute, because it was not at the forefront at the time. They are exploring adult use legalization and the draft legislation has equity provisions overseen by a cannabis commission, which includes certain criteria e.g. disadvantaged areas, prior convictions for marijuana, etc.

Ms. Juran: How many patients are in your program? What is the demand by formulation? How do you define a need (to issue a new RFA)?

- 47,000 registrants out of a population, so about one percent.
- From what they hear from the industry, about 60% - they don't have seed to sale to track.
- They know about how many patients are served by each dispensary. Almost all counties are covered. Sometimes the RFA is also driven by complaints from the patient community. There is also a statutory cap (3-10 producers, no cap on dispensaries, once they get to 10 they can open some sister facilities). Supply is a challenge to manage since it is six months from seed to plant, plus drying/processing. The flower supply can fluctuate because they are trying to predict six months out – it's more of a biologic process than a typical pharmaceutical product. So you have to sort through whether it is just a temporary or minor shortage.
    - They do not have canopy or square footage requirements, so their production facilities can expand. As such, they don't do as many RFAs as you would see for dispensaries.

Dr. Caughron: Do you allow home grow in your state?

- No.

Mr. Page: Is there a cap on plants that the producers can grow? What is the difference in cost between concentrates and flower?

- There is no cap and they don't track prices. Patients complain about cost in general (no third party insurance as is typical). Flower does have second-cut options that are less expensive. To some degree, patients shy away from concentrates because they appear more expensive, but he does not know if that is the case on a dose-by-dose basis.

Do you tax anything in Connecticut?

- No, but have steep licensees fees ($75,000/year for processors and $5,000 for dispensaries.) Patients have a licensing fee of $100 to have a marijuana card; caregivers have a $25 fee.

Mr. Marriott: When you introduce flower into the market, there are specific challenges re: enforcement and complaints. Because it is a biologic product there are complaints of mold, staleness, imperfect (e.g. too many stems). They also get complaints based on weight, since sometimes there is too much water/humidity is left in the product. Those take a significant amount of time for their investigators to track down, especially for mold issues. The concentrates have a more streamlined enforcement in comparison of flower.

Del. Davis: From a law enforcement perspective, have you implemented anything e.g. testing for saliva?

- The only real prohibition is that you can't consume while in a motorized vehicle. There are significant challenges around assessing impairment of marijuana. There is really no test that is accurate and reliable.

Mr. Page: Do the patients have to carry a card? They are seeing patients who are confused about what they have to carry (card or written certification).

- They have to carry a document from their agency, which is an email, and then a paper card. Some states just do the email. They also upload information into the PMP, so law enforcement can check that is real time, as do the dispensaries (specialized portal). Patients are restricted to using one facility at a time.

Ms. Strand: You mentioned mold complaints with flower. Is the testing parallel for concentrates and flower? What kind of remediation is allowed for molded flower? How do they make sure products are safe?

- Mold, pesticides, microbiologicals, and some toxins are tested regardless of the product form. The labs grab a random sampling during production. If the facility identifies mold on flower, they must request a pesticide from a list provided by their department of energy and environment protection that they have approved for any cannabis product. If applied during flower stage, they must test out for that specific pesticide.

Guest Speakers: Utah's Medical Cannabis Program

The Utah Department of Health (DOH) is responsible for patient, provider, and pharmacy registration. The Utah Department of Agriculture and Forestry is responsible for the processors or manufacturers and cultivators, as well as the independent testing laboratories. Rich Oborn, the director of the Utah DOH's medical cannabis program, presented. Cody James, manager of the Utah industrial hemp and medical cannabis program at the Utah Department of Agriculture attended to answer any questions.

Legislation passed through propositions in November 2018 (note the legislation made changes to proposition, e.g. home grow was allowed in proposition). Implementation was rolled out in March 2020 so they have had product being purchased for about 8 months.

They have 13,000 patient registrants since March 2020, ahead of projections, and 500 medical providers. To get a card as a patient you have to have a recommendation from a registered provider, who must pay $100 fee and take a training course. Physicians, APRNs, and PAs can register as long as they have a controlled substance license.

They have six FTEs and part time help from budget managers and few others (at DOH only, does not include the Department of Agriculture).

In terms of dosage, they have tablets, capsules, concentrated liquid, liquid suspension, topical, transdermal preparations, sublingual e.g. tincture, gelatinous cube or lozenge in a cube shape - like a gummy in a cube/rectangular shape, since they don't allow for candy-like shapes - also resin/wax. Initially a requirement of the allowance of flower was a blister pack, but that was removed and replaced with the requirement that the packaging be a glass or a container that is child resistant. It also must be opaque when transported (so the jar doesn't have to be opaque as long as it is in an opaque bag).

Under law, Utah can have 14 pharmacies. Currently there are seven, and an additional seven will open by March 2021. Utah is smaller than a lot of other medical cannabis program states, so the legislature felt 14 was sufficient. However, they do have the authority to approve additional locations in the future if market demands. They would do so in conjunction with the Department of Agriculture and likely would set criteria. Licenses were awarded through an RFA done through the Department of Purchasing. The DOH reviewed, but generally it was similar to the vendor process. The process was similar for the eight cultivators

Ms. Juran: Does Utah have a medical conditions list?

- They allow 17 conditions. 75% of those with cards have qualified under chronic pain, similar to other states, which is defined in law as "pain lasting longer than two weeks that is not adequately managed despite treatment attempts using conventional medications or physical interventions." The definition is very broad. Other conditions include: HIV, Alzheimer's, ALS, cancer, persistent nausea, Crohns, ulcerative colitis, epilepsy, debilitating seizures, Multiple Sclerosis or persistent muscle spans, autism, terminal illness with less than 6 months to live, and PTSD. PTSD is the only psychologically related condition, so they do not include anxiety of depression. There is also a caveat with PTSD in that it must be treated by a therapist and diagnosed by either the VA through an evaluation by a psychiatrist or a masters level mental health professional. The list also includes rare conditions that effect less than 200,000 individuals in the United States and is not effectively managed through physical or non-opioid interventions. There is a list of rare conditions on a federal government website that they rely on.

  Since there are only 17 conditions, the legislature allows for other conditions to be reviewed by the compassionate use board. It meets once a month for those without qualifying conditions that have a recommendation from a registered practitioner. The compassionate use board at the DOH has approved conditions like anxiety, depression, and others. They have an assigned staff member and have received over 200 so far, where the board has approved those exceptions. The compassionate use board also reviews 100% of card applications submitted for minors (under 21). There are three pediatricians on the board, including neurologists and psychologists. Board members get a small stipend, but it is basically pro bono. He thinks the compassionate use board has only denied one petition that they have received.

Regarding flower, rather than requiring the blister pack, they do require a legal use termination date, which is 60 days after the date of purchase. After that date, the cannabis cannot be transported outside the patient's residence. Patients can only transport flower within 60 days in order to minimize the amount of cannabis being transported throughout Utah and to make sure patients are actually using and not distributing it. There have been some complaints about the "legal use termination date," but it is there to make sure people aren't purchasing more than their recommended amount each purchase.

Home delivery of medical cannabis is going to roll out soon. They are working on the software that will support that. It will only be able to be delivered to the home of the cardholder and the cardholder has to be physically there to accept it.

Dr. Caughron: Who does the training for the registration for the registered practitioners?

- The DOH approves the education providers. They currently have four education providers. Three are online and one is a health system that does in-person classes (prior to pandemic). One is a University of Utah Medical School and two are private providers. The DOH has identified the criteria that those providers are required to cover, including specific topics on what is the law. They have to do at least four hours of education, anyone can register, and it is $150-$300 for the four-hour course. The DOH just vets the courses to make sure they meet the rule criteria. The purpose of the course is more introductory and the hope is that providers will go above and beyond. Most do learn more and some are even taking masters coursework, e.g. University of Maryland has some masters coursework that some have found helpful. In other words, the initial course is a low hurdle for providers but is a requirement. There is also a similar four-hour course for the pharmacy medical provider. Each dispensary must have a pharmacy medical provider in-person during operating hours, who must be licensed physician, DO, or pharmacist. This is who will consult with the patient on their first visit and is probably the most knowledgeable about the product. They must be there 100% of time and they have gotten some pushback because it is expensive. but Utah lawmakers felt strongly about the logic behind it.

Mx. Pedini: How is the 60-day limit enforced?

- The package has a date of purchase and a warning on the label or receipt that the patient cannot transport it outside their resident beyond 60 days. They are trying to program their software to calculate that date, though most people can figure it out. If law enforcement stops them they can ask about it. The idea is that law enforcement will know when it is illegal, though he has yet to hear of many cases of that happening and is curious to how that is going. They are also working on educating law enforcement on the legal use termination date. He thinks patients are having trouble when they have products in their own package instead of the original, in which case the date would not be on there, so they encourage patients to keep that with them.

One of the challenges they had is they opened their pharmacies on the same day they started issuing cards and the supply was thin. They couldn't compromise their statutorily mandated opening date in March 2020. Their card numbers increased quickly, but one of the frustrations has been the thin supply including for certain strains or products. Flower especially sells out fast. They hope that will be resolved by next summer when production is more robust, but that has been one of the major concerns. Another issue is that all products had to be purchased with cash. Over time, there have been solutions to that including bank-to-bank transactions in compliance with federal standards through a certain company. A lot is still done in cash, but that has helped.

Dr. Caughron: How much do you think the economy and the state benefits from this?

- **Mr. Oborn**: In Utah, they were concerned about taxing the product. They conduct $3 per transaction regardless of the size of the purchase to help DOH cover its costs. The legislature did give them an initial $4.1 million to frontload the costs with employees and the electronic system. It will take a few years for them to be able to pay that back. They don't expect to use the funding for anything else in the future, just to collect enough to cover their costs. In terms of jobs and worth to the community, they haven't done analysis on that yet. They know that it's a growing industry, but most lawmakers wanted to keep the program as small as possible while still meeting the demand of patients as opposed to creating economic activity for the entire state. Even though it's a business friendly state, lawmakers were more concerned with the fact that this is federally illegal and should be limited, at least at the beginning. Licenses are limited to fourteen and cultivators to eight at the beginning. Other restrictions also decrease the amount of economic benefit, just because it is still federally illegal.
- Mr. James reiterated that they don't have anything going back to the general fund. However, anecdotally, they have seen a boost in jobs especially in some of their rural areas with the growers - close to about 20 jobs in addition to construction company work as growers expand. He has also noticed a larger number of folks interested in both the medical and industrial hemp industry. He thinks there will be some economic boost even though Utah has not quantified that.
- Dr. Caughron: Documentation is a big deal and that is one thing that we are very interested in accurately documenting here in Virginia, so if you have tools or forms that they use to create documentation that we could use to help with documentation that would be very useful.

