STATE OF MICHIGAN

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

STANDARD ADVISORY COMMITTEE MEETING

BEFORE JAMES FALAHEE, CHAIRPERSON

333 South Grand Avenue, Lansing, Michigan

Thursday, March 14, 2024, 9:30 a.m.

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TABLE OF CONTENTS

Lansing, Michigan

Thursday, March 14, 2024 - 9:30 a.m.

MR. FALAHEE: Welcome, everybody. Let's call the meeting of the CON Commission together, and a couple of logistical items.

There is a new sound system here that works great if you're on Zoom. If you're not on Zoom, and you don't have a mic in front of you, you need to shout so the rest of the room can hear you. And for Rachelle's benefit, our court reporter, she's -- she doesn't know all of us like Marcy does. So please, if you can, remember to say your name. I'm Chip Falahee. I always go through. I apologize.

So thank you for being here. Let's proceed with our agenda, and we'll start first with the review of the agenda, which is item number two on our agenda. Tiffani sent out the final agenda a couple days ago in our electronic packet. Any questions about it? If not, I would entertain a motion to accept the agenda as final as presented.

DR. FERGUSON: So moved. Ferguson.

MS. GUIDO-ALLEN: Guido-Allen. Second.

MR. FALAHEE: Thank you. Any discussion? All in favor say aye.

ALL: Aye.

MR. FALAHEE: Great. Any opposed? Okay, thank

you.

(Whereupon motion passed at 9:31 a.m.)

MR. FALAHEE: Next item, declaration of conflicts of interest. Given the agenda items that we just approved that are on the agenda in front of us, is there anyone to have any conflicts of interest they would like to declare? Hearing none, we'll move forward.

Next item, review of minutes of our meeting on January 25 of 2024. Any questions or comments about those minutes? Otherwise, I'd entertain a motion to approve those minutes of January 25.

MS. TURNER-BAILEY: Commissioner Turner-Bailey. Move to approve minutes of the previous meeting.

MR. FALAHEE: Thank you.

DR. ENGELHARDT-KALBFLEISCH: Engelhardt-Kalbfleisch. Second.

MR. FALAHEE: Thank you. Any discussion? All right. All in favor please say aye.

ALL: Aye.

MR. FALAHEE: Opposed? Great. Thank you.

(Whereupon motion passed at 9:32 a.m.)

MR. FALAHEE: Next item, and I won't ask you to leave the room, but there is -- there is a commissioner resignation in front of us. I'll turn it over to Commissioner Haney, if he wants to make a few words, and --

but you're required to stay for the length of the meeting, then.

MR. HANEY: I will stay for the length of the meeting, no worries. Thank you. It's been an honor and a privilege to serve on the commission and to work with all of you and do the work that the commission has. And I have retired and I am looking forward to spending more time with my grandkids and my wife and traveling a bit. So it seemed like the perfect time to go ahead and step aside.

MR. FALAHEE: Well, thank you. Commissioner Haney has always been my go-to source and I know the department's as well. If you had a nursing home question, call Don and you will get an answer right away and no beating around the bush, either. You'd get the straight answer from Don.

So, Don, thank you so much for your service here, for all you've done for the nursing home association and groups and all the patients and residents in those homes for many, many, many years. So thank you.

MR. HANEY: Thank you.

MR. FALAHEE: So with -- with reluctance, we need to make a formal motion to accept Commissioner Haney's resignation. So I would entertain, reluctantly, that motion from anyone who would care to make it, please.

DR. MCKENZIE: Commissioner McKenzie. I'll make the motion, reluctantly as well.

MS. GUIDO-ALLEN: Guido-Allen. Second and wish you only the best in your retirement.

MR. HANEY: Thank you.

MR. FALAHEE: And -- and the effective date will be immediately after this meeting.

MR. HANEY: Okay.

MR. FALAHEE: Is that okay with the people that made the motion?

MS. GUIDO-ALLEN: Yes.

DR. MCKENZIE: Yes.

MR. FALAHEE: All in favor of the motion say aye.

ALL: Aye.

MR. FALAHEE: Opposed, other than Don? Thank you.

(Whereupon motion passed at 9:34 a.m.)

MR. FALAHEE: Don, thanks again.

MR. HANEY: My pleasure. Thank you.

MR. FALAHEE: All right. Next, our friends from BAMF are here about a pilot program extension request. They approached the department and me a couple weeks ago, maybe three weeks ago, and for those of you that aren't familiar with BAMF, there was a lot of information in our packets, but I'm going to turn it over to them to explain what's going on and what -- what the request is. And then there is an issue in terms of how many legislative days our Legislature is in session that may impact timing on the

request. So we'll get into that and I'll turn it over to them. Go ahead. And we -- we give them, not three minutes, but ten, but I say they don't have to use it all.

Go ahead.

JEREMIAH JOHNS, M.D.

DR. JOHNS: Thank you very much for having us. I'm Jeremiah Johns. I'm our vice president of medical affairs for BAMF Health and physician with a background in health informatics, and I'm joined by Dan Rogers. He's our director of clinical trials. And I'll kind of move through this.

I know that a lot of people might not have been here initially when the comprehensive fixed PET referral service pilot program was initiated. So we are here today to ask for an extension of the deadline to apply for new pilot programs. And that -- that deadline ended in September of '23. And so we want to be able to bring this to Detroit, and the short answer to why we need to extend the deadline was we opened our doors. We scanned our first patient at the end of July of '22, and it simply takes longer than that to establish yourself and be ready.

So many of you might just need to know what is a comprehensive fixed PET referral service. So what's entailed in a comprehensive center is a cyclotron equipped radiopharmacy, so the ability to make the diagnostic

pharmaceuticals that are used in a PET scan, paired in the same location with the molecular imaging clinic, which is the actual fixed PET scanners themselves, and paired with a molecular therapy clinic where regular pharmaceutical therapy is administered by IV for treatment of cancer.

So the pharmacy was -- started up operations in late '21, started scanning patients in late '22. And the concept of what is being done here is -- is called theranostics. It's -- it's a mash-up of diagnostic imaging and therapy. So the concept is you take a precision medicine molecule that combine directly to a target, which in this case is cancer, but can also be amyloid plaques for Alzheimer's or many other indications. You attach a radioactive isotope that's the camera so you can image it in the PET scan to see the cancer.

Now you take that same molecule. You swap out the camera for a therapeutic isotope, the bomb, goes -- is injected into the patient, binds to the cancer, and has been shown to be very effective, especially in prostate cancer and neuroendocrine tumor, which are being treated right now, and these are some of the -- the outcomes.

So this is the -- the radiopharmacy with the cyclotrons particle accelerators used to make the diagnostic isotopes paired with a molecular imaging clinic, which in ours in Grand Rapids is a highly advanced total body PET CT

and Michigan's first PET MRI machine.

On the second floor is where you administer the radiopharmaceutical therapy. There's a SPEC CT scanner there used to tailor this therapy to the individual patient, resulting in significantly improved outcomes and significant cost savings for these therapies.

This busy slide is meant to show you the rapidly increasing indications and uses for PET imaging that are either approved or in development, key point being the top three are cardiovascular. Alzheimer's disease, which I mentioned in the letter to the commission, that a very large demand rapidly rising for the need for amyloid PET scans, and even we're doing trials for endometriosis, which one in ten women of reproductive age can have, currently only diagnosed with surgery. There's many indications coming on where there's going to be a big rapid rise in the need for PET Scans.

This slide indicates all of the therapeutic targets for cancer being either approved or in development for multiple different cancers. And this is why a comprehensive center is needed in order to bring trials for these types of therapies to bear because of the complicated nature of producing the isotopes and running the trials, as well as performing the standard of care imaging.

Proof of the pilot concept lies in the

achievements that we've been able to make in the very short time we've -- we've really only been open just over a year and a half. We've actually delivered 600 doses of radiopharmaceutical therapy, placing us in the top ten in the country. We are one of the first three IAC-accredited radiopharmaceutical therapy centers and another reason down here in the bottom right for us not meeting the September deadline is working to gain the partnerships and the $20 million state appropriations to help us open a site in Detroit, which was only recently passed.

We are a referral center. This is -- has been well-proven now in our short time. We've treated patients in 19 states and Canada. Referrals from all over the state, including -- you know, this is not a comprehensive list of everyone who sent us, but we're partnering in trials with Corewell Health on multiple trials, including -- just kicked off within Cranes (phonetic), our pediatric sarcoma trial. So that's very exciting. U of M Health West, Trinity Health Cancer Network, Cancer Hematology Centers. I highlighted Memorial Health Care of Owosso. They're kind of -- they're an independent hospital, and sending us amyloid imaging referrals.

So it's been highly successful and we would love to have the opportunity to bring this to Detroit. A comprehensive center like this will enable enhanced

collaboration. I've already shown how there's rapidly increasing demand for these new indications. And what BAMF Health exists for is we're trying to shorten the time to translate these things from the bench to -- into the clinical patients.

These patients getting these therapies, especially in these trials, they don't have any other options. They're -- chemotherapy is done. They have no other options. These therapies are frequently actually very effective and usually very well-tolerated with very low side effect profiles.

So we want to be able to give patients more access. It's very difficult for them to travel from Detroit. They're very sick. They may have a lot of social determinants of health problems keeping them from traveling. Sometimes they have to stay in our facility for five or six or more hours as well when they're getting these therapies. So a day over and back isn't easy. The -- the collaboration that we've had with the health systems has been astounding in our short life, and this will really be an -- enhanced with a Detroit facility.

And so those are -- really are the -- the key aspects of it. And so we published this on Facebook when the Lions were in the -- going to the playoffs and I do like to keep things a little bit light, but a lot of people don't

see the lion in our logo. So I wanted to see if you can see it now.

But with that, I would open it up for questions and I would ask you to consider extending the deadline.

MR. FALAHEE: Thank you very much. I've got a few questions but I'll let the other commissioners chime in first.

Commissioner Ferguson?

DR. FERGUSON: Yeah. Thank you for your innovation. Some series of questions as I try and understand the unique value proposition. So you said you've delivered 500 rounds of therapy to date or over 500 rounds. How much of that is in the PSMA or DOTATATE space?

DR. JOHNS: About 90 percent probably is PSMA is Pluvicto or other clinical trials, and around 10 percent probably is the Lutathera for neuroendocrine tumors.

DR. FERGUSON: So I guess my question and follow-up on --

MR. FALAHEE: Can I -- this is, yeah, Falahee. Can I interject for the lay people in the room, what did you just say?

DR. JOHNS: He's asking me how -- what -- what drugs are we giving for which indication. So there's two currently FDA-approved for prostate cancer and one for neuroendocrine tumors.

DR. FERGUSON: You'll see where I'm going with a follow-up question. So there are unique things that you can do having a cyclotron at your facility in terms of creating certain types of isotopes that aren't either experimental or not readily transported in the commercial space. Prostate neuroendocrine PSMA, DOTATATE realm, is available in a commercial space and we have numerous hospitals around the state that are giving those therapies, you know, PSMAs available broadly.

And so what I'm trying to understand is what's unique about this circumstance that warrants, essentially an exemption from the usual path of PET approval because there are lots of PETs. And -- and clearly you're doing some innovative stuff that a traditional site can't do. But I'm trying to figure out the balance of the two, because I think it has a profound impact on is an exception -- an innovation exception warranted or not? And I'm struggling a little bit if the vast majority of what you're giving in terms of therapy to patients is commercially available for other sites.

DR. JOHNS: That's a good question. And it -- it does boil down to the infrastructure in the comprehensive center. And there's a couple of things.

