COMMONWEALTH OF PENNSYLVANIA

DEPARTMENT OF HEALTH

MEDICAL MARIJUANA ADVISORY BOARD

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IN RE: ADVISORY BOARD MEETING

PUBLIC MEETING

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BEFORE: ALISON BEAM, Chair

Janet Getzy Hart, R.Ph., Member

Colonel Robert Evanchick, Member

Denise Johnson, M.D., Member

David Steffen, Member

John Adams, Esquire, Member

Geith Shahoud, M.D. Member

Bhavini Patel, Member

Molly Robertson, Member

Reporter: Richard J. Lipuma

BEFORE: Daniel Kambic, D.O., Member
I. William Goldfarb, M.D., Member
Shalawn James, Member
Luke Shultz, Member

HEARING: Tuesday, November 16, 2021
10:00 a.m.

LOCATION: Virtual Meeting

A P P E A R A N C E S

ALSO PRESENT:

Katelyn Maltais, Attorney For Board

John Collins

Sunny Podolak

I N D E X

E X H I B I T S

Number	Description	Page Offered

NONE OFFERED

P R O C E E D I N G S

CHAIR: Good morning.

Welcome to another virtual Board meeting for this crew. I'd like to call this meeting to order.

This is the Medical Marijuana Advisory Board Meeting being held at 10:00 a.m. on November 16th, 2021. Before we officially get started today, I want to take a brief moment to introduce a new Board member that's with us today, Dr. Geith Shahoud.

Dr. Shahoud was recently appointed by the majority leader at the Senate. He provides child and adult psychiatric services to Western PA and local areas.

Before I move on to roll call, because it's his first Board meeting, I wanted to ask if he would like to take a moment to introduce himself.

Dr. Shahoud.

DR. SHAHOUD: Yes. Thank you very much. I appreciate it.

CHAIR: Welcome.

DR. SHAHOUD: My name is Geith Shahoud and I'm an adult psychiatrist. I do practice

psychiatry since 2004, when I graduated from Mississippi. And then I did a fellowship in child psychiatry also in Columbia, Missouri.

Then I moved to Pennsylvania in 2007 and I have been working in Pennsylvania since then in the Pittsburgh area.

The two main jobs I handle now is I'm Director of Child Psychiatric Hospital in Pittsburgh, Pennsylvania. They call it Southwood Psychiatric Hospital, where we see children and teenagers. And also I am the Medical Director of the Intermediate Unit 1 for three counties in the area, where we see children. Plus I have my outpatient.

So thank you for the opportunity and I thank you again.

CHAIR: Of course. Welcome.

And I apologize for not pronouncing your name correctly at first, but we are grateful to have you here and thank you for doing the brief introduction as well.

So now we will be able to officially move on to roll call. And so I think I will just start off. Alison Beam here.

Colonel Evanchick?

COLONEL EVANCHICK: I'm here.

CHAIR: Good morning.

Janet Getzy Hart?

DR. GETZY HART: Present.

CHAIR: And as mentioned at the top of the call, I believe Kalonji Johnson is not able to make this one because of a conflict.

Dr. Johnson?

DR. DENISE JOHNSON: Here.

CHAIR: Good morning.

David Steffen?

MR. STEFFEN: Here.

CHAIR: John Adams?

ATTORNEY ADAMS: Here.

CHAIR: Dr. Shahoud:

DR. SHAHOUD: Here. Sorry.

CHAIR: Oh, of course.

Bhavini Patel?

MS. PATEL: Here.

CHAIR: Molly Robertson?

MS. ROBERTSON: Here.

CHAIR: Dr. Kambic?

DR. KAMBIC: Here.

CHAIR: Dr. Goldfarb?

DR. GOLDFARB: Here.

CHAIR: Shalawn James?

MS. JAMES: Here.

CHAIR: And Luke Shultz?

MR. SHULTZ: I'm here.

CHAIR: I wanted to ask legal counsel to the Board, Katelyn, to confirm do we have a quorum today Katelyn?

ATTORNEY MALTAIS: Good morning, Secretary. Yes, we have a quorum.

CHAIR: Great.

So folks should be able to see on the shared screen, the agenda for today is listed. So next up is the approval of the minutes for the meeting held August 17, 2021.

I understand that you all have been provided the minutes from the last Board meeting which was held on August 17, 2021, which I hope you all had a chance to review.

Upon review of the meeting minutes, we noticed that pertaining to the Medical Marijuana Program update and comments made by John Collins, it was recorded in the minutes that the update and comments were attributed to John Adams.

With that being clarified, would I be able to get a motion to approve the meeting minutes

from the August 17, 2021 Board Meeting?

DR. GETZY HART: I'll make a motion.

CHAIR: Thank you Janet.

DR. GETZY HART: No problem.

CHAIR: Would I be able to get a second?

MS. JAMES: Second.

CHAIR: Katelyn I might ask for help there. I heard multiple folks chime in on the second.

Is there one voice that you heard that you want to note?

ATTORNEY MALTAIS: I particularly saw Shalawn pop up on my screen.

So we'll attribute the second to Shalawn.

CHAIR: Great. Thank you so much.

All in favor of this motion to approve the minutes, please say aye.

AYES RESPOND

CHAIR: Is anyone opposed?

Are there any abstentions?

Okay. The meeting minutes from the August 17th Board meeting are approved.

At this time I will turn things over

to John Collins, Director of the Medical Marijuana Program for an update.

MR. COLLINS: Thank you, Secretary.

Good morning, Board. We're going to step through a number of items this morning. Joining me in this update from the Office of Medical Marijuana is our Assistant Director and Chief Compliance Officer Sunny Podolak.

It's worth noting that today we cross the rather significant milestone for the program. The program to date we are now reporting $4 billion, that's $4 billion in total sales.

The agenda is laid out in front of you. A couple of key points before I begin. Act 44 implementation contained 33 initiatives that we are currently implementing. And one of those key initiatives important to patients is the Medical Marijuana Assistance Program, which Sunny will provide a lot of clarity on.

The next three agenda items focus on volume, the mix of product purchased, and basically at what price, as we continue to monitor that carefully to be sure that we have continued affordable access.

Next slide, please.