Ms. Juran: Do you all allow for both indoor and outdoor growing?

- Initially growers had to be one or the other - up to 100,000 square feet indoors or 4 acres of outdoor. Last session they changed it to allow both, but capped each so folks can do both up to 50,000 sq. ft. indoors and 2 acres outdoors. Two folks have tried outdoors and one got completely destroyed. They are seeing most people stick indoors, because of the kind of quality and control they are trying to achieve.

After Utah concluded their presentation, **Asst. Sec. Finley** outlined her recommendation for the rest of the meeting and the report. For the final report, the work group has discussed some areas of the report more than others, so the report will likely include: discussion with industrial hemp industry around marketing, conversation with MSV and VHHA around their survey results, Dr. Grice video on his views on botanical products (since he was not able to attend most workgroup meetings), robust conversation around health effects of different modes of use, and an overview of Connecticut, Utah, and possibly other states she has connected with. She asked for feedback on that outline of the report. She also has a couple summaries from other states she talked to that she found informative and would like to share in the meeting today.

Senator Marsden: There are a lot of smaller issues that they need to look at to streamline the process for the cannabis processors. Because they erred on the side of the caution, there are overly onerous requirements that people would feel comfortable backing away and that we

should discuss. They are considering a package of those legislative clean up items and the report would be critical for that thinking as they go into the legislative session. He doesn't have the details today, but thinks there are small improvements they could make in statute and regulation to make the process work more smoothly.

- **Asst. Sec. Finley:** Are you envisioning starting that discussion today and then potentially have another meeting?
- **Senator Marsden**: Yes, he is envisioning listing some of the concerns where we are being overly prescriptive or onerous. He would like to get a list for everyone's feedback before they introduce any bills.
- **Del. Davis**: Yes, he would like to get a list and see what they want to discuss to be in statutory language for either more protection or loosening things. We have talked about everything from false advertisements to how we enlarge the number of dispensaries, so we should put those together and let people decide as a group which ones they want to pick off going into the next session.

Asst. Sec. Finley provided a summary of Louisiana's medical program, since they have decided not to allow raw flower at this time:

- While the Louisiana Legislature did approve some significant changes to the medical marijuana law during their regular session earlier this year, they did not change the prohibition on the use of raw or natural cannabis products. The two producers, which are licensed and regulated by the state agricultural department, are authorized to produce pharmaceutical-grade products in dosage forms approved by the Board of Pharmacy.

- Louisiana also does not permit smoking of medical cannabis. However, inhalation using metered dose inhalers is allowed.

- In addition to raw flower products not being permitted by law, they have determined they do not meet the definition of a pharmaceutical grade product (21 CFR 111).

Dr. Caughron: The flower product is a good option as far as people's ability to monitor their use of the product. It is a larger question whether that is going to be an option in the medical program or if we end up going to the larger picture. It has been used medically, so he thinks it should be something we should consider.

Senator Marsden: He was interested in the per transaction fee as opposed to tax, since that directs towards a service industry and helps recover costs without having a tax. He wants to keep it consistent and predictable for folks, but will let Caroline and Dr. Brown speak to whether it would be simpler than putting everything on the back of physicians and processors.

Mx Pedini: They find it hard to stomach another fee being put on patients in this program. These are multi-million dollar companies and if anyone should carry an additional weight it should be those making money not those using it for a medical necessity.

Dr. Brown agrees with Jenn Michelle on where the taxes should be placed. He would like to look at one area in which we are least restrictive, and that is not having a list of conditions for which marijuana could be used.

Mx. Pedini: The legislature already weighed in on this. There have been several bills that have suggested adding additional conditions and ultimately the state wisely decided in favor of allowing health care practitioners to practice medicine instead of the legislature or an agency. They cannot see the state walking that back and putting in place an arbitrary list.

Ms. Abebe agrees. In most other states with a patient condition list, the growing trend, including in Los Angeles and a recommendation in New York that it has not yet enacted, has been opening up the rules around their condition list. It is time consuming and takes more time for them to change regulation and legislative policy to catch up with the science. She is not aware, outside of abortion, where the state mandates treatment options that should best be treated by scientists and patients.

Del. Davis: They do have a doctor in the General Assembly with Senator Dunnavant, but as legislatures they are not experts in medicine. Jenn Michelle and others wisely suggesting getting rid of the patient condition list. We trust our doctors and if we don't, we get a new doctor. He would hate to see walking this back and putting the decision of what this allowed in the hands of the legislature.

Mx. Pedini: They do not think Senator Dunnavant would want to roll this back either.

Dr. Brown: The reality is that most physicians currently have very little knowledge about the science behind cannabis. He is not envisioning lawyers passing a list of conditions, but instead a well-informed body that looks at the science and changes the list as needed, as Utah described. He thinks there is value in having a list from an educated panel.

Ms. Smith: There are too many rare conditions to keep a comprehensive list.

Dr. Caughron: He agrees and thinks that being restrictive like this…the education is best done when people are becoming a prescriber for marijuana and that if they are good about doing the education…many of his colleagues are being asked to look into this by their patients. He thinks putting it in the hands of doctors is a wiser choice.

Asst. Sec. Finley: Of the handful of states she talked to, almost all if not all of them had patient condition lists. Do Jenn Michelle or others know how many other states don't have a list?

- Mx. Pedini can look in their catalog. Those who do have a list often later added caveat language that allows doctors to make additional considerations. They have also seen more and more states move away from it entirely.

Ms. Juran: One issue that has been challenging with this program is that laws often pass directing the Board of Pharmacy to promulgate emergency regulations within 280 days, which would usually take effect the following January. On the heels of that, there is another bill that directs them to promulgate another set of emergency regulations on the same program. In addition, they have received petitions for rulemaking. It will likely be two years before those

regulations are in effect due to the APA standards. She thinks VDACS has exemptions from the APA with respect to how it promulgates regulations for the hemp program (she is not sure but wanted to raise the question). Does this program need to be exempt from the APA in order to facilitate timely regulation enactment, in lieu of everyone going to the General Assembly every year to put a lot of minutia in statute? That is typically contrary to how a program would be run and requires legislators to have very detailed knowledge about producing cannabis, etc.

Ms. Strand: There are a number of items in the petition for rulemaking to help streamline the program from a regulatory standpoint. Caroline described very well the frustration that the industry feels with the time it takes to get things done in an industry that moves at lightning speed nationwide. The quicker they can get to remedies the more people can benefit. In terms of the patient condition list, she thinks the current language is one of the greatest things in the program and limiting it would be detrimental to patients. She would like to see the current law regarding patient conditions remain in effect. In terms of funding, absolutely agencies needs funding to run a program like this. She envisions something like a fee per transaction that is shareable and equitable across the program. Many processors did invest multi millions into this, but only one of them has seen any kind of revenue coming in. She thinks it needs more research and discussion, including looking at other states with innovative models. The industry wants to reduce patient cost and you will hear in every state that patient costs are high since insurance does not cover it. However, there are several ways to reduce costs without increasing fees for patients or processors and that would help reduce the cost to patients in the end.

Senator Marsden: Is our fee structure sufficient to cover the costs of the regulation and management of this program?

- **Ms. Juran**: If it expands to flower, where the number of patients would grow significantly, they would need to purchase some type of software to facilitate a provider registration process in a more automated fashion like many other states have. Their current program is not ideal in terms of registering patients, so they currently have some manual touchpoints and work. However, if it expands to flower, they need to look at procuring a more automated software system to facilitate the workload. She is not sure the cost and questions whether they will need more. She does know that their current fee structure, especially as it relates to the processors, is pretty low compared to other states. Right now they are financially in a good place, but will soon need to hire someone to manage current growing patient load. With flower, they would also need to procure the new system.
- **Dr. Brown**: By the time the legislature meets, he thinks they will be able to answer that question.

Del. Davis: If a doctor puts me on opioids, do I have to be on a registration? Why do we need that in place for flower but can be on opioids and do not have to be on a patient registry?

- **Asst. Sec. Finley** mentioned that physicians do need to get an X-Waiver for Medication Assisted Treatment, but Del. Davis reiterated that he was referring to the patient registry.

- **Ms. Juran** is not aware of another state out there that does not require the patient to register under the medical program as a means to identify themselves to the dispensary or to a law enforcement official. Del. Davis is correct that if you receive an FDA-approved prescription product you do not have to obtain a registration to obtain that dispensed drug. However, this is not a dispensed drug and therefore does not fall under the laws of a prescription drug, it is instead recommended by a prescriber.
- **Del. Davis:** A treatment that has been recommended by a doctor is just as valid as a prescription to him. He would like to revisit having a registry. If he has oxycodone, does he just have to show the bottle with his name on it? If that is the case, that should be all he has to do with this product. He doesn't want to pass on costs to patients and doesn't understand why this needs to be more restrictive than products that are on the market and are worse.
- **Dr. Brown**: The difference they are operating under now is that they need to create a registry of physicians who can recommend it and don't need to do that for any other medication. They also need a registry of patients who are allowed to process it, which again is not done for any other substance. Those are in law and they are complying with them. As the number of patients and prescribers grows, the system they are jerry-rigging to comply with the law will prove to be inadequate.
- **Del. Davis**: That may be something they want to reconsider in law.
- **Dr. Caughron**: This remains illegal for the nation and as a result, the registration is like get-out-of-jail-free card.
- Ms. Payne: Patients are protected by a budget rider and what they are doing with patient registration is providing that legal protection and clarification. In 2021, they should look at legislation that eliminates the practitioner registry and reduces the burden for patient registration using Oklahoma as a model. They have a functional website that patients and practitioners can easily navigate. If a practitioner is authorized to practice medicine in their state, they can download the form, much like when Virginia's program first started, and then can issue written certifications. Those patients can then register with the state and get product for a period of two years, and there is a low cost option for patients on a limited income. That is what Virginia should be looking at.
- **Ms. Juran**: Their fees are in line with other states, but they frequently hear from patients who have to pay $300-400 to the issuing practitioner, so that may be the real financial burden.
- **Mx. Pedini** agreed that $50 is not burdensome on its own, but coupled with other fees it gets out of hand. There should be a low-cost, no-cost options for patients for whom $50 is out of reach.
- **Sen. Marsden**: For those physicians that are charging the heavy duty fees, should their license be based on a percentage of how much they charge? So if you are charging $400-500, should the burden be a percentage of what they are charging people? As opposed to encouraging gouging?
- **Mx. Pedini** doesn't think that the practitioner registry is providing any benefit, other than the nominal funding for the program. Patients should get medical cannabis in the course

of their regular health care, including as part of their physical which is covered by their copay.

