STATE OF MICHIGAN

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

CERTIFICATE OF NEED COMMISSION

COMMISSION MEETING

BEFORE AMY L. MCKENZIE, VICE CHAIR

333 South Grand Avenue, Lansing, Michigan

Thursday, June 13, 2024, 9:30 a.m.

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Thursday, June 13, 2024 - 9:30 a.m.

DR. MCKENZIE: Good morning. This is Commissioner McKenzie. I'm going to get us started here this morning. Thank you all for joining us for our June Certificate of Need meeting. I am Vice Chair Commissioner McKenzie. We do not have Chip Falahee with us. Commissioner Falahee, he is in Denmark. We've already heard from him this morning, so no fear. He's still giving us instructions from afar, so, and wishes all of us well.

So we do have a couple of new folks who are joining us this morning, so I wanted to quickly recognize Mark DeLano, Dr. Mark DeLano, who is joining us representing medical schools; Daniel Velez who's new with us joining for nursing homes, Commissioner Velez; and then also Katherine Tucker from the Department. So thank you all for that.

We do have a fairly long agenda this morning so I am going to just do a gentle reminder that for your public comments as you move forward, that we will be giving you reminders and those comments are limited to three minutes. So for the reports that are coming in we have longer for the workgroup leaders and the SAC leaders for commissioners to ask questions, but we will restrict those public comments to three minutes so please help us out with that.

So with that, I will get us started and we will

start of the review of the agenda.

So the agenda is before you. We do have several items that we're going to be reviewing for proposed action. The Surgical Services SAC Committee, we'll be hearing a final report on that; the Bone Marrow Transplant Services draft language, we will be hearing about that with proposed action; we have Hospital Beds informal workgroup proposed action; we have MRT proposed action; and then we also are going to be hearing about a pilot program on BAMF which we talked about a little bit at the last commission meeting, and then with all of our routine updates, legislative updates, and administrative updates. So we do have a long agenda, so we're going to try to move through it quickly. I'm not quite as efficient as Commissioner Falahee, but I will do my best here. So I need a motion to approve the agenda.

DR. FERGUSON: So moved.

DR. ENGELHARDT-KALBFLEISCH: Second.

DR. MCKENZIE: Great. All in favor?

ALL: Aye.

DR. MCKENZIE: Any against? Okay. Thank you.

(Whereupon motion passed at 9:33 a.m.)

DR. MCKENZIE: Our next item is the Declaration of Conflicts of Interest. There is a summary in your packet about what is a conflict of interest, and so this time

period is for any of the commissioners to step forward and declare if they have a conflict of interest on any of the items on the agenda today.

DR. DELANO: This is Commissioner DeLano. I am a medical director with BAMF and have a conflict.

DR. MCKENZIE: Okay. So you'll be abstaining from that?

DR. DELANO: I will abstain.

DR. MCKENZIE: Okay. Great. Thank you for that declaration. Any other declarations, a conflict of interest? Okay. All right. Hearing none we'll keep moving forward.

Next item on the agenda we have our review of our minutes from March 14th, 2024, and those are contained within your packet. So I'll give a moment for that review and then I will take a motion if everything looks good.

DR. ENGELHARDT-KALBFLEISCH: Commissioner Engelhardt-Kalbfleisch. Motion to approve the minutes from March 14th.

DR. MCKENZIE: Thank you.

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

DR. MCKENZIE: Great. Thank you. All in favor for approval of the minutes?

ALL: Aye.

DR. MCKENZIE: Any against? Great. Minutes pass.

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

DR. MCKENZIE: Okay. Our first action, action item on the Certificate of Need standards is on the Surgical Services Standard Advisory Committee. And we do have a final report that is contained within your packet as well as some draft language associated with that final report and recommendations. So first up we're going to have Dr. Joe Patton who's going to be delivering that final report. And I just want to first say thank you. We know this is a lot of work leading a Standard Advisory Committee and so we appreciate the time and effort and look forward to hearing your report.

JOE PATTON, M.D.

DR. JOE PATTON: Yeah. Great. Thanks. Good morning, everybody. First of all, I'd like to thank the SAC members who participated. We had six meetings, from November of '23 through May 2nd of '24. We addressed 12 charges. We developed four subcommittees to further discuss and address those charges. As was mentioned, my full report I think was in your pre-reading packet. I was going to quickly go over each of the charges if that's the order you want me to get there with.