These are the program metrics to date. 681,000 patients and caregivers have registered. The more dynamic numbers, the second point 384,254 active patient certifications. These represent those patients that have in their possession a authorization and an active ID card to be able to enter dispensaries. About half of those do each week and purchase about 2.5 products and visit our dispensaries at least twice a month.

The average purchase continues to be around $130 to $135, although it's continuing to trend down. And I'll cover that a little bit later on. A very positive sign.

16.5 million patient dispensing events has occurred, which is noteworthy in terms of keeping patients safe and using a track-and-trace program through our electronic means, as required under the statute. 47,000,000 products have been dispensed. And as I've already mentioned across the $4 billion total sales mark, that's program to date, and that's made up of the values you see below.

$1.6 billion are sales from grower processors to dispensaries, and $2.4 million, the higher value represent those purchases made by patients attributed to the 16.5 million visits and

the 47,000,000 products dispensed.

Next slide, please.

Next we'll look at the Act 44 implementation. This was signed into law by the Governor on June 30th of this calendar year. And as I mentioned in the openings, it has more than - well, almost three dozen - actually 33 key initiatives that we're going to go into in some detail now.

I'm pleased to report that as of this morning, 25 or roughly 75 percent of the total have been successfully implemented. We're going to focus, though, I'm going to use this as the opportunity, Sunny, to hand this off to you, to talk a little bit more about those implementation projects in process, some of which are rather noteworthy, one of them being the Medical Marijuana Assistance Program.

Sunny.

MS. PODOLAK: Thank you John.

Can you got back to the previous slide, please?

Thank you.

So you'll notice the column that is talking about the implementation in progress. And

there you'll see there are two items in that column which represent major projects or new programs.

The first program is the Medical Marijuana Assistance Program or MMAP, M-M-A-P, which I will discuss in more detail shortly.

The second program is the Enterprise Resource Planning or ERP application programming interface with our seed-to-sale tracking system.

Moving to the next row, you'll see that there are grower processor and labs that have four items in the implementation and progress column. One of those is enhancing our seed-to-sale system to include stability testing results with our approved laboratories.

One includes creating medical marijuana products in topical form by utilizing remediated medical marijuana. One is obtaining and processing harvested hemp from a person holding a permit from the Department of Agriculture.

And finally, the introduction of a 30-day window to allow grower processors to obtain and transport seed and immature plant material from outside this Commonwealth.

I'm happy to announce that this will be implemented shortly. The first 30-day window

will open December 1st through December 30th. Moving forward, this 30-day window will open annually on December 1st.

And in addition, grower processors will be able to request additional 30-day windows to obtain and transport seed and immature plant material from outside this Commonwealth throughout the year.

The implementation of these items requires enhancements to this seed-to-sale system and the office has been working very closely with them on the details on how these will work.

Once these items become available, the office will communicate that to the partners who will be impacted.

Moving down, you'll see that background checks has one item in the implementation in progress column. Currently fingerprinting results are received by the office in hard copy. And once this is implemented, the office will receive these results electronically, thus improving efficiency with the caregiver approval process as well as the affiliation process for Pennsylvania's permittees.

And then finally we'll move to

permitting, where there is still one item in our implementation-in-progress column. And you will note that the office has made applications available for one clinical registrant permit. Those applications are currently open. And once we award a clinical registrant permit, we will be able to move this out of implementation progress and into the implemented column.

Next slide, please.

I would now like to update you on the implementation of the Medical Marijuana Assistance Program or MMAP.

With the passage of Act 16, the Office of Medical Marijuana was tasked with establishing programs that will assist the cost of providing medical marijuana to patients who demonstrate financial hardship or need, assist patients and caregivers with the cost associated with the waiver or reduction in fees for the identification card, and provide for the cost of background checks for caregivers.

The office has been providing assistance since 2017 to participants in two ways. Patients and caregivers who are registered in an existing Commonwealth Financial-Hardship Program are

provided a 50-percent discount on their annual identification card fee. And 65 percent of background check fees for caregivers is currently covered.

With the passage of Act 44 in June, the expansion of the Medical Marijuana Assistance Program is underway. I'm excited to share that the Medical Marijuana Assistance Program is expanding by eliminating the annual identification card fee for eligible participants, eliminating all federal background check fees for eligible caregivers, and assisting eligible patients with the purchase of medical marijuana from Pennsylvania dispensaries.

To expedite - excuse me, expedite the availability of assistance, we are rolling out the expansion of the MMAP in three phases.

Next slide, please.

Phase one will eliminate annual identification card fees for eligible participants registered in an existing Commonwealth Financial-Hardship Program.

You'll notice that the current price of an annual medical marijuana ID card is $50. Moving over, the reduced fee is $25 for those eligible participants who are registered in an

existing Commonwealth Financial-Hardship Program.

And moving over to the next column. When phase one is implemented, the annual medical marijuana ID card fee will be eliminated. We expect this to be implemented during the first quarter of calendar year 2022.

Next slide, please.

The next row will talk about phase two.

Phase two eliminates all background check fees for eligible caregivers. The full price for obtaining fingerprints for the required background checks for caregivers is $20.85. Currently, caregivers pay a discounted rate of $7.60.

And moving over, when phase two is implemented, the fee for eligible caregivers to obtain fingerprints for the required background check will be eliminated.

The implementation timeline for phase two is to be determined, but we will continue to communicate this once it is made available.

Next slide, please.

And finally, phase three will distribute assistance in a to-be-determined amount

to eligible patients to use to purchase medical marijuana products at dispensaries.

Again, the amount of assistance has not yet been determined. And the implementation timeline for phase three is to be determined. But again, we will communicate this once it is made available.

So to review, the implementation of the Medical Marijuana Assistance Program will eliminate the annual identification card fee for eligible participants, eliminate all federal background check fees for eligible caregivers, and assist eligible patients with the purchase of medical marijuana from Pennsylvania dispensaries.

There will be an FAQ document posted to the website this afternoon on the Medical Marijuana Assistance Program. And as a reminder, our website is www.medicalmarijuana.pa.gov.

I'll turn things back to John now.

Thank you.

MR. COLLINS: Thank you, Sunny. I appreciate that.