- **Ms. Abebe** agrees with Jenn Michelle. Laws passed in other states make it clear that if doctors provide their recommendation in the course of their regularly scheduled appointment, the doctor cannot charge an extra fee in the same way that you don't get to charge for every prescription you get renewed at an annual appointment. That also lets patients have the conversation with their primary care physician and the doctors with whom they have a relationship.

Ms. Smith agrees with Jenn Michelle and Ngiste re: burden on patients, especially with insurance not covering. In Massachusetts, they passed a law saying that it is illegal to make someone pay to access medication. She would like to see that. Separately, is Virginia open to creating a medical cannabis commission to take it out of the Board of Pharmacy?

- **Del. Davis**: He thinks they are open to that, but the most important thing is that they wanted to program to pay for itself. DHP has to balance the fees and revenues of overseeing the program.
- **Sen. Marsden** agrees we can consider that. BOP has to be involved to some extent, because pharmacists are involved. They would have to think through the structure, whether it would be an NGF agency, and whether it would be able to make its own decisions about what it charges to operate the program. He thinks she brought up good points about barriers to patient involvement in terms of making it part of their regular healthcare, but that does put costs somewhere. He has generally been a fan of spreading costs out as broad as possible in the sense of fairness, because they have industry that has been investing heavily in their products without any guarantee of success. He doesn't want to overly burden that industry either. It will take a lot of work over a number of year to get a non-general fund agency that could "get it right" in terms of keeping the burden down on patients while not overburdening the processors and their distribution networks.
- **Asst. Sec. Finley**: The reason she was going to highlight both New York and Louisiana is that part of their rationale for limiting or partially limiting flower products to is because they made a decision to keep medical cannabis as a pharmaceutical product. In other words, they are using their definition of pharmaceutical grade to determine what you can and can't do with flower. If you are thinking of taking medical cannabis out of the Board of Pharmacy, is that a way to get at the fee issue and make sure there is sufficient agency infrastructure? Or is there a policy reason for taking it out of a pharmacy program, in light of how a couple states I talked to have decided to keep it as a pharmacy-based program?
- **Mx. Pedini**: There are extreme policy considerations when it comes to how we regulate cannabinoids in the Commonwealth and they do not think an agency specific to medical is the most pressing policy issue for the state, rather an agency that is more specific to cannabis and that allows participation by existing regulators like Board of Pharmacy and VDACS for their specific silos. That is what they would consider to be most urgent.
- **Ms. Payne**: To be clear, New York might have allowed the first botanical product in a very narrow sense in their medical program, but the industry has evolved a lot since then and New

York is now talking about an umbrella cannabis agency that will get its own section of code. Having one umbrella regulator does not preclude separation within that body with different cannabinoid based programs. Sara was asked to provide policy guidance on how to set up the New York regulatory structure and especially on the hemp cannabinoid side. New York plans to move the medical program from the department of health and put it into a cannabis regulating agency with adult use, then bring in hemp that has been produced for its cannabinoid content and is intended for human consumption e.g. CBD products. Just because it is under the same regulatory umbrella does not mean it will all be treated the same, but it centralizes people with cannabinoid specific expertise, for example the security issues, lab testing, labeling.

- Asst. Sec. Finley: That is helpful and helps clarify what Lisa meant by the separate cannabis commission. However, to be clear, my comments around New York were specific to dosage forms and not to agency structure. Because New York currently prohibits smoking cannabis and therefore don't allow whole flower, to ensure people are using in that fashion they have said that inhalation is allowed through vaporization using only a metered dose and in a ground format. Her remarks regarding New York were only related to what they allow in terms of dosage forms.
- **Mx. Payne**: She thinks you can carry that through to separate out things like dosage forms and other issues and still keep it very clean.

Asst. Sec. Finley: It seems another meeting is needed, so she will send out a doodle poll this afternoon. Is there any comment or objection on that?

Public Comment

Megan Dolecki: Have you ever had to hire a babysitter so you could run to CVS? She is a single parent and struggles with the accessibility of dispensaries. She does not have a nearby family to care for her daughter while she makes a 328 mile drive to Bristol or soon the 65 mile commute to Richmond. Her daughter can come with her to her brain injury appointments and CVS, but not to pick up her medical cannabis. She has been unable to access medically necessary treatment because of arbitrary restrictions. She is not an outlier case and many patients do not quite meet the threshold for having a registered agent to pick up their cannabis. She wants the barrier removed and appreciates this panel for working to ensure equal access for medical cannabis patients.

Edward Tobler: Marijuana in a ground format is not wise, because the nature of it would make it less beneficial for the patient. He is a disabled single parent on a fixed income and having insurance cover would really help him afford his monthly medical cannabis and other bills. DSS is not behind the idea of letting a single parent be a parent because they don't trust them. Perishable equity of marijuana needs to be looked at. After the elections there may be some changes that throw a monkey wrench in financial institutions as it pertains to perishable resources.

Lisa Davis: She has a toxicology background. Child proof and tamper evident packaging needs to be addressed and there needs to be a central adverse reporting system, given what one of the states said about mold.

Elly Tucker: It is good to listen to other states but we are also unique in Virginia. It is good to include botanical cannabis as that form is more easily regulated by the patients themselves and also hopefully does not have additives and is not pre-ground. She also thinks this form would be lower in cost and provide more equity. She encourages licensing additional cites since travel to these locations is a barrier for patients.

Elly Tucker on behalf of Tamara Netzel: Why are practitioners in the Virginia medical cannabis program able to charge as much as $500 and some charge nothing for the same written certification? The fees are also sometimes a surprise after the first visit. Patients recovering from debilitating conditions should not have to go into this blind and then get a surprise bill.

Sara O'Hanlon: Sara is a patient and mother of a patient. She agrees with earlier comments around patient access. She has been unable to access medication due to her son's intractable epilepsy. She has not yet received an answer on the accommodations that are in place. Whole plant flower allows patients to self-titrate and to get immediate relief as opposed to oral use, so flower is more versatile and economical. She has been unable to access a specific terpene for seizures, and with flower she can make her own oil, have it tested for that specific terpene, and have a specific type of medicine that she has not been able to access since the program has started. She speaks for others as well.

Ryan Pokorny: Ryan works for Delegate Heretick, who was unable to attend today, and thinks this has been a productive session. Delegate Heretick is glad to see this moving forward and eager to be part of the process.

The meeting adjourned at 11:45am.

Chat Box

from Edward Tobler to All Panelists: 9:53 AM

What if aspects of dairy farming were implemented into the marijuana industry? Agencies make the purchase from growers as a means of equity and increase in the perishable gdp format?

from Edward Tobler to All Panelists: 10:21 AM

post operation pain?

from Laura Georgiadis to All Panelists: 10:52 AM

Big thanks to the directors of successful cannabis programs from around the country joining us this morning. My first comment is: There is no reason to homogenize the flower. The cannabis flower is made perfect in its natural form. Keep it pure. My second comment is that I know VA can do this and do this well. Our Pharmacy schools need to add cannabis as medication to their curriculum.

from Christine Stenquist to All Panelists: 10:59 AM

My name is Christine Stenquist, I'm a brain tumor patient and leas advocate in Utah. I run TRUCE, a nonprofit behind the Utah effort. I would be happy to off some real patient concerns to the team. If you have questions please contact me.

from Christine Stenquist to All Panelists: 10:59 AM

801-888-8931 csteny@gmail.com

from Christine Stenquist to All Panelists: 11:01 AM

Thank you. And, best of luck to you all as you embark on access for patients. You're helping heal and change lives.

from Jenn Michelle Pedini to Everyone: 11:13 AM

A complete list of state medical cannabis laws that includes qualifying conditions and caveat language is availabel at https://norml.org/laws/medical-laws/

from Elly Tucker to All Panelists: 11:42 AM

I have signed up to speak also. I am also providing a comment for Tamara Netzel.

from Elly Tucker to All Panelists: 11:45 AM

Should I post my comments here?

Dr. Preston Grice Presentation:

In between the fourth and fifth meetings, Dr. Preston Grice, initially a work group member, submitted a narrated powerpoint presentation to the work group members for consideration.

Medicinal Cannabis: Forms and Methods of Delivery & Related Considerations:

Dr. Grice, Associate Professor, Department of Physical Medicine and Rehabilitation, University of Virginia, put together this presentation since he was not able to attend the majority of the work group meetings.

Considerations: The Patient Perspective

- Accessibility to product
    - Unfortunately things are currently somewhat spread out in the state.
- Cost of product
    - Given that insurance companies will not pay for this, he has a lot of patients who are concerned about cost.
- Ease of use
- Discreteness
- Lifestyle (e.g. active or sedentary)
- Stigma (often goes along with cannabis use)
- Dependence / addiction
- Legal and criminal limitations (will always exist while cannabis illegal nationally)

Considerations: The Product

- Safety - #1 issue. Needs to be unadulterated.
- Quality
- Purity
- Stability – Product should not degrade on your weeks or months down the road.
- Strength
- Dosage
- Effectiveness – Similar to all medications, it can be an individualist perspective.
- Reproducibility (from dose to dose)
- Consistency! Consistency! Consistency! – He wants to see a product that has the same effectiveness, dosage, and strength from batch-to-batch and lot-to-lot

Considerations: The Three Main Constitutions

- Cannabinoids are lipophilic (fat soluble) – These are the main active ingredients we look at.
- Terpenes are lipophilic (fat soluble) – These give cannabis its traditional smell and potential flavor, quite extensive.
- Flavonoids are hydrophilic (water soluble) – These give many plants their colors.
- Entourage effect often refers to not only how the cannabinoids interact amongst themselves but also how these three chemicals go to produce effects and benefits in the body.