So recently for the neuroendocrine tumor, literature was just published demonstrating the dramatic

benefit to -- in the pre-chemo indication, which is going to boost the demand for those therapies. And this is expected for the prostate cancer as well. And then -- but the other thing to point out is with the comprehensive center it enables the combination trials where you're doing the diagnostic isotopes that are paired with the therapy isotopes. That's very hard to do in a fragmented systems. And then the therapies are only offered at the clinical trials for these therapies, get offered in relatively limited sites. So the --

DR. FERGUSON: Yeah, I certainly understand that, you know, clinical tri- -- there's different flavors of clinical trials; right? There's clinical trials that could in theory be done in a variety of centers, even if they're currently only done at yours. And then there is clinical trials that, because of the nature of the pharmaceutical, because of the nature, the need to have an onsite cyclotron, can't be done anywhere else by definition. And the two, I think, are -- are meaningfully different scenarios for considerations in the CON space.

MR. ROGERS: I -- I think that's a great point. I think -- and -- and what you're getting at is really PET agents, which have the shortest half life or -- or the need to have a very proximal cyclotron that -- and -- and imaging plan.

To add to that, though, going to the -- that slide about the rapid growth in this area, the -- the capacity that we have in our current systems to be able to take on even just the trials in this space is woefully inadequate in the state of Michigan and much beyond that, across the nation. And that's just clinical trials.

All these products are going to -- not all make it to the clinic -- but a good majorities are going to make it to the clinic in a commercial, and then where are we going to be from a commercial standpoint in being able to deliver both the -- the imaging and the therapy? And so having comprehensive centers like this really puts Michigan at an advantage to be able to take care of our patients in that way.

DR. FERGUSON: Yeah, I'm still struggling with what is innovation and development, which is highly desirable -- right? -- highly desirable, and what is overlap with existing structure and/or direct competition against existing structures. You're treating the same cadres of patients with same age and it's, like, others could be providing, I -- that's -- that's a different -- different conversation. And -- and, obviously, there's an overlap and I'm -- I'm not disputing that you're not doing great work. I'm Just wrestling in my own mind.

MR. ROGERS: Yeah.

DR. JOHNS: We're -- we're not disputing that there is overlap on that, either. And the thing that we actually advocate for is actually, like, we really need to increase capacity in this area. Like, we're -- we are severely constrained. When I say we, I mean all health care providers are severely constrained in capacity, and especially as we look into the future, we know that we're -- we're severely, severely constrained. And so when we're thinking several years in advance, we know that we need to be moving forward on this.

MR. FALAHEE: Thanks, yeah, when you threw out those acronyms, I wasn't quite sure what they mean. That's why I asked.

DR. FERGUSON: Sorry.

MR. FALAHEE: No, that's okay. That's all right.

DR. FERGUSON: Get way technical on it, but --

MR. FALAHEE: That's okay. When this first arose over two, three years ago, we talked about, as you did, the innovation and development piece and -- and how this was, to my recollection, exactly an example of innovation and development, and we see how it's grown.

One of the questions I've got -- I -- I understand why you could not meet the deadline that was set, because the appropriation didn't happen until after the deadline had passed; is that correct?

DR. JOHNS: That's correct.

MR. FALAHEE: Okay. All right. So the next question is: You're asking us to set another deadline to say, Apply in Detroit by X date; correct?

DR. JOHNS: Correct.

MR. FALAHEE: Okay. Do you have a recommendation for what that "X" date would be?

DR. JOHNS: I -- I will defer to the judgement of the commission on that and the procedures that -- that are involved in that, which I'm not an expert on. But I would -- I -- I know that going into an election year, I would propose that it be delayed, you know, at -- at least through December 31st of this year, but, if not, taking into account procedures and things, into '25.

MR. FALAHEE: Commissioner Ferguson?

DR. FERGUSON: I guess, rather than that, you know, this whole extension of the innovation and -- and whatnot. So if you're getting referrals from a wide array of sources and institutions that are feeling the need to refer volume because of whatever studies or unique tracers, whatever it may be, why can't you go through a regular -- apply for a PET CON with pledged signatures, pledges volumes from the different hospitals and oncology groups and do it the way everybody else is having to do it?

DR. JOHNS: Uh-huh. That's a -- a great question.

So the -- the PET CON standards are not up for review until 2026, and they are -- are definitely in need of review, only account for oncology indications and only attributed to each institution. So, I mean, that would definitely not be possible. They would have -- you know, an individual institution would have to decide that they want a comprehensive solution, such as this.

DR. FERGUSON: I don't know how that works. So that's transferable volumes?

MR. FALAHEE: Right. Yeah, I mean, I'll get there in a minute by throwing it to the department, but that's why I wanted first to ask. Let's -- what date would they propose and -- and what -- what Dr. Johns is throwing -- we're talking about, if we set a date -- correct me if I'm wrong -- that's an action that would need to be to approved by the commission, maybe public comment about it as well or not? Or can we take final -- if we so choose, could we take final action today?

MR. HECKMAN: You continue to discuss and (indiscernible) that up.

MR. FALAHEE: If -- even if we were able to take final action today, like with anything else we take final action on, it has to go back to the Legislature before it's finally approved and there has to be, I think, nine session days --

MR. CONNOLLY: Yes.

MR. FALAHEE: -- before it's approved. This is an election year. Who knows when nine session days would happen between now and the end of calendar year. It could happen, it might not. We don't know; right? We know right now in the House, because there's an even split -- let's just say there have not been a lot of session days since January 1st. So that's an open question that Jeremiah is -- is asking us. Like -- and that's why I'm asking him, How -- I don't want to set it out too far if we decide to do that.

So that's -- that's where I'm at, and that's why I think we got to be sensitive to the nine session day issue. Beth?

MS. NAGEL: So we just kind of back of the napkin did some calculations, and I -- you know, depending on what Brien says, but we didn't list a draft of this language on today's agenda or post it on our website five days before the meeting. So I don't believe you can take proposed action on it today.

MR. HECKMAN: We don't even have the proposed on that.

MS. NAGEL: Correct.

MR. FALAHEE: All right.

MS. NAGEL: And so that would be mean proposed action would be in June. There would be a public hearing,

final action in December -- or September, and then that -- then we run into the session date issue.

So we -- kind of our calculation was, I think, June at the earliest; September for some buffer.

MR. FALAHEE: Since we have some time and addressing what Commissioner Ferguson was talking about, number one, maybe the department could refresh, at least my memory, on why we set up this pilot in the first place two, three years ago -- I forget how many -- and then why, to Commissioner Ferguson's question, should we do a pilot in Detroit versus, Hey, here's the CON process. Go through the CON process to open up business in Detroit?

Any comments about that from the department at this point?

MS. NAGEL: On the first part as to how we came to where we are today, I may call on some experts to fill in. I -- I don't have the expert words, but when BAMF first came to the department and to the CON Commission, there wasn't anything in the standard that spoke to their type of technology and what they did. I think it was a PET CT; am I right? A PET CT?

DR. JOHNS: Right.

MS. NAGEL: There wasn't anything in the standard that -- that contemplated that piece of equipment and what it could do. And so at that time the commission agreed to

start a pilot. I think at -- also at that time it was only envisioned that there would be one potential site. I don't know when the -- the second site became part of the vision. But that's what the original deadline reflected was a -- a pilot.

That pilot was also -- that same language was -- also had a state legislative component in it as well. And so in that respect, that -- that state -- the legislative part in the statute gave the commission a bit of a deadline to develop standards. And so there was a clear impetus to develop standards at that time because of that legislative mandate as well.

DR. FERGUSON: Can I ask a follow-up question on that? So PET CT, you're saying there wasn't any language in the standards. I'm hearing from earlier that your PET CT is -- but it's a -- it's a full-body -- fuller field or what? I mean, the PET CT has been around for a long time and --

DR. JOHNS: Yeah.

DR. FERGUSON: -- essentially every PET scanner out there is a PET CT; right? So this is not new.

DR. JOHNS: Yeah.

DR. FERGUSON: Now, you may have a super-duper version of it, which I would love to have a super-duper version of it too, but I'm a little surprised that there

were no standards around PET CT because that's been --

MS. NAGEL: Not full-body.

DR. FERGUSON: Well, not full-body --

DR. JOHNS: Yeah.

DR. FERGUSON: -- but, I mean, that's a little bit like saying --

MR. DRAKE: A PET CT --

DR. FERGUSON: -- 3T -- a 3T MR versus a 1-1/2 MR; right? Like, I understand that it's different and better and I'm not disputing that, but it's the same general class.

MR. DRAKE: It's PET.

MS. NAGEL: I -- I may have misspoke. I'm -- I'm sorry.

DR. FERGUSON: Yeah, okay.

MS. NAGEL: There wasn't anything to address full-body and the theranons.

DR. KONDUR: Obligational sporings. The initial signers for futuristic oncology. Now obligations are so extended, so it does not in the standards. Then we need to (indiscernible) like, need to bring the standards into the picture.

DR. FERGUSON: How much of your volume is -- so I understand to go forward it's hopefully that there's more neuro and cardiovascular. How much of your current volume is?

DR. JOHNS: A very small amount, but keep in mind -- two things to keep in mind. Number one, all we're asking right now is to extend the deadline for applications, and later an appli- -- a formal application with letters of support and everything else would obviously be forthcoming. But the percentage of our patients that are not oncology right now is very small, but keep in mind that Lecanemab for treatment of Alzheimer's was only approved recently and then October CMS reversed their national coverage decision to not cover amyloid PET scans. So now amyloid PET scans are only just now being approved and there's something you can treat.

So now we have -- I put in my letter -- but even just an estimated literally 60,000 people in Detroit could have mild cognitive impairment and could benefit from an amyloid PET scan. That is a huge amount of PET scans when you consider only 49,000 PET equivalents were done in a previous year in the whole state.

MR. FALAHEE: Okay. This is Falahee. Beth, I'll turn to you. So, number one, we can't take any action today, even proposed. So my thought is -- and chime in commissioners -- number one, ask BAMF to give us a specific date to extend it to, but more importantly, to look to the department to clarify -- and I think you remember it was wrong -- how did we get there -- get here in the first place?

And then, to Commission Ferguson's point, why -- what's the department's position on, yeah, let's do a pilot in Detroit versus, wait, there's standards out there. Put this through the regular standards and have the -- and I don't know the answer to that -- but have the department at least recommend or advise the commission, you know, Here's where the department is on this issue.

Let me first turn to the commi- -- does that make sense for the commissioners?

MS. GUIDO-ALLEN: Guido-Allen. That makes, but I have a question. You already did the pilot in Grand Rapids. Why do we need a Detroit pilot? What do you -- what will it different -- what will a pilot in another area show other than patients coming from southeastern Michigan or the Detroit area there?

And then on the slide that shows all the different conditions in which you are treating, once they are approved, which is a lot of them are, so you did a lot of research studies -- phase -- phase two, phrase three, phase one -- once they're approved -- and I'm assuming FDA-approved for our -- for a general treatment; right? -- do you stop that therapy and just focus on the investigational?

And how do you get your referrals? Is it from a tumor board that cites how -- if this is last options?

DR. JOHNS: Yes.

MS. GUIDO-ALLEN: How do the referrals come to you beyond the -- I understand the research studies -- right? -- and how you -- how people are enrolled. So you must have a pipeline of what studies you have to different health systems, different systems, different physician groups. I'm just trying to understand that piece of it.

DR. JOHNS: Yes, we participate on all the local tumor boards and work with all of the health systems that you -- and oncologists on therapies and the trials. And then we also participate with them in other spaces too. So for imaging trials, you know, a lot of oncology, but, for example, with Corewell Health, we're partnering with them on a new oxygen 15 PET stress -- PET -- cardiac stress test. We're partnering with them on -- in -- in the other spaces for other imaging trials as well.