Understandably this is a lot of information. Thank you for calling out that a FAQ document will be posted before close of business

today, and also for clearly illustrating that the Medical Marijuana Assistance Program, MMAP, continues to address savings that were implemented several years ago.

Overall, the program does capture assistance as it pertains to ID cards, background checks, and some assistance provided regarding the purchase of product for qualified patients. More details to follow.

Next slide, please. Next, we're going to take a look at one of the key items pertaining to what and how are patients interacting with our dispensaries.

Next slide. This is an ongoing graphic and illustration pointing to the continued growth and total dispensary sales. For those looking at this maybe for the first time, the green bars represent monthly total sales and are illustrated on the left-hand side of the page. Meaning for the month of October sales were in excess of $120,000,000 for that month alone.

The blue line is legend on the right-hand side. And it's showing and ever-increasing growth of the program since its inception and represents program to date numbers that I called out

previously of 2. - I think it was 2.4 million for total sales for dispensaries to patients.

One of the things I want to call out before we move on here is, there is a bit of a concern, Secretary and the Board, with the long-term viability of supply. Weekly sales continue to outpace sales by grower processors at about a 20-percent rate. So we keep our eyes and ears open looking for stock-outs as the number of dispensaries continue to grow, and we appreciate the heavy lifting done by our permittees. They have expanded aggressively and I know continue to do so. But there is that long-term view that basically says we're going to need more growing space here in the program.

Next slide. This is the mix of product. What products are going to authorize patients at the point of sale, meaning dispense to those. And what you're seeing is the continued prevalence of dry leaf followed by vaporization products as being those leading items relatively unchanged, a little bit up and down as you look back, but relatively unchanged. Said a different way, vaporization products account for in excess of 80 percent of total products, as you're seeing here.

So we remain steadfast, Secretary and the Board, in monitoring additives and being sure that what is approved and authorized by FDA as approved excipients, meaning additives to products, is safe for patients. And we continue to monitor that very, very carefully.

Next slide, please. Next, I want to take a look at pricing trends at the permittee level. So we'll begin with dry leaf sales.

Next slide, please. What you're looking at, because dry leaf is, one, the highest volume item that we have, and two, likely the most competitive, meaning pricing changes dramatically or it becomes a point-of-sale reference for those that are purchasing product with their choice of where they go to buy those particular items, you need to see that dry leaf sales continue to be a substantial part.

As you saw on the last slide, nearly 45 percent of the total volume here. On the lower right-hand corner, those represent 138 was the number of operational dispensaries closing out October, but I'm pleased to report that since then in the last couple of weeks we've added two more, actually. So we're now at 140.

Next, let's take a look at, you know, what is the pricing trend and what's happening at the point of sale.

Next slide, please. What you're seeing here is a slope of a line. We're going to take a look at actual prince points in just one moment. But this becomes very important when comparing it to the - next slide, please.

This slide indicates that pricing at the wholesale level is falling much faster than pricing at the retail level. And there's a reason for that, which I'll go over in just a moment. We have seen so far pricing savings being passed along to patients. Or said a different way, price reductions at the wholesale level, meaning by growing processors to dispensaries, represented as lower price points at some future point in time at the dispensaries and we're carefully monitoring that. Let's take a little bit of a deeper dive here, though.

Next slide, please. These are those trend lines. And you can see that the sloping line for wholesale pricing continues to trend downward. It is driven by - data point that I will go over in just a moment. But because of that, we would

anticipate more recent savings are passed along to patients relatively soon.

(WHEREUPON, AN INTERRUPTION IN THE PROCEEDINGS WAS HELD.)

(WHEREUPON, AN OFF RECORD DISCUSSION WAS HELD.)

MR. COLLINS: Just to restate, what these trend lines show, and they're very important metrics, is they show the relative direction for both discounts at the point of sale, which is what our patients pay, and the acquisition costs incurred by our dispensaries.

So in a competitive market, we would expect those price savings at some point to flow through the system. One other thing I want to point out before we move forward is that what I'm going to show you next does not, I repeat does not include additional point-of-sale discounts.

Let's go to the next slide, please. What you're looking at is representative of what people pay. Our patients don't pay percents, they pay dollars. Right? That goes without saying, but it's worth pointing out, because what we're tracking here is something called average purchase or average

selling price, often referred to as ASPs. And I'll get into more detail about the significance and its lack of significance for our patients. But it is an important trend to monitor if you're monitoring it the same way each time, because you can track trends.

So what you're seeing here on the wholesale price per gram for dry leaf is you're seeing 18 - I'm sorry, $8.17 when compared to the $10.19 back from January of 2020 is almost a 20-percent reduction. You're not seeing that yet when you take a look at $14.05 compared to $15.67. But because the $8.17 is very current, we anticipate and will monitor because we believe our patients expect those savings to be passed along to them in terms of what they are paying.

Before we move forward, I want to lay some groundwork here. We're going to look at very granular information as to what really is going on at the point of sale. When we call out an average selling price for an ASP, in this instance $14.05, it's often asked, Secretary and the Board, who pays that. Well, that's not what that's about.

Let's go to who pays what on the next slide, please. We're going to take a look at a

series of slides broken out into three geographic regions, East, Central, West. Each one of those geographic regions contains two medical marijuana regions. In this case, you're looking at the Eastern region and that is southeast and northeast.

What you're looking at is an explanation from our prior point. If you see the average selling price at the last Board meeting when this analysis was actually started, we had the $14.27 number, but what you're looking at is diversity of pricing at the point of sale.

So if you take a look at harvest in Scranton, you'll see a price point down to what appears to be $8.50 per gram up to nearly $20. And that is represented and replicated in other lines that you're looking at. What that represents is the variability of price based on the type of strain, what the patient might believe or the dispensary might position as a particular rich terpene profile or cultivar mix. It can be the volume, meaning a one-gram purchase might be priced a tad higher than someone that's buying a larger amount. Or said a different way, someone that's buying a 90-day supply versus a 30-day supply.

And these types of pricing trends are

very consistent in the pharma space. They are representative of an open-market model. They are evidence of a competitive process going on.