DR. MCKENZIE: That would be great.

DR. JOE PATTON: Yeah. Tiffani, I think, or somebody's got my slides. I'm just going to go through

these relatively quickly. I don't know if we're -- you want me to get through them all and then we'll ask for questions or comments afterwards if that's okay?

Charge 1 was to review the amendments to the ownership and volume requirements for applicants proposing to relocate an existing surgical service or operating room in Section 5(6). So the recommendations of the SAC were to modify Section 5(6) to make it clear that no specific ownership was required to qualify for relocation of ORs between two existing surgical services. There was also a change to the volume requirements to require a receiving facility to demonstrate compliance with the applicable maintenance volumes rather than a donor facility and to require the receiving facility to project annual maintenance volumes on all existing operating rooms plus the proposed relocated ORs by the end of the second 12 months of operation after the relocation was complete. These changes were consistent -- I'm sorry. Consistent changes are also recommended in Section 5(8) which applies to similar rules, but with reduced volumes for rural hospitals. Sorry.

Charge 2 was to consider revisions to allow application of excess cardiac catheterization maintenance volumes to the maintenance volume requirement for a freestanding outpatient facility that will be used exclusively for cardiac catheterization services. The SAC

determined not to really address this charge and so we are recommending no changes to the standards at this time. I think as was previously presented to this Commission, we did recommend that the Cardiac Catheterization SAC, though, look at potential changes to both the definitions and the provisions for OR cardiac cath labs in the Cardiac Cath standards. And then it was our assumption that once that was determined, that we could bring it back to a future SAC to make the applicable changes to the Surgical Services standard as well. I think that's already been addressed by the sheet.

Charge 3 was probably one of the more complex charges that we had to deal with and probably resulted in, in the most commentary. Charge 3 was consider revising initiation requirements for ambulatory surgical centers to accept dialysis access procedures performed in office-based labs. So for this one the SAC recommended new provisions to Sections 2, 3, 4, 6, and 11 to allow for the creation of a dedicated dialysis access center utilizing the commitment of dialysis access procedures to demonstrate need. Those procedures would not, were not, would not have been done in existing licensed ORS, but cases performed in a dedicated dialysis access center could not be used to demonstrate need for any other type of surgical service. Dedicated dialysis access centers would be treated similarly to the dedicated

endoscopy and cystoscopy freestanding outpatient facilities in all respects of the CON standards.

I think this, this one probably needs a little explanation and I know we have some public commentary available to even further get into this. Basically the, the ask here was to allow cases that are not currently done in an operating room to count for projected volumes for establishment of a dedicated dialysis access center which would be defined very similarly to what we have currently existing for an endoscopy and cystoscopy operating rooms. There was a lot of rationale behind this primarily because most of these current cases done are not done in operating rooms so there is not really applicable volume to use for that initiation, and therefore it was determined to try to really put guardrails around what types of cases could be counted for the initiation volumes of these things. So there is a lot of, you know, discussion and determination of what exactly those procedures were, how they were defined, et cetera because there was quite admittedly a little bit of apprehension on some of the committee members that this might be a slippery slope and lead to other, other types of cases wanting to be able to use non-OR volume as initiation volume for operating rooms. And so we, we tried to address all those concerns and I think we did so successfully that led to our recommendation. And, again, if there's further

questions or need for further discussion on that, I know that there is those present that would have availability for public comment.

Charge 4, review and revise volume requirements to protect access to surgical services provided by rural hospitals. There was a lot of language in here that had to do with definitions. So the recommendation of the SAC was to add language to treat critical access, sole community, and Medicare dependent hospitals with five ORs or less, the same as hospitals located in a rural or micro-, micropolitan county with five ORs or less. We also recommend to reduce the annual maintenance volume requirements for those rural facilities from 1200 hours to 906 hours per operating room. We recommended to reduce the expansion volume requirements for these rural facilities from 1400 hours to 1,057 hours per operating room in the previous 12 months. And to modify the project delivery requirements to clarify that rural hospitals with two operating rooms or less are exempt from annual maintenance volumes requirements. As far as the numbers go, these were to bring these rural operating rooms into kind of consistency with the current urban operating room numbers. And so that's, was the main rationale for some of those recommendations.