So there's a lot of collaboration.

MS. GUIDO-ALLEN: So the question is, again, once the -- the study is approved and it is then no longer investigational, does BAMF -- B-A-M-F -- stop doing that and focus on just investigational?

DR. JOHNS: No, we will still do that. I mean, at the end of the day, I mean, this -- this has to be sustainable. I mean, we -- we do need that to be sustainable in order to bring that to the committees.

MR. ROGERS: So the ben- -- the benefit of doing

the clinical trials is getting the expertise and working -- really a complicated delivery of -- of imaging and therapy in these centers. Not only that, but the -- helping to extend that expertise out into our community partners where they can then take on those commercially available products and help deliver that care.

There is an absolute tidal wave of -- of novel imaging therapy that's coming within this space, and it's going to need our entire community of hospitals to meet this continuum that's coming. And so with our radiopharmacies being able to deliver those PET tracers locally, not just in Grand Rapids, but in the Detroit area, this is going to be something that's very treating in time.

So I think that speaks to the need for continuing this pilot in the Detroit area.

MS. GUIDO-ALLEN: So just to -- just -- I just have one more follow-up. So essentially, then, you become a competitor?

DR. JOHNS: Yeah, it's -- it's very important to -- in terms of competition, but, yes, that's true. We -- we treat that.

MS. GUIDO-ALLEN: Thank you.

DR. JOHNS: But the magnitude of the volume that's necessary is extremely high. So we need -- we just need more. It won't be an issue of there aren't enough PET scans

to go around. The -- the problem is there's not enough PET scanners, and also on therapy. So, for example, in 2022, an article was published indicating that the U.S. would need about 70 centers like ours designed for high through-put, high efficiency to meet the coming needs of these radiopharmaceutical therapies.

MR. FALAHEE: Okay. Thanks Dr. Johns and Mr. Rogers up there. Thank you. There were two voices. So for Rachelle's sake, whose got her back to you, there -- there were two voices you were hearing there.

Other comments from the commissioners? Let me turn it over to the department. Any comments about what we've heard so far? I get it. I understand, you know, there is innovation and development, but there are also CON standards, and we can't let, you know, innovation and development be an end-around to what would otherwise be a CON-reviewable project. And that's why I want to hear from the department, where they are at on this and how the pilot was created and where we go from here.

Any other comments from the department or Assistant Attorney General Heckman?

MR. HECKMAN: I'll just chime back in with my point. So the way in which this was set up according to Tulika, it would require a change in the standard.

MR. FALAHEE: What would require a change in the

standard?

MR. HECKMAN: So the standard currently, they applied -- they -- under that standard that -- that we have and so they have a Certificate of Need pursuant to that standard or at least an exemption pursuant to it with the -- the date that's therein. The statute would allow -- would have allowed you to have permitted a similar program potentially outside of the context of the standard, but that's not how this was set up.

So because of that, keeping it consistent with the standard that they applied under, an amendment should occur to that standard, which we don't have no language for today.

MR. DRAKE: Commissioner Drake. I'd give a clarified question, and I saw on -- on one of your slides. The pilot ends in 2027. So does that mean that was the timeline by which we have to adjust the standards or amend the standards? What magically happens in 2027 just to that pilot?

MS. NAGEL: So that's a great question. Let me go back just little bit. There was a statute that was passed by the Legislature that created the pilot program. In that pil- -- in that -- in the statutory language it said that once the CON Commission develops standards to support this pilot, anyone who has a pilot under the statute has to apply under those standards. I'm sorry if this is very confusing

and I'm using the same words over and over again.

And so that's what BAMF did. They applied under the statute to the department and then when the commission developed and passed and the standards became effective, BAMF then applied under those standards. The deadline in the standard for them to apply was September of '23.

MR. DRAKE: Okay.

MS. NAGEL: So from our perspective, we cannot accept any more applications under that bit of language. However, we can hold -- we will maintain the CON for anyone who did apply under those standards through '27.

MR. DRAKE: Understood.

DR. FERGUSON: But they can apply for regular PET CON as opposed to a pilot.

MS. NAGEL: Anyone, yes.

DR. FERGUSON: Yeah; right.

MS. NAGEL: Yeah.

DR. FERGUSON: So it's not -- they all are paths. It's just that there's not this path. There's not a pilot path. There's the --

MS. NAGEL: This -- yes.

DR. FERGUSON: -- traditional path.

MS. NAGEL: The way that the standards are written right now, there is no more pilot path unless that date is changed.

DR. MCKENZIE: Commissioner McKenzie. I have another question related to what you just stated. If the pilot ends in the standard under 520.27, for BAMF to continue to operate, do the standards have to be amended at some point related to the language that they came in under for them to continue to operate beyond 2027? I know that's different than the question they're asking, but I'm not sure how that works.

MS. NAGEL: It says specifically -- can I borrow this? All right, Tulika. It says specifically to that,

> "If the commission does not take action to make the pilot program a permanent part of the standards, the provision of this section will expire on September 30th of '27, and after that date no further force or affect of those standards."

So the commission must take action to make the pilot permanent by '27.

DR. MCKENZIE: Okay. One pilot.

MR. FALAHEE: Other questions from the commissioners? If it's -- the last five minutes has been very helpful at how we got here, where we're at, and where we're headed. I think I -- for my sake, and maybe speaking on behalf of the commissioners, if you could put that together in detail so we know how we got here, where we're at, and what needs to happen going forward, try to address

some of the questions that Commissioner Ferguson tee'd up and others have joined in on. Why should this -- not that it's a bad project -- why should this project be piloted, if you will, and not be subject to CON?

MS. NAGEL: Certainly, we can put down in -- in writing and perhaps more clearly how we got to this point, where we are, and what some of the options are.

MR. FALAHEE: Okay.

MS. NAGEL: I don't think that we can answer why this should be a pilot or not.

MR. FALAHEE: Okay.

MS. NAGEL: I mean, we can technically tell you the paths to getting a CON.

MR. DRAKE: That's -- thank you.

MR. FALAHEE: If you can just lay out the paths for us and then the commission will decide in its infinite wisdom which -- which path to take.

DR. KONDUR: Beth, I have one question. Commissioner Kondur. Is there any way we can extend, because of the new obligations of, like, a difference -- I mean, other than oncology, that we can extend what the different location they are asking for pilot project as a pilot program? Extend the program of the pilot?

MS. NAGEL: Do you mean the end date or, like, locationwise?

DR. KONDUR: Locationwise. Location and date, both.

MS. NAGEL: So Certificate of -- each Certificate of Need is specific to the person and the location. So they're asking for a -- a new Certificate of Need for a new location.

DR. KONDUR: New location, yeah.

MS. NAGEL: Uh-huh.

DR. KONDUR: So do we think we can extend to the pilot program?

MS. NAGEL: If you want to extend the pilot program, they would need to apply for a new CON under that pilot program. You would have to extend the date.

MR. DRAKE: For the date. What's -- '24 -- September --

MS. NAGEL: The '23 date.

MR. DRAKE: Got it.

MS. NAGEL: Yes.

DR. FERGUSON: When -- I think this was mentioned earlier, but when are the traditional PET CON standards up for review?

MS. NAGEL: '26.

MR. CONNOLLY: '26.

DR. FERGUSON: And did I hear correctly that in terms of case count, neither cardiac nor neuro currently

counts towards case count? Was that -- is that what someone said earlier? I would be surprised if they don't count towards case count.

MS. BHATTACHARYA: They do.

DR. FERGUSON: They do.

MS. BHATTACHARYA: It can -- sorry. This is Tulika. You can count new cancer cases. You can count cardiac cath data, but there -- you have to read all of the methodologies. They are always on restrictions as to who can commit. For example, if I have a fixed service myself as a hospital, I cannot commit on cases towards a new project.

And also, in March of '23, there was -- there were some revisions to Section 13 as to what type of cancer cases can be counted. I think that one group amended that section to add some new case codes or site codes, excuse me. But without looking at what is the volume of new cancer case and who can commit, it's really difficult to assess, you know.

DR. FERGUSON: So the hospitals can't. So I'm hearing the hospital can't assign its case volume across, but the physicians could. Actually, the oncology group that happens to be aligned with the hospital could pledge volume elsewhere; right?

MS. BHATTACHARYA: So the PET methodology is not based on physician commitments.

DR. FERGUSON: Okay. That's fine. Thank you.

MS. BHATTACHARYA: It's institution --

DR. FERGUSON: Thank you, yep.

MS. BHATTACHARYA: -- specific.

DR. FERGUSON: Thank you. That's fine. Thank you. That's clarifying.

MR. FALAHEE: Thank you. Commissioner Haney?

MR. HANEY: I have a question. Commissioner Haney. It seems to me right now that there are really two options that -- that may be requested. The first one is to extend the pilot application deadline that was September '23 to the end of this year, allowing for another pilot application. Or, option B, to adopt the pilot standards into the CON standards.

From a legal processing, which one is a quicker path?

MS. NAGEL: The first one.

MR. HANEY: The first one is.

MS. NAGEL: For sure. So what -- what -- and this is just -- this is just off the top. But what I would recommend if -- if the commission wanted to adopt the pilot standards into the actual standard, I think you would need a SAC of experts. I don't feel comfortable with our limited expertise proposing language to the commission in that way.

MR. HANEY: That was going to be my follow-up

question, so thank you.

MS. NAGEL: Yeah. And so, you know, right now we do have a SAC planned or a -- we'll bring this back to you for 2026. I'm anticipating MRI -- or MRT always has a SAC, always. I would assume it would be no different in that year as well. Okay. I'm sorry. Getting them all -- this is why we need experts, yeah.

MR. FALAHEE: Any other comments? Very, very good discussion, and then you can see why ten minutes was not enough. I think it's a very good discussion. So let's look forward to some path forward options from the department when we get together in June. And then we'll figure out where to go from there.

Is that all right with everyone? Any other comments?

MS. STANTON: We did have someone that did want to add -- answer.

MR. FALAHEE: Oh, sorry. Sorry about that.

MS. STANTON: We didn't -- yeah, Arlene from Arbor Advisors.

ARLENE ELLIOTT

MS. ARLENE ELLIOTT: Good morning, my name is Arlene Elliott. I'm with Arbor Advisors and I've been working with BAMF, and I think Tulika and Dr. Ferguson just clarified, but as somebody who does submit a lot of CON

applications, the reality for PET CON is that the hospitals, because they are the tumor registry sponsors, they control all of the cases that can be committed, but if you already had a PET scanner service at your hospital, whether it's fixed or mobile, you can't commit any cases to somebody like BAMF, who is clearly not a hospital.

There isn't, as to my knowledge, any hospital in the Detroit area, just like there really wasn't one in the Grand Rapids area where they are today, that did not only have a PET service. So there was no way for a non-hospital like BAMF to stand up a service. They didn't have their own cancer registry. They didn't have any hospitals who would be happy to refer to them who could commit cases to them because of the current standards.

The physicians do not control or are able, as Tulika clarified, to commit cases. So it's kind of this thing where there wasn't -- there was not a pathway for a non-hospital to do this, especially because PET is prolific across the state, whether it's through mobile or fixed. So that was part of the answer to why can't they go through the normal pathway? It's because the normal pathway has kind of been clogged up already. It's already being well used and well situated. What this doesn't do is doesn't preclude any of the existing providers in Detroit or anywhere else to do exactly what BSMF is doing. So people who could -- wanted

to could do this, setting up all the infrastructure.