All right. So what you're looking at and what we're going to hit in the next two slides is what makes up 14 - what makes up the average selling price of $14.27. And what you're looking at is the variability. Meaning it's unlikely that anybody's paying that. That's a point of measure for ourselves.

So Secretary and the Board, as a matter of clarity, this is very complex and we do monitor it. These data, by the way, for those that might be interested, actually were pulled from the respective menus for each of these dispensary or permittees. Okay. This came right off the menu.

And as well I had mentioned earlier in my presentation, these do not account for additional discounts to veterans, seniors and other qualifying individuals that can run from 5 percent to 15 or 20 percent on top of what you're seeing there. Okay.

So let's take a look at the next slide. This is the Eastern region. These are the two regions. This is now the Central region. And you'll see the same kind of diversity. You'll see a

difference attributed to what is going on from a competitive perspective, what strains, what brands are being carried, what the quantity is that's being purchased. But again, these are advertised point-of-sale menu-driven analyses that anybody can do.

And it's worth pointing out - let's go to the next slide that represents the Western area. You'll see the same type of diversity in these markets.

So in conclusion here, in taking a look at these trends, Secretary and the Board, we continue to see broad-based evidence of a competitive market.

The two things that we monitor and closely wish to manage, and I know there's a subcommittee of the Board that is also very interested in this, which is reasonableness, meaning is there a reason, and then the affordability piece. Which is, you know, is it excessive regardless of the variability?

So two important metrics. We're focused on the former, which is, is what you're seeing, in my opinion, evidence of a competitive market? Yes. Is there evidence of appropriateness

based on competition and volume? That's exactly what I'm seeing here.

So with that, I'll stop, Secretary. Hand you back the floor and see if there are any questions not covered here. Thank you.

CHAIR: Thanks, John.

Does anyone have questions for John regarding the information that he just presented?

MR. SHULTZ: This is Luke. I actually have some questions for Sunny.

CHAIR: All right. Go ahead.

MR. SHULTZ: Okay.

First of all, Sunny, thanks for the update, especially in regards to the Assistance Program. That's welcome news to the patient community. And I appreciate your hard work in getting that implemented.

You had mentioned about an application process for one clinical registrant be coming online.

Could you please restate that? I'm not sure if I got it correctly.

MS. PODOLAK: Of course. As you know, Act 44 allowed for two additional Academic Clinical Research Centers. We did approve one Academic

Clinical Research Center, and that means that one clinical registrant permit is now made available. Applications were posted on October 14th and applications are due to be postmarked no later than this Thursday, November 18th.

MR. SHULTZ: Okay.

And is there an effort to get the second permit awarded?

MS. PODOLAK: An additional Academic Clinical Research Center will need to be approved and that approval is still open.

MR. SHULTZ: Okay. That answers my question.

CHAIR: Anything else, Luke?

MR. SHULTZ: No, that's it. Thank you.

CHAIR: Any other questions? All right.

So John, we can progress through the agenda, if that works for you.

MR. COLLINS: Yes. Let's please go to the next slide.

CHAIR: Great. So the next agenda item is old business. There was an outstanding request to change subcommittee Chairs. And after

serious consideration, based on the expansive nature of Act 44 and the authorities and the responsibilities that it gives this Board, at this time I have decided to keep the current subcommittee Chairs intact.

This would mean that the Regulatory Subcommittee will continue to be chaired by Janet Getzy Hart. The Medical Review Subcommittee will be chaired by Dr. Denise Johnson. The Medical Research Subcommittee will be chaired by Bhavini Patel. The Patient and Caregiver Subcommittee will be chaired by Molly Robertson. And the Report Subcommittee will be chaired by Luke Shultz.

With that being said, I wanted to remind everyone that even though you're assigned to a specific subcommittee, you are able to request and participate in other subcommittees that may be of interest to you. And you can do that by reaching out to Holli.

Next, we're going to now on to new business. And the first item is to review the qualifying medical conditions for the medical marijuana usage applications. As you are aware, the Board voted to adopt a process for changing, reducing or adding serious medical conditions. As a result, today we have one application for review.

I just wanted to take this opportunity to remind everyone of what happens when an application is rejected or approved. An approved application comes to me, as Secretary, for consideration. Rejected applications do not. However, a requester has the ability to request reconsideration by the Chair, myself, in writing, providing the reasons for a requested reconsideration.

Per our published process, upon a grant of reconsideration, the requester will be able to present their case directly to the Board. A preconsideration by the Chair is denied after granting reconsideration, the request is rejected, then the requester's request will be deemed denied for one year or until new scientific evidence is available.

At this time I will turn things over to Dr. Denise Johnson, Chair of the Medical Subcommittee to lead the discussion on the application.

Dr. Johnson?

DR. DENISE JOHNSON: Great. Thank you very much, Secretary Beam.

Good morning, Board members. As Secretary Beam mentioned, we have one application for review today. Board members were sent the application

electronically last week to prepare for today's meeting. I would like to present the feedback from our committee and the application for your review.

So the next task for the Board is going to be to reject or approve the application SMC 21-004 for chronic hepatitis. This is - this application requests to add chronic hepatitis as a qualifying serious medical condition for the Medical Marijuana Program. Our subcommittee discussed the application and some of the notes from our discussion include that the subcommittee had previously reviewed a similar application that was for hepatitis in general. At that time we felt that the case was made for chronic but not acute hepatitis. This application has been modified to include only chronic hepatitis.

Also, we consider that 16 states already approved this serious medical condition. The articles that were presented with the application reference decreasing in cirrhosis and fatty liver and other conditions with the use of medical marijuana. And also suggested some mechanisms for decreasing inflammation. But there's a lot of other literature out there that confirms that there's a increase in nausea and vomiting and pain symptoms with cannabis use.

Those were the main points of the discussion. I'll ask Dr. Kambic, Dr. Goldfarb or Molly if you have anything to add.

DR. GOLDFARB: Nothing to add.

DR. KAMBIC: Dr. Kambic. Nothing to add.

MS. ROBERTSON: Molly, neither.

DR. DENISE JOHNSON: Great. Thanks.

So based on, again, our review of the application, pertinent literature, as well as the acceptance in other states, our committee would recommend accepting the application as proposed. And so I would like to make a motion to accept this application as proposed.