Charge 5, revise definitions for "ambulatory surgical centers," "freestanding outpatient -- freestanding

surgical outpatient facilities," "procedure room" and "surgical cases." These definitions were recommended by the Department and I won't read through them all here, it's just kind of changing the verbiage.

Charge 6, was to revise Section 6(1)(a) to clarify expansion volume. So the recommendations of the SAC were to streamline the language in Section 6 by moving references to the most recent 12 months of data that is verifiably by the Department and in the second 12 months of operation to the top of subsections rather than repeating for each volume measurement option just for ease of readability. We also recommended adding language to 6(1)(a)b) to clarify, to clarify that facilities must first demonstrate a minimum volume of their existing operating rooms based solely on actual surgical cases performed not utilizing any projected increases in volume. Increases in volume are only included in the projection sections of 6(1)(b). We also added an option for demonstrating need in additional operating rooms, utilizing a hiring volume in the previous six months without a requirement to project volumes consistent with the expansion criteria of other CON standards.

Charge 7 was revise Section 6(1)(b) to include existing operating rooms. So we recommend adding language to 6(1)(b) which clarifies the applicants expanding their surgical services must project the requisite volume to

demonstrate that they will meet maintenance volume requirements by the end of the second 12 months of implementation, including both their current operating rooms and their proposed additional operating rooms. It was not clear in the standards that that was the case. We added similar language to Section 6(2)(b) that applied to rural hospitals as well.

Charge 8, revise Section 9 to clarify that an individual physician Medicaid enrollment is not sufficient for the facility's Medicaid enrollment. This was language also submitted by the Department and the SAC recommended as such.

Charge 9, clarify reasonable projections under Section 11. The SAC recommended to add language in Section 11 to make it clear that projections must use the most recent 12 months of verifiable data by the, by the Department or if using more recent data, they must provide detailed surgical case data for the facility that is being used. This is so that we could make some of those case specific types of determination like cystoscopy/endoscopy/ dialysis access, et cetera. Add language to clarify that in-, inpatient cases or hours cannot be committed toward a freestanding outpatient facility/ASC project. That was unclear in the current standard surprisingly. Add a new option of utilizing consistent (at least five years) of

historical growth, projections and future volume. So if you were consistently growing at a rate over the last five years you were allowed to assume that that rate was going to continue. That was a, my understanding, a previous practice of some of the Department's reviewers in the past but had not been necessarily carried forward so we wanted to include that in the standards. We also recommended to add language to clarify that an applicant that is not yet a dedicated dialysis access center cannot use cases performed at a dial--, dedicated dialysis access center to project need. So this is, again, one of those guardrails we wanted to put in in relation to Charge number 3 so that folks couldn't use those non-, other non-OR cases for non-dedicated dialysis access procedures.

Charge 10 related really to some more review of definitions of rural and micropolitan counties. We covered, I think we covered Charge 10 in our recommendations for Charge 4.

Charge 11 was to revise Section 5, improve clarity around the requirements. This was a lot of wordsmithing. We streamlined the language in -- recommend streamlining the language in Section 5 by moving references to the most recent 12 months of data that is verifiable to the, by the Department and in the second 12 months of operation to the top of the subsection rather than repeating for each volume

measurement option. We recommend remove, to remove the need for, for -- to project volumes for applicants -- applications involving replacements of ORs on the same site or replacement of an entire surgical service within the replacement zone. And also recommended updating the definition of replacement at the beginning of the section to better provide clarity around replacement versus relocation.

And then finally, Charge 12 was just to consider any other technical changes from the Department, updates or modifications based on either wordsmithing or typos or things like that. So we recommended three things primarily -- these were recommendations from the Department -- to remove an outdated reference to the American Osteopathic Hospital Association as it no longer exists; add language stating that planned decreases in services shall be reported to the Department within 30 days of the decrease, consistent with other standards; and other various corrections to spelling errors, spelling errors and use of consistent terminology throughout the standards were made.