Dosing Considerations

Once size does not fit all so many things must be considered:

- Age
- Body weight / body composition – May metabolize or store cannabinoids differently than someone else.
- Sex
- Ethnicity – This comes into play with any medication in general, different ethnic groups may metabolize medications differently.
- Delivery method
- Liver function
- Kidney function
- Underlying disorders
- Other medications and supplements – This is an important issue that needs to be further examined with medicinal cannabis, since there is not a lot of information out there. Physicians often have to make generalities to avoid interactions with other over-the-counter and prescription products.

Delivery Methods

- Systemic (throughout the body)
- Local (focal in specific area where used or applied)
- Mixed (both local and systemic)

Delivery Methods cont'd

- Systemic
    - Inhalation (common with medical cannabis products)
    - Oral (becoming more popular)
    - Transdermal
- Local
    - Topical
        - Transdermal is placed on skin and you want systemic effect where topical agent is applied locally where you want the effect.
    - Trans-rectal / trans-vaginal
- Mixed
    - Intranasal

Inhalation

- Smoke (combustion)
    - Cigarettes (joints, blunts)
    - Devices (pipes, bongs, hookahs, etc.)
- Vapor (vaporization) – involved heating but not combustion
    - Flowers ("buds")
    - Concentrate (oil, resin, wax, budder, shatter, etc.)
- Aerosol (aerosolization) – less common because it requires more production, similar to what someone would use for asthma
    - Inhaler / Metered Dose Inhaler (Vapen, MUV)
    - Nebulizer (non-portable)

Inhalation – Smoking

With every form or delivery there are pros and cons:

- Pros
    - Simple and traditional
    - Little to no equipment needed
    - Ease of use?
    - Rapid onset of effects (2-15 minutes)
    - No first pass metabolism (when something is taken orally or through digestive system and the first pass goes through liver so do get degradation or metabolization)
- Cons
    - It's still smoking!
    - Exposure to toxic chemicals and carcinogens
    - Can cause / increase negative respiratory symptoms (e.g. coughing, phlegm production)
    - Not discrete!
    - Dosing consistency!!! A product being used as a medication needs to be consistent and reproducible.
    - Not recommended for treating children!!!

Inhalation - Vapor

- Pros

        - Considered cleaner, less harmful, "safer" than smoking
        - Convenient
        - Discrete
        - Multiple substances and compounds can be vaporized (oil, concentrate, bud/flower)
        - Rapid onset of effects (2-15 minutes)
        - Easier to control (relative to smoking)
        - More potent (i.e. more concentrated)
        - More cost effective than smoking? (There have been several non-medical studies that have looked at the cost effectiveness of vaping vs. smoking the cannabis bud.)
        - No first pass metabolism
    - Cons
        - But, it ain't completely safe!
        - Over-medicating issues with infrequent users
        - Easier to "over use" (especially when product is easy/accessible like a pre-packaged concentrate in a vaporizer pen)
        - Up front expense (vaporizer, can be $60-$600)
        - Dosing consistency!!! (similar issue to smoking)

<u>Inhalation – Aerosol (less common)</u>

- Pros
    - Non-pyrolytic (no heat, no fire)
    - Discrete
    - Rapid onset of effects
    - Easier to control
    - Tasteless, flavorless (generally)
    - No first pass metabolism
- Cons
    - Still in early stages of development and marketing
    - The aerosol ideally needs to be aqueous based (water soluble and many cannabinoids themselves are not)
    - Up front expense (nebulizer)
    - Metered Dose Inhaler (MDI) use learning curve

<u>Oral</u>

- Ingestion
- Sublingual / transbuccal (goes between cheek and gum)

<u>Oral - Ingestion</u>

- Tablets / capsules
- Tinctures (extract in ethanol)
- Oils
- Edibles (brownies, cookies, candies, chocolates, gum, ice cream, etc.)
- Drinks / liquids (teas, infused beverages, "energy shots", powdered mixes, etc.)

- "Juicing" (don't hear a lot about since generally we are look at processed products, but this is probably one of the purest ways with drawback being that you need a very fresh product)

Oral - Ingestion

- Pros
    - Easy to use
    - Discrete
    - Palatable (depending on what it is mixed in)
    - Consistent dosing (e.g. if have a chocolate bar with sections, you know roughly how much of the cannabinoids are in each section by weight)
    - Long duration of effects (12-24 hours)
    - Good for chronic, persistent conditions (not a lot of sudden onset, symptoms)
- Cons
    - Slow onset of effects (30 – 180 minutes)
    - Variable absorption (including what you have eaten)
    - Unpredictable bioavailability (how much of the product actually gets to the blood system)
    - First pass metabolism (may be broken down before gets to full systemic effect)
    - Long duration of side effects

Oral – Sublingual/Transbuccal

- Pros
    - Easy to use
    - Discrete
    - Consistent dosing
    - Rapid onset
    - No first pass metabolism
- Cons
    - Mouth irritation
    - Taste
    - Potential absorption issues (lipophilicity, mouth pH, mouth moisture, etc.)
        - Mouth likes to absorb aqueous or hydrophilic products, and mouth pH and mouth moisture may change how the product is absorbed

Transdermal

- Pros
    - Easy to use
    - Discrete
    - Consistent dosing
    - Long duration of effects
    - Good for chronic, persistent conditions
    - No first pass metabolism
- Cons
    - Cost (some of the products are expensive)
    - Slow onset of action (up to 3-4 hours from application)

        - Local skin irritation
        - Patches may inadvertently come off (sweating, bathing, clothes)

Topical (getting into more localized use)

- Pros
    - Easy to use
    - Discrete
    - Consistent dosing
    - Allows for application in specific affected and localized areas
    - Not typically associated with systemic effects / side effects
    - No first pass metabolism
- Cons
    - Not good for diffuse or systemic problems
    - Often mixed / compounded with other materials / agents
        - Frequently see topical products mixed in with menthol, camphor, lavender, etc. and it can be hard to know whether the cannabinoid or one of the other compounds is providing the benefit. Ideally you want a compounded topical agent that has little to no other products.
    - Questionable benefit?
        - There is data out there and people swear by topical products, but after having used about six products over the years, he has found them ineffective. He does not doubt or deny people if they experience benefits, but does question the extent of their effectiveness.

Intranasal (not into mixed effect)

- Pros
    - Discrete
    - Consistent dosing
    - Rapid onset
    - No first pass metabolism
- Cons
    - Difficult to use (similar to Afrin, takes practice)
    - Nasal irritation
    - Variable absorption (depends on the nose)
    - Rebound congestion

Trans-rectal/Trans-vaginal

- Some debate about whether it is localized or systemic, though he thinks it is under localized
- Pros
    - When other methods aren't doable (ingestion, smoking, etc.)
    - Localized effect
    - Little-to-no systemic side effects (some debate, but his opinion based on the data from controlled studies)
- Cons
    - The "down there" factor (below the waist can be a turn-off)

    - Requires a degree of undressing
    - Messy
    - Unpredictable bioavailability (depends on patient)
    - Partial first pass metabolism (to a certain degree, especially trans-rectal suppositories)
- There has been a lot of debate about suppositories. There is a chemical called THC semi-succinate that is not a natural cannabinoid product, but instead a THC that has been attached chemically to a molecule. It can take the bioavailability of the THC product up into the 50-60% range. The suppository absorption can be impressive but, again, it is not a natural, standard, raw cannabis product but more so a type of THC that has been chemically modified.

Summary

- **Medicinal cannabis MUST be viewed as a "MEDICATION", not just a supplement!** It should not be taken lightly and it should be viewed as a medication with certain interactions and side effects.
- **Just because it is "only marijuana and natural" does not make it necessarily safe!**
    - He has had many patients say to him it is "only marijuana," but that is really looking at it more from a recreational perspective.
- Multiple factors must be considered when recommending and "prescribing" (described earlier)
- Multiple ways and forms by which to consume and dose medicinal cannabis products (often must be customized to the patient)
- Products quality and potency **must be consistent with reproducible results** (including consistent benefits and side effects)
- Patients must be able to distinguish between symptom relief and intoxication
    - This is what we saw happen frequently in the opioid world. Patients could not always distinguish between the "buzz" and symptom relief or desired side effect. For example, he had patients that would take 60 mg oxycodone twice and day and report little to no effect, but would take half of that through an immediate release and report better results than the sustained release. It was often because of the acute buzz from the immediate release product.
- There is lack of support for "smoked cannabis" in the medical field
    - He knows there are a lot of potential pros, but in the medical field it is really not viewed as a true pro. Smoking anything is not really viewed as an appropriate delivery method in the medical field. He does not deny it is a potential mode of delivery, but it is still frowned upon to a degree by the medical field.
- "Start low, go slow" when introducing and dosing
    - This is true for any medication with intoxicating or central nervous system side effects. Patients can experience dizziness, sedation, nausea, etc. with too high of a dose.
- **Medicinal cannabis IS NOT a panacea!!!**
    - He has a lot of patients come in looking for medical cannabis, especially CBD, as a magical wand that will make all their symptoms go away. Neither THC nor CBD are cure-alls.

- There are a variety of ways to provide medical cannabis, from picking the appropriate dose to mode of delivery. It is an individualized issue and you have to look at availability, discreteness, and a lot about the patients themselves.

Feel free to reach out with questions through Catie. He has presented some controversial information here and played devil's advocate. He is a huge believer in medicinal cannabis but one of the biggest opponents of any time of medication that is not used or prescribed appropriately.

Medicinal Cannabis

Forms and Methods of Delivery
and
Related Considerations

D. Preston Grice, MS, MD
Associate Professor
Department of Physical Medicine and Rehabilitation
University of Virginia

Considerations
The Patient Perspective

- Accessibility to product
- Cost of product
- Ease of use
- Discreteness
- Lifestyle
- Stigma
- Dependence / addiction
- Legal and criminal limitations

Considerations
The Product

- Safety
- Quality
- Purity
- Stability
- Strength
- Dosage
- Effectiveness
- Reproducibility
- Consistency! Consistency! Consistency!