MS. ROBERTSON: I would like to second that.

CHAIR: Dr. Johnson, I'm happy to take over. I just want to make sure, Katelyn, should we have discussion on this motion?

ATTORNEY MALTAIS: Yes, Secretary. At this time the motion can be open for discussion for the remainder of the Board members.

CHAIR: Great. Is there further discussion on this motion? Seeing no more -.

COURT REPORTER: Madam Chairman, -

CHAIR: Oh, sorry.

COURT REPORTER: - who made the second? Who made the second?

CHAIR: I believe it was Molly.

Is that right?

MS. ROBERTSON: Correct.

COURT REPORTER: Thank you.

CHAIR: Seeing no more discussion, we'll take a vote on this motion. So as I call your name, you can either approve, reject or abstain the vote on the motion. Perfect. Sorry. I just wanted to make sure I got the process for this right.

And so first, we'll go with myself. Approved.

Colonel Evanchick?

COLONEL EVANCHICK: Approve.

CHAIR: Janet Getzy Hart?

DR. GETZY HART: Approve.

CHAIR: Dr. Johnson?

DR. DENISE JOHNSON: Approve.

CHAIR: David Steffen?

MR. STEFFEN: Approve.

CHAIR: John Adams?

ATTORNEY ADAMS: Approve.

CHAIR: Dr. Shahoud?

DR. SHAHOUD: Abstain.

CHAIR: Bhavini Patel?

MS. PATEL: Approve.

CHAIR: Molly?

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: All right.

Holli or Katelyn, check me on this. I have 12 approved and 1 abstain.

MS. SENIOR: I have 11 yeses and 1 abstain.

Secretary, you - well, I'll let Katelyn verify.

ATTORNEY MALTAIS: Yes. Secretary Beam, I have the same as Holli; 11 yeses, 1 abstention.

CHAIR: Right. I'll take your math over mine. Wonderful. All right.

Katelyn, any more to do on that?

ATTORNEY MALTAIS: No. With that, the application has been approved. And after today's Board meeting, it will come to your office for review.

CHAIR: Excellent. Thank you so much. Wonderful.

So on a related topic, as most of you are aware, a virtual conference was held on October 20th to help educate Board members on our roles and our responsibilities, and to better understand the current processes and procedures that are currently in place.

We also talked about having more virtual conferences to help further educate the Board on certain topics of interest. After consulting with legal Counsel to the Board, and in order to ensure compliance with the Sunshine Act, it was determined that if the education being presented may in some way assist in the development of a Board policy, then the education should be presented at a public meeting versus a virtual conference.

I know that was different than where we had left it at the last virtual conference. So that was what informed our decision to not have another virtual conference prior to this Board

meeting. There were some items, though, that would possibly result in the need to addition - to develop additional processes and procedures for the Board to follow.

And as folks who participated know, one of the items that came up past discussions pertains to the Board's approval of serious medical conditions, particularly limited to patient research conducted under Chapter 20. It was determined that it could be beneficial for the Board to have a better understanding on how medical marijuana research is currently being conducted in Pennsylvania under Chapter 20. It's also important for the Board to have this knowledge as they consider developing a policy.

Consequently, I will turn things over to John Collins to talk about Chapter 20 medical marijuana research that's being conducted in Pennsylvania.

John?

MR. COLLINS: Yes. Thank you, Secretary.

What you're looking at here are two of the three types of research that may be conducted under the statute. These two types, what's shown here in blue and in green, represent those pertaining to

patient-based studies. The one not shown here is called a research initiative. It's described as a nonpatient research study type, often referred to additionally an in vitro, meaning outside the body not pertaining to a patient study. So I'm going to focus on those two things, Secretary and the Board, that pertain to where a patient, a human study subject might be involved.

A further explanation, on the left-hand side, there are five key segments. I'm going to focus on four of those, number two, three, four and five. The middle column is labeled current in blue. It's called a research program and that is the extent to which research under Chapter 20 may currently be initiated and conducted and managed. It is done through our very experienced Academic Clinical Research Centers. We currently have nine. And they are world-renowned and experts, as I mentioned, in conducting patient-based research.

What's also important is all research done at these nine ACRCs must be reviewed and approved by an oversight group, which I'll go into in just a moment, often referred to as an IRB, or Institutional Review Board, which is an FDA-defined term.

So now we're going to walk through the

current. A point of contrast before we get into the detail is on the right-hand side, the research project or study actually requires medical cannabis or cannabis in general to be rescheduled by the federal government. So we're showing these here because the regulations were drafted to account for at some future point rescheduling or e-scheduling of cannabis. But today, all of our ACRCs that are conducting active research of patients are focused on what you're looking at on the current column.

Just wanted to add some additional clarity there, Secretary, because we're covering a lot.

In terms of - I'll begin with item two. In terms of the conditions that can be studied, only those that are approved. Meaning, should someone want to conduct a study, as an example, on sleep apnea, that is not currently an approved serious medical condition. Whereas if it's rescheduled, then any medical or psychological condition can be studied.

Looking, then, at item three. Also, there's a restriction here on the forms. So particular forms that are approved, pills, oils, topical forms, dry leaf or other plant form, appropriate forms for vaporization and nebulization,

those are the types that may be utilized while we're conducting research. Now, it's not restricted. It doesn't restrict the ability to do, for example, qualitative and quantitative studies, or attitudinal studies and double-blind placebo control studies. And what I just mentioned is currently going on with all of our active ACRCs.

One point of notation here. There is a clear distinction between what might be viewed as an open study, meaning an attitudinal study that's being done. And the implication there is that where they're dispensed and what they're dispensed isn't important. What's important is capturing the study subjects experiences and how that might be impacting whatever the study design is, whether it's quality of life, or reduction in other pain medications.

The opposite of that, if you will, is the quantitative study. Those are definitely highly-structured. They're restricted as to where patients can be dispensed and also the form in which they can be dispensed.

Naturally if we have a double-blind placebo controlled restricted study going on at a particular medical school, and they have a cohort or a study group of 50 patients, they're, of course,

wanting to make sure that they're being appropriately dispensed, managed by their research professionals and medical staff, and that they have assurity that what the patient has been provided is exactly matching study design.