And then finally, I just have one final comment. There were a couple issues that came up in the discussions of the subgroups that were not addressed formally by the SAC and we would like to recommend that these come forward for future review. Very quickly, these are in regards to the

dedicated endoscopy and cystoscopy operating rooms. We would like to ask for clarification regarding how an operating room is dedicated for these exclusive endoscopy or cystoscopy cases. We recommend the clarity because there's some confusion currently between the Department's interpretation of the current definition and provisions under Section 5(5). And then finally regarding lithotripsy exclusions. Because lithotripsy procedures are now performed in normal ORs like any other surgical procedure, we would like to revise the standards to -- should update to reflect the current practice and technologies. Currently lithotripsy cases do not count as cases even though they're done in an operating room. They are excluded from that count due to the, some of the wording definitions in the standards. So we'd like to have that revised in the future.

That's my report. I guess we'll go on to question, comments, or discussions.

DR. MCKENZIE: Thank you very much. I know we had an extensive number of charges for the SAC to look at, so really appreciate your leadership on that. So I'll open up to the commissioners for any questions that they have on the recommendations and the report.

DR. FERGUSON: Commissioner Ferguson. Thank you for your hard work on this. It's an incredible number of charges and a lot of detail into it. Thank you. Question

on Charge 1 which will betray some of my lack of understanding on how -- what happens when there's a transfer of ownership of an entity that happens to have a CON. And presumably there is at a minimum a reporting of that change of ownership. Are there other regulatory hurdles or is it just a passthrough notification? I guess that would be a question to the office.

MS. NAGEL: I would ask Tulika to answer that.

MS. BHATTACHARYA: Thank you, Dr. Ferguson. This is Tulika. So change of ownership for CON purposes has been the licensees changing from one entity to another entity. If they're saying the licensee is staying the same but shares are being transferred, members are being added or deleted, that is not a change of ownership for a CON. So we recommend that they file letter of intent and request a waiver from review from the Department, but that's just a suggestion. It's not mandatory because it's not a change of ownership.

DR. FERGUSON: Thank you. So a follow-up question then on this -- and it may not be a problem. I'm just asking whether or not it matters. If there's no specific ownership requirement to relocate an OR, is that facilitating easier sale of any of these with CONs because you can then simultaneously physically move it. Right? So you can sell your entity and physically move it as part of a

sale of a entity. May not matter, just asking the question. It sounds like it's a non-issue. That's fine. Literally I'm just asking the question. So is, is -- was that part of the intent was to facilitate frankly an easier market for transfer of, of ownership structures, transfer a physical location? Because this would facilitate that which may be good.

DR. JOE PATTON: I, I think it will. My, my understanding is that this was never really addressed in the standards and so it was more of a clarity that, that, that you didn't have to have common ownership to transfer operating rooms from one facility to another and so we just wanted to clarify that. Will it make it easier moving forward? I don't know.

DR. FERGUSON: Okay. Thank you.

DR. MCKENZIE: Yeah, we were just stating -- I was just talking. I, I'm not sure it's a change from how it exists today; right?

DR. FERGUSON: Thank you. Thank you for clarifying.

DR. MCKENZIE: I don't think it's any different. I think it's just a clarification, yeah.

DR. FERGUSON: Thank you.

DR. MCKENZIE: But it's a good call-out, so thank you. Any other questions from the commissioners? Okay.

Thank you, Dr. Patton.

DR. JOE PATTON: Thank you.

DR. MCKENZIE: We may reserve the right to recall you if we have additional questions as we get public comment, so thank you. Okay. So do we have public comment on this?

MS. STANTON: We have not received any blue cards.

DR. MCKENZIE: Okay.

DR. VIDOOSHI MARU: We, we do have comments, but wanted to sort of help you guys with discussion, not necessarily having to offer it. Otherwise --

DR. MCKENZIE: Yeah. Why, why don't you come up and, and offer your public comment then. Thank you.

VIDOOSHI MARU, M.D.

DR. VIDOOSHI MARU: Morning. My name is Dr. Vidooshi Maru. I'm lead nephrologist for Nephrology Associates of Michigan. I served on the Surgical Standards SAC and was a separate lead on the dialysis access charge. I'm here to represent my own patients, but also the 20,000 estimated dialysis patients in the state of Michigan.