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“The Three Main Constituents”

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  - Simple and traditional
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- Pros
  - Discrete
  - Consistent dosing
  - Rapid onset
  - No first pass metabolism
- Cons
  - Difficult to use
  - Nasal irritation
  - Variable absorption
  - Rebound congestion

Trans-rectal / Trans-vaginal

- Pros
  - When other methods aren’t doable (ingestion, smoking, etc.)
  - Localized effect
  - Little-to-no systemic side effects
- Cons
  - The “down there” factor
  - Requires a degree of undressing
  - Messy
  - Unpredictable bioavailability
  - Partial first pass metabolism

Summary

- Medicinal cannabis MUST be viewed as a “MEDICATION”, not just a supplement!
- Just because it is “only marijuana and natural“ does not make it necessarily safe!
- Multiple factors must be considered when recommending and “prescribing”
- Multiple ways and forms by which to consume and dose medicinal cannabis products
- Products quality and potency must be consistent with reproducible results
- Patients must be able to distinguish between symptom relief and intoxication
- There is lack of support for “smoked cannabis” in the medical field
- “Start low, go slow” when introducing and dosing
- Medicinal cannabis IS NOT a panacea!!!

Appendix X – Meeting Five

Virginia Medical Cannabis Work Group
Meeting Five
November 18, 2020
11:00am – 1:00pm

Agenda

Welcome & Approve Meeting Three Minutes

Open Discussion on outstanding items:

- Increasing patient registration from 1 year to 2 year?
- Expand telehealth options for both practitioner visit and dispensary visit?
- Eliminate practitioner registration?
- Eliminate the practitioner patient certification cap?
- Allow botanical product?

Public Comment

Adjournment

Meeting Minutes

Catie Finley, Assistant Secretary of Health and Human Resources, called the meeting to order at 11:05am. Workgroup members in attendance were:

Dr. Dan Carey, Secretary of Health and Human Resources
Delegate Glenn Davis
Senator David Marsden
Dr. David Brown, Director, Department of Health Professions
Caroline Juran, Executive Director, Board of Pharmacy (joined part of the way through)
Annette Kelley, Deputy Director, Board of Pharmacy
Ngiste Abebe, Columbia Care
Jack Page, Dharma
Sara Payne, Dalitso
Joy Strand, GreenLeaf
Lisa Smith, patient advocate and mother of Haley Smith
Jenn Michelle, Virginia NORML
Dr. Sam Caughron

Asst. Sec. Finley: There are some outstanding policy proposals that the group wanted to discuss (summarized on the agenda). She proposes going through the six policy proposals individually

and looking at: what is the problem we are trying to fix; what would the change look like in terms of improving patient access (focusing on good actors like we have on the workgroup); and any unintended consequences of the policy in terms of potential misuse. To the best of our knowledge, we should also discuss how these policies align with what other states do with medical cannabis and what Virginia does with other medical drugs with both benefits and harms, for example Schedule II-V drugs. She opened it up to Secretary Carey and the group for any opening remarks or comments on that approach.

Secretary Carey thanked everyone for their commitment to this process and finding great policy options.

Asst. Sec. Finley: The first potential policy change proposed by members of the group is to "improve patient access by increasing patient registration from 1 year to 2 years."

Del. Davis: Assuming we are keeping the cost the same, this lowers costs for patients which has been a point of discussion. He knows there is a fiscal impact that will require analysis. In terms of reducing stigma, he doesn't think it changes it. He likes the idea of not having a patient registration but understands why we do.

Ms. Payne: Patients struggle with the registration process. It is very hard for patients to get registered. These are often really sick people; they are often not particularly mobile and need assistance. They have to take time off from work, hire someone to help, hire a babysitter, and handle a lot of complicated factors to get registered. The difficulty for patients should be taken into account.

Dr. Caughron: He agrees with increasing the time frame. It is a pain for people to be able to get this license. They can spend hundreds of dollars to do so and then have for only one year. The reasons people get these licenses don't go away, so why restrict to only one year? The goal is probably monitoring them, but medically it doesn't make sense. Two years is a reasonable time frame, potentially even more.

Ms. Smith echoed the lowering cost for patients and the fact that these conditions don't go away. Patients are often juggling additional appointments and therapies. Spreading it out for two years would be beneficial.

Asst. Sec. Finley: Her general understanding is that there are some Schedule II-V drugs that require prescription renewal every six months, but that there is flexibility for the prescriber on whether that requires an in-person visit. Dr. Brown - how do we handle this for other drugs?

Dr. Brown: He thought they were talking about the requirement that the patient register with the Board of Pharmacy (BOP).

Asst. Sec. Finley: That's a good point of clarification. If you change the time frame for registration for the BOP, does that also mean you change the requirements for when patients have to see the practitioner or the pharmacist at the dispensary?

Ms. Kelley: It is the visit with the practitioner where patients are incurring the greatest cost. Practitioners are charging anywhere from $200 to over $400 for that initial written certification, which can currently only be written for up to 12 months. The Board registration is only a $50 fee, and only patients are only required to present themselves to the dispensary for the initial visit. After that, if they can work out a delivery agreement with the processor, they don't have to go back into the dispensary unless they need to discuss things like dosage or the product they are using. Currently, you have to see your doctor every year, since 99% of practitioners are writing for the full 12 months. Both the written certification and the BOP registration are needed to participate in the program.

Dr. Brown: For medications that are prescribed, does a practitioner typically see a person once a year in order to write that prescription? It seems to me we should follow the medical model, similar to the powerpoint that Dr. Grice provided. What do we do with other medications – is there a one-year requirement for the prescriber?

Dr. Caughron: For opioids, it is required to get a urine screen on people every six months. Usually he sees the people on narcotics every three months. People with chronic pain are frequent flyers if they are flying at all. He tries to see everyone in his practice at least once a year, but there is no law that says he has to do so.

Dr. Brown: If I was seeing you for anxiety and you were prescribing something for me, would you expect to see me once a year?

Dr. Caughron: I would not let you go that long and would probably be checking on you every three months, or every six months if you are doing very well. But with chronic medications like this, most people are seen more frequently – he sees most of his narcotics patients every month or sometimes every two to three months.

Del. Davis: The dynamics have changed with Monday's statement from the Governor. The more onerous you make something, the more people look for alternatives and shortcuts. The Governor just said in 18-24 months we are going to legalize marijuana in Virginia. Del. Davis already has a problem with patient registration when you don't have to be registered to get opioids, which is significantly worse than CBD oil. If someone can get legal adult use marijuana why will they get medical cannabis? The people on this call know that medical grade is different, but the lay person out there has no idea – THC is THC for them. We need to keep in mind that marijuana will be legal and if we want people to go through the medical process, which is important, we can't make it onerous without expecting them to bypass the whole process.

Asst. Sec. Finley: The Governor's announcement was about starting a process, and there is a difference between starting a process and flipping a switch. She thinks it is important to address the timeline as we talk through these policy changes. Your point is well taken that the context did change on Monday.

Sec. Carey: While we want to make the medical cannabis program patient friendly, we don't want to abandon a medical model. He doesn't think we want to make it unnecessarily onerous, but patients are coming to the medical system for something that you might get at an adult-use dispensary two or three years down the road. He thinks there is a higher standard and degree of predictability and reliability to meet. While he doesn't want it to be more onerous, he doesn't think legalizing marijuana recreationally means we should abandon the medical model.

Ms. Abebe: She agrees that medical cannabis consumers are coming in with very specific needs and expectations. Medical needs to persevere alongside adult use. Individuals are coming in under the oversight of two clinicians. Sometimes there are even three – a primary care physician (PCP), cannabis doctor certification, and the pharmacist - because their primary care provider might know about their use or write a diagnosis letter but not be able to recommend cannabis due to hospital policies or other limitations. She wants to talk about ways to address access to a medical provider who can write a certification. One of the biggest challenges facing patients is that you cannot have your PCP have a conversation about medical cannabis and write a certification. Other states have made it clear that if the cannabis certification is being considered as part of an annual visit, it can't be a separate fee. Being able to reduce burdens for practitioners to participate is key. Recognizing that insurance reforms are no small feat, there might be other policies that this group needs to look at. Again, many PCPs are involved in their patients' medical cannabis use but are unable to write certs for any number of bureaucratic reasons. We should be tackling that issue, whether it is removing the provider registration, some of the classes that providers have to do, or extending that registration for three to five years. Breaking that barrier would reduce the cost of participation and ensure that the medical nature is protected by keeping the continuum of care as simple as possible for participating patients.

Mx Pedini agrees with Ngiste. We should be looking at increasing the patient registration timelines, which means the time that the written certification is valid as well as the time that the BOP registration is valid. Extending that to a two year timeline and also making it less arduous for practitioners. When this program first started, practitioners simply downloaded a form and filled it out for their patients, so we have experience with that in Virginia. The registration for practitioners was created later. The third bullet point in the discussion is eliminating the practitioner registration.

Asst. Sec. Finley: To close out the first conversation about patient registration - that is helpful to clarify that you really do mean extending the timelines for both parts of the process, the BOP registration and the written certification. For the second part of the process, I will clarify my notes from Caroline, but I do think there is some precedence for having a requirement that the

practitioner renew the prescription every 6 months or so, though with other drugs the in-person piece is at the discretion of the provider.

Ms. Kelley: She doesn't know which substances have to go back and have a provider renew them.

Asst. Sec. Finley: I will clarify for the report. If there are no other comments on the patient registration piece, we can more formally move to the practitioner side of things. While this isn't on the list, I hear Ngiste's point on having insurance cover written certification visits if they are part of another visit. Do you know which states do that, what that looks like, and how it has played out?

Ms. Abebe reiterated the concept that she has heard in other policy conversations, but said she would have to look into exactly which states do it.

Asst. Sec. Finley: Let's skip to the proposal to eliminate the practitioner registration. There would of course be some budget implications, but thinking through the problem we are trying to solve with this…how do patients identify who prescribes medical cannabis without a registry, especially since right now it is such a minority of practitioners? Does this create problems for the patient or for doctors who are now getting calls about whether they recommend medical cannabis?

