COMMONWEALTH OF PENNSYLVANIA

MEDICAL MARIJUANA ADVISORY BOARD

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IN RE: VIRTUAL MEETING AND LIVE BROADCAST

ZOOM

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BEFORE: ALISON BEAM, Chair
Colonel Robert Evanchick, Member
Dr. Janet Getzy Hart, Member
Dr. Denise Johnson, Member
District Attorney John Adams, Member
Bhavinin Patel, Member
Molly Robertson, Member
Dr. Daniel Kambic, Member
Dr. I. William Goldfarb, Member
Shalawn James, Member
Luke Shultz, Member

HEARING: Tuesday, August 17, 2021
10:00 a.m.

LOCATION: Zoom

Reporter: Shannon C. Fortsch

A P P E A R A N C E S

ALSO PRESENT:

Katelyn Maltais, Attorney For Board

Carol Mowery, Esquire

Dr. Denise Johnson

Holly Senior

John Collins

I N D E X

E X H I B I T S

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P R O C E E D I N G S

CHAIR: Good morning and welcome everyone. Thank you for joining us today for another virtual Board meeting.

I would like to call this meeting to order. This is the Medical Marijuana Advisory Board meeting being held at 10 a.m. on August 17th, 2021.

Before we officially get started today I want to take a brief moment to congratulate Dr. William Goldfarb on his reappointment to the Board. He's been with the Board since its inception and was recently re-appointed by the minority leader of the House of Representatives.

Dr. Goldfarb has been a valuable asset to this Board and we appreciate having his institutional knowledge available to us. So thank you so much.

DR. GOLDFARB: Much appreciated. Thank you.

CHAIR: Of course.

Additionally, we have a new Board member joining us today, Dr. Daniel Kambic. Dr. Kambic was appointed by the Speaker of the House of Representatives. Dr. Kambic brings a unique

perspective to this Board as he's an approved practitioner that can certify patients for the medical marijuana program.

Before we move on to role call since it's Dr. Kambic's first Board meeting and we did brief introductions at the last meeting, I wanted to ask Dr. Kambic if he would like to take a moment to introduce himself to the Board.

Dr. Kambic?

DR. KAMBIC: Well, many thanks for putting me on this Board. One of my first questions I had when I was asked to do this was I'm not going to be able to --- or I don't have to give up my private or certified rights because I won't do that. This is helped so many people so dramatically and I just want to make sure we're still in good standing with being able to prescribe.

And, you know, I'm born and raised in Steelton, Pennsylvania which is just south of Harrisburg. So I practice in my hometown. I just started my 39th year. I'm also a program director for the family medicine residency program at UPMC and I've done that for 20 years so to bring docs to our area and train them here and keep them here.

And so I'm still amazed that nobody

told us anything about medical marijuana when I was in med school. And I'm also going to point out that my current residents who graduated top in their class, they haven't learned anything about it either from our med schools which is kind of a shame.

So we make sure we inaugurate all them into the positives of this and this program how well it works in Pennsylvania. And that's a tool for the box to use when they practice also.

So I'm excited to continue this and hopefully I don't let anybody down throwing my two cents in on this too.

CHAIR: You are welcome. We're glad to have you and I think you'll only add to the Board. So I appreciate the perspective.

So now we're going to officially move on to role call.

First is myself, Secretary of Health, here. Colonel Evanchick?

COL. EVANCHICK: I'm here.

CHAIR: Janet Getzy Hart?

MS. HART: Here.

CHAIR: Kalonji Johnson?

Dr. Denise Johnson?

DR. JOHNSON: Here.

CHAIR: David Steffen?

John Adams?

ATTORNEY ADAMS: I am here.

CHAIR: Bhavini Patel?

MS. PATEL: Here.

CHAIR: Molly Robertson?

MS. ROBERTSON: Here.

CHAIR: Dr. Kambic? He is muted but I believe he is here.

Dr. Goldfarb?

DR. GOLDFARB: Here.

CHAIR: Shalawn James?

MS. JAMES: Here.

CHAIR: And Luke Shultz?

MR. SHULTZ: This is Luke. I'm here.

CHAIR: Wonderful. Great.

So legal counsel do we have a quorum?

ATTORNEY MALTAIS: Yes. Confirming we do in fact have a quorum.

CHAIR: Thanks Katelyn. I appreciate it.

The next order of business is to approve the previous meetings minutes. I understand that you all have been actually provided a copy of the meeting minutes from the last Board meeting which was

held on May 18, 2021 which I hope you all had a chance to review.

At this time may I get a motion to approve the meeting minutes from the May 18th, 2021 Board meeting?

DR. HART: I make a motion to approve. Janet Hart.

CHAIR: Thanks Janet.

And do I have a second?

COL. EVANCHICK: Second.

CHAIR: I think I heard Col. Evanchick on that one.

COL. EVANCHICK: Correct.

CHAIR: Okay. Thank you.

Perfect. All in favor of the motion to approve the minutes say aye.

BOARD: Aye.

CHAIR: Is anyone opposed?

Are there any abstentions?

Okay. The minutes from the May 18th Board meeting are approved.

Thank you all.

The next item on the agenda is house bill 1024 which Governor Wolf signed into law on June 30th of this year. The law is now commonly referred

to as Act 44 of 2021. Specifically we would like to use time today to discuss exactly how Act 44 impacts this Board.

So Act 44 gives the Board the authority to continue to present recommendations and finding through written reports that will be submitted to the Secretary of Health. We have highlighted reports to draw attention to the fact that while originally Act 16 of 2016 gave the Board the authority to issue a written report within two years, Act 44 from 2021 empowers the Board to issue written reports.

Therefore, the Board can issue and adopt reports at any time as often as we deem necessary. Act 44 also outlines the recommendations and the findings that the Board shall submit reports on. So as you can see from the slide being presented, the Board is empowered to consider providing recommendations and findings on the four items in blue.

These items include whether to change the types of medical professionals who can issue certifications to patients, whether to change, add or reduce the types of medical conditions which qualify as serious medical conditions under this Act, whether to change the form of medical marijuana under this

Act, and how to ensure affordable patient access to medical marijuana.

Act 44 addresses effectuating recommendations from the advisory Board in addition to the blue here on the slide. At the discretion of the Secretary, the Department of Health can transmit a notice to the Legislative Reference Bureau also known as LRB setting forth the Secretary's rationale for effectuating or declining any recommendation of the Board within 12 months of receipt of the report.

So Act 44 has given this Board a significant amount of authority. And with that being said, we wanted time today to make sure that the items that this Board can consider providing recommendations and findings on including those in blue that we just went over are appropriately assigned to the Board's already established subcommittees for additional visibility and review.

Therefore, we're issuing the following assignments: The Regulatory Subcommittee chaired by Janet Getzy Hart will be responsible for looking into one, whether the change in the types of medical professionals who can issue certifications to patients. The medical review subcommittee chaired by Dr. Denise Johnson will be responsible for the second

item which is whether to change, add or reduce the types of medical conditions which qualify as serious medical conditions under this act. We already have a process in place to address exactly this.

The medical research subcommittee chaired by Bhavini Patel will be responsible for the third item, whether to change the form of medical marijuana permitted under this Act. And the patient and caregiver subcommittee chaired by Molly Robertson will look at how to ensure affordable patient access to medical marijuana.

And the report subcommittee chaired by Luke Shultz is responsible for compiling any reports and incorporating each subcommittee's recommendations and findings accordingly.

So I will leave it up to you and your subcommittees to decide the best way to go about addressing the items that have been assigned to each of the subcommittees. And please remember as Board members that even though you're assigned to a specific subcommittee, you're able to request to participate in other subcommittees that just may be of interest to you. You can do that by reaching out to Holly Senior.

So aside from these new responsibilities that we've assigned to the

subcommittees today, at our last meeting we asked the Board to think about the best ways to use the active subcommittees under --- to further the Board's work. These new assignments will reactivate all of the subcommittees at the time of previous meeting and referred to as the active subcommittees as medical review, the patient caregiver subcommittee and the medical research subcommittee. You will notice these three subcommittees that we've referred to as active previously are bordered on the slide being presented.

It was also decided at the last Board meeting that the chairs of the active subcommittees will provide an update today on what they want to focus on and how they plan to do so. Although we realize that what we just shared by way of the ramifications for Act 44 will likely expand the focuses of the subcommittees, we did want to take a moment today understanding that we asked previously was to have the chairs update us to actually allow the chairs to provide the updates they were planning on providing today prior to receiving any of today's assignments.

So Dr. Johnson I know as chair of the medical review subcommittee you and your subcommittee has a reoccurring responsibility of reviewing the

serious medical condition applications and presenting them to the Board. We also know that you're going to be presenting some of these applications in a few minutes but just wanted to check with you before we go through the other subcommittees to see if there's anything else you wanted to add or share at this time from the medical review subcommittee's perspective.