From my perspective, the thing that makes this unique is that theranostics clinic, which, having been there twice -- and I know I went through the department most recently -- you know, the patients are served because they're -- I learned this -- I'm -- I'm a -- new on this whole thing -- because the patients are radioactive after they get this therapy. They have to stay there for a long time until they're sufficiently not radioactive, and it takes a lot of clinic time. You have to build a specific clinic to support that type of risk profile for the patients and the staff in keeping that on time.

So I don't know if providers want to do that with the cyclotron, et cetera, but that is kind of why BAMF can't go through the normal pathway.

MR. FALAHEE: Thank you very much. We'll be back in June or thereafter. Thank you.

DR. JOHNS: Thank you for having us.

MR. FALAHEE: Any -- anyone else on this issue?

DR. ENGELHARDT-KALBFLEISCH: Just to comment. I mean, I think using the term "pilot" is a little misleading, because to me I think of, like, research when I hear that. But, like, hearing the volume needs in the future and hearing that they can do treatments, like beyond that pilot phase, going back to, like, cost, access, quality, I don't

see -- I think it could set a dangerous precedent. Like, I want the innervation in a technology, but there's a lot of innervation in technology in a variety of areas.

So I just think we need to be careful not to set a precedent here as a way to circumvent the normal process.

MR. FALAHEE: Thank you. I think we all agree with that, hence the questions and the discussion.

Okay. Thank you. Let's move on to the next item, and it's a recommendation from the Surgical Services SAC to modify a charge. So I'm going to let Tiffani talk us through this, and it would require that a motion of approval, if we so choose to do that.

Go ahead, Tiffani.

MS. STANTON: Thank you. So Tiffani from the department. The Surgical SAC -- Surgical Surgeons SAC is currently meeting monthly to work on the standards. One of the charges that they have to review, it says,

> "To consider revisions to allow the application of excess cardiac catheterization maintenance volume to the maintenance volume requirement for a FSOF that will be used exclusively for cardiac catheterization services."

So recently, the SAC has decided to not make any changes to the standards with that charge, and instead have requested the department present to the commission to add a

charge for the cardiac cath, which this was in your binder as well. It is highlighted, that sixth charge, to review the provisions and definitions for hybrid OR cardiac cath labs and recommend modifications to allow for hybrid OR cardiac cath labs in facilities or even those with open heart surgery on site.

So, essentially, they are wanting to have this part reviewed first before they -- whatever the outcome comes from the cardiac cath, they want the department to bring back to the surgical service with the next review cycle to then kind of decide how they want to handle. They may bring back that charge. I'm not sure how it will go, but this is where they want to start before proceeding with the charges that is presented.

So if it is something that the commission does agree with, it will obviously require the motion and second to vote to allow us to amend the cardiac cath charges presented.

MR. FALAHEE: So in a sense, the Surgical Services SAC is saying, Take what was assigned to us, move it to the new, has-not-met-yet Cardiac Cath SAC, let them decide it as the experts, and we'll figure out later whether -- if that makes changes in the surgical services standards as well.

Did I say that right?

MS. STANTON: Yes, sort of. That was where --

it's very close. So it -- they --

MR. FALAHEE: Well, that's all I have. That's all I have at this point.

(Crosstalk.)

MS. STANTON: -- that was how we were interpreting it as well, but apparently there is something that needs to be specified or clarified in the cardiac cath before they can proceed with their charge as it's presented.

MR. FALAHEE: Okay.

MS. STANTON: So -- then, basically, they'll come back to it. They'll be able to align this cardiac cath change, whatever the outcome is from that charge, into the surgical standards, and then proceed with their charge, if that makes sense?

MR. FALAHEE: I worry, though, about the six-month rule for the length of SACs.

MS. STANTON: Yep. They -- this would be for the next review cycle for surgical.

MR. FALAHEE: Okay. All right. Thank you. All right.

MS. STANTON: They've already voted not to make any changes on charge -- their charge.

MR. FALAHEE: All right. Okay. Any questions of Tiffani? Let me just add, we -- we talked about the Cardiac Cath SAC. This week, I think, we got -- we got the list of

nominees. Commission McKenzie and I got the list of nominees from the department and you all know that many times it's like pulling teeth to get people to nominate; right?

While we've changed the rules, you don't have to be in person. So I don't ever recall a SAC having this number of nominees. There are 24 nominees for the Cardiac Cath SAC. Escanaba. You would never have somebody from the U.P. ever being present on a SAC.

MS. STANTON: Or Pennsylvania.

MR. FALAHEE: We've got a couple from Pennsylvania too. All right. So that's what's going on with the Cardiac Cath SAC. I've to work with Commissioner McKenzie on who we put on here. We're not going to put all 24. Most SACs are 12, because that was the number we hoped to get combinations from. We've got 24. 24, I think, is a little unwieldy, so we're figure out -- Commissioner McKenzie and I -- what do we do with that. But -- and some people around the table know some of these people very, very well. So I think it's great that we've got experts and non-experts to talk about the issue.

So there will be a robust Cardiac Cath SAC to take on this charge --

MS. STANTON: Six.

MR. FALAHEE: -- six that's highlighted if we so

chose to bump it to that Cardiac Cath SAC. But it shows the merit of not having a SAC being subject to the Open Meetings Act, which is great.

Okay.

MS. GUIDO-ALLEN: Guido-Allen. One of the things I would ask them if -- if indeed we chose to -- to move this to the Cardiac Cath, is the -- a review of the safety of doing the procedures that are done in a hybrid OR cath combo of not having open heart surgery on site. We have to look at that, because in many settings the open heart -- the CV surgeons are on standby when these procedures are occurring, and there's a reason for that. So I would want to make sure that they really review that and look at the standards within their own professional organizations as well.

DR. KONDUR: So -- Commissioner Kondur. To echo her comments, this societal guidelines are changing actually because of the -- the innovations that Congress are ongoing, like, make it much more time being convenient, and you can safely perform these kind of complex cases without onsite. That's why -- look at the new CMS guidelines, societal -- society of those case when that's the reason they put that statement there.

So there's a lot of changing, actually. Some like ten years ago, hundred percent agreed. Now it's completely changing. Societal guidelines, like expert opinions,

everything giving society the big paper. Recent paper. That's the reason that charge is there. That's why part of the last segments also asking to tie up the experts, see where they -- where they stand.

MR. DRAKE: This is Commissioner Drake. And I definitely echo what you're saying there. And I hope they will also look at how would you determine which patients could and couldn't have it done. I -- I agree with you, Commissioner Kondur, that with the new technologies and just overall just the new experience in this space, there's more and more that's done and non-open heart could be done in this space, but we got to be careful that there is some way to determine who would be applicable for which site.

MR. FALAHEE: This is Commissioner Falahee. Hence the need for the SAC. And looking at the nominees, there are experts from both sides of the aisle, if you will, on that issue, which is great. That's what you want.

Are there any cards on this issue? I see a card floating around. I didn't know if it was this issue or not.

MR. CONNOLLY: Yeah. He just withdrew.

DAVID WALKER

MR. DAVID WALKER: You got to the point I was going to make. The last SAC tied everything to the professional site guidelines and CMS for that exact reason because they were very concerned with the safety, and one of

the reasons that -- that there were no recommendations to try to make it easier to initiate these programs is because we haven't seen a lot of data on the safety yet from these new -- at the facilities in the state. And that's why they're asking to put a SAC up.

MS. STANTON: And for the court reporter, that's Dave Walker from Corewell Health.

MR. FALAHEE: David Walker who did -- who submitted a card, then withdrew it, but then chose to (inaudible).

MR. DAVID WALKER: Just my style.

MS. STANTON: True Dave fashion.

MR. FALAHEE: So we need to -- Beth, you have your hand up?

MS. NAGEL: I just wondered if the commission wants to add anything into this SAC, like --

MS. STANTON: The charge.

MS. NAGEL: -- or into this charge like considering safety, professional standards, and patient selection. Things like that.

MR. FALAHEE: I think what -- I think it's proposed that based on comments that Commissioners Drake, Kondur, and Guido-Allen have made that the department and the chair and vice chair come up with language to talk about the safety issue, where it can be performed, which patients

can be selected -- I'm -- I'm rattling on the top of my head my recollection -- knowing that there's potential arguments one way or another. But if we could -- we hear approval. If we could work together with the department to edit this charge, I think that would be appropriate.

DR. KONDUR: And also to add -- Commissioner Kondur -- add a professional standard and also the payor standards too. Payor, like CMS, because they are changing with needles moving and the -- and the cost savings and everything. So we need to add those language too.

MR. FALAHEE: Any other discussion? We still got to have a motion coming up, but I wanted to make sure we have a good discussion about it. So we have in front of us a motion to move from the Surgical Services SAC to the Cardiac Cath SAC, which has yet to be seated, number six up there that's highlighted, and to edit that charge with the joint work of the department, the chair, and the vice chair to reflect the discussions that we've had around the table the last 10 or 20 minutes.

DR. MCKENZIE: Commissioner McKenzie. I'll move to move the charge from the Surgical Standard Advisory Committee Review to the Cardiac Cath Review with amendments to reflect the discussions around safety, to be drafted by the chair and co-chair.

MR. DRAKE: Commissioner Drake. I second.

MR. FALAHEE: Any discussion? Very good discussion by the way. Thank you.

All in favor please say aye.

ALL: Aye.

MR. FALAHEE: Opposed? That motion carries.

(Whereupon motion passed at 10:32 a.m.)

MR. FALAHEE: Cardiac Cath SAC now has another item on their plate.

MS. STANTON: Good thing we're adding more commissioners or numbers.

MR. FALAHEE: Yeah, right. I now envision three subgroups from the cardiac cath.

Next is MRT update, and it says "update" because when we last met we looked at what was -- at the time, what we thought -- maybe some still do -- is, like, oh, all right, let's change the vol- -- let's change the distance requirement for those in the U.P. from the current 90 miles to 45 miles driving distance. And there's also in there that no volume requirements are needed for those in the U.P. to get an MRT. That -- that no volume requirement has been in effect for 10 years, 11 years, something like that. So that's not new. What was new is changing the 90 driving distance to 45.

And so I think that breezed through without any discussion. But then within the last couple weeks I

started -- either you know there's CON Commission meeting coming up or people are suddenly reading -- reading what came out of the last meeting. And I started to get phone calls. So did Commissioner McKenzie. E-mails, request for Zoom meetings, you name it. So -- and which caused me to look at the proposed language.

What I told those and I'm going to tell again, anybody that has issues about this, that's why we -- why I, with the department's approval, hold this off for a final vote because there's comments both sides of the issue coming up here on that 45-mile driving distance. And so we took it off and just an update. So I would encourage anyone in the U.P. who has a comment, pro or con, to let us know about it.

And then what I did, if you want to pull that up, this is sort of like Tim Russert in Meet the Press. So what I did, I said, All right. Let's look at driving distances. If we did 45 miles -- right? -- I -- if I played the game right and I used to do this in the CON Department, drove -- I drove them nuts -- I could build 11 MRTs in the U.P. There's 70 in the state right now, give or take. And if we look at quality, access, and cost, an unintended consequence of a 45-mile is 11 MRTs. And I -- I joked, If I'm in Detroit I could probably drive and get a quicker MRT scheduled in the U.P. if there's 11 of them there. Right?

So when I saw that, I went, All right. And you

can see that what I've done is I'd go to Google Maps and look at driving distance from A, B, to C. There's three -- three facilities that wouldn't count, but the other -- like I said, I get 11.

And I don't want any final discussion or decision, but I think that we need to consider that when we wear our quality-access-cost hat. I understand the sometimes unique needs of the U.P., but that's what happens when you go from 90 to 45 miles of driving distance. Hence, we're -- that's why I encourage those hospital in the U.P. to contact us, to say, Here's why we're for this or against this so that we can bring this back for a formal decision at a future meeting.