Dialysis patients are a vulnerable patient population burdened with an average four-hour dialysis appointments three times a week with numerous comorbid conditions, national hospital readmission rates approaching 35 percent, over represented minority populations, and in

many communities dual eligibility rates of almost 50 percent. An important aspect of the care of these fragile patients lies in the management of their dialysis accesses. These are the catheters, fistulas, grafts that allow patients to get their dialysis treatments. Access dysfunction can prevent completion of dialysis which we know increases morbidity and mortality of these patients. Our practice operates a dialysis access center as an office-based lab. Patients are referred to the center when their accesses don't support their dialysis treatments. Expeditiously the issues are addressed, patients are returned to their units when they are met. And you will find in your packets a couple of written statements from patients attesting to the quality and efficiency of the work that we do.

The procedures done are surgical procedures, and they include catheter changes under fluoroscopy, angioplasties, sub (indiscernible), percutaneous placements of fistulas, and PD catheters. This may come as a surprise to some, but this outpatient dialysis access work has been the standard of care for over 20 years now.

Through a series of reimbursement cuts, CMS is trying to move these surgical procedures from OBLs to ASCs, and the goal is to increase a data collection via increased transparency of the cases that are being done. With the

cuts in reimbursement five percent per year since 2017 just in the OBL setting, those access centers that cannot convert to ASCs have been forced to close. And nationally we're seeing the ramifications of this manifested by a decline in quality of care. Without access centers, patients are forced to go to hospitals for this outpatient work. They present in the ERs, they're admitted for days waiting to have this elective outpatient work done. And I want you to think for a moment on the additional burden of care this places on these patients and their families.

So locally we were unable to convert our OBL to an ASC within the current CON structure. Even if anyone committed their surgical cases to us, bringing them to our center would mean that we would have no room to handle our own 1600 cases that we do a year. The language the Surgical Standard SAC with the help of the Department approved grants a carve out specifically for these patients and procedures. There's no other equivalent site of care for this work. The language ensures preservation of the patient experience, quality of care, access to care, and is related to a cost of care in the state of Michigan. I thank you for your time and I'm happy to take questions.

DR. MCKENZIE: Go ahead, Commissioner Ferguson.

DR. FERGUSON: Commissioner Ferguson. Thank you for your work on this. So a question -- and I don't know if

you can answer it or maybe somebody else can answer it. With respect to -- so we've heard that there are similarities in the proposed structure with how the endoscopy has been transferred over. With endoscopy for the initiation volumes and the ability to count OBL work towards the initiation volumes, is that true of, like, the endoscopy centers as well or is that unique for that direct dialysis access? And then the follow-up on that is, is this a permanent path in being able to take OBL volumes and apply that for initiation or are the OBLs really going away and this is a temporary scenario? Again, just wondering if this is a, a permanent route to getting an ASC or a temporary because we're in a transition phase?

DR. VIDOOSHI MARU: In, in answer to your second question, this is permanent. I think the OBLs for dialysis access work are going away.

DR. FERGUSON: Okay.

DR. VIDOOSHI MARU: And I cannot answer your first question. But does anybody that I'm here with, can you answer?

DR. FERGUSON: I'm just trying to figure out how parallel the model is. I mean, our symmetry -- consistency is valuable if we can be consistent.

DR. JOE PATTON: Thank you. It's a very, very good question and one that we did consider at the subgroup

level. And so in that regard the answer is no. Endoscopy cases done currently in, say, an office-based lab or a non-OR facility are not currently usable as initiation volume for a new -- for a freestanding, dedicated endoscopy procedure. I don't think any of us on the SAC or in the subgroup were around when the dedicated endoscopy OR standards were written or even if this was a similar consideration at the time. But I think to your second question about this being a transitional period or a permanent solution is the answer is I don't know. If it had been done 20, 30 years ago for endoscopies and it was a -- and that that was allowed in transition and then it went away, I don't know if anybody in this room was around way back then to know whether that was done or not. I couldn't find anybody in our subgroup or supporting that would answer -- that knew the answer to that question.

So I guess in my opinion I know Vidooshi said that it was a permanent solution but, but your -- you may be right. It may just be transitory as outpatient dialysis access labs go away, but then all cases will be done in ORs and those volumes will be usable to initiate more operating rooms just like endoscopy cases are done today. You can only use endoscopy cases done in an OR to initiate another endoscopy operating room. You can't take volumes done, for instance, in an endoscopy suite procedural room,

office-based lab or anything to, to project or initiate an endoscopy dedicated suite. So that, that's, it's a little bit different.