DR. JOHNSON: Thank you very much Secretary.

I think you have covered it and I think it's covered in sort of our charge so that, you know, we see our role as evaluating these applications for new and changes to the serious medical conditions and then making recommendations to the Board for your consideration.

So that's how our role has been defined. I don't see any modifications at this point so we're just happy to contribute.

CHAIR: Wonderful. Thanks so much Dr. Johnson.

Next is the medical research subcommittee chaired by Bhavini Patel. Bhavini, do you want to provide an update on the subcommittee at this time?

MS. PATEL: Yeah. Thank you

Secretary.

So the subcommittee had a chance to meet and I think again you've also covered everything based on what's outlined in Act 44 in Section 2003.1 related to the research initiative and having a better understanding of how the academic clinical research is taking place and updating the Board on anything that we think is important for you to be aware of.

CHAIR: Thank you Bhavini. I appreciate it.

And finally we have the patient and caregiver subcommittee. Molly, do you have an update to share at this time?

MS. ROBERTSON: I'm going to defer to Luke Shultz to give the update for the committee.

MR. SHULTZ: Okay. This is Luke here.

Up until last evening when we received the information packet for today's meeting the patient and caregiver subcommittee had committed to taking on the task of revisiting adding edible forms of medical marijuana to the program.

I say revisit because I made a presentation on this issue on behalf of the patient and caregiver subcommittee at the February 2019 Board meeting as well as a recommendation to add edible

forms of medical marijuana which was overwhelmingly approved by the Board at that meeting.

However, the recommendation was not able to be considered by the Secretary at that time due to the Board no longer having the authority to make recommendations other than for medical conditions. I would ask that I as well as other members of the patient and caregiver subcommittee who are interested be included as members of the medical research subcommittee since we had previously gathered considerable information on the benefit and value of adding edible forms and could greatly add to the discussion.

The other issue that the patient and caregiver subcommittee wanted to pursue was how to ensure affordable patient access to medical marijuana which we've been now assigned anyway.

Thank you.

CHAIR: Thank you Luke. And I apologize. There are sirens going behind here. So hopefully it's not too distracting.

But in the meantime I do want to reiterate that Luke and Molly and others on the patient and caregiver subcommittee, I think and I don't want to speak for Bhavini but I do think you

would appreciate that participation within the medical research subcommittee to be able to have, I think, to the extent that there was already groundwork laid on some of those topics of concern. It makes a lot of sense to incorporate that into how the medical research subcommittees were moving forward.

MS. ROBERTSON: Yeah, I'd agree.

And I'm happy to share information for that subcommittee's second meeting and happy to kind of review that information and bring it to the table.

MR. SHULTZ: Okay. Thank you.

CHAIR: Thank you so much.

And so now that we've established that all of the subcommittees have been reactivated at this point, at future Board meetings we'll hear an update from the subcommittees from each chair.

The subcommittee updates will be a reoccurring agenda item moving forward and so folks can become aware of all the work going on given the more recent assignments too and we can stay on top of them.

So next we're going to review the qualifying medical conditions for the medical marijuana usage applications. As you all are aware the Board voted to adopt a process for changing,

reducing or adding serious medical conditions and as a result of that we have five applications for you today.

Just as a reminder for everyone of what happens when an application is rejected or approved. An approved application actually comes to me as acting Secretary for consideration. Rejected applications do not.

However, that requester has the ability to request reconsideration by the chair and myself in writing providing the reasons requested for reconsideration. Per this established process upon a grant of reconsideration, the requester will be able to present their case directly to the Board.

If reconsideration by the chair is denied after granting the reconsideration --- I'm sorry. If reconsideration by the chair is denied or after granting reconsideration the request is rejected, then the requesters request will be deemed denied for one year until new scientific or until new scientific evidence is available.

So at this time I'm going to turn things over to Dr. Denise Johnson, chair of the medical subcommittee to lead the discussion on each application.

Dr. Johnson.

DR. JOHNSON: Okay. Thank you very much Secretary Beam and good morning to the Board members.

As Secretary Beam just mentioned, we have a total of five applications that we're going to be reviewing today. All of the Board members should have received these applications electronically in advance of today's meeting and I've had the great honor to chair the medical review subcommittee to present these applications to the Board and offer the feedback from our committee.

I have to say that we have got a very passionate committee that is really committed to make sure that the patients have access to these treatments and really took a lot of deliberation in evaluating these applications. So I'm very proud of the work that they have done.

I'm going to present briefly some of the feedback from our discussions and then invite our committee members to chime in on any other feedback that they had.

The first application that we'll discuss is the application SMC20-0002 for traumatic brain injury or TBI. This is an application request

to add TBI as a qualifying medical condition for the medical marijuana program.

The application was discussed previously at two Board meetings. It was tabled on November 10th, 2020 and also postponed at the May 18, 2021 Board meeting. Our subcommittee got the application and we looked at the reference materials.

There was not a lot of compelling evidence that was presented. There were several concerns that our committee noted. The first is that traumatic brain injury was not defined in any way. It seemed very broad. Many of the forms of TBI also include transient cases would qualify so an acute insult that resulted in some symptoms may qualify the way that this is written.

We also --- there was also a lot of concern about treatment of children, especially after sports injuries. Again, these are transient injuries and as the application is presented might extend to those as well. It also was noted that many cases of TBI would be appropriately treated with medical marijuana if they had chronic pain or other conditions.

We're charged to evaluate the applications as they are presented and our concern for

this TBI application, again was that it was very broad, not well-defined and the evidence that was presented was not very compelling.

We --- Molly, Dr. Kambic, Dr. Goldfarb do you have anything to add to the discussion?

DR. GOLDBARB: I do not. I think you summarized our discussion very well.

DR. KAMBIC: Dr. Kambic and I totally agree also. That was very well done.

DR. JOHNSON: Molly, anything additional?

Okay.

So then speaking then for the medical review committee, I make a motion to reject the application SMC20-0002 for traumatic brain injury as proposed.

CHAIR: All right. Thanks Dr. Johnson.

So Dr. Johnson has made the motion to reject the application as proposed.

Do I have a second?

DR. GOLDFARB: Dr. Goldfarb second.

CHAIR: Dr. Goldfarb okay.

Is there any discussion on the motion?

DR. KAMBIC: Dr. Kambic. I have a

short discussion because I'm new.

The people who proposed this, do we simply tell them it was rejected or do we tell them it was rejected why so they can redefine it or how does this work?

CHAIR: Sure. I'd be happy ---. I actually don't know if the medical marijuana program staff might be the best to speak to how it's communicated to individuals who actually submitted the application.

Holly or Katelyn?

MS. SENIOR: Sure Secretary. This is Holly.

So typically when the application is rejected, they receive a letter letting them know that it was rejected. There is not specific information in the letter as to why it is rejected. However, they are able to access Board meeting minutes from the Board of when that happens to may have been discussed to kind of go through departments and determine what may have been the concerns.

MR. COLLINS: And Secretary this is John Collins. I also want to have counsel for the Board comment on this topic as well, please.

ATTORNEY MALTAIS: I was going to say

exactly what Holly said. These meeting minutes once we get the transcript back they'll become available on the Board's website and see the submitted applications they will be able to review the meeting minutes, see the comments that were made by the Board, what there are concerns for and then from there that will help them to cure any future requests should they wish to resubmit an application.

CHAIR: Great.

Dr. Kambic is that helpful?

DR. KAMBIC: Yeah I just --- when we had the discussion that some of these need to be more clearly defined and I just didn't want our Board to have a reputation of just saying no it's a slam dunk. Don't even like, you know, try again.

We just needed it a little more clearly defined because the discussion on this one was we really didn't want people in the childhood or adolescent applying for this for a concussion. But people that were older perhaps, you know, there is definite need for them.

And I just ---. I didn't know how that got transmitted back on why it didn't go through. That's yeah, that was --- I'm just new to the process. So I --- that's what information I was asking.

CHAIR: That's helpful. Thanks Dr. Kambic.

MR. SHULTZ: This is Luke. I have a question. It sort of relates to what Dr. Kambic just mentioned.

Can these applications be approved by the subcommittee conditional to say excluding pediatric patients or just in a medical research protocol at the research part of our program or would that take a change in the process of how the applications are accepted?

DR. GOLDFARB: I don't know what legal would say but I would be opposed to that as being too broad and I think it's a for lack of a better phrase, a slippery slope. I'd rather see these applications be accurate and focus on a clinical condition and not give blanket approval and make some other submission.

ATTORNEY MALTAIS: So the Board ---.