So I'm describing a lot of granularity here, Secretary and the Board, but I'm pointing out how sophisticated and systemized our processes and engagement with our medical participants or ACRCs are. Okay.

Looking at item four, who supervises the research? Currently, it includes what can be described as a Research Approval Committee or an IRB, depending upon the particular institution itself. I can share that I am aware that most are using their IRBs, which are very much aware of how to keep patients safe, and to approve any study in making sure that the patient is made well-aware that they are participating and actively engages in that decision to be part of a research initiative.

Item five, how medical marijuana is dispensed, is also noteworthy here, because, one, it ties back to what I just outlined as a restricted study. That means it must be dispensed at particular clinical registrants' dispensaries or it's a more open

study and can be dispensed elsewhere. But the key here is that it must be provided through an approved dispensary permitted in the Commonwealth.

And that is linked to our system. We can manage exactly at the direction of the medical school, manage how things are dispensed, who interacts with the patient, and whether or not what coding is used, what research initiative or initiatives they're signed up for, when they might expire, and when they might be in or out of a particular research initiative.

I do want to call out - and a lot of our ACRCs have contributed to our design, but I do want to, Secretary, call out how involved Thomas Jefferson University has been over the last two years. Noteworthy is Dr. Brooke Worster, who heads up the research initiative there. And we really appreciate her and Thomas Jefferson's guidance on helping us design a system that all of the ACRCs are benefitting from.

So with that said, I'll go ahead and pause and take whatever questions are needed to educate the group on how guided our medical research initiative is under Chapter 20. Thank you.

MS. ROBERTSON: This is Molly. I have

a question.

MR. COLLINS: Sure, Molly.

MS. ROBERTSON: For number three, is there any room to allow any kind of research into - and I hesitate to use the word edibles, but different forms such as lozenges and things like that for the research program?

MR. COLLINS: Molly, I will answer that two ways.

One, if this pertains to how you might be contemplating further research initiatives under the empowerment granted under Act 44, I'm not going to be able to answer that question, because I can't provide guidance there. Okay? But the other part of the question I can answer. I don't know if it's the question you're asking me, though.

But if you're asking me, for example, can a troche type of buccal administration, which is applied to the inside of the gum or cheek, if you will, because it is not to be swallowed. It is to be administered that way. You know, if a study design requires that type of administration, then it would normally be submitted with the research initiative itself. Okay?

So I can't say that that would be

allowed, per se. But I can tell you that that's how I would expect to be able to review it, Molly, is it would have to be directly related to this particular - to any particular research initiative. To where that route of administration, using an approved form, which would be a pill, oil, topical form and how that particular applicant may consider a trocheal application or buccal application to represent a pill based on its needed route of administration and support of that research initiative.

Okay?

MS. ROBERTSON: Okay. Thank you.

MR. COLLINS: Yep. Secretary, hearing no other questions, I'm going to hand you back the floor. Thank you. Thank you, everyone.

CHAIR: Thanks, John. That's great.

So the next section of today's agenda actually deals with processes and procedures that the Board may wish to consider implementing based on past discussion as well as the expansive nature of Act 44 and the authorities and the responsibilities that that Act gives the Board.

Act 44 gives the Board the authority to continue to present recommendations and findings through written reports that will be submitted to the

Secretary of Health. While originally Act 16 of 2016 gave the Board the authority to issue a written report within two years, Act 44 of 2021 empowers the Board to issue written reports. This means that the Board can issue and adopt reports at any time and as often as they deem necessary.

We talked very briefly at the virtual conference about the likely need to create a reports policy. And I'm pleased to share that the Report Subcommittee, chaired by Luke Shultz, has prepared a proposed policy for discussion today.

So at this time, I will turn things over to Luke Shultz, Chair for the Reports Subcommittee to lead this discussion. Luke?

MR. SHULTZ: Okay. Thank you, Secretary. Holli, could I have the first slide? Oh, there it is.

You should have all received a copy of the proposed reports policy, so I won't read through all of it. But basically the background section indicated the need for the reports is basically, as the Secretary said, it came about because of Act 44, which requires the Advisory Board to produce written reports for the Governor, the Senate, and the House of Representatives to include recommendations and

findings on program changes. It also describes the action to be taken by the Department of Health and the Secretary.

So what we see up on the slide is the beginning of the process part of the proposed policy, which is what we need to focus on and have any discussion on.

So reading through this, the policy part, after each meeting where a recommendation is approved by the Advisory Board to change the Medical Marijuana Program, the Reports Subcommittee will produce a written report.

Recommendations to change the Medical Marijuana Program include, one, whether to change the types of medical professionals who can issue certifications. Two, whether to change out or reduce the types of medical conditions which qualify serious medical conditions under the Act. Three, whether to change the form of medical marijuana permitted under this Act. And four, how to ensure affordable patient access to medical marijuana.

The thought behind this section is that by generating a report after each meeting where a change to the program is recommended, it will keep the process moving as quickly as possible to allow for the

Secretary and the Department to make their decision on the recommendation and implementation of that recommendation for the program.

Go to the next slide. Then step two of the report policy. Reports shall include approved recommendations and related findings. The reports may also include findings on recommendations not approved or other issues, other Advisory Board activities, and general information and updates on the Medical Marijuana Program.

We would not have to generate an extensive multi - multipage document, but we could include a general update on where the program is at, and what, if any, other initiatives the Board is working on. I believe we could accomplish this in four or five pages, at most.

Then step three, reports will be presented by the Report Subcommittee to the Advisory Board for adoption at the next regularly-scheduled public meeting. That's self-explanatory.

And finally, four, adopted reports shall be provided to the Secretary of Health, the Governor, the Senate, and the House of Representatives, and will be public record under the Right-to-Know Law. Also self-explanatory.

That's the proposed reports policy as we've developed this draft. At this point if there's any questions or discussion, we can go from there.

CHAIR: Are there any discussions, any questions for Luke?

Luke, the one piece I wanted to just make sure that I was understanding, I think it's important to note that we may wish to consider developing a formal way for the Board subcommittees to submit recommendations for Board consideration. Is this something that we see fitting under this reports policy or is this a stand-alone policy?