Mx. Pedini: There are a number of providers who specialize in medical cannabis, especially in providing telehealth services for that. It is reasonable to assume that they will continue to do do. That is wonderful for patients who can afford it. However, early in this program, patients simply printed out the certificate, took it to their provider, and asked them to sign it. It is not perfect but it does increase opportunities to have their certification issued. When a patient is not able to do that through their own provider, they will have to look for a practice that specializes in cannabis therapy.

Ms. Smith: Haley's initial certification was done by her neurologist and that kept the lines of communication and information open. Now that the process has changed and her neurologist is not registered, he doesn't necessarily hear her full health care regimen. It was better when the primary provider was in the conversation, and removing the practitioner opens that line of communication.

Dr. Caughron: The limiting factor can often be the system that providers work under. Some are not favorable to allowing their practitioners to give a license form to their patients, which is really a problem on a larger scale. The hospital systems have to concur that their physicians can do that. The amount of money that it costs to register is not the real barrier, it is more the hassle. He appreciates the situation that Lisa's neurologist is in. The question is whether he doesn't want to recommend medical cannabis, which is often not the case, or whether he is being limited in

another way. The group should make a recommendation to the legislature to ease that process so it becomes more feasible for practitioners to recommend (since can't prescribe).

Ms. Smith: She agrees it is more than likely the health system that is limiting her neurologist. However, the previous system showed Haley had a condition that could be treated by it *not* that he recommended it. At that time, medical cannabis was only allowable for intractable epilepsy. The neurologist was certifying that she had the condition and not recommending it.

Dr. Caughron: All you have to do is say that they need it, not why. That has not changed.

Ms. Smith: She agrees it is often the health system. It also helped that the FDA eventually said you were able to prescribe one form for the condition. However, she has not changed to that one because Haley is sensitive to change and Lisa doesn't like the side effects.

Mx. Pedini: I forwarded responses to Catie from healthcare systems in the state informing their practitioners they could not issue written certifications for medical cannabis.

Dr. Brown: The sense I am getting from Jenn Michelle and Dr. Caughron is that the health systems may prohibit their members from registering, but if a patient were to ask them to sign a form to get medical cannabis that would probably not rise to that same level. Is that what I am learning from this?

Dr. Caughron: There is no way that if the employer says you can't do this without potential risk to yourself that will go ahead with that, unless they want to ignore the system. It is a tough thing to ask a physician to risk his job.

Dr. Brown: So the system might come back and say you can't issue the certifications, but for right now the restriction is on joining the BOP registry? That is his sense of what he is hearing.

Ms. Payne: The liability burdens are very mismatched and contemplate much more physician involvement in the process. It is important to bring the physician regulations and liability burdens in line with the processor regulations and how the program operates in practice. The regulations are still in the world where CBD was only for intractable epilepsy." Now the pharmacists are really the front line in terms of assisting patients with routes of administration and dosages, but the doctors are still on the hook for liability for the wrong decision. Those pieces should come into alignment.

Asst. Sec. Finley: There is not Administration position on this, so this is a question rather than a suggestion. However, one of her big takeaways from both cannabis workgroups is that there are some well established indications for patients for medical cannabis and some promising indications, but we are not there yet on a lot of the research (though it may come in the next twn years or so). Recognizing there are different ways to achieve the goal of better practitioner education, are we missing an opportunity for education by removing the practitioner registration?

Mx. Pedini: The intent of the medical cannabis program is not to provide education to healthcare providers. CMEs are widely available on this issue. The point of the program is to provide safe access to Virginians.

Ms. Strand: While Jenn's comment with providers using CMEs to get educated would be ideal, the experience in other states is that education to key stakeholders including providers is not widespread. She does not know of a medical school that is teaching medical cannabis science and a lot of providers say they are interested but don't know where to get information. Education programs are becoming available, but she thinks operators need to facilitate education across the continuum so that preparation is accurate, updated, and widely available to those who need it.

Asst. Sec. Finley: How many other states do or don't require practitioner registry?

Mx. Pedini can get that information.

Ms. Juran: We can look into it. To clarify since I joined late, are we talking about whether to remove the practitioner registration, but to still require the written certification from the patient?

Ms. Kelley: Yes. She believes it is all but one or two states that require a written certification of some sort from a practitioner, but is not sure how many require the separate registration outside of normal medical requirements.

Ms. Abebe: In 2018, the New York Department of Health, in their required biannual report on the medical program, recommended allowing all prescribers of controlled substances to participate in order to increase the number of providers in the program. The implication is to remove the specific registration for medical cannabis. However, she doesn't believe New York has acted on most of the recommendations made in that report, including this one.

Ms. Payne: She doesn't think anyone should be advocating to remove the requirement for patients to be registered or certified, she thinks that certification gives patients a fair bit of protection from entanglement with federal law. She thinks that it is only the practitioner registration that is causing program complications.

Ms. Juran: One of the advantages of the registration is having a public list of practitioners that are willing to recommend available to patients. They have had a couple physicians say they got the written certifications but are not ready to recommend, and are getting a lot of calls from patients but don't want to be publicly listed. If we don't have the registration process, how would the public and patients identify the willing practitioners in lieu of inundating them with calls?

Mx. Pedini: We talked about this earlier before you joined, but there will continue to be practitioners that specialize in this. The hang up is that we want to return to the previous system and have patients ask their provider to sign the form. If their primary provider cannot do that,

they will have to look to a specialty practice. There is no perfect solution, but what is in place now is problematic for patients.

Ms. Juran: So they will be advertising to identify themselves to patients?

Mx. Pedini: They are restricted in the way that they can advertise but should have some ability to communicate that they are a certifying practice.

Ms. Abebe: Should a patient be able to just bring the form to an appointment, it would be beneficial for that to include educational information from BOP on the provider's ability to fill out that form. Some providers have thought about medical cannabis but other patients have to educate their providers. It helps that conversation to understand their legal authority.

She knows some folks do get a lot of calls, but it is already hard to find. People always ask her where to go to get a certification. That is just a part of the process with a new program. Doctors will figure out how to participate and folks like MSV will continue to provide education on their program. However, the more we can make this part of the normal course of healthcare, the easier it will be for everyone.

Dr. Caughron: I agree with that.

Asst. Sec. Finley: Another proposed change is removing the patient certification cap, which is currently set at 600. Are we hearing that is currently a true limitation? How does that compare to normal patient loads? In the context of wanting to bring this into the course of normal healthcare, does that have unintended consequences of creating more opportunity for specialty practices instead of people going through their PCP?

Dr. Caughron: The people most impacted by the cap are the folks who specialize in pain who have large numbers of people, which is not the usual situation. Not many physicians have more than 600 people. This would impact people who would run a "mill" similar to those that developed for opioids with no meaningful patient interaction and just signing a form. The more people you can have, the greater the financial incentive you have to do that. 600 is not a bad number for those in normal practice, even those in a health system. Removing the cap will really only affect those in it for the money, and that is not good medical care.

Ms. Abebe: Are there other areas that we cap the number of patients that doctors can see?

Dr. Caughron: We cap them with narcotics. For example, you can only have a set number of patients for buprenorphine. It varies, and he would need to confirm but thinks the caps vary from 30 to 200.

Mx. Pedini: Have any practitioners requested a variance?

Ms. Juran: Not as of yet.

Mx. Pedini: Are any practitioners approaching that number?

Ms. Juran: It does not currently appear to be an issue. She is not sure if the number of patients per practitioner is public information, but they are monitoring and it generally does not appear to be an issue.

Ms. Abebe: She does not disagree with Dr. Caughron's point, if this were better integrated into the continuum of care. However, she has heard from providers that are very supportive but have not been able to register in the program and are only able to write a diagnosis letter. In the current setting, the biggest obstacles are that it is costly (since it is outside of insurance) and time intensive to find someone outside your existing care team. If we are removing barriers to make this part of normal healthcare instead of ostracizing it, hopefully that will help obviate the need to address the cap issue.

Asst. Sec. Finley: The final new proposed change is to expand telehealth options. Her current understanding is that the request is to expand telehealth options for both the practitioner – for example remove it from the Schedule II-V category – and also for the pharmacist. On the practitioner side, the Code currently says that practitioners can provide telehealth in accordance with the requirements for Schedule II-V drugs, so she believes the proposal is to move it to Schedule VI. Could someone provide clarification as to the proposed change, especially on the pharmacist side?

Del. Davis: A lobbyist he talked to on the insurance side has issues with telehealth, in part because it causes more doctor visits and incurs costs. Could Secretary Carey provide insight on what may be coming down the pike on telehealth?

Sec. Carey: I do not have any insight except that there has been some resistance against audio-only telehealth, especially for new patient evaluations and physical therapy. He is interested in ways to build on lessons learned from telemedicine, within Medicaid for example, to encourage its use in appropriate settings. There has been a significant improvement in access with telehealth and we would like to learn from our experience during COVID-19, including with the private plans. He thinks the folks at Anthem would agree with that statement, but would also say there also needs to be quality interaction and physical exams, especially since not everyone has the devices they need at home. In summary, he has no insight but knows folks are struggling to apply lessons learned from the pandemic.

Sen. Marsden: How do copays work with telehealth?

Sec. Carey: It depends. Some plans have waived all copays, since people weren't coming in for important things. The state health plan has waived all copays and most of the commercial plans either followed suit or lead the way. It has evolved and it depends on the goal. Philosophically,

he thinks there should be no copays for high value care to include vaccines, colonoscopies, and infectious diseases where there is a public health implication. There is no across-the-board standard and it depends on the plan design, which often depends on the employer paying for the health plan. He hopes the state continues to lead in looking at value-based care.

Dr. Brown: He believes legislation passed in the last couple of years that requires in-person visits to be reimbursed in the same fashion as for telehealth. He knows that is true for the commercial plans. The first year it did not apply to Medicaid, because of state budget implications. He believes the limitations stem from the requirements around establishing a doctor-patient relationship, which is what Dr. Carey was referring to.