DR. FERGUSON: Yeah. You know, I think it sounds like we need a mechanism to facilitate a new model and I'm fully supportive of that. What I'm trying to figure out is, is there a unintended permanent back door five years or ten years from now for somebody who's like, well, I can't get an ASC through a norm-, what, what then is the normal route and so I'm going to take this other route. Again, maybe it's not a problem.

DR. JOE PATTON: Those were the exact considerations brought forward.

DR. FERGUSON: Okay. So it was something that was already contemplated?

DR. JOE PATTON: Correct.

DR. FERGUSON: Thank you.

DR. MCKENZIE: Thank you. I do have a question, Dr. Patton, before you step away. There were two recommendations of things that came up during discussion at the end on your last slide, I believe, related to cystoscopy, endoscopy and then also lithotripsy --

DR. JOE PATTON: Lithotripsy, correct.

DR. MCKENZIE: -- for future consideration. Could you speak to those discussions and the level of urgency so

that the Commission can kind of consider how those would need to be handled? And I'm also going to talk to the Department about that as well.

DR. JOE PATTON: Yeah, thanks. I, I, I don't think there's any level of urgency. I think the next time that the Commission puts together a SAC for the Surgical Services standards to be reviewed, we would just like to ask that they, that be addressed at that time.

DR. MCKENZIE: Okay. Thank you. And then my companion question over to the Department was how was that considered? Was it also thought that the next time the standards would be routinely opened that those items would be addressed or was that discussed at all within the Department of how to handle that?

MS. NAGEL: Thank you. It was discussed and we are happy to add that to the next agenda.

DR. MCKENZIE: Okay. Thank you.

MS. GUIDO-ALLEN: I've got -- Guido-Allen -- a quick question about dialysis access centers. Quality appears to be better, access is better when you can do it there, and cost. If we reclassify it as a ASC under CMS, right, does the level of billing change to make cost not favorable?

DR. JOE PATTON: To make -- to make cost not --

MS. GUIDO-ALLEN: Is there a difference between

what you bill in an ASC versus what you bill in an OBL?

DR. JOE PATTON: I'll let Dr. Maru address that. My understanding maybe the bill's not different, but the payment reimbursement is.

DR. VIDOOSHI MARU: Correct. So the, the billing is the same, the procedure codes are all the same, but the reimbursement is different depending on the site of service. So the -- so the, so the reimbursements for an ASC are more than an OBL, but they're less than the hospital-based settings. And so if you don't have the OBLs, really your comparisons are ASCs to hospital settings and then the ASCs come out ahead in terms of total cost of care.

MS. GUIDO-ALLEN: Thank you.

(Off the record interruption)

UNIDENTIFIED SPEAKER: Sorry.

DR. MCKENZIE: Other questions from the commissioners?

DR. JOE PATTON: I, I would just like to say that the subgroup did consider cost and quality in, in all these discussions and there, there were heated discussions on this one. This was not an easy one. I think we were overwhelmed, though, by the patient need. As these OBLs close the only access that these patients are going to have for care is in hospitals and I think we all, we've gotten -- had multiple examples of the care in the hospitals not to be

as efficient as a -- and perhaps as high quality and although, and more costly in fact. And so this was an alternative that was very carefully considered and not without a lot of discussion.

DR. MCKENZIE: Thank you for your comments. Other questions from commissioners? Okay. Then I'll open it up for discussion. Any discussion? If there's no discussion, then what we have before us is the proposed language from the Department. This is for initial action. And looking in your packet there is also, you know, the Department is -- my understanding was the Department was supportive of the language and if the Commission chooses to take proposed action, then the draft moves forward and there's public hearing and comments related to that, and then also it will go to the JLC. I mean, it will come back here. For the new commissioners, there's a whole process and I know it took me awhile to understand that. So it goes out public comment, but this language will come before us again, we'll have another opportunity to hear public comment on it before we would take final action and make the changes, so --

MS. STANTON: So back for the September meeting for final action on proposed actions taken.

DR. MCKENZIE: Correct. So if there's no discussion, then I, you know, I'm willing to accept a motion.