MS. ROBERTSON: I'm not sure I understood that Dr. Goldfarb. This is Molly.

DR. GOLDFARB: What parts didn't you get, Molly?

I don't want to give conditional approval and then wait for additional submission that may not be adequate.

MS. ROBERTSON: Oh okay. I understand.

So I do think though Luke brings up a good question in that is there any room to approve any serious medical conditions for research purposes only.

COURT REPORTER: I can't hear you.

CHAIR: It's really difficult to hear you.

ATTORNEY MALTAIS: Is this any better?

CHAIR: That's not very much.

ATTORNEY MALTAIS: I'm sitting as close to my screen as I can. I apologize. Is this getting better?

CHAIR: It's a little better yes.

ATTORNEY MALTAIS: Okay.

So under the act the Board has the authority to change, add or reduce serious medical conditions. So arguable under that authority, the Board could approve a serious medical condition just for the purposes of research.

It can limit the use of --- it can limit the parameters of the condition. Of course that's all subject to approval by the Secretary power.

And I will say the motion that we're addressing right now is to reject the application. So

that motion needs to be addressed on the table first. And from there further motions could be made.

MR. SHULTZ: This is Luke again.

One of the reasons I'll bring that up is if an application came through that was otherwise acceptable to the subcommittee except in a concern about allowing pediatric patients to use that qualifying condition, it would be a shame for the adult population for that application to get denied simply because it would include the pediatric population.

So I'd hate to see applications be rejected just outright because of one small concern which could be a conditional issue.

DR. JOHNSON: Luke, this is Dr. Johnson.

Thanks for your comment there. But I do want to note that the pediatric population was not the only reason. So there was a concern that the TBI diagnosis is too broad. And so it doesn't discriminate if cases are acute. And the acute cases are really not appropriate for medical marijuana treatment.

MR. SHULTZ: Yeah I understand.

I'm just talking at it in broad terms

going forward with future applications. I'd hate to see them disqualified just for one aspect that we could easily add as a condition for the approval.

CHAIR: Luck, I'll just say I appreciate the raising of the concern.

Are there any other discussions on this specific motion to reject the TBI application?

All right. Well, seeing no more discussion we'll take a vote on the motion. And so as I call your name if you could either approve, reject or abstain the vote on the motion and just a reminder this is the motion to reject the application.

Colonel Evanchick.

COL. EVANCHICK: I reject it.

CHAIR: Janet Getzy Hart.

DR. GETZY HART: I vote to approve the motion.

DR. JOHNSON: I'm sorry just a point of clarification, Secretary. I just want to make sure everyone is clear if you're rejecting the motion or rejecting the application.

CHAIR: It's an approval of the motion to reject the application. Katelyn correct me if I'm wrong on that. But I think these are considered approvals or yeses because the motion was to reject

the application.

Is that correct?

ATTORNEY MALTAIS: Yes. An approval would be a yes to reject of the application.

CHAIR: Okay.

And just for folks who couldn't hear Katelyn. She said an approval is a yes to reject the application.

And so just to make sure I want to be abundantly accurate Colonel Evanchick I believe that you voted yes then on that?

COL. EVANCHICK: I approve to reject the motion, yes.

CHAIR: Great. Thank you.

And Janet I believe you actually stated the entire sentence of I vote to reject the motion. So I think we've got the first two.

Dr. Johnson, hopefully that has clarity.

DR. JOHNSON: Yes, thank you.

CHAIR: And Dr. Johnson just to make sure you also are a vote to approve the rejection.

Correct?

DR. JOHNSON: Correct.

CHAIR: Thank you.

Kalonji Johnson. I don't know if he joined.

And did David Steffen join?

MR. STEFFEN: Yes.

I approve to reject the motion.

CHAIR: Thank you.

John Adams.

ATTORNEY ADAMS: I approve to reject the motion also.

CHAIR: Bhavini Patel.

MS. PATEL: I approve to reject.

CHAIR: Molly.

MS. ROBERTSON: I approve.

CHAIR: Dr. Kambic.

DR. KAMBIC: Approve.

CHAIR: Dr. Goldfarb.

DR. GOLDFARB: Approve.

CHAIR: Shalawn James.

MS. JAMES: I approve to reject.

CHAIR: And Luke Shultz.

MR. SHULTZ: I'm going to abstain.

CHAIR: Okay.

All right. And so Katelyn check me on my math here. I have 10 approvals and 1 abstention.

Yes?

ATTORNEY MALTAIS: Yes.

CHAIR: I think you said ---. I'll take a thumbs up as the affirmative.

Great. And so we can now proceed with the next application for review Dr. Johnson.

DR. JOHNSON: Thank you, Secretary.

So the next application that we're going to review is application SMC20-0004 which is for hepatitis.

This request --- this is an application request to add hepatitis as a qualifying serious medical condition for the medical marijuana program.

Our subcommittee reviewed the application and the supporting reference materials and it was noted that there is a benefit for treatment of chronic hepatitis with medical marijuana based on the mechanism of action and the outcomes that we've seen in these cases.

Treatment for acute hepatitis, however, is inappropriate and the application did not distinguish between acute and chronic hepatitis. As we were charged to evaluate the applications based on how they were presented, our committee felt that medical marijuana was inappropriate for treatment of

acute hepatitis.

I'll leave space there for Molly, Dr. Kambic or Dr. Goldfarb to add any comments.

DR. GOLDFARB: No additional comment.

DR. KAMBIC: No additional comments.

MS. ROBERTSON: So I have one.

Maybe I'm going out of order here but I would like to make a motion for the Board to approve chronic hepatitis.

It seems to me that as you said the problem with the application was it said hepatitis and acute hepatitis isn't appropriate. But I believe that we all agree that chronic hepatitis is. I don't know why we would wait to make them resubmit to add one word to an application and I believe the Board has power to approve chronic hepatitis.

CHAIR: So given that motion I'm going to a little bit lean on counsel here for the right process by way of handling Molly's motion.

ATTORNEY MALTAIS: Can you hear me okay Secretary?

MS. SENIOR: Katelyn was actually dialing back in.

ATTORNEY MALTAIS: It shows that I'm in right now. I think I'm in the waiting room.

MS. SENIOR: No you're in the meeting Katelyn.

Katelyn.

ATTORNEY MALTAIS: Okay. For some reason the audio on my phone isn't working.

Can you hear me?

CHAIR: We can.

You're really close to the screen. I think we've got to change the ---.

ATTORNEY MALTAIS: Perfect.

So I think a motion's on the table now but I believe at the time Dr. Johnson was opening up for further discussion on the application as submitted. So I don't believe we were at the point where the Secretary had asked for a motion to be made.

Am I correct in understanding the process?

CHAIR: Correct.

We were still at the point of each subcommittee member was, I think, offering their comments on their review of the application.

ATTORNEY MALTAIS: And Molly given that, would you be okay with the rest of the subcommittee getting the chance to give their thoughts before a motion's made?

MS. ROBERTSON: Okay.

Yeah, sorry.

DR. JOHNSON: So Katelyn, this is Dr. Johnson here.

So the rest of the subcommittee gave their thoughts. And we gave the feedback from the subcommittee. I think the point where we are now is to recommend a motion.

And I guess we want to know what the options are. Do we make a motion strictly on the application that as is proposed or if there's room to make a modification before that motion is made?

ATTORNEY MALTAIS: Sure.

So at this point Dr. Johnson we'd be making a motion whether to accept or reject the application as presented.

DR. JOHNSON: Okay. Great.

Okay. So based on the feedback from our committee and --- I would make a motion then to reject the application SMC20-0004 which is for hepatitis as proposed.

CHAIR: All right.

So Dr. Johnson has made the motion to reject SMC20-0004 as an application.

Do we have a second?

DR. GOLDFARB: Second. Goldfarb.

CHAIR: The second is Dr. Goldfarb.

Any discussion on this discrete motion to reject?

MS. ROBERTSON: So I have a question.

Do I make another motion to approve chronic hepatitis, do I make a motion to amend the application or what do I do here?

CHAIR: Katelyn.

ATTORNEY MALTAIS: So at this point there's currently a motion on the table. This motion needs to be addressed and disposed of before another motion can be made.

MS. ROBERTSON: Okay.

CHAIR: Any other discussion on the motion.

All right. So seeing no more discussion we'll take a vote on the motion as we just did. I'm going to go through and again this is the motion to reject the application SMC20-0004 for hepatitis.

Colonel Evanchick.

COL. EVANCHICK: I vote yes to reject.

CHAIR: Janet Getzy Hart.

DR. GETZY HART: Yes to reject.

CHAIR: Dr. Johnson.

DR. JOHNSON: Yes to reject.