Asst. Sec. Finley: A lot this conversation pertains to insurance coverage for telehealth as opposed to allowances for the provision of telehealth. Since most insurance does not cover medical cannabis, it would be helpful for Caroline to also address what COVID-19 waivers are in place around the provision of telehealth. She was previously conflating rules around insurance coverage with rules of providing telehealth and wants to make sure we are understanding the current landscape around the provision piece.

Ms. Juran: The U.S. Center for Medicaid and Medicare Services (CMS) has put in place a variety of waivers around the pandemic that primarily apply to insurance coverage. From a BOP perspective, they are focused more on the laws around having a valid prescription and the requirements for establishing the bona fide practitioner relationship, which is required in code. To perform telemedicine in a way that will result in the issuance of a prescription for a Schedule II-V prescription drug, the patient needs to be physically at a DEA registered facility or in the presence of a DEA registered practitioner. For example, if you are in a rural area and the primary care provider doesn't have a psychiatrist, you can meet with the nurse in the DEA registered clinic and connect via telehealth with the psychiatrist in a larger urban area. The psychiatrist can complete the evaluation and treatment process and ultimately issue a prescription for a schedule II-V drug. That is what is required by state and federal law. The only waiver currently in place for those requirements relates to buprenorphine/methadone and out-of-state providers: the DEA is not currently requiring an already registered DEA practitioner in another state to obtain DEA registration in the state where the patient resides. In other words, under current federal law, they would have to obtain a DEA registration where the patient resides, but during the emergency the practitioner only needs to hold a DEA registration wherever they reside. For schedule VI, patients can be at home and connect with their practitioner through a secure connection like teledoc and can establish the bona fide relationship that way to issue a schedule VI drug. The distinction comes down to the federal requirements that require the patient to be in a DEA facility or in the presence of a DEA registered practitioner as opposed to the patient just sitting at their home – that is the biggest difference.

Ms. Abebe: Is it the federal requirement that this happen in a DEA registered facility? Around the bona fide relationship, she has heard this used in other discussions and wants to remind the group that, while that is ideal, it is not always realistic in the current industry. Due to the nature

of her employment, she often gets her insurance on the exchange and has not been able to meet the standard of a "bona fide" relationship. She has chronic conditions and has had to make due with whomever aligned with her insurance plan. There are a significant number of Virginians who have no insurance and for whom the definition of "bona fide" is unrealistic, especially in areas of the state with limited health care access to an in-person appointment at a DEA registered facility. We should think about the risk as compared to other things treated the same way, as well as what it actually means for patients to be able to access a bona fide relationship with a practitioner given the realities of the current health system.

Ms. Payne: For a substance that is not legal under federal law and for which we have protection under the federal appropriations rider Rohrabacher-Farr (for participants in a highly regulated state programs like Virginia's), she is not quite sure why we are so wed to the federal standards in this instance given that we are in the middle of a pandemic and do have serious patient access issues.

Ms. Juran: She thinks the thought process behind the General Assembly passing that standard just this past session was that this is a psychoactive product and should align with how we treat other prescriptions that are psychoactive and therefore are under Schedule II-V. The General Assembly needs to decide, from a policy perspective, are we going to handle this as a recreational drug for which there are no prescription standards and for which the potential of abuse does not apply - in the sense that we don't need extra security protections with respect to practitioners following requirements? Or are we going to allow this to be treated as a schedule VI where the patients can have their appointment at home, and with an unlimited cap, which will potentially incentive "pill mills" where it is easy to obtain a recommendation for this product. We are either treating it as over-the-counter or like a psychoactive product and Virginia should decide how this is going to be treated.

Ms. Payne: You added a lot into that that no one is advocating for or would support. No one on this call is suggesting that we treat medical cannabis like a recreational drug or remove practitioners or anything of the sort. We are instead trying to call to attention the fact that we have a vulnerable population and are in an unprecedented pandemic. We have a group of folks who may be at high risk for poor access to health care generally and are struggling to pay for health care services. Anything that Virginia can do to make that easier across the board, not limited to medical cannabis, is probably a good thing. No one should think the processors want to make the medical program into a recreational program.

Ms. Abebe: She agrees that they are talking about increasing provider access in order to increase patient access to health care. No one is trying to make this recreational or remove the healthcare experience, but instead tackling the very real hurdles that patients face every day trying to achieve this medical care because of the regulatory environment that is in place. This type of stigmatization is part of why patients face hurdles in having conversations with their providers and communities as they pursue life changing treatment.

Asst. Sec. Finley: As outlined at the beginning of the meeting, she thinks it is helpful to hear from both sides. She does not think Caroline's comments were suggesting bad intentions on the part of anyone here or the industry. She understands there is stigma, but it is also important to think through how these policies play out – there are patients that have valid concerns, but she has also heard stories of folks who are interested in misuse. There is not an administration position on these policies, but it is important to hear from both sides. In addition, she understood Caroline's statement about "treating this like other psychoactive drugs" as referring specifically to the part of the statute that says we will treat this like other schedule II-V drugs for telehealth purposes.

Ms. Juran: She was not suggesting any type of stigma or taking a position of any sort. She agrees with Catie's comments that my own comments were based factually on how the current Virginia law is written, and that we need to figure out which category of laws these products fall into. She was not trying to stigmatize, but from a regulatory protections standpoint we have to identify the oversight requirements for this product so that all parties have clarity. It feels like we are having discussions that are blurring a bit and she is just sharing that she thinks we need to land somewhere.

Dr. Caughron: Both MSV and others have been pushing to be able to expand telehealth. The reason it never took off is because the insurance companies don't want to pay for it. With telephone-only, if he can take a phone call over the weekend or at night that prevents someone from going to the emergency room, he is actually saving money for the insurance companies. He has been able to diagnose things like hand injuries over telemedicine, which otherwise would have required his patients to go to the ER to get a referral to an orthopedist. He thinks most in the medical community feel the telemedicine option is an excellent one that will be expanded. He should get paid for his time and expertise regardless of where the appointment occurs.

Mx. Pedini: As one of the drafters of the telemedicine legislation, the schedule II-V language was added in Committee and she doesn't think anyone there knew what that meant.

Asst. Sec. Finley: Can you clarify which bill you are referring to?

Mx. Pedini: The bill specific to telemedicine for medical cannabis. Previously telemedicine was not allowed for the first visit, but was allowed for the second and subsequent visits. They were trying to correct that in Code during the Committee meeting to allow telemedicine for all visits.

Dr. Brown believes it was HB 1460.

Ms. Abebe: The FDA classifies epidiolex as an unscheduled drug.

Senator Marsden: With the Governor's announcement about legalization, Senator Marsden called him and expressed his concern that the legalization discussion this year may create a problem for the medical cannabis industry that we created and that people have invested millions

of dollars in. An analogy is that they don't allow two trains to arrive at the station too close to each other. He relayed to the Governor and Deputy Secretary Brad Copenhaver that he does not want adult-use legalization to interfere with this program, including the bill to expand to flower that they will likely to see this year from Senator Lucas. One way to move forward is to have legalized cannabis with a delayed enactment until all the regulations are in place to ensure minority involvement and get all the details right on how to integrate their existing medical cannabis providers into the new system. The new system may determine it is not vertically integrated. We can get the intent of the bill to legalize cannabis in place, but not have it up and running for 2-3 years. In the meantime, we don't want to interfere with the medical program and lose sight of getting folks access to medicine while getting caught up in the legalization argument. We have to figure out taxation on legalized marijuana. He wants people to have relationships with their providers in place and that, down the road, there be a clear choice between the medical and recreational market. He wants to make sure the medical market is protected against any negative aspects of the legalization discussion. The industry they have created is for helping folks and he wanted to make sure to note that he has been engaged in that discussion. (*Senator Marsden had to leave after these comments.)*

Mr. Page: In terms of patient telehealth options, they have been contacted by numerous hospice organizations across the state that want their patients to have access to his medicine, but cannot make the drive to Bristol for the initial visit. Patients generally want access to this medicine but cannot drive to Bristol. It is a burden to entry to require folks to be in person at the first visit.

Mx. Pedini: We want to allow patients to have a consultation with the pharmacist with telehealth. (Jack Page agreed.)

Ms. Juran: Right now we have a law that requires a form, developed by the State Supreme Court in coordination with the Board of Pharmacy, to be issued by the practitioner. We are literally dealing with a piece of paper. How are other states allowing for practitioner recommendations to be transmitted to a processor? Right now in Virginia, the patient or their registered agent (which those in hospice could use) have to present the written certification. She is guessing in other states there is some integration with licensing software, so that when a patient sees the registered practitioner they are required to indicate in the software system that they are recommending this type of product, then the patient completes the registration electronically with the licensing authority, and finally the dispensary has access to that central database to identify which patients have the valid written certification. Do Ngiste or other multistate operators know of how the dispensaries become aware of the valid written certification if there is no in-person visit?

Ms. Strand: In Maryland, there are two centralized databases. One is the seed-to-sale tracking system that both regulator and licensees have access to that tracks production, products, distribution, and sales. The other system more related to this discussion is a centralized database where the patient and provider both register and have accounts. The patient registers in the database then connects with their provider – some states allow through telemedicine – then the

provider goes into the database and marks the recommendation. In Maryland, the system automatically stipulates that they are recommending a 30-day supply and the provider can adjust that amount. There is a complete paperless registration and certification. The dispensary can access that database to see that their registration and certification are current, as well as how much is left for them to purchase that day. It works extremely well and there are no paper copies. There are several models that would streamline this process in many ways. However, that does require providers to register in the system, so it goes back to more providers registering over time, which goes back to education, which goes back to the knowledge base of patients and providers. She is happy to answer more questions about that system.

Mr. Page: The registered agent is great for many patients, but for hospice patients if you are limited to two patients per agent that does not work well in nursing homes and hospice. Is there a way to add the function of verifying to the written certification to the VCPRL system they are currently verifying patients with?

Ms. Kelley: The issue there is that the patient is not required to submit a renewed written certification to the Board, so they only obtain the initial written certification and not the renewed certification.

Ms. Juran: They are simply required to attest to the fact that they have the renewal.

Mr. Page: Can we have them submit the renewal every year then?