MR. SHULTZ: I would see that being developed by the Regulatory Subcommittee. I believe that's who developed the bylaws for the Board. So I don't see it being part of this.

CHAIR: Others thoughts on the proposed reports process? Okay.

Katelyn, I want to make sure I'm clear with you on next steps on how to proceed.

What are your thoughts?

ATTORNEY MALTAIS: Sure. So hearing no feedback on the proposed reports policy, at this time, Secretary, you can go ahead and open the floor and see if anyone would like to make a motion to

approve the proposed reports policy.

CHAIR: Okay.

I am opening the floor to see if anyone would like to make a motion to the proposed reports policy.

ATTORNEY ADAMS: I'll make a motion.

MS. ROBERTSON: I'll second. This is Molly.

CHAIR: I believe that was John Adams and Molly as a second.

Is that correct, folks?

ATTORNEY ADAMS: That is correct.

MS. ROBERTSON: Yes.

CHAIR: Okay.

Katelyn, we should just move forward with a traditional vote, then, with everyone saying aye who is in agreement or do you want -?

ATTORNEY MALTAIS: Yes, we can.

CHAIR: Okay. Great.

All those in favor, please say aye.

AYES RESPOND

CHAIR: So anyone who objects, say nay. Anyone that abstains?

All right. Katelyn, I believe then we actually have adopted the proposed reports process as

presented by Luke.

ATTORNEY MALTAIS: Yes, Secretary. That's correct. We've officially adopted the proposed reports policy and we can put that in final form and provide that to the Board members after the Board meeting.

CHAIR: Great. Wonderful.

So the next item on the agenda under the category of processes and procedures, is serious medical conditions or SMCs. This is broken down into three separate sections, so that we can make sure that we address all of them.

The first one, which we touched on earlier, is approving SMCs for Chapter 20 research. It has been confirmed by legal Counsel that this is something that can occur under the Board's authority. And some preliminary discussions acknowledge the importance for the Board to establish a policy as to how this would be done.

As John mentioned earlier, we thought it was important for the Board to have a better understanding of how research is currently being conducted under Chapter 20 in order to help develop an effective policy. And I'm hoping that information that John covered proved to be helpful in this matter.

We also talked about the ability for SMCs to be presented through the Board's recommendation process. This means that subcommittees could recommend that SMCs be changed, added or reduced through the Board's recommendation process.

While we have touched on creating a policy around submitting recommendations by subcommittees, if SMCs being changed, added or reduced is part of the subcommittee's recommendation for consideration by the Board, should there be a unique process for which this must occur, or does it make sense to somehow incorporate the already existing SMC application process?

Given that, I'd like to propose something, and then I would appreciate the group's feedback. To me, given that the Medical Review Subcommittee was instrumental in the development of the current SMC application process, or the public submittal process, it makes sense to have them take the lead on advising us on what may be needed in these instances.

Does that seem reasonable to the group to ask that the Medical Review Subcommittee first determine if a policy is needed? And two, if so, what the policy should look like?

I will pause for feedback and any comments. And of course, want to particularly create space for those that are actually assigned to that Medical Review Subcommittee to get their feedback on this proposal.

DR. DENISE JOHNSON: Well, Dr. Johnson here, if others won't weigh in. I think it makes sense for consistency, so that we can have some consistency in terms of the process for approving these conditions. And I know this is something that our subcommittee has done in the past. And so we'd be happy to take this task on to review it and bring forward some recommendations for the Board members to consider.

I don't know if any of my other subcommittee members have any thoughts.

DR. KAMBIC: Yeah, Dan Kambic. I certainly agree with that synopsis.

CHAIR: Any others with thoughts or feedback? All right.

Given that we're not hearing any objections, I'd like to formally ask the Medical Review Subcommittee -. First, propose a policy for the Board to consider that would allow for the submission of SMCs limited to patient research and

conducted under Chapter 20.

And secondarily, determine if a separate policy should be developed for when subcommittees wish to recommend that a change be made to SMCs. If the answer to this is yes, please also draft a proposed policy to this process.

Additionally - oh, go ahead, Dr. Johnson.

DR. DENISE JOHNSON: No. Yes. Thank you, Secretary.

Our subcommittee would be happy to consider and draft for the Board members.

CHAIR: Thank you. Really appreciated.

On this topic, at our last Board meeting, we had discussions on the possible need to revise our current SMC application process. And at this time, I will turn things over to Physician General Dr. Denise Johnson who chairs the Medical Review Subcommittee to talk about this. Dr. Johnson.

DR. DENISE JOHNSON: Great. Thank you again, Secretary. For the Board members, our subcommittee was asked to review the process for modifying a condition for a serious medical - modifying a condition for consideration as a serious

medical condition. You all would have gotten a copy of that draft in your email in preparation for this meeting, but I'm just going to go over basically what our outline was.

So in the past when we reviewed these applications, we reviewed them as presented and accepted or rejected them based on the application without modifications. As you heard before, Act 44 allows us, as a Board, to make modifications. And so we proposed a change to the process that we were currently using.

So for the changes, what we have recommended is that when an application is submitted, this committee will review it with the supporting data that's presented on the application, as we have in the past, and any other information that's at our disposal.

Based on the review completed within our committee, we're going to provide the Board members with a recommendation to either, A, approve; B, reject; or C, consider modifications. And we also will note the rationale for our selection.

This communication will occur to the Board members in advance of the Board meeting, so that the Board members might be better prepared to discuss

at the Board meeting. Then at the Board meeting, after deliberation, the Board members will then make the decision to either approve, reject or approve with modifications.

Dr. Goldfarb, Dr. Kambic, Molly, is there anything that I omitted?

DR. GOLDFARB: Not to my end, no, Goldfarb.

DR. KAMBIC: Kambic, I agree completely.

MS. ROBERTSON: This is Molly. I agree also.

DR. DENISE JOHNSON: Great. Thank you, Committee members.

And so that would be our proposed change. Again, making sure that the Board members are aware in advance of the Board meeting what our thoughts and our concerns were, so that you can be prepared to discuss at the meeting. The actual Board, then, would make the final decision, as you always have, on whether to accept or reject, but also in this case to make a modification before accepting.

Thank you, Secretary.