CHAIR: Katelyn should I continue to seek from Kalonji knowing that he's not here?

ATTORNEY MALTAIS: No that's fine. You don't have to.

David Steffen?

MR. STEFFEN: I vote to reject.

CHAIR: John Adams.

ATTORNEY ADAMS: I vote yes to reject.

CHAIR: Bhavini Patel.

MS. PATEL: Yes to reject.

CHAIR: Molly Robertson.

MS. ROBERTSON: Yes.

CHAIR: Dr. Daniel Kambic.

DR. KAMBIC: Yes to reject it.

CHAIR: Dr. Goldfarb.

DR. GOLDFARB: Yes.

CHAIR: Shalawn James.

MS. JAMES: Yes.

CHAIR: And Luke Shultz.

MR. SHULTZ: Yes to reject.

CHAIR: All right.

We have 11 approvals or yeses.

Katelyn or Holly check me on my math.

ATTORNEY MALTAIS: Eleven (11) also.

MS. SENIOR: Correct.

CHAIR: Great.

Dr. Johnson let's proceed onto the next application for review.

DR. KAMBIC: Molly --- would this be the appropriate time for Molly to make her motion?

MS. ROBERTSON: I feel it.

Should I do it?

CHAIR: Katelyn, I'll use you as a guide here.

ATTORNEY MALTAIS: So since Board voting on applications that have been submitted for serious medical condition, if the Board would like to on their own doing recommend the addition of a serious medical condition, that's something that would be best achieved through the five committees and then issuing a report to be approved by the Board to be sent to the Secretary.

MS. ROBERTSON: What?

ATTORNEY MALTAIS: So the Board has the authority under the act to suggest reducing, adding or changing serious medical conditions. So the Board, if the Board feels that that condition should be added as a serious medical condition, that would be

something that would be prepared in a report and that would be adopted by the Board at a future Board meeting. And if that report is adopted, it goes to the secretary.

DR. GOLDFARB: Katelyn, Bill Goldfarb.

If the Board --- if the subcommittee had already felt that they were comfortable approving chronic hepatitis, it seems like a convoluted way to move forward.

Couldn't Molly just make that motion now and have the entire Board vote on it?

MS. ROBERTSON: I mean we're talking about one word.

DR. GOLDFARB: One word that ---.

ATTORNEY MOWERY: This is Carol. I'm going to jump in and so Katelyn isn't the only bad guy here. I'll add a second label opinion.

You know you have two processes here to get new medical conditions added. One is via an application submitted from the public or from a practitioner. And the other is now the new statutory method through issuing a written report under the statute.

So I agree 100 percent with Katelyn that at this point you are limited to approving or

rejecting applications as submitted. And if the Board would like to move forward with recommending the addition of a serious medical condition outside of an application, it needs to do it through a written report under the statute.

MS. ROBERTSON: So is there anywhere in the law here that prevents us from making a motion to amend the current application?

ATTORNEY MOWERY: It's not spelled out in the law. It's the procedure that the Board itself implemented was to accept an application and to approve or reject that application as submitted.

MS. ROBERTSON: So again, I'm going to ask.

Can I make a motion to amend the application to say chronic hepatitis?

ATTORNEY MOWERY: And that's in my opinion also something that you can't do today. You could later amend the process that has been created for review of applications. But at this point the process is established and we have to follow it.

In addition, I'll just throw out there that there was recently a change to the Sunshine Act that requires agencies to list their agendas 24 hours in advance of any public meeting. And anything that's

no on the agenda cannot be considered.

That's the new change to the law. That's --- so if our agenda said that the Board was going to consider hepatitis not chronic hepatitis, I don't --- even if you took action today I don't think it would be valid.

MS. ROBERTSON: Okay.

MS. JAMES: This is Shalawn.

I think my confusion is is that when we voted I was under the impression that Molly was then going to be able to make a recommendation or a --- to ask to add the chronic part to it after we voted to reject it as it was. And then now that's not the case.

I think that's where the confusion is coming in. It is for me.

ATTORNEY MOWERY: So the Board is allowed to do that in the future. Given the process now by the law, the Board has the authority now to address that submission. And that would be done through the process set forth in the act which is through a written report presented to the Secretary.

ATTORNEY MALTAIS: And I'll say ---. I will add as Carol mentioned the process for reviewing these applications was established by the Board.

So if the Board would like to discuss at a future Board meeting amending that process, changing that process, that's certainly something the Board could discuss. But today this is the process for how to vote for these applications.

DR. JOHNSON: Thank you for that Katelyn and Carol. I think that, you know, as Molly has indicated our subcommittee thoroughly discussed these and, you know, feel strongly about the chronic hepatitis is appropriate but also feel very strongly that acute hepatitis is not appropriate. And we were charged to look at these applications as proposed.

And so now understanding the process I believe that our subcommittee then can go back and look at these and make a recommendation for going forward. That will shorten the process then for these applicants going through the whole process again if that's something that we've already discussed.

But it seems now that we understand the process then would be in our subcommittee to make that report to present then to the Secretary and I guess that would be for the next Board meeting.

Is that correct?

ATTORNEY MALTAIS: Yeah.

So the report would be prepared and

under the act the report has to be adopted by the Board at a Board meeting. As long as that report is adopted by the Board, that report then goes to the Secretary for consideration.

MS. ROBERTSON: Just so I'm understanding.

So the medical subcommittee would make a report to approve chronic hepatitis, or is the medical subcommittee making a report to change the process to allow us to do this?

ATTORNEY MATLTAIS: So I believe Dr. Johnson's question was specific to a report to add that as a serious medical condition.

Is that correct Dr. Johnson?

DR. JOHNSON: That is correct.

Understanding the new statute it seems that we are able to take that action within our committee.

ATTORNEY MALTAIS: Yes.

So your committee would work with the report subcommittee and work to prepare a report recommending that addition of the serious medical condition to be presented to the full Board at the Board meeting.

MS. ROBERTSON: I don't know. This

whole thing seems a little backwards and upside down to me. I don't ---. I mean I will do whatever you need me to do but we are talking about one word. The committee itself has already discussed and basically agreed that chronic hepatitis is an approvable serious medical condition.

And now we are going to go back to the committee to make a report to go to the report committee to submit to the Board. This seems weird and kind of convoluted and I'm not happy about it.

But I'll do what I need to do.

MR. SHULTZ: This is Luke.

One thing that I'm a little fuzzy on here with this discussion is according to the law as I read it the reports are to be issued to the Governor, the Senate and the House of Representatives. It doesn't say that it goes to the Secretary of Health.

Are you telling me that the Secretary of Health can only consider any Board recommendations if it's in an approved report?

ATTORNEY MALTAIS: So the law says that these reports that the Board prepares need to be adopted at a public meeting. And then after receiving a report from the advisory Board, at the discretion of the Secretary, she can transmit a notice for

legislative reference bureau for publication in the bulletin effectuating that recommendation.

DR. KAMBIC: This is Dr. Kambic.

I mean I think we're beating around the bush here a little bit. But isn't the most efficient way of handling this is once again sharing the decision feelings of the Medical Advisory Board to the certifying physicians who proposed this that the reason the committee denied it was we would really like the use only with chronic hepatitis instead of acute.

And, therefore, they could reapply again and put chronic in front of the hepatitis C or generally just hepatitis and that would accelerate the reevaluation of the medical subcommittee which has already tipped their hat and said that we probably will approve chronic hepatitis just not acute.

So wouldn't that be the fastest and more efficient way of doing this to get to the end goal which is allow hepatitis --- chronic hepatitis patients to have access to marijuana?

CHAIR: So Carol and Katelyn I'll defer to you. But I think that it seems like the question before us is, what's the most efficient way to have the medical review subcommittee have in front

of it, again, the ability to actually review chronic hepatitis as a condition.

And so I think to Dr. Kambic's point, if it's going back to the submitters using the minutes from this meeting to educate or and give context to any sort of communication on the vote, I just I think the intension here from the Board is to allow the medical review subcommittee to again have in front of it the opportunity to discuss chronic hepatitis.

And I'm wondering what the most efficient way we can recommend to this Board to have that happen maybe and also within the parameters of the statute and processes of the committee?

ATTORNEY MALTAIS: With the current process that's in place there's two routes that it could go. The requester can resubmit their application and change it to chronic hepatitis or the Board can use its statutory authority to prepare a report recommending the addition to chronic hepatitis as a serious medical condition.

ATTORNEY MOWERY: So I agree with Dr. Kambic that having the applicant resubmit. If that's the question which is faster, the Applicant resubmission is faster. It's going to beat the report on the Board by even if the Secretary acted

immediately after the meeting, you still have a couple of weeks to get publication in the bulletin.

So it's going to win by a couple of weeks.