Commissioner Ferguson?

DR. FERGUSON: So there -- so miles are easy to use, whether it's as the crow flies or whether it's driving. I understand the natural tendency to do that. Are there societal standards? Are there some -- is there some easy federal methodology that lets us calculate actual transport time or transit time as opposed to mileage, because transit time is more relevant in a day-to-day practical basis, but it's very subjective unless there's clearly defined standards. Is there a federal -- do the feds have some standard that we could adopt?

MR. FALAHEE: As far as I'm aware, there are no

federal standards in terms of travel time. You can get driving distance --

DR. FERGUSON: Yeah, right, right. That's why --

MR. FALAHEE: -- as you see here from Google Maps. This is not as the crow flies, especially in the U.P. That's driving distance. And that's how, for example, critical access hospitals. You can become a critical access hospital in a rural area if you are more than 15-mile driving distance from the closest other hospital on two-lane roads. But no one, as far as I know, has done time.

We've talked to Professor Delamater about this over the years. He's not aware of anything either because it takes -- we all know, living in Michigan, except this last winter, it's hard to sometimes get from A to B in twice the time. You just don't know.

So that's -- that's why I wanted to give everyone around the table here an update and to encourage any of the U.P. facilities to comment on the proposed change from 90 driving miles to 45, pro or con, so that we can bring that back to a future CON meeting for a discussion.

Had I known this was going to be broadcast up here, I'd have been a little bit more careful about how I was trying to write, but that -- that gives you an idea.

MS. STANTON: I think you did a really good job.

MR. FALAHEE: Okay. Thank you all. Any other

comments about that?

All right. Next, open heart surgery, public hearing summary. Marcus, turn it over to you, please.

MR. CONNOLLY: All right. At the December commission meeting, the commission took proposed action on the informal workgroup's language that is in front of you today. The draft language was sent for public hearing and to the Joint Legislative Committee. Testimony was received from one organization in support of the language as presented with no suggested changes.

The department is supporting the language as presented at the December meeting. If the commission chooses to take final action on the language as presented, it will require a motion, a second, and a vote to approve. The language will then be forwarded to the JLC and the Governor for the 45-day review period. The 45-day review period must include not less than nine legislative session days. If the language is not disapproved, it becomes effective upon the expiration of the 45-day period.

Does anybody have any questions?

MR. FALAHEE: Is there any questions of Marcus about that? Any discussion? Really there was no one that opposed the proposal so -- the one comment was in support.

MR. CONNOLLY: Yep.

MR. DRAKE: I do have a comment in -- in looking

at this. And probably people on the commission -- this is Commission Drake -- are more informed to this than I am, but I seem to recall, is the -- is there a contemplation of the star rating going away? Does anyone know anything about that? Maybe I'm -- read something else.

MS. STANTON: I think it's more that they were standing.

MR. DRAKE: I knew something was changing, but I --

MS. STANTON: Yeah, yeah. And that was why they decided to adjust the standards to kind of fulfill the --

MR. DRAKE: I knew something was changing but it was more in the labor.

MS. STANTON: Yeah, yeah.

MR. DRAKE: Okay, okay. Thank you.

MR. FALAHEE: Okay. Marcus laid out the path before us if we choose to proceed. So I'll entertain a motion along the lines that he commented on.

DR. MCKENZIE: Commissioner McKenzie. I'll propose that we take final action and -- on the language and forward it to the JLC and the Governor for the 45-day review period.

DR. ENGELHARDT-KALBFLEISCH: Commissioner Engelhardt-Kalbfleisch. Second.

MR. FALAHEE: Thank you. Any further discussion?

All in favor say aye.

ALL: Aye.

MR. FALAHEE: Opposed? That motion carries.

(Whereupon motion passed at 10:40 a.m.)

MR. FALAHEE: Thank you, Marcus. Thank you very much.

Tiffani, we'll turn it over to you to try to explain the hospital beds.

MS. STANTON: All right.

MR. FALAHEE: The bifurcated hospital bed summary. I see you got that one.

MS. STANTON: Yes. So we'll start from the top. So at the December commission meeting the commission decided to take the proposed action on both the hospital bed draft language and the hospital bed REH addendum that was proposed by the department. It did go to the JLC in a public hearing. We did receive comments from seven organizations. All that did make comments on the hospital draft of the seven were in support of the hospital bed draft language as presented, and none of them were in support of the addendum as presented.

We did start a workgroup, a hospital bed REH workgroup in February. So we are actually recommending that the department -- or, I'm sorry, the commission allows the department to continue working with the workgroup to create

language or changes to the addendum. If there is any changes, we'll bring it back to the commission at a future date for proposed action. If they decide there is no changes, we'll bring it back at a later date for final action.

We are recommending the department do take the hospital bed draft and continue that on for final action and proceed as necessary with the same -- it will be sent to the JLC and the Governor for the 45-day review period, and then effective at a later date.

MR. FALAHEE: This is -- this is Falahee. Just for a little add-on to that. So recall at our last meeting we set up a workgroup, which I volunteered to chair, to look at the REH issue, period. That was a -- and that's why we bifurcated REH standards, hospital standards. And so we've had one meeting of the workgroup. I think it went very, very well. Very good discussion. Several members of the department were there, several other people from the hospital community; a very good, open, professional, reasoned discussion. And we've got our next meeting next week.

And so I know we're -- we're having good discussions and we're moving forward with it, and a lot of things -- no one felt unabashed about throwing ideas out there in the workgroup meeting, which is what you want. So

I think that's moving forward well. So we're sort of setting that off to the side when we're looking at -- as potentially approved today. And all, as Tiffani said, we're looking at is just the non-REH, the hospital bed standards for potential final action. So that's where we're at.

Any questions or discussion?

DR. FERGUSON: Question about the REH workgroup. You implied -- but I'm just looking for a more active affirmation that all sides are meaningfully represented in the workgroup?

MR. FALAHEE: Yes.

DR. FERGUSON: Okay.

MR. FALAHEE: All sides -- however many sides there are.

DR. FERGUSON: Right. Yeah. A zillion; right?

MR. FALAHEE: Yeah. I think that was part of it that I was pleased to see those. For the workgroup, as you all, there's no set memberships. It's whomever clicks into that Zoom meeting that day. But when I looked around at the Hollywood Squares on your screen, we had representation from the entire gamut of the community, not just large hospitals, but smaller hospitals, rural hospitals represented in strong rural areas. So we had a good -- good cross-section.

DR. MCKENZIE: Commissioner McKenzie. I will make a motion to move forward the hospital bed standard to the

JLC and the Governor for the 45-day review period, and continue on with the workgroup to work on the REH addendum.

MR. FALAHEE: Is there support for that motion?

DR. KONDUR: Commissioner Kondur. I support for the motion.

MR. FALAHEE: Thank you. Any further discussion? All in favor say aye.

ALL: Aye.

MR. FALAHEE: Opposed? Okay. Great. That carries.

(Whereupon motion passed at 10:44 a.m.)

MR. FALAHEE: County designations. Tiffani, I'll let you tee it up and I'm -- and let me know if we have any cards.

MS. STANTON: Yes. So following the CON Commission's approval of the update to the county designations during the January 2024 meeting, the department -- we were able to work with Assistant Attorney General Brien Heckman. He did provide the proposed amendment to -- that were referenced in the standards. So he will go over that -- and I can pull it up as well, Brien.

MR. HECKMAN: So the rural micro county designations are impacting the standards that you see on the -- projected on the screen. Ultimately, there may need to be a standard in the future that deals with general CON

standard issues is probably the cleanest way to deal with this. There is a number of things kind of in the pipe that would potentially go into that standard. And so weighing into that project at the moment seems premature and just affecting these individual standards, and just making this quick fix is what's proposed.

That being said, we've received an e-mail from an interested person. Do you want to go into that, Chip?

MR. FALAHEE: Well, I think that might be the public comment part.

MS. STANTON: Yep, we do have a public comment part. Jennifer Groseclose from Munson.

MR. HECKMAN: But generally speaking, this is just kind of clearing this up, and I think Jenny is about to come on and say, Hold up, everybody.

So I don't have anything further. I'll let Jenny speak.

MR. FALAHEE: So Jenny with that intro -- this is Jenny Grose- --

JENNIFER GROSECLOSE

MS. JENNIFER GROSECLOSE: I would like a -- I would like a little more -- so I'm Jenny Groseclose from Munson Hospital, and I -- we have eight hospitals in Northern Michigan, one happens to be a satellite, in Kalkaska.

The new county designations now have Traverse City and three other counties that are all contiguous. They are now considered metropolitan. This is a huge shock to us.

So the first is Leelanau County. It has a population of 22,000. Benzie County, which is just underneath that, has a population of 17,900. Kalkaska has a population of 17,900; and Grand Traverse County, Traverse City, has 95,000. So adding it all up together, you have a population of less than 200,000, which, to us doesn't feel metropolitan. So we have three hospitals: Paul Oliver in Frankfurt, which is Benzie County; we have Traverse City, which is our tertiary center in Grand Traverse County; and then we have Kalkaska.

What we're asking is for pause on that county designation pointing to this new metropolitan standard and a workgroup to talk through maybe additional layers to that county designation that's noted throughout the standards. And we've had some conversations separately about that proposed idea.

Do you have questions about our recommendation to -- we understand there is some technical requests in the language, which I think could occur, and then we can talk about a workgroup.

MR. FALAHEE: Sure. Let -- thank you. Other commissioners first, any questions? All right. I'll --

I'll start, because I've had discussions with Jenny about this, with the department, and in my area -- I live in Kalamazoo County -- the county to our west, Van Buren County, used to be metropolitan because it got tied into Kalamazoo. All right. And my phrase of others, is there are "more ears of corn" in Van Buren County than ears of people. All right? So Van Buren County just became rural under the new census.

And that's what's driving this as -- as Brien pointed out. It's driven by the Office of Management and Budget. Every ten years they look at the census and say, All right, based on that most recent census, here's what happens. It just so happened that the 2020 Census resulted in five or six counties in Michigan being redesignated. That didn't increase the number of people in those counties, the density per mile. So if you're in Benzie County or Leelanau County, all of a sudden you're metropolitan as far as the U.S. government is concerned, and the question is should that have been carried over to the CON Standards?

Now in -- in talking to -- to Beth and Tulika, they're going to -- if I -- if I'm wrong -- if you're in a rural county and the rural standards apply to you and all of a sudden the Federal government says overnight, You're metropolitan, that will not change your CON. We're not -- it's not going to be yanked away. You won't be held to any

stricter standards because of what the Federal Office of Management and Budget has said.

But I think Jenny raises good points. Do we need to somehow say that and what Brien talked about is that a new general standards, if you will. And I think that raises some -- some good questions. Do you do it populationwise? Do you do it density per mile? Who -- who knows? Those are all things that we can talk about. So I think there's -- there's merit to that. And that's -- that's kind of the discussions we've been having.

Anybody else want to add? Any from -- from the department? And Jenny may want to comment as well.

MS. NAGEL: Yeah. So I'll just add. I think that -- I don't know if it's helpful -- but I think there's, like, three different things going on here. I think, one, we've got the 2020 Census update, and how we normally handle those is that every standard that passes in front of you, like, in it's normal course of business, we update those standards. And so you've never seen them like this. You've never seen them in a whole package because -- the number two thing that's happened is we asked Brien, Is there a way for us to update all of these at the same time without having to go through the whole process; right? The proposed action, public hearing, and final action. All of that, if we're just updating these -- these federal designations, do we

have to go through that?