CHAIR: Katelyn, I'm going to defer to you again on whether or not we want to actually move

forward with adopting this process today.

ATTORNEY MALTAIS: Sure. So I think at this time, just like we did for Luke's proposed policy for reports, we should take a moment and see if there's any discussion or questions from Board members.

CHAIR: Okay.

Do any of the Board members have questions or have any topics for discussion?

MR. SHULTZ: This is Luke. I have one minor thing. It refers to the Medical Marijuana Advisory Board Subcommittee. Should it state the Medical Marijuana Advisory Board Medical Review Subcommittee to be more specific?

DR. DENISE JOHNSON: You're correct, Luke. Thanks for that clarification.

MR. SHULTZ: Okay.

CHAIR: Any further discussion? All right.

Katelyn, I think we should pursue the vote, if that works for you.

ATTORNEY MALTAIS: Yeah. Seeing that the only modification that's been pointed out is adding in the clarifying language regarding the Medical Review Subcommittee, we can go ahead and take

a vote to approve the application with the - policy, with the understanding that subcommittee will be updated to properly reflect the Medical Review Subcommittee.

CHAIR: Katelyn, you are so precise. That works. So all in favor of the motion to approve the policy, please say aye.

AYES RESPOND

CHAIR: Is anyone opposed? Are there any abstentions?

Okay. Policy is approved. Thank you, Dr. Johnson.

DR. DENISE JOHNSON: My pleasure.

CHAIR: We will continue on with the agenda. So something else that came up at the virtual conference was whether or not there was a way for the public to provide feedback directly to this Board.

While we continue to look into this and determine the best path forward, we're going to begin to address the need for the public to have access to the Board by modifying an existing process used by the Department. Right now there is a contact form that is available on the Department of Health website as a way for the public to ask specific questions or provide feedback. Individuals are able

to select the most appropriate category for their inquiry from the list that drops down. And we're going to be adding the Medical Marijuana Advisory Board as an option.

Additional details are still being worked out and we will get back to you with more information prior to implementation. But I did want to acknowledge that this item is being worked on currently.

Next, I wanted to hear from our subcommittee chairs. I know that you all had a call with program and legal Counsel to the Board after our last Board meeting regarding duties and expectations. And at this time I'd like each - I'd like to speak to each Chair and get feedback on your subcommittee activities and address any questions or concerns you may have. Today we're going to start with the Medical Research Review Subcommittee.

Bhavini Patel?

MS. PATEL: Hi. Yes. We don't have any updates. We haven't met since our last meeting prior to the January meeting. So no new updates on our part.

CHAIR: Thank you.

Next we have the Patient and Caregiver

Subcommittee.

Molly Robertson?

MS. ROBERTSON: So I'm going to defer to Luke, although a lot of our discussion was the patient affordability. So that was covered earlier. But Luke, go ahead.

MR. SHULTZ: Okay. Thank you, Molly.

We're still collecting information and data on initiatives for affordable access for the patient and caregiver communities. And we'll be ready to present our findings and suggestions at the next meeting.

However, I can report that there are two things that keep coming up time and again related to affordable access. One is the need for home cultivation of cannabis plants by patients and/or their caregivers. This came up in a patient survey that we conducted in early 2020 and it continues to be something that the patient community is in strong support of.

Allowing for home cultivation, which is part of many other state Medical Marijuana Programs, will significantly improve affordability for those patients who would choose to pursue that effort. And from what I understand, there is currently

bipartisan - a bipartisan effort in the PA Senate that is being formulated to address this issue. So I'm sure there'll be more information on that by the January meeting.

The other thing that keeps coming up has already been addressed, and that is the Patient Assistance Program. We already had discussion on that.

And that's about it for now. Thank you.

CHAIR: Thank you, Luke. Thank you, Molly and thank you, Luke. Appreciate it.

Now let's hear from the Regulatory Subcommittee.

Janet Getzy Hart?

DR. GETZY HART: Sure. Madam Secretary, we have not have the opportunity to meet either. We will meet prior to the January meeting and the agenda will be to look at the type of professionals in the dispensaries and now, I believe, an additional formal page for changes or putting some type of a form together for what was approved at this particular meeting. We can start working on that. I do believe that we're the right subcommittee to do that. And I think we are.

CHAIR: Great. I appreciate you volunteering. That's really, really helpful. And I think that would be extremely helpful. I, of course, defer to John and others in the program to make sure that I'm not off on that, but understood.

DR. GETZY HART: Thank you.

CHAIR: That transitions nicely for the Reports Subcommittee.

Luke, do you have an update?

MR. SHULTZ: Yeah, very briefly. Given that we approved the policy for reports and also at this meeting we approved the condition of chronic hepatitis, it looks like we have to have a report ready for the next meeting, which we will.

CHAIR: Thank you, Luke.

And lastly, the Medical Review Subcommittee, Mr. Johnson.

DR. DENISE JOHNSON: Thank you, Secretary.

I believe that we gave all of our updates in the modification of our process. I don't think we have anything additional to add. Any of my subcommittee members can think of anything else we need to add?

I think that's it, Secretary. Thank

you.

CHAIR: Okay. Thanks, Dr. Johnson.

So with that, we have officially covered all the items on today's agenda. At this time, I wanted to open it for more broad additional discussion.

Are there any other questions that you may have that haven't been answered today?

All right. Well, hearing no more discussion, we will conclude today's meeting. Our next Board meeting is scheduled for Thursday, January 27th, 2022 from 10:00 to noon. Thank you again for everyone's participation today. Look forward to continuing our work together.

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

DR. GETZY HART: Motion to adjourn.

CHAIR: Thanks, Janet.

Will I be able to get a second?

DR. DENISE JOHNSON: Second. It's Dr. Johnson.

CHAIR: Thanks, Dr. Johnson. This meeting is adjourned. Thank you all.

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MEETING CONCLUDED

CERTIFICATE

I hereby certify that the foregoing proceedings, hearing was held before Chair Beam, was reported by me on November 16, 2021 and that I, Richard J. Lipuma, read this transcript, and that I attest that this transcript is a true and accurate record of the proceeding.

Dated the 22 day of January, 2022

Court Reporter

Richard J. Lipuma