MS. ROBERTSON: So Carol would it be appropriate for our staff when we do communicate the motion to reject on hepatitis to again bolster that communication with meeting minutes or a communication from Dr. Johnson as chair of the medical review subcommittee encouraging those applicants to resubmit with the qualification of chronic hepatitis rather than just hepatitis or what's the most appropriate way to make sure the communication gets back to the requesters?

ATTORNEY MOWERY: I'll defer to Katelyn on this cause I'm not 100 percent versed on the Board's procedure, but I don't see a problem with conveying to the applicant the reason the application was rejected. And I say that because it will take several weeks for us to even get transcripts of this Board meeting and then post it to our website. So there'll be a time delay there if you don't want to wait on the transcripts it would just be best to convey the reason to the applicant.

ATTORNEY MALTAIS: Yeah, I agree with

Carol. We can certainly discuss after the meeting about how to change and how we respond to the applicant offline and conveying to that potentially the main reasons why the Board rejected their application.

MS. ROBERTSON So can we also take a look at perhaps going forward if there are applications like this again that the medical subcommittee is reviewing that --- is there a way to change this process to perhaps allow us to amend the application prior to the Board voting on it?

ATTORNEY MALTAIS: So the process that the Board currently has in place, that process will need to be amended by a majority vote of the Board. The Board can certainly discuss changing that process. But that would have to be conducted at a future Board meeting and we would need to give notice of that at the time to add that to the agenda because as Carol mentioned because of the new Sunshine Act amendment, if it's not on the agenda posted 24 hours before, we can't take action on it.

MS. ROBERTSON: So I would like to have us take a serious look at that for our next meeting. Because I find this --- and I don't mean to be disrespectful but this is --- I find it ridiculous.

I mean we've looked at the application. We all agree and we can't do anything about it because of that.

So if there's something that we can do to amend our process, because the bottom line is patients are waiting. And every time, you know, we look at these things and there's one word difference and I mean they have to reapply. I mean and I don't know it just seems --- well, I've said it ridiculous.

If we can change this I think we should take a serious look at it.

CHAIR: So Molly completely appreciating that, I wonder what you would think of a two-fold ask coming out of this. And it's going to be a combination of maybe Dr. Johnson and Katelyn.

One is on changing the communications to the applicants to give further context around any qualification that they may want to reconsider if they want to resubmit their application or the like.

And so how we're going to give context to the applicants that if they want to put certain qualifiers within a resubmission that they could actually prevail.

The second is actually changing the serious medical condition application review process. And I think this would be done within the medical

review subcommittee. That while they're doing the debate, if it emerges that there is a nuance to the application that the submitters did not include but that the committee would be more likely to recommend to the committee approve and then the Board approve it as a serious medical condition that there be some ability to speak to the applicants almost in the meantime.

I think that's --- you're trying to put another opportunity for that communication to happen within the review process.

Is that fair Molly?

MS. ROBERTSON: That is correct.

CHAIR: So would ---. If I can ask Dr. Johnson and Katelyn to work together on those two pieces and report back at the next Board meeting while realizing that there will likely be action taken on the communication to specifically the hepatitis applicant in the meantime that would be indicative of this additional context around the rejection.

Does that sound right to everyone?

DR. JOHNSON: That's great Secretary Beam. I think that --- yes, I'll work with Katelyn to come up with what our communication will be specifically to this applicant.

But I think as you point out, we really need to define the process going forward not only in terms of notification of a rejected application but what our process will be within the committee in terms of whether or not we would be communicating or adjusting the application.

So I think that will be something that we discuss within the committee and come up with a recommendation and also bring it to the full Board so that the full Board would approve that new ongoing process.

MS. ROBERTSON: So I just have another question perhaps.

The --- like if we have an application --- well let's just say TBI like we have the application. Let's say we all wanted to approve that but not for pediatrics. So wouldn't that be the same like we couldn't actually do that like right now.

According to what they're saying the process is, we can't --- if that application didn't say TBI for adults only, we couldn't even act on it.

ATTORNEY MALTAIS: That's correct.

The current process is to vote to accept or reject the application as submitted.

And just to clarify, Secretary, if I

may briefly cause I think there is some confusion around this for chronic hepatitis going forward.

That application can be resubmitted to be chronic hepatitis. However, the Board would still need to vote on it and that wouldn't be able to be done until the next regularly scheduled Board meeting in November.

CHAIR: Great Katelyn, I appreciate that.

Okay. So with that I think we've got some marching orders for improving the communication back to the applicant with context and then also allowing us to review the new process at our follow-up Board meeting as to how there could be a change in the serious medical condition application review process.

So with that let's proceed to the next application for review.

DR. JOHNSON: Okay. All right.

So the next application that we have is application SMC21-0001 which is for hepatitis C. Just to be brief we reviewed this. We reviewed the supporting documentation, the evidence and the same as for hepatitis, for patients with chronic hepatitis C, there certainly can be a benefit with medical marijuana. But it is inappropriate for acute

hepatitis C. And we were charged to receive the applications as they were presented.

Our subcommittee members Molly, Dr. Kambic, Dr. Goldfarb any additional comments?

DR. GOLDFARB: No additional comment.

DR. KAMBIC: No additional comments.

DR. JOHNSON: Okay.

So speaking then for the medical review subcommittee I make the motion to reject the application SMC21-0001 for hepatitis C as proposed.

CHAIR: All right. Dr. Johnson has made the motion.

Do we have a second?

DR. KAMBIC: Kambic second.

CHAIR: All right. Dr. Kambic second.

Any discussion on the motion?

All right. So seeing no more discussion we will take a vote on the motion. Again, this is the motion to reject SMC21-0001 for hepatitis C.

Colonel Evanchick.

COL. EVANCHICK: Approve.

CHAIR: Janet Getzy Hart.

DR. GETZY HART: Approve.

CHAIR: Dr. Johnson.

DR. JOHNSON: Approve.

CHAIR: David Steffen.

MR. STEFFEN: Approve.

CHAIR: John Adams.

ATTORNEY ADAMS: Approve.

CHAIR: Bhavini Patel.

MS. PATEL: Approve.

CHAIR: Molly Robertson.

MS. ROBERTSON: Approve.

CHAIR: Dr. Kambic.

DR. KAMBIC: Approve.

CHAIR: Dr. Goldfarb.

DR. GOLDFARB: Approve.

CHAIR: Shalawn James.

MS. JAMES: Approve.

CHAIR: And Luke Shultz.

MR. SHULTZ: Approve.

CHAIR: Total of 11 approvals. Katelyn or Holly any corrections?

ATTORNEY MALTAIS: No. I have 11 myself.

MS. SENIOR: That's fine.

CHAIR: Okay.

So now we actually --- sorry. With that the motion is approved. And with that we can

proceed to the next application for review.

DR. JOHNSON: The next application is SMC21-0002 which is for chronic insomnia refractory to standard therapies.

Our subcommittee discussed this and looked at the evidence. We found no compelling supportive evidence for chronic insomnia. There was further concern that the patient with insomnia need to be appropriately evaluated and treated for their root cause. But we just found really no good evidence that medical marijuana would be helpful for these patients.

So Molly, Dr. Kambic, Dr. Goldfarb any additional comments?

DR. GOLDFARB: No additional comment.

DR. KAMBIC: No additional comments.

DR. JOHNSON: Molly, anything to add?

MS. ROBERTSON: No.

DR. JOHNSON: Speaking for the medical review subcommittee then I would make a motion to reject the application SMC21-0002 which is for chronic insomnia refractory to standard therapies as proposed.

DR. GOLDFARB: Second, Goldfarb.

CHAIR: You beat me to it. Thank you Dr. Goldfarb. I appreciate it. We have a second.

Is there any discussion on the motion?

Seeing no more discussion we will take a vote on the motion.

Colonel Evanchick.

COL. EVANCHICK: Approve.

CHAIR: Janet Getzy Hart.

DR. GETZY HART: Approve.

CHAIR: Dr. Johnson.

DR. JOHNSON: Approve.

CHAIR: David Steffen.

MR. STEFFEN: Approve.

CHAIR: John Adams.

ATTORNEY ADAMS: Approve.

CHAIR: Bhavini Patel.

MS. PATEL: Approve.

CHAIR: Molly Robertson.

MS. ROBERTSON: Approve.

CHAIR: Dr. Kambic.

DR. KAMBIC: Approve.

CHAIR: Dr. Goldfarb.

DR. GOLDFARB: Approve.

CHAIR: Shalawn James.

MS. JAMES: Approve.

CHAIR: And Luke Shultz.

MR. SHULTZ: Approve.

CHAIR: Thank you. We have 11

approvals.

Holly, Katelyn, same?

