Meeting Minutes
Virginia Medical Cannabis Workgroup
Meeting Five – November 18, 2020

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 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 was has been a point of discussion. He knows there is a fiscal impact that will require analysis. In terms of reducing stigma, he don't think it changes it. He likes the idea of not having a patient registration but understands why we do.

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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 a handle lot of complicating factors to get registered. The difficulty for patients should be taken into account.

Dr. Caughron: He agrees with increasing the time frame. It is 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 appointment 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 charing 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 in to 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?

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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 is 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 they 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 that 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 expect 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 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 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

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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?

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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?

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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 what 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 the 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 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.

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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.

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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 if 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 effect those in it for the money, and that is not good medical care.

Ms. Abebe: Are there other areas that we cap the number o 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 disagrees with Dr. Caughron's point, if this were better integrated into 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 to it to

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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 issue 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 think 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

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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 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 though 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 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 discussion 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 sig 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 thinking 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 Rorebacher-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 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 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 understand 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 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 Committee 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 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 option, they have been contacted by numerous hospice organizations across 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.

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Mx. Pedini: We want to allow patients to have a consult 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 discussed 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 database and marks the recommendation. In Maryland, the system automatically stipulates that they are recommending for 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 requires providers register to 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.

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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 not 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 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?

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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 license that was 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 cost 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

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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 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.

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Elly Tucker: Medical cannabis has changed her life. She thinks we should include botanical products. It should be whole plant, since homogenized effects the product by including parts of the plant that aren't medicinally valuable and are less costly. We should allowing 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 send back regarding certification after registration says two weeks but it seems more like month at this point.

Conculsion

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 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

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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 relativey 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 prescrption 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

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