And then the third thing that happened was that Jenny brought to our attention that throughout the standard there are, like -- I don't know, for lack of a better term, "carve outs" for if you're in a rural county? When those were written, it meant a county with a small number of people. It did not mean this federal designation.

MR. FALAHEE: Right.

MS. NAGEL: And so it's point -- and -- and at some point those were one and the same. They are not anymore for various reasons. And so there are three different issues.

We have to update for the new census standards. That -- that does have to be done. Do we do it all at once, as Brien has worked a way for us to do, or do we do it as each standard comes up as we make changes and you look at it and -- and it's kind of a rolling process then.

And then, third, how are we using these words in the standards that point to these definitions. And I -- I absolutely love the idea of having a workgroup to discuss that, because I think we have gotten a little bit far away from what we really mean or what we really meant when the standard was created and how it's being implemented.

I -- I am -- you know, I have some concern about not updating the new 2020 designation, because right now

we're running off 2010 designation. I -- so, you know, I don't have -- I don't know what all of that impacts to -- to not accept the 2020 designation, but, you know, I -- I see the process that Jenny has laid out and I'm not -- that I support and I'm excited about taking a lot longer than -- and -- and then we continue to delay, we're going to be, you know -- we're already 14 years away from the previous designation. I would hate for us to continue being so far out of date.

MR. FALAHEE: This is Falahee. Beth, there's one option -- I understand where Brien is coming from, to do it all at once. Anticipating a workgroup, could we do it the old-fashioned way and roll it out standard-by-standard, which would take longer, but maybe taking longer helps, because then we can have the workgroup get together, figure out what to do, what's -- what's rural?

MS. NAGEL: Yeah.

MR. FALAHEE: And then apply that going forward, and maybe going backwards, any standard that's been approved in the regular process. Does that work?

MS. NAGEL: I -- I -- at my first blush, is I really like that. I really like that idea because I think the -- the workgroup needs to decide, What did we mean when we said rural? Specifically, what did we mean? And then I think each, you know, SAC or workgroup that we have going

forward can interpret that to kind of compare and contrast that with the standard and say, Well, actually in this case that's not what we meant. We meant -- who knows what? Or, yes, it is exactly what we mean and that -- that's how that word should be used in this specific.

So, I mean, I think I like that because it treats each standard as its own individual standalone service, which it is. So that makes sense to me.

MS. GUIDO-ALLEN: Guido-Allen. I have a question, Beth. When you say we would have to apply the federal designation to each county based on census regardless, so we would go back and define on a CON perspective what rural means in that standard, what micropolitan means, and what metropolitan means?

MS. NAGEL: Yeah. So when there are places where we say, This is what the standard means, except if you're rural, did we mean the --

MS. GUIDO-ALLEN: The federal?

MS. NAGEL: -- the OMB definitions of rural or did we mean less than 20,000 in a specific defined area or something like that.

MS. GUIDO-ALLEN: And, question, would that definition depend on the standard or would that definition -- the CON definition of rural, would it depend on each standard or would it be a blanket like the Federal

government does?

MS. NAGEL: So what I would like to see is for this workgroup to come -- to come up with some agreement of, Yeah, for us it means this.

MS. GUIDO-ALLEN: Okay.

MS. NAGEL: But then if we take that process of updating it as each standard comes up for review, a group of experts can determine, Yeah, that makes no sense, or if that makes perfect sense.

MS. GUIDO-ALLEN: Okay, got it. Thank you.

MR. FALAHEE: Commissioner Ferguson?

DR. FERGUSON: I'll pick up on your point. I would strongly encourage that whatever definition we come up with for rural, that rural be the same thing across all the standards eventually; right? It may take a little while to converge, but to have different definitions would be problematic.

MS. JENNIFER GROSECLOSE: And can I share: That's kind of what started happening. With MRI we added critical access hospital in one spot in addition to the whole micropolitan-metropolitan. And then in the hospital standards we added 200,000 or less in a county. So we could see, once we started looking at everything, we were kind of working away on it in -- in different manners.

So we agree with one -- one approach.

MR. FALAHEE: So let me ask a follow-up question. This is Falahee. So let's assume we sort of take the -- that middle approach. If doing it not all at once, as Brien correctly set it up, but instead doing it standard-by-standard, and then to give the workgroup time to do its work, what would we need to do today besides appointing a workgroup?

MS. NAGEL: I don't think any -- Brien, wants to talk.

MR. HECKMAN: What did we say regarding the effective date of the -- the data? Didn't we push that out for this reason, like, the -- the classifications?

MS. NAGEL: I think if -- are you thinking of a different?

MR. HECKMAN: I probably am thinking of a different. If it's -- if currently -- currently you don't have to do anything unless there's a deadline. I want to say there was something that we delayed implementation of.

MS. NAGEL: I think you're thinking of psych bed data.

MR. FALAHEE: Psych bed data.

MS. STANTON: Yeah, that's --

MS. NAGEL: Yep, yep. That's --

MS. STANTON: This is just the proposed amendment.

MR. FALAHEE: Okay.

MS. NAGEL: No. I think what we have is just when the -- when it -- I -- I can't -- Tulika might have it up in front of her, but when new OMB data is available, that's when it tells us to update these standards, when the new OMB data is available. So -- and we have always done that on a rolling basis.

MR. FALAHEE: So then if we so chose, what we could do and only need to do is then appoint a workgroup -- authorize a workgroup to look at this issue?

MS. NAGEL: Yes, I think so.

MS. STANTON: Did we want it a set date by?

MS. NAGEL: I'm sorry, what was that?

MS. STANTON: Oh, do you -- with a date -- do you want it set by so not pro- -- for clarification, not proceed with putting this in? Just kind of hold off until we have more -- further clarification on it?

MS. NAGEL: But as new standards come to the commission, we can take that opportunity to --

MS. STANTON: Yeah.

MR. FALAHEE: So let me -- I see the Three Musketeers standing over here. Does anyone care to submit an additional card besides Jenny?

MR. DAVID WALKER: Yes.

MR. FALAHEE: Mr. Walker?

DAVID WALKER

MR. DAVID WALKER: Dave Walker with Corewell Health. First of all, Mr. Chairperson, let me apologize. Yesterday I told you I would not submit a blue card and now I've done that twice.

MR. FALAHEE: The commissioner -- the chair will remember this.

MR. DAVID WALKER: Second, I think what we -- we were just talking about is -- is maybe we could do a hybrid approach where the workgroup meets, come up with a recommendation that standardizes, and then do the AG Heckman approach and put it all in one. I -- I think that we would -- we would support that if that is something the department is okay with.

I -- and I could be completely wrong here, but I'm not -- I think that -- I understand the concern about not having the most recent census data in the standards, but I think that we want to get this right. And if there isn't a deadline or some sense of urgency that I'm not aware of, then I don't -- I don't know why we don't proceed along the lines that we've been discussing.?

MR. FALAHEE: Thank you, Dave.

MR. DAVID WALKER: Yep.

MR. FALAHEE: Any questions of Dave? Okay. All right. Thank you, Dave.

MS. GUIDO-ALLEN: Guido-Allen. What I would like

to see is a term -- you know, that rural for CON, metropolitan for CON -- that wouldn't change each time we did a census; right?

MR. FALAHEE: Yeah; right.

MS. GUIDO-ALLEN: That we would be able to apply from here on out.

MR. FALAHEE: Right. Beth, I see --

MS. NAGEL: I mean, it would still change based on -- we'd still need the census data; right?

MS. GUIDO-ALLEN: No. The census data -- the census data would dictate what the counties are classified as, but our CON definition would not be dependent upon that census data. Does that make sense?

MS. NAGEL: I think -- yeah. I think it probably does. I think I'm over thinking it.

MS. GUIDO-ALLEN: Yeah.

MS. NAGEL: Yeah.

MS. GUIDO-ALLEN: Or I am, but -- yeah.

MS. NAGEL: No.

MR. FALAHEE: So I think to sum it up, what we're looking for in terms of an action for today, based on all of its great discussion, is an authorization to create a workgroup to look at, yes, there are OMB definitions, but what, for CON purposes, should be the definitions for rural, micropolitan, and metropolitan across the CON standards.

All right. Would anyone care to make a motion sort of like that?

DR. MCKENZIE: Commissioner McKenzie. I will move to seat a workgroup to define for the standards the metropolitan, micropolitan, and rural standards.

MR. FALAHEE: Support for that motion?

DR. FERGUSON: Second. Ferguson.

MR. FALAHEE: Discussion? All in favor of the motion?

ALL: Aye.

MR. FALAHEE: Opposed?

(Whereupon motion passed at 11:02 a.m.)

MR. FALAHEE: We will add this to the department's work list, setting up a workgroup, and I will guarantee that Mr. Walker and Ms. Groseclose will be on the workgroup and Ms. Linderoff (phonetic) is probably on -- going to be on it as well. But I think it will be a -- a good result to resolve these issues. Thank you all. Great discussion.

All right. Moving on. Psych bed need update. Tiffani?

MS. STANTON: Okay. You do recall at the December 2023 CON meeting we did present because the psych bed has been waiting for data. What was presented at December, the commission ultimately decided to postpone that effective date for those psych beds until July 1st of '24. We -- and

have the department provide the 2022 MiDB data to Dr. Delamater to perform an update.

We were able to get the data to Dr. Delamater. He did provide the update, which you did see in your packet. And I apologize, I know it's -- I know it's a big and it's still really hard to see, but based on the data that was provided, there was very little change, if any at all, from what he ran in May of 2023 compared to what was ran in February of '24.

Yeah. So today the commission just needs to determine if they want to set, like, an effective date for that or how they want to pursue with that. For a reference, the next psych bed need update is required by April of '25.

MR. FALAHEE: So, Tiffani -- this is Falahee. We've already said we're going to at least hold off until July of this year.

MS. STANTON: Yeah.

MR. FALAHEE: All right.

MS. STANTON: True, yes.

MR. FALAHEE: So what's in front of us today for potential action?

MS. STANTON: You could -- I guess you could take action before the effective date or we could bring it back in June. It'd be -- we pushed off to July just in case we didn't have it by March. So we were able to get it in

February and have it presented for the meeting.

So if you wanted to take action or if you wanted to -- for us to bring it back in June to discuss, we can. But essentially, we were just trying to get ahead of the effective date. But if you want to decide to postpone that effective date or however the commission wants to move forward with that.

MR. FALAHEE: Okay. I think for those of you that have read it, I thought that the last paragraph of Professor Delamater's report was interesting. He said,

"Overall, the projections for adult beds was lower than recent updates, which can be attributed to this -- to a substantial downturn in utilization over the last three years of data. The projections for pediatric beds is slightly less than the previous update. It's unclear whether the pediatric bed utilization is a new steady state following the COVID pandemic or if there will be an eventual bounce-back to utilization levels from five to six years ago."

And interesting, other comment he makes. "One other potential issue that may be in place, artificial depression of adult patient data utilization due to staffing issues."

MR. DRAKE: Yeah.

MS. GUIDO-ALLEN: That's exactly it.

MR. FALAHEE: You can -- you -- okay. You can tell those of us that wear hospital hats, that's why I said that because that's in his last paragraph.

MS. GUIDO-ALLEN: Yeah.

MR. FALAHEE: I will let them comment because there are staffing issues in the extremist throughout there. I don't know if Commission Drake or Commissioner Guido-Allen want to comment about that.

MS. GUIDO-ALLEN: There are.

MR. DRAKE: Yeah. I mean, this is Commissioner Drake. I'll -- I'll go first. When I saw the reduction of numbers, I mean, it looks like the need is based on beds that were filled and, you know, if hospitals are holding a high number of these patients that never get to the facilities because they don't have staffing, of course, on the hospital side, the psych hospital side, they don't have the need, but the needs far exist.