MS. SENIOR: Same, Secretary.

CHAIR: All right. And with that the motion to reject SMC21-0002 passes.

We will proceed with the next application for review Dr. Johnson.

DR. JOHNSON: The next application is SMC21-0003. This is for major depressive disorder refractory to standard therapy.

Our subcommittee reviewed the supporting evidence and really was supportive of medical marijuana for anxiety but could not find any good supporting evidence that there's any benefit for depression or that based on the mechanism it wouldn't make the depression worse.

There's also no supporting --- no support from any other states that are certifying medical marijuana conditions. And so we really saw no benefit to add this condition.

Molly, Dr. Kambic, Dr. Goldfarb any additional comments?

DR. GOLDFARB: No additional comments.

MS. ROBERTSON: No.

DR. KAMBIC: No additional comments.

DR. JOHNSON: Okay. Speaking for our committee then I make a motion to reject the application SMC21-0003 which is for major depressive disorder refractory to standard therapies as proposed.

CHAIR: Do I have a second?

DR. KAMBIC: Second.

CHAIR: Kambic. Thank you so much. So Kambic seconds.

Any discussion on the motion?

All right. Seeing no more discussion we'll take a vote on the motion.

Colonel Evanchick.

COL. EVANCHICK: Approve.

CHAIR: Thank you.

Janet Getzy Hart.

DR. GETZY HART: Approve.

CHAIR: Dr. Johnson.

DR. JOHNSON: Approve.

CHAIR: David Steffen.

MR. STEFFEN: Approve.

CHAIR: John Adams.

ATTORNEY ADAMS: Approve.

CHAIR: Bhavini Patel.

MS. PATEL: Approve.

CHAIR: Molly Robertson.

MS. ROBERTSON: Approve.

CHAIR: Dr. Kambic.

DR. KAMBIC: Approve.

CHAIR: Dr. Goldfarb.

DR. GOLDFARB: Approve.

CHAIR: Shalawn James.

MS. JAMES: Approve.

CHAIR: And Luke Shultz.

MR. SHULTZ: Approve.

CHAIR: We have 11 approvals.

Katelyn and Holly, yes?.

MS. SENIOR: Confirmed, Secretary.

CHAIR: Thank you. I appreciate it.

And with that the motion to reject SMC21-0003 passes.

All right. So actually at this time thank you all for your patience with that. That was really good dialogue too and I think it will put us on a better spot moving forward with future SMC serious medical condition applications.

So I greatly appreciate that and all of the work of Dr. Johnson and the medical review subcommittee. Really, really appreciate that.

So at this time I'm going to actually turn things over to John Collins, Director of the

Medical Marijuana program for an update.

John Collins.

MR. COLLINS: Yep. Thank you Secretary and good morning everyone.

We're going to cover a number of topics here. The first one will be focused on how the program is progressing especially since our last Board meeting.

The next three are focused on affordable patient access and then a couple comments on where the research program is and what our regulatory focus has been.

Next slide. Here are the metrics that are reported out on a continuous basis. Referencing our last report at the last Board meeting, the program continues to grow dramatically. Most notably here is 14 million patients having visited dispensaries since the start of the program and over 40 million products dispensed.

During the last Board meeting I noted that I expected us to be for dispensary sales at two billion and that's exactly where we're at. And things are progressing very nicely. Good cooperation with all stakeholders in helping us to meet ever growing market demands.

Next slide please. The next series of slides is going to focus on patient purchasing activities. One of the cohorts of affordable patient access is of course the price of the product.

As I mentioned during the last Board meeting one of those other components happens to be the expense incurred in not only getting certified but the travel time and the commitment that needs to be made by our patients in getting to their physician-guided pharmacist dispensed medication.

Next slide. This is an again very informative look at where the point of sales are going. This represents what purchasing trends have been. You're looking at two illustrations, one overlaying the other. The line itself represents from the beginning of the programs. So that indicates that we have just met the two billion dollar number in terms of dispensary sales program to date.

And also most notably for the last reported month, a total which should be July here, we have exceeded $120 million a new record for the program for a standalone month.

The next thing that we're going to look at is, you know, what does the product mix look like.

Next slide please. So the product mix continues to move towards less expensive items. Also items where there continues to be a ready supply of product and that goes to the affordability of the product. So dry leaf is the green line at the top and it's continuing to grow at a small incremental rate.

Next we're going to look at how those dry leave purchasing trends specifically focusing on that particular product and overlaying pricing trends not only at the retail meaning the dispensary counter but for the first time looking at what the wholesale pricing trends have been.

Next slide please. Next slide please. This represents dry leaf sales alone. So you can see the upward movement reflected in the product mix slide previously. Also at the bottom you see the number of operationalized dispensaries meaning the locations to which are patients are able to see and be dispensed their practitioner guided medication.

The 129 number for the number of dispensaries available to patients has increased by two since this report was created. So we're currently at 131 and continuing to grow.

Next, we're going to look at what the retail pricing trend has been over the same time

period.

Next slide please. This illustration points the downward trend which is very encouraging for dry leaf sales. Again, this is the highest volume, highest mixed product meaning the product generally selected for the majority of purchases and pricing trends continue to climb around seven percent.

Just a point in clarification because at the last meeting Secretary this got picked up incorrectly. So let me clarify.

This trend is for the reported period not from the beginning of the program. So we've seen about a seven percent reduction overall since January of 2020 for this particular product. As I noted previously, it needs to continue to fall.

We have multi-state operators participating in this program. We continue to be encouraged by point of sale discounts, most notably to veterans and to senior citizens and those on assistance programs. But it needs to fall more.

Now we're going to look at what the impact of wholesale pricing has been. This means the price that the dispensaries are paying from our grower processors, as we've been adding more grower processors, you would expect pricing to fall due to

competition in that space as well.

So next slide please. Here you see with the upper line a rate of decline not quite as steep as what we're seeing at the retail counter if you will. And because of that it raises some concern.

The number of operationalized grower processors between January and today has continued to grow, but pricing is kind of flat. And that's, Secretary, very surprising to see when looking at other markets in other states for this exact same permittees.

Next slide please. To kind of tease out the actual trends, we can see the retail price trend at the top reflective of an ongoing decline as more dispensaries are opening.

Point being, more outlets are creating more competition, more demands for service. Patients of course can go anywhere they want. Dispensaries can buy from any grower processor. Any grower processor can sell to any dispensary in the Commonwealth. Consequently you would expect that to happen.

I'm also expecting to see a similar decline not yet evidenced in the data with the wholesale pricing trend. We're not seeing yet the competition that we were looking for in this space and

we'll continue to carefully monitor this going forward.

Next slide. Now understanding the prior illustrations were trends, these are actual data points. So when we look at the resale price of dry leaf on a quarter over quarter basis, you can see some upward and downward movement which is expected either based on bulk purchases for a lot of new dispensaries as they stock their shelves so to speak.

And we're also seeing a very encouraging trend with the last data point, Secretary, with wholesale pricing trends. That represents about a seven percent reduction from the January starting point. But that line needs to continue to go down.

Next slide. Next we're going to look at approved patient access. One of the benefits, Secretary, of Act 44 has been the continuance of a particular waiver that allows for a lot of flexibility both for approved practitioners in our program and patients which is the setting aside now permanent removal with requirement rate in-person certification.

Now that does not eliminate the need to have the patient records in hand when issuing a certification for an approved practitioner just for clarity, but it makes it much, much easier to make a

larger group of practitioners available to patients. Meaning medical locations tend to follow population. Let's take a look at that in the next slide please.

This is an illustration. Actually here we're looking at two different shots. So the blue columns represent the number of approved practitioners per county. And this information is found on our website. The information is presented as the list of approved practitioners by county but this is an illustration that basically points out with the top line at about 80 percent of all of our approved practitioners earned about a half a dozen of accounts.

Now that probably correlates very well with the population without regard to number of patients but the population as we would expect to see as with any other service provider is those entities tend to follow market demand meaning where the patients are is generally where the medical institutions are.

That stated it becomes very difficult, for example, if you're in Perry County and chose to see a physician in Philadelphia to issue your certification, that's your choice. But that in the past prior to the waivers, implemented March of 2020 would require you to drive there. So that is no

longer the case.

The other benefit that isn't so clear on this slide is we have specialists within this program. Those specialists are noted on our approved practitioner list. So should a particular patient let's say in Pike County chose to seek a specialist or a sub-specialist in this space, this also allows them to access that medical practice if that medical practice wishes to participate in doing this type of certification.

If you take a look at the next slide it will be a little bit more evident how beneficial Act 44 of this year is for patients. Next slide please.

The next slide is a heat map. This shows the relative perspective of practitioners. About 85 percent of all of our practitioners self identified the remainder under their right to do so choose not to be on the published list. However, those practitioners are available to approved patients within our system.