Ms. Juran: They could do something as a stopgap but are generally trying to get out of the paper business. This goes back to the point raised at different meetings that the introduction of flower many overwhelm BOP from a workload standpoint. They are looking into electronic software for the licensing process, which sounds like it would dovetail into what Joy is describing for facilitating it electronically on the processors end as well. They are researching that kind of software. They are open to what would be necessary to facilitate patient access, but do not want to set up a process in the long term where they are collecting more paperwork than is necessary.

Mx. Pedini: Would it be more appropriate to have patient access at the dispensary based upon their state registration as opposed to on this multi-requirement process of having both state card and written certification? Many states only require your card.

Ms. Juran: Since the affirmative defense got removed, it does raise the question of the need for the certification other than the processor need to validate that the patient has a current written certification. As long as the law requires a recommendation from practitioners for the authority to dispense and there is no electronic system, they may be forced to present that paper document. Initially, the certification was needed for an affirmative defense whereas now their card is their legal defense. She doesn't see a legal need for the patient to have the written certification on them except for to show the dispensary that they have the authority to provide them with a product.

Mx. Pedini suggested changing the Code to have it be contingent upon valid registration with the state.

Ms. Juran: Their process does not validate that the patient has a written certification.

Mx. Pedini: It seems we would want to have them present a valid certification at the time of renewal.

Ms. Juran: That goes back to the paper collection process. If this is necessary could do temporarily but in the long term a better solution would be an electronic platform to address some of these issues.

Asst. Sec. Finley: The last proposal on the agenda is one we have discussed in prior meetings: adding botanical products to the program. We have about ten minutes left, while we haven't come to a conclusion here do we feel like we have covered this in terms of discussion?

Del. Davis: Just to clarify, these proposals are on top of the topics we have already discussed including another round of licenses and the delineation between hemp and medical CBD?

Asst. Sec. Finley: Yes, but with a caveat. Her understanding of what has been discussed other than the list today are: 1) the conversation with MSV and VHHA, and 2) the conversation with the industrial hemp industry (the second thing that Del. Davis mentioned). In terms of an additional round of licenses, she does know that is an option that is being considered, but does not recall an explicit conversation in this group about another round of processors. Is that what you are referring to?

Del. Davis: There are two scenarios: 1) The five additional licenses that were in the bill initially, and 2) the distribution allowed in each region as well. He is referring to another set of vertically-integrated processor licenses which presumably come with their own dispensaries.

Asst. Sec. Finley: She has understood the bulk of this conversation to be around ensuring that the processors and dispensaries that currently exist are able to come to fruition. She is happy to note in the report that another consideration in the program is how and when to expand the number of licenses around supply/demand, etc.

Del. Davis: Fair enough. That was the conversation point around the initial piece of this legislation.

Asst. Sec. Finley: Her takeaways around flower is that it would: increase patient options, choice, and price. In terms of price, there is a Drug Policy Alliance study referenced in an earlier meeting. She also looked up a price study in Colorado, since that is one of the more mature markets. It found that the average cost per dose for flower and concentrate was the same for both

products ($1.35 per dose on the medical side of the market). Anecdotally, we have certainly heard that the price of flower is lower, but she found them to be even in the Colorado report. She is open to other studies on cost, especially those done by states, since that has been such an area of focus. The biggest things she has heard about flower is around self-titration, patient cost, and the likely increase Board of Pharmacy workload.

Del. Davis: Last year people came into his office to talk about the benefits of vaporizing flower products, specifically on the military side with PTSD. Let's make sure that those who are facing challenges with access. Those on the medical side have said that inhalation of the flower product provides something they can't get elsewhere.

Mx. Pedini: This is a consumer safety issue. Patients are purchasing this on the illicit market or driving to DC to purchase medical cannabis. We should provide this safely and easily to patient here.

Ms. Strand: Flower is the number one requested product from patients. 50% or higher of sales are with flower. In any state, you can see different prices and costs and there are a lot of factors that go into that. Colorado's market is apples to oranges with Virginia or other states because there are so many moving parts to any program. In Colorado, there are no license caps; they have 1,500 growers and a much bigger supply of products - that impacts that cost of products. Price will start quite high and come down when the supply goes up and other changes are made to the program. The general rule is that flower is cheaper than processed, no matter where you are. In terms of patient dosage, they have confines and are working within those, but every patient is going to determine their own dose regardless of those. Flower is different in every state, so we need to keep in mind what patients want, need, and have been using already in the illicit market. We can move them into a safe legal market. By and large, flower is a necessary product for patients to have access to.

Dr. Caughron: He supports the provision of flower because it allows flexibility that is quite useful.

Ms. Davis: When they started it was tailored to epilepsy. We have expanded the conditions but not the way to treat those conditions. It makes sense to expand the program to allow all those with conditions access.

Asst. Sec. Finley: Another takeaway is the importance of testing for consumer safety.

Mr. Page: He has data that he will send from an industry that compares a gram and a gram and it is roughly three times as much for concentrate (approximately $49) as for flower (approximately $17).

Asst. Sec. Finley: She asked him to send that over – she is curious whether that is equivalent when it comes dose in addition to weight.

Ms. Abebe: Jack's data aligns with the data she has seen. With flower, it is also important to have a reasonable testing standard. Herbal pharmacopeia is reasonable for thresholds of what is safe to make sure it's being held to an apocopate standard for the product format. Also, there are minor endocannabinoids with different therapeutic resources that are not included in oils.

Public Comment:

Tamara Netzel: Please remember the patient perspective. In a year as a patient it would cost her $8,000-10,000 a year for all her medications from Bristol. Doctors are charging more than $500 for the recommendation, while also billing insurance for their visit. Patients pay $50 and so do doctors, so why is it $500 for a piece of paper with no education (when the pharmacies are required to provide education). Her medications are too costly and there needs to be options for low-income patients. Senator Marsden has said he would work towards getting insurance coverage but last meeting he was talking about taxing the patients more. We also need employment protections for medical cannabis patients to encourage healthy choices.

Tamara Netzel on behalf of Tim McCabe: Why are the doctors for Holstone Medical Groups in Big Stone Gap not willing to work with medical cannabis patients? They aren't aware that it is legal in Virginia.

Elly Tucker: Medical cannabis has changed her life. She thinks we should include botanical products. It should be the whole plant, since homogenized effects the product by including parts of the plant that aren't medicinally valuable and are less costly. We should allow more locations for plants and dispensaries to improve access, especially for low-income patients who can't afford to drive to get their medicine. Child proofing is important but please include options for arthritic patients.

Roger Sillman: He is a patient. For his signed certificate, he went to his PCP of 22 years. She initially agreed to sign it, but her malpractice insurance company said they would drop her coverage if she signed it. Flower should be available for inhalation, as opposed to oral use. He prefers the inhalation vape products from Dharma, but many folks are priced out of that and are still on the illicit market.

Loyd Sawyer: He is a disabled veteran from injuries while serving in Iraq. He prefers botanical products, but found concentrates most effective but not fast acting. Currently he can't afford anything, but ideally he needs 100mg of concentrate a year. At Dharma, that would cost him $1,700 for a 30-day supply which is $20,000 a year. VA disability and Social Security disability are his only source of income. His PCP was not able to provide a recommendation and he had to pay $200 to another doctor, in addition to $50 to BOP. The only way he would be able to afford the medication is by growing his own.

Edward: The email you all sent back regarding certification after registration says two weeks but it seems more like a month at this point.

Conclusion:

Asst. Sec Finley: Any final comments from the workgroup?

Dr. Brown: He would like to thank everyone for their time, especially Dr. Caughron who has taken time out of his busy practice to participate in both this workgroup and the adult use legalization work group.

Mx. Pedini: They have been hearing from patients who registered in October and have not received their cards, which is a concern. They have also received emails that written certifications signed electronically are not going to be accepted. Why was that acceptable for some electronic patient certifications but not others, especially if they are being received through telehealth?

Ms. Juran: They received advice from the Attorney General's office that a manual signature is required. At first, the quality of the signature may not have been as closely monitored. Once they noticed the electronic signature, they reached out to legal counsel and received the advice that a manual signature was required. At that point, they added that to their evaluation for the written certification. With respect to those who applied in October, they have one fulltime employee processing 300-350 every week. It has gone from 3-5 to 14 days. They will adjust their language on the bounce back email to provide more clarity on the timelines. This is a growing pain and they are in the process of hiring a temp, and possibly another full time employee. They are working to get a process in place as soon as possible.

Mx. Pedini: Thank you so much for that clarification. If the appointment is via telehealth and the communication is via PDF, what is a manual certification? Does that mean they must have a captured image signature?

Ms. Juran: It needs to be manually signed, so no computer generated signatures or fonts. It has to be a wet ink signature but then they could transmit it via PDF back to the patient.

Asst. Sec. Finley: Thank you again for all your time and on this important subject.

The meeting adjourned at 1:05pm.

Chat Box:

from Joy Strand to All Panelists: 11:06 AM

I reconnected -- my mute button is still now working. Says I'm muted by the host :)

from Joy Strand to All Panelists: 11:06 AM

Sorroy -- message should say my mute button is NOT working. I'm muted by the host.

from Joy Strand to All Panelists: 11:16 AM

Looks good now - thank you!

from Shannon Spiggle to All Panelists: 11:30 AM

Thank you for addressing patient access. I am a member of the public and just completed the process of applying last week. It was somewhat difficult and very expensive. It will be extremely difficult for indigent members of the community to access the program especially if they have to recertify relatively often. A lot of providers had Medicaid rates, but even those rates were $100. How can someone on Medicaid afford an additional $100 for one prescription in addition to the actual cost of the Marijuana. Thank you again for this hearing and working to help chronically ill patients like myself have better solutions for care.

from Caroline Juran to All Panelists: 11:37 AM

This is caroline juran. I have joined the call but it is not recognizing me as a panelist. Thanks.

from Shannon Spiggle to All Panelists: 12:11 PM

HANK YOU NGISTE!

from Shannon Spiggle to All Panelists: 12:11 PM

Thenk You*

from Shannon Spiggle to All Panelists: 12:11 PM

Wow, I need coffee.

from Antione Hines to All Panelists: 12:26 PM

Yes Hampton Roads

from Antione Hines to All Panelists: 12:44 PM

Reducing Veteran suicides