What we don't know is if they were fully staffed, would that be enough? That's the question we can answer, but I think the numbers are falsely low.

MS. GUIDO-ALLEN: Yeah; right. Guido-Allen. Same. So the current beds is the current licensed beds, but how many were staffed during that time? How many patients were they able to take during that time? On any given day -- I'll just talk my own hospital, you know, 15 to 20

mental behavioral health patient holds in the ER or on the floors because we can't get beds. We, you know -- so I think the -- as much as I appreciate Dr. Delamater's approach, it's flawed in the sense that since 2020 licensed bed does not mean staffed.

MR. DRAKE: Exactly, yeah.

DR. MCKENZIE: This is Commissioner McKenzie. I was also going to make a comment because we're hearing about it on the payor side of patients who are sitting in the emergency department for very long periods of time. It's something we've been working to monitor as well. And so it brings up the question to me -- well, first of all, I don't want to put numbers in place, but it also brings up the question of do we need to go back and look at the methodology and are there other things that need to be incorporated, because it -- it's sounding to me like there are.

MR. FALAHEE: Commissioner Ferguson?

DR. FERGUSON: Yeah. So it's one thing to have a licensed bed count. I don't know how hard it is to obtain. I have no idea what datasets you have, but an understanding of -- and I'm not going to get the language part right here -- of those licensed bed, how many of them are in kind of permanent hold status and so to- -- you know, truly offline, and then what's the actual occupancy on the

remaining beds, knowing that you can't be a hundred percent occupancy because you can't actually run internal for et cetera, et cetera. But having some understanding of that would let us know indirectly how bad the staffing needs are; right?

Like, I mean, if somebody is only at 50 percent occupancy and yet they're backlogged in the emergency room, what have you. Just using a licensed bed count is marginal data at best.

MR. FALAHEE: And this is Commissioner Falahee. I'll just interject that for years, yeah, the -- when you looked at licensed beds in any hospital, that was -- that was, like, okay, fine. How many do you staff? I was aware of one hospital -- they were licensed for 91 beds. They staffed 16. It wasn't Bronson Hospital -- okay? -- but -- but that was going on throughout, and you -- the fear was, Oh, my God, I can't lose my licensed beds, because if I give them up I'll never get them back.

So the licensed bed count, it's a fiction. It's more of what the staffed bed is, and I think that gets into the comments that --

DR. FERGUSON: How do you get the data?

MR. FALAHEE: I echo what Commissioner Drake and Guido-Allen said, that at -- at Bronson Level 1 Trauma Center, we have behavioral health patients sitting in our

ED. There was one that was there over 90 days, and we had to reach out literally to a woman who used to sit around this table, Director Hertel, to get Director Hertel's help to put this patient somewhere where they belonged, behavioral health patient. That's what's going on.

So I echo Commissioner McKenzie. I would rather not put these in -- set in stone in terms of the data.

MS. GUIDO-ALLEN: So Guido-Allen. To answer that, in the AHA annual survey, you have to -- you have to submit both, number of licensed beds and number of staffed beds.

MR. FALAHEE: Right.

DR. FERGUSON: So and to that end, and I guess I would ask the department maybe to consider how would you actually operationalize that data in general, because it's relevant not just in a psych bed conversation. It's relevant in all of our bed conversations.

MS. GUIDO-ALLEN: All.

DR. FERGUSON: And I'm not trying to make more work, but that's a more meaningful or at least a meaningfully complementary set of data.

MR. FALAHEE: We come close to -- this is Falahee -- in the high occupancy standards. If you wanted to get high occupancy beds, you need to be at 75 percent occupancy. We looked at patients in a bed, not just licensed beds, but those staffed total beds. So we looked

at that a little bit.

But I agree. It -- licensed beds isn't the way to look at it. Commissioner Haney?

MR. HANEY: Commissioner Haney. My question is -- and I guess it's just a rhetorical question -- but what is the likelihood that someone will add beds or ask for a CON to add psych beds if they can't staff them? All right? So, you know, but I appreciate, you know, the backlog in the hospitals. I understand the problem and that, you know, I think that until they're getting staffed and the current beds are -- are at capacity because they've got the staff now to get them up there, I'm not sure how that changes the -- the calculation, I guess, is what -- what I'm trying to...

MS. GUIDO-ALLEN: Guido-Allen. I don't think it necessarily changes, but this is public documents. People would be in an uproar if they see that we're projecting that we're going to decrease the availability of beds.

MR. HANEY: I missed the decrease piece. I was thinking of adding beds. So...

MS. GUIDO-ALLEN: That -- that is -- that is my concern because we're giving this artificial sense that, Oh, our behavioral health population is actually decreasing. And nobody believes that.

MR. HANEY: Right.

MS. GUIDO-ALLEN: And yet it will be formally documented as such.

MR. HANEY: Thank you.

MS. GUIDO-ALLEN: In my opinion.

MS. NAGEL: So I would add one or two -- or two things. One, the -- the issues that you've brought up with the deficiencies in the methodology would need to be looked at by a workgroup or a SAC. I believe that is on the -- we'll look at the work plan. I don't need to put Tiffani on the spot --

MS. STANTON: That's okay.

MS. NAGEL: But in the -- well --

MS. STANTON: (Indiscernible) October.

MS. NAGEL: -- but while she's looking at that, the other thing I would say, believe it or not, the department does try to reserve our opinion on a lot of CON stuff. You can believe whatever you want at that. But I will say at least on this case, we have deemed that it is distressing to us if these numbers would come -- would be put into effect. For all the reasons that you've discussed and also that our researcher has also noted that it's because of an artifact.

And so, you know, we wanted our opinion on the record to support the commission that this is clearly not the right direction for these beds, that we should ask a

workgroup or SAC, which I guess is October?

MS. STANTON: November.

MR. CONNOLLY: November.

MS. NAGEL: November? To look at what data is available. I believe you've already done that in a charge to look at the methodology and -- and see, you know what can be done, what -- what could be done differently to get to the heart of the matter.

MR. FALAHEE: So, Beth, building on that and what Commissioner McKenzie said in the general discussion, right now these are scheduled to go into effect July 1; is that correct?

MS. NAGEL: Yes.

MR. CONNOLLY: Yes.

MR. FALAHEE: Could we take action today to say, No, we're not going to put that date? Do we need to put a set date on it, though, or can we leave it indefinite until a workgroup gets back to us?

MS. NAGEL: I would ask Brien on that for the specifics, but I --

MR. HECKMAN: I think my opinion is that you should have a date.

MS. NAGEL: In the past, we have always had a date.

MR. FALAHEE: If we set it -- let's say we picked

July 1 of 2025.

MS. NAGEL: Yeah.

MR. FALAHEE: Is there a problem with that? I'm just throwing that date out.

MS. STANTON: Yeah. I know we have -- the next update is due by April '25. I'm not sure if that will interfere at all.

MS. NAGEL: Oh, yeah. Then naturally the next cycle would be April of '25. So it would -- by then we should have 2023 MiDB data to be able to analyze to see if, you know, any -- what changes have happened. Also, we would have had a SAC or --

MS. STANTON: Workgroup.

MS. NAGEL: -- a workgroup to have met to determine issues. So, you know, I think April '25 makes some sense.

MS. STANTON: Tentatively?

MS. NAGEL: Yep. And we could always come back with a March '25 commission meeting to be able to say, No good. You need to set a new date, you know, whatever we need to do.

MS. GUIDO-ALLEN: So do we just say with the possibility of an extension based on data and findings?

MS. NAGEL: You could.

DR. MCKENZIE: Were you saying April of '25 was

your recommendation or --

MR. FALAHEE: Or July?

MS. NAGEL: Or July. April with the --

MS. STANTON: April. April is the next cyc- -- when the cycle is due. So it is due for review or an update by April of '25.

DR. MCKENZIE: With a right to extend.

MR. FALAHEE: Okay.

DR. MCKENZIE: All right. Commissioner McKenzie. I'll make a motion that we move the effective date for the psych bed implementation to April of 2025 to allow for another review, with a possibility to extend, depending on the findings, and also that we would seat a workgroup to look at the methodology for the psych beds.

MR. FALAHEE: Support?

MR. DRAKE: Commissioner Drake. Support.

MR. FALAHEE: Any discussion? All in favor say aye.

ALL: Aye.

MR. FALAHEE: Opposed?

(Whereupon motion passed at 11:15 a.m.)

MR. HANEY: Mr. Chair, I have a -- Commissioner Haney. Just this is just a comment as I'm rolling off at the conclusion of this meeting. But we postponed the bed need calculation for long-term care the last time around

because of data anomalies that was in the data.

I will share with you that when I retired, I have a 27-bed unit offline because I couldn't staff it, and I had a 33-person wait list to get into my building. So this same issue, I just -- food for thought. When the bed need calculation for long-term care comes back up, please -- this is going to be an issue in that arena as well. So I just want to throw that out there for you to consider.

MR. FALAHEE: You're welcome to come back as a witness and talk to us.

MR. HANEY: If need be, I shall do that.

MR. FALAHEE: We'll give you four minutes instead of three. Okay. Thank you. Another good discussion. Thank you, everyone, for your input.

Legislative update. I'm pleased to introduce our new member of the team. Justin, if you'd like to introduce yourself and then throw some --

MR. EASTER: I'm Justin Easter. I've been working here for about a month. I came from a legislator. I spent six years over there and now I'm part of the CON team.

Legislative update, there's three bills that were from the January CON Committee. There's been no movement on them. I've talked to the chief of staff for Rep. Fitzgerald who is the head of local government, in which he's got House Bill 4693 and 4817, and he says there is no movement on it

whatsoever. No stakeholders have reached out to even progress with it. Then 4834, Rep. Rogers, she's the head of Health Policy Committee, and I reached out to her -- reached out to her chief of staff, and she said same thing, no movement whatsoever.

And then between January and now, there was 29 bills that were recently introduced to repeal the whole Certificate of Need in its entirety, but there's nothing we need to worry about. It got referred to Government Operations, but we will keep track of that.

MS. GUIDO-ALLEN: Who submitted that?

MR. EASTER: No comment.

MR. FALAHEE: This is Falahee. Some of us are aware of who submitted it and the likelihood it will advance anywhere is very, very, very, very low.

MR. EASTER: Any questions?

MR. FALAHEE: Any questions of Justin?

MS. GUIDO-ALLEN: Is today pink tie day? I need to find out.

MS. NAGEL: That's amazing.

MR. CONNOLLY: Great minds think alike; right?

MR. FALAHEE: All right. With that, to bring us back to -- to reality, we'll turn it over.

Administrative update. Marcus, anything?

MR. CONNOLLY: Yes. Currently, I am in the

process of hiring a specialist that will work with the CON Commission as a liaison along with us. I have four interviews scheduled next week, so hopefully we can get a good candidate that fits in.

Also, just wanted to give you an update on the psych bed, CT, nursing home standards. All went into effect February 26, 2024. Also, Air Ambulance was officially deregulated on that same date. Any question?

MR. FALAHEE: Thank you, Marcus. I think air -- that's the end of -- what? -- 20 years of history with the Air Ambulance deregulation.

MR. CONNOLLY: Yes.

MR. FALAHEE: Yeah. Okay. Next, Tulika?

MS. BHATTACHARYA: Thank you, Chairman Falahee. This is Tulika from the department. So we have the FY 23 CON Annual Report in your packet. I'm not going to go over the whole report, but maybe catch up on some of the highlights.