But this illustrates how any patient, Secretary, anywhere provided that that medical practice is participating in sequence interaction of remote certifications will allow patients to access

their practice. And this is very, very beneficial to patients. It helps reduce cost. It helps reduce travel time and makes it much, much more efficient.

So we looked at the cost of the product declining. I'm encouraged what I see at the retail space looking for more competitive advantages. To happen in the wholesale space, we must see those declines.

We also have practitioners becoming much more efficient, being less burdensome on patients for travel and those are the things that overall contribute to affordable access.

And one other note on that topic, the office is very happy to participate with the patient and caregiver subcommittee, Secretary, should we be able to support them in any way in helping them to better define what affordable access means to our program.

Next slide please. This I believe concludes, Secretary, my final slide. Let me just check a moment. Yes it does.

I want to make a couple of points on the bolded bullet point on research in regulatory. On medical marijuana research, it continues to progress. Calls are done by our research division under the

chief of that division, Arthur McNulty and Loli Bench is also working in that division.

Calls are happening. For example this week with our approved academic research centers that are actively doing research. There's been at least one publication so far that has benefited patients immediately by Penn State and we look for more of that.

We also want to understand how we can better support our medical schools. In addition, Act 44 allows for the addition of two more medical schools to participate here. Applications went up per the statutory requirement a couple of weeks ago. And we're looking forward to seeing who might apply here in this space to ever increase and meet the need for continued research of medical marijuana.

From a regulatory perspective and with this, I'll hand it back to you Secretary to see if you have any questions from you or the Board. From the regulatory matter we are very busy implementing Act 44. There are a lot of programs there that are there to benefit everyone. I appreciate the collaborative nature of all concerned. And we're looking forward to putting Act 44 into use to benefit patients and all stakeholders in the program.

Also one other final point, we continue to review and reissue permits. These review annually at different times of the year and very important to keep our permit holders, if you will, growing processors and dispensaries active. We also review laboratories and reissue approvals for our laboratories as well.

With that, I'll pause and see if you have any questions from you or the Board Secretary. Okay. Thank you.

CHAIR: Thank you so much John. I appreciate it.

I actually don't have any questions at this time but I do want to open it up.

Do any of the Board members have any questions?

MR. SHULTZ: Yeah this is Luke. I have some questions.

CHAIR: Please go ahead.

MR. SHULTZ: Related to implementing the changes brought about by Act 44, it's my understanding it now requires that the initial loan will be paid back and I was wondering where things are with that as it relates to establishing the patient hardship program?

MR. COLLINS: Certainly Luke.

I've been informed that the loan has been paid. Where that goes in terms of the next steps if you will for the, what will be called the medical marijuana assistance program for the individuals you spoke of, is actively under development.

When the timeline is known for its implementation, I certainly will be advising you Secretary and subsequently the Board.

So it's underway Luke.

MR. SHULTZ: Okay. Thank you. That's great to hear.

MR. COLLINS: Wonderful. Thank you.

MR. SHULTZ: I have some product concerns that I'd like to share. Patients continue to experience problems with certain products, in particular flower that has mold, numerous seeds, stems, buds that are poorly trimmed and not properly dried or cured.

The patients, especially those with compromised immune systems or allergies should not be getting moldy medicine. I assume the mold is growing after packaging. So maybe better packaging needs to be considered such as packaging with an inert gas such as nitrogen.

Do you have any comments on that?

MR. COLLINS: Yeah, certainly Luke.

One is no moldy product leaves the door. So if that is actually occurring, one request I have is for those complaints to be submitted to the department so they can be adequately researched. Okay.

So if you or anyone else could encourage patients to contact us. We do actively investigate every single patient complaint that's submitted.

Regarding remedying a situation, we'd like to be able to investigate it. So please encourage where you're hearing patients reporting occurrences of this. We need to have more information there. Okay.

MR. SHULTZ: Okay. I appreciate that. I will do that.

MR. COLLINS: Yep.

MR. SHULTZ: And finally I'd like to again ask that all ingredients be listed on the labels of the products. Recently there was a patient that had an allergic reaction after using a flavored vape. It wasn't actually determined that the reaction was something in the vape but it took valuable time to

track down from the grower processor exactly what was in the device.

Fortunately she recovered but it could have turned out differently. I've asked that, not just me, patients all across the border are asking that all ingredients including additives, flavors, dyes, etcetera be labeled on the lists of --- or in the labeling of the various products or at least have listed on the GP's website under each product what the complete list of all ingredients is.

MR. COLLINS: Well thank you for the feedback Luke. I can understand the concern there.

I also want to inform you, the Secretary, and the Board that every additive must be an approved additive and must be pharmaceutical based.

We have a very granular process that those seeking additives must go through. We follow FDA standards on additives and pharmaceutical practices, meaning, you know, recipients must have a basis on having approval and can't just be ad hoc put into product. That's not allowed.

And any incidents where that might come to our attention it should have come to our attention, action is immediately taken on it.

Of course we're well aware of the

potential for adverse events if approved product additives are not submitted to the department. So we continue to monitor that, Luke, very carefully.

If you are aware of any incidents where someone has an adverse event, then again they need to seek medical attention and contact their practitioner. They also need to let the dispensary know because we have a very prescribed process that many must follow and they do follow that to report adverse events.

Fortunately there are very few. Not directly so far noted to the product but we want to keep very, very close on that. So in summary here, we want to be made aware just as there were product complaints as you brought up in your prior comment but also I wanted to assure you and the Board that every additive must be submitted for our review.

We have a very detailed process that does a look back to FDA requirements and approvals for amount, substance and route of administration and maximum amounts per dosage and that is looked at very, very carefully.

Thank you.

MR. SHULTZ: Thank you for that and I appreciate that. But in the time of emergency when

somebody's having a reaction after taking an approved medical marijuana product, they go to the emergency room, they take their medicine with them, it's limited as to what's listed on the label.

There might be other things that the person is allergic to within that product that are not listed.

How do we get that information?

MR. COLLINS: If you're asking me if I got a phone call and then I'll ask Carol to comment on how I would advise in that particular instance is contact the medical professional at the dispensary which is noted on the label, Luke.

Okay. That is the first immediate action beyond the medical provider taking care of the patient themselves.

Carol.

ATTORNEY MOWERY: Yeah.

I just wanted to add that Luke that is something we had added to the proposed regulations is to require all ingredients be listed on the label.

MS. SHULTZ: Okay. And that's great to hear, Carol. Thank you.

ATTORNEY MOWERY: Sure.

DR. GETZY HART: Hey John, it's Janet

Hart. I just have a quick question going back to the research side of it when you talked about some more institutions being added.

In the various schools, are the pharmacy schools involved in the research at present that you know of?

MR. COLLINS: Well, there's a definition for an academic clinical research center, Janet, and that means they need to be a certified medical program themselves.

If you're asking me during the sessions if there are findings on the call as researchers or those with doctorates with pharmacy backgrounds, the answer is yes.

DR. GETZY HART: Okay. Thank you.

MR. COLLINS: Yeah certainly.

DR. GETZY HART: No. I was just curious because obviously there's pharmacists in the dispensaries as well and I just wanted to try to make the connect of, you know, all the different practices of pharmacies.

And I know the medical doctor talked about no training in, you know, medical school for the students and I think we see that in pharmacy as well for some of the institutions that are out there which

is why I was asking.

MR. COLLINS: Yeah.

And just to thank you. An additional point is all of our affiliated individuals and medical professionals are required to take training which does include training as you might be aware on medical marijuana.

DR. GETZY HART: Right.

MR. COLLINS: Yeah.

And again, just to reemphasize the working teams for research, and I've seen them all, all have a pharmacist or a --- someone with a terminal degree in that discipline on their teams, actively a part of the team.

DR. GETZY HART: Thank you.

MR. COLLINS: You're quite welcome.

CHAIR: Any other questions for John?

All right. John, thank you so much. That was an incredibly informative.

MR. COLLINS: You're welcome.

CHAIR: And so I want to allow just a quick moment here for any additional discussion and open it up for any questions more broadly.

MS. ROBERTSON: Hello. Molly here.

CHAIR: Hey, Molly.

MS. ROBERTSON: So I had reached out a while ago and I just want to bring it up at the meeting is I would like to ask that Luke Shultz be made the chair of the patient committee, not because I don't want to do it, but Luke is very thorough and is in constant contact with the patient committee or patient community. And I think he would, you know, does a really good job and should be the chair of the committee.

CHAIR: Thank you.

John, I know we have spoken about this at some point to deal with any change of assignments.

Can you remind me procedurally what we would need to do for that purpose?

MR. COLLINS: Yes.

I think it's a matter of understanding that we have unique individuals as chair of each subcommittee. And I understand that Molly is the chair of the patient caregiver subcommittee while Luke currently is the chair of the report subcommittee.

So I would suggest that we have to yet resolve that matter where you would have an individual chairing both subcommittees. But Katelyn, other than it being a discussion for the Secretary to approve and consider, is there a procedure here that we need to

follow?

ATTORNEY MALTAIS: Per the Board's bylaws subcommittees are under the parameter of the Secretary. That's their decision to make. And if one of the CCs fit qualified from resolving the issue of having one individual serving as the chair of two subcommittees, there's no issue with Secretary appointing a chair she sees fit.

CHAIR: Thanks, Katelyn.

Luke, are you interested in serving as chair of both committees?

MR. SHULTZ: Yes. I can take both or hand the reigns of chairmanship for the report committee to someone else.

CHAIR: Understood.

If it's okay, Molly, what if we do this through a follow-up discussion understanding Luke's workload. I want to, again be respectful of what the reports committee may have before them now with Act 44 and the opportunity to have potentially more reports.

I think that might make sense to just do an offline discussion.

Would you be okay with that, Molly?

MS. ROBERTSON: Absolutely.

CHAIR: Okay. Great.

And so John and Katelyn if you all don't mind following up.

MR. COLLINS: Yes.

CHAIR: We can figure out how to create a path forward on that and have a recommendation by the next Board meeting too.

MR. COLLINS: Will do.

MS. ROBERTSON: Great. Thank you all.

So, I just at the risk of beating a dead horse back to this whole application process for the medical subcommittee.

I guess I would like to be able to have the medical subcommittee amend applications before presenting them to the Board. So how, again, like how do we make that happen?

CHAIR: So I believe the directives are two fold right now. And Katelyn tell me if I'm off on this.

First in the more urgent issue of directly related to any rejected applications today, they'll become in the rejection communication as to whether or not a relatively quick revision of that application could take place to have it resubmitted in front of the medical committee again.

Alternatively, I think Katelyn and Dr. Johnson are both going to look to that change in process by which it's throughout the subcommittees review of one of the SMC applications is to determine that a tailoring by way of population or condition or the like could have expedited the path to actually seeking approval that medical condition to the Board and changed it from a recommendation to reject to a recommendation to approve, there would be a quicker pathway to have amending an application.

And I don't quite know how that would all work out but I think that those are the two tasks of Katelyn and Dr. Johnson at this time.

MS. ROBERSON: Very good. Okay. Thank you.

CHAIR: Any other discussion?

MR. SHULTZ: Yeah. This is Luke again. As it relates to issuing reports from the Advisory Board, moving forward do we anticipate that a report would be written after each Board meeting where a recommendation is approved for something or another schedule of how often reports would be put out?

I'm just wondering what the thoughts of the Board are.

CHAIR: I'll open it up to others and

John welcome your take too.

I don't know that I would anticipate that frequency of reporting but open to others on that.

MR. COLLINS: Yes Secretary. I'll offer something here.

It might be best if we schedule one on ones with the subchair or the chairs of the subcommittee. We can address Luke's question in addition to any other feedback that occurs today and anyone else that, you know, has any feedback, support they're looking for from the department or the office and getting granular on, for example the timing of the reports and how they are effectuated as required under the statute.

So my recommendation to you is that we set up leaving the programming area and legal counsel to the Board set up these follow-up meetings with each of the subcommittee chairs on any topic they have.

CHAIR: Yes. Absolutely. That's a smart move John.

Luke, will that be able to help the affirm for discussion on your question about reports?

MS. SHULTZ: Yeah, I believe so. Thank you.

CHAIR: Of course.

All right. So John if you wouldn't mind spearheading that effort that'd be great.

MR. COLLINS: Will do.

CHAIR: Thanks.

DR. GETZY HART: This is Janet again.

I just have one question or perhaps a suggestion when we're talking about like, you know, denying an application and the person not knowing why it was denied.

I think if I was an applicant it would be beneficial if at the time that it was going to be on agenda that you let the person know that submitted the application that it's going to be on the agenda so they have the ability to listen in to the meeting to get that information sooner rather than later to hear all the discussion.

And I don't know if that can be done but I know if I submitted an application, I'd want to hear the discussion and maybe they don't know when it's going to appear on an agenda but that might be beneficial to the person submitting the application as well.

CHAIR: Yeah. John, what are you thoughts on that?

MR. COLLINS: Outstanding idea.

CHAIR: Excellent. Let's integrate that into our communication improvement.

MR. COLLINS: Exactly.

DR. KAMBIC: Dr. Kambic.

I have a question about that proposal.

Is that going to be to subcommittees or is that going to be the Board committee? Because if we're having an active discussion about somebody's requested diagnosis, we might not be as candid if we're going to be having somebody monitoring what we're discussing and possibly even chiming in.

So I don't know about that.

DR. JOHNSON: Dr. Kambic, I think it's the Board meeting which is already public would be the recommendation not the subcommittee.

DR. GETZY HART: Yeah, that was my suggestion that it's a public meeting and individuals can stream it or watch it live. So that would be --- they would hear this discussion on the day that they're there the disease state was considered so that they could start drawing their game plan to resubmit at that time to give them some additional time as well.

DR. KAMBIC: Okay. I agree. But it's

a big Board.

And another comment I'm going to have is I think we're going down a slippery slope if you're going to have the medical advisory subcommittee modify proposed diagnoses.

I think as a submitting physician submitting a diagnosis, I think better communication after the committee has had their discussion can allow them or lead them to modify the diagnosis and then resubmit is the more proper way of doing it as opposed to have the Board assume what that sponsoring practitioner wants and have all us change it.

I just think that's a little bit dangerous.

CHAIR: Yeah, Dr. Kambic that's a point well taken.

Dr. Johnson I don't know if you have thoughts on the ability to almost communicate for a resubmission versus any sort of changing of an application. I think probably leaning towards heavy communication for a resubmission.

DR. JOHNSON: Yeah, I think in our subcommittee I think we'll discuss this because I think that there's definitely a lot of points that need to be made on whether or not the subcommittee

will have a role in modifying. But I think certainly a role for the subcommittee to discuss and then make a recommendation to the Board on how we'd like to proceed.

CHAIR: Any other ---.

MR. COLLINS: Secretary just for clarity, let me restate what our action plan is on this topic ---

CHAIR: Great.

MR. COLLINS: --- so there is no confusion. The Sunshine provision requires us to publish on our publicly accessible website the agenda the day before, 24 hours specifically before this meeting takes place.

So based on Janet's recommendation, once that occurs we will separately inform the submitters or requesters for those serious medical condition submittals the exact same information.

So although they're a member of the public, we're very happy to guide their attention to that matter just to be able to be sure that they're aware that the topic that they submitted is on the planned discussion list for the Board meeting occurring the next day.

That's what we're going to do and I

just wanted to double check with Janet to be sure that that is in fact what she was asking us to do.

DR. GETZY HART: Yeah, that is fine notification. And again it doesn't have to be the significant --- knowing what the growers and processors hear in another states, I would say that if I had a facility and I wanted my condition or I submitted it, that if I couldn't be on it I would have one of my members of my team at least pay attention to the discussion. And, you know, know that it was being acted on at that point.

MR. COLLINS: Thank you.

Thank you, Secretary. I don't have anything else.

CHAIR: Yeah. That's great.

Any other points for discussion today?

Okay. Hearing no more discussion we're going to conclude today's meeting.

Our next Board meeting is scheduled for Tuesday, November 16, 2021 from 10 to noon. It was advertised that the next Board meeting would be held virtually. However, if that changes we'll make sure that everyone is informed well in advance of the next meeting.

And thank you to everyone for

participation today. I really appreciate the dialogue and look forward to continuing to work together.

May I have a motion to adjourn today's meeting?

DR. GETZY HART: Motion to adjourn, Hart.

ATTORNEY ADAMS: Second, Adams.

CHAIR: Thank you very much.

I appreciate it. Hart and Adams on a second.

The meeting is adjourned. Thank you so much. Have a good day.

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MEETING CONCLUDED AT 11:45 A.M.

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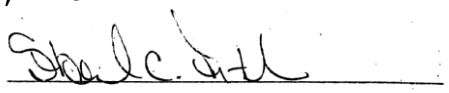
CERTIFICATE

I hereby certify that the foregoing proceedings, Medical Marijuana Advisory Board was reported by me on 8/17/2021 and that I, Shannon C. Fortsch, read this transcript, and that I attest that this transcript is a true and accurate record of the proceeding.

Dated the 1 day of November, 2021



Court Reporter

Shannon C. Fortsch