As you can see, we -- the department processed about 301 Letters of Intent, 195 applications for review, and we issued, amendment up to low, of course, 66 projects that we gave some sort of change after CON approval.

We also approved 195 projects resulting in approximately $953 million of new capital expenditure in the Michigan health care system.

On the commission side, the commission advised the review standards for MRI, MRT, psych beds and services, PET scanners, NICU beds, be we also reviewed for expected implementation or effective dates in FY 24, like open heart surgery, MRT, hospital beds, psych beds again, nursing home beds, CT scanners, and surgical services is being reviewed by a SAC. So we have been busy.

As you can see, the department really takes the timeliness of our processing because we know that providers, like you said, make an obligation. They're waiting for approval so that projects can be implemented and services can be offered in the communities. And throughout the report you will see that we do meet our timelines for processing, and sometimes we do expedite to review as requested by applicants and as needed.

So of that 301 NOI, 65 projects were waived because they did not meet any of the review thresholds. And then so out of the 195 projects, applications we received, we processed them within the required 15-day timeline, meaning we accept it then review for additional information and send out the questions in order to complete the applications.

The statutory deadline for issuing a decision to the department director varies, depending on the type of project. Non-substantive takes 45 days or should take 45

days, and our average was 36. Substantive reviews should be 120 days, and our average was 110. And for competitive, we had three applications, and our average review was 148 instead of 150 days. And we expedited 39 applications for decision.

We did receive six emergency CONs in FY 23, not COVID bed related, but other services and other emergent situation, and we issued the decision in an average of two days.

Also, on page 12, there is a nice figure. That tells you -- like, the CON decision and videographic, like, location of that in the eight pages is in Michigan. Like, for example, in Agency 1, there were 88 CON decisions. In the U.P., there were six. In Northern Lower there were 13 CON decisions, just to give you an idea of where the -- most of the projects are.

Out of the 198 final decisions, 162 were approved, 35 approved with conditions or stipulations, and one was disapproved, which was for a psych bed project in Agency 4.

Now, in years past or in general, we get asked -- the department gets asked the question, Why our denial rate is almost next to nothing? I think the credit goes to the CON Commission for developing standards to be clear and specific requirements; and then to the department, the policy team and the evaluation team, to kind of follow the

requirements consistently and help the applicants kind of understand the requirements and what they need to do to meet those requirements. And we work with them as much as possible to bring them into those guardrails of approval, and at the end of the day it's not -- if it is not possible, then only we deny a project. So it's really a team effort, and lots of credit goes to the providers for working with the department when they file an application.

Table 11 on page 14, and you will notice that our applications have not increased from where we used to be. So the numbers are still low. In terms of applications, it's 21 percent lower than previous year. In terms of decisions, obviously, when we don't get as many applications the decisions are also 31 percent lower and also -- like, last year our capital expenditure was about 2.5 billion, and this year it is 960 million. So the capital expenditures have gone down also.

On page 15, Table 13 is the -- tells you about the new capacity that the department approved in last year. So, for example, there were six new surgical centers, not hospitals or free-standing, and 14 new operating rooms in Michigan. There was one new hospital which was LTAC, not like an acute care hospital; three new nursing homes, 153 new nursing home beds. No new psych hospital or unit, but 129 new psychiatric beds were approved, including psych

special full beds.

And there was one open heart surgery hospital that received approval to become a PCI provider without onsite open heart surgery service. So they basically gave up the open heart surgery service and became a PCI hospital for the first time in the history of the program.

Table 14. So on page 16, so we don't just approve projects. We need to follow up and make sure that they're being implemented; otherwise, you know, services are not being offered. And so there were 264 projects that we followed up for implementation, extending the project if they need more time to start construction or things like that. 204 projects were expired as part of our follow-up. Now, that is not necessarily new CONs that we expired, but also, let's say, you started a service ten years ago, then you decided to stop it or downsize from ten ORs to eight ORs or five CT to four CT scanners. So those are all included in that number, but that's the total.

We also issued 47 settlement agreements as part of our statewide compliance review for CT services, which we completed last year.

And on the last Table 16, as you see, that our funding came at 88 percent of our total program cost. We have been exceeding 100 percent, but this year it was a little low in terms of revenues.

And then after page 17, there is a detailed list of all of the commission's actions in FY 23. It's just that -- just tells you how busy and how many revisions we made to our CON standards as appropriate and as brought up by the providers.

With that said, I'm happy to answer any questions.

MR. FALAHEE: Before I open up for questions, I want to thank Tulika, her entire department, and the entire staff over here. It -- it's a pleasure to work with you, to solve complicated issues together. From those -- from the hospital community that submit CONs and the nursing home community -- I'm one of them -- the department is very, very professional, and Tulika is a great head of that department. The entire team there is helpful. That's why you see the low decline rate, because the standards are solid, thanks to everybody around this table, and the department helps people. Yeah, you might want to look at this. You might want to look at that. Or, no, you need this volume. And that's why you get what you get.

And it's a very good, solid, strong program, and it's our pleasure around this table to work with you on all of these complicated issues. So thank you for your usual, very detailed, thorough report. It's -- it's great. Thank you. As one who's gotten one or two emergency applications approved within the last year, so thank you. Tulika and her

team do a great job.

Any other comments? Commissioner Ferguson.

DR. FERGUSON: Yes. So this is remarkable work, the promptness, the timeliness, the -- for the amount of work. It's really, really impressive.

Do we have a formalized structure of receiving, soliciting customer feedback? Because it might -- it might be useful, both in terms of validating what we know is good performance. I'm not doubting the performance, but also in identifying if there is anything that could be improved. There may not be anything, but if there's anything that could be improved, having some formalized mechanism rather than anecdotal mechanism for feedback. I don't know if it's after a decision is made. Like, I don't want to say what the process would be. I'm just asking the question.

MS. BHATTACHARYA: So as far as application reviews, you know, if there is a public or a competitor or if a party who wants to submit comments about deficiencies in an application, it's not that we hold public hearing, but every month we post all of our applications under review, the Letters of Intent we have received, and the decisions we have issued. So if anyone wants to comment on any of those pending applications under review, they can submit those public comments. But we don't hold public hearings on applications.

DR. FERGUSON: Yeah. I'm less interested in the actual decision and whether or not people think the decision was, you know, right, wrong, whatever, or I don't like that rule. That's -- that's not my -- my point more is on a -- somebody went through the process. Was the process satisfying? Was the process -- did the process do what the customer thinks the process should do in terms of -- or, Gee, oh, there was a profound miscommunication at this step and that's a repeat error scenario or opportunity to improve. Just looking for some customer feedback at the end of the day. Focused more on process than actual decision or rule.

MS. BHATTACHARYA: Yeah, I have to admit that there isn't a formal process. Usually it comes up during our webinar trainings that we hold from time to time. But, no, that is actually a very good point, to kind of seek customer comments. Actually, the online system that we have currently in place since 2008 or so, that was a result of receiving customer feedback and how burdensome the paper application process was. But, yes.

MR. FALAHEE: Other comments? Tulika, thanks again. Next item, legal activity report.

MR. HECKMAN: Assistant Attorney General Brien Heckman. So we have no pending litigation involving the department, so there's none reflected on the report. The

one line item for action today is part of -- is part into the Attorney General's representation of the CON Commission is the resolution amending the bylaws. It's been reviewed. It's been contemplated and today is the date for final action.

The two sections of changes, just for a reminder, were we were getting rid of the prohibition on seating individuals on a SAC based on their affiliation with a program that had submitted a Letter of Intent or an application. And then the other point was to release the -- or remove the requirement that SACs meet pursuant to the Open Meetings Act -- that's not required by law -- with the goal being that we would be able to get broader representation from -- from hospitals and other providers in the Upper Peninsula, because, obviously, it's difficult to get to Lansing, especially from the Upper Peninsula.

MR. FALAHEE: So -- Falahee. So, Brien, you would recommend if we so chose a motion to approve this resolution --

MR. HECKMAN: Correct.

MR. FALAHEE: -- that's in our packet?

MR. HECKMAN: Yep.

MR. FALAHEE: Okay, thank you. Any questions? Any motion would anyone care to make?

DR. MCKENZIE: Commissioner McKenzie. I'll move

that we approve the bylaws before us.

DR. ENGELHARDT-KALBFLEISCH: Second. Commissioner Engelhardt.

MR. FALAHEE: Questions? Comments?

MR. HANEY: Commissioner Haney. It sounds like the current SAC workgroup that you received applications for has proven this to be highly beneficial.

MR. FALAHEE: And when we sought accommodations we informed them that we do not need to be in Lansing. So you're exactly right.

So there's motion before us and it's been seconded. All in favor say aye.

ALL: Aye.

MR. FALAHEE: Opposed? Great.

(Whereupon motion passed at 11:35 a.m.)

MR. FALAHEE: Brien, thank you very much. Any other public comment?

MS. STANTON: Abby, did you still -- okay. Just making sure. No, we don't have any.

MR. FALAHEE: Okay. Tiffani, the ever-changing commission work plan, if you could fill us in, please.

MS. STANTON: Yes. Okay. Really the adjustment we made was for the MRT. I think it was for final action in March, and moved that -- at least for the final action, we put that in June until we can have further notice of what

will happen.

Really, that's the only change that was updated to what you guys were able to see in January.

MR. FALAHEE: So you would need a motion to approve that one change to the work plan?

MS. STANTON: Yes, please.

MR. FALAHEE: Okay. I'd entertain a motion for that, please.

DR. MCKENZIE: Commissioner McKenzie. Motion to approve the change in the work plan.

MS. TURNER-BAILEY: Commissioner Turner-Bailey. Support.

MR. FALAHEE: Thank you. Discussion? All in favor say aye.

ALL: Aye.

MR. FALAHEE: Opposed? Great.

(Whereupon motion passed at 11:36 a.m.)

MR. FALAHEE: Just as a reminder, future meeting dates, June 13, September 19, and December 5. Full disclosure, I will not be here at the June meeting, so Commissioner McKenzie will do her usual great job. I'll find out what happened when I get back.

Anything else to come before the commission? Otherwise, a motion to adjourn, please.

MR. DRAKE: Commissioner Drake. Motion to

adjourn.

DR. KONDUR: Support.

MR. FALAHEE: Second by Kondur. All in favor?

ALL: Aye.

(Whereupon motion passed at 11;36 a.m.)

MR. FALAHEE: Thank you all very much. Great discussion.

(Proceedings concluded at 11:36 a.m.)

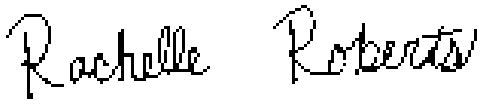
CERTIFICATE

I, Rachelle Roberts, a Certified Electronic Recorder and Notary Public within and for the State of Michigan, do hereby certify:

That this transcript, consisting of 95 pages, is a complete, true, and correct record of the proceedings held in this case on Thursday, March 14, 2024.

I further certify that I am not related to any of the parties to this action by blood or marriage; and that I am not interested in the outcome of this matter, financial or otherwise.

IN WITNESS THEREOF, I have hereunto set my hand this 14th day of March, 2024.



Rachelle Roberts, CER 9585
Notary Public, State of Michigan
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I, Sandra K. Bolton, a Certified Legal Transcriptionist, do hereby certify:

That the foregoing is a complete and true transcription of the original digital audio recording of the proceedings captured in the above-entitled matter. As the transcriptionist, I have reviewed and transcribed the entirety of the original digital audio recording of the proceeding to ensure a verbatim record to the best of my ability.

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IN WITNESS THEREOF, I have hereunto set my hand this 24th day of March, 2024.

Sandra Bolton

Sandra K. Bolton, CER 3193