MS. GUIDO-ALLEN: Guido-Allen. Is the motion to move it forward to public comment and the JLC or just public comment?

DR. MCKENZIE: To public comment and the JLC.

MS. GUIDO-ALLEN: JLC.

DR. MCKENZIE: Yep.

MS. GUIDO-ALLEN: So I'll make the motion to move the Surgical Services' recommendations forward to public comment and the JLC for review.

DR. FERGUSON: Second.

DR. MCKENZIE: Thank you. Okay. We're not going to a roll call vote. So we can do all in favor?

ALL: Aye.

DR. MCKENZIE: Any against? Okay. So that moves forward for public comment and review with the JLC and then we should see that back on our September agenda. Thank you all. Appreciate that.

(Whereupon motion passed at 10:06 a.m.)

DR. MCKENZIE: Okay. Next on our agenda we have the bone marrow transplant language, draft language, and we are going to be hearing a report on that from Katherine Tucker from the Department.

MS. TUCKER: Okay. Again, I'm Katherine from the Department. At the January 2024 CON Commission meeting, the Department was charged with adding language to the

standards, technical edits being added across all (audio interruption) that required -- this required notifications of the Department no later than 30 days after any planned decrease or discontinuation of the CON service. We're not aware of any public comment before the meeting. Proposed action from the Commission will require a motion and a second and vote to approve. The Commission's proposed action will move the language to a public hearing and to the Joint Legislative Committee, JLC. A report and language for a final action will be, will be brought back to the CON Commission at the September meeting.

DR. MCKENZIE: Thank you, Katherine. Do we have any public comment on the language changes that are before us?

MS. STANTON: We have not received any blue cards.

DR. MCKENZIE: Thank you. Any Commission discussion on the language that was drafted by the Department for this more technical change? If there's no discussion, again, just as a reminder this is the proposed action is for initial language so this would go out for review, public hearing, it will go to the JLC and we'll have it back on our agenda in September where we would take final action before the changes would be made. So I am open to a motion to that effect if there's no further discussion or questions.

DR. FERGUSON: So moved.
DR. MCKENZIE: Thank you.
MS. GUIDO-ALLEN: Second.
DR. MCKENZIE: Thank you.
MS. STANTON: I'm sorry. Who was the second?
DR. MCKENZIE: Guido-Allen. Commissioner Guido-Allen.
MS. STANTON: Thank you.
DR. MCKENZIE: Yep. Okay. All in favor of moving forward on this initial proposed action?
ALL: Aye.
DR. MCKENZIE: Any against? Great. Thank you very much.
(Whereupon motion passed at 10:08 a.m.)
DR. MCKENZIE: And next on our agenda is the Hospital Beds informal workgroup and on this we have a final report and draft language and Tiffani Stanton from the Department is going to be reviewing that for us today.
MS. STANTON: Yes. I do have a report on behalf of Chip. It was included in the packet, so I'll go through it and I'll kind of briefly explain some of the -- there's a lot of language in here from the SAC so I'll kind of touch on those as well.
So the Hospital Bed Rural Emergency AA -- REH workgroup was charged by the CON Commission to work with the

Department to review comments from the public hearing and develop language that incorporates the public comments. The workgroup met three times from February 2024 to April 2024. From the outset, the members of the workgroup functioned in an open, professional, and collegial manner. Divergent positions on the many REH issues were thoughtfully presented, and respectfully discussed, and mutually resolved.

The workgroup discussed the issues related to the REH unknowns and the Department's proposed addendum. The workgroup members had extensive discussions about, one, adding language to the Hospital Bed standards for REH as an alternative to the Department's addendum; two, reviewing the "Excluded Hospital" definition in the Hospital Standards and adding language that includes the REHs as an "Excluded Hospital"; and three, how to best define an REH and the Hospital Beds given, the possible CMS reimbursement issues.

So following the extensive discussions, a few members of the workgroup were asked to prepare draft language and share it with the members of the workgroup for their review and comment. This draft was -- this working draft was used by the Department to prepare suggested edits to the Hospital Bed standards. The Department's suggested edits were discussed over the next two meetings of the workgroup. As a result of those discussions, the Department

prepared proposed action -- or proposed final edits to the Hospital Beds standards, circulating them to the workgroup. Each members of the workgroup agreed with those final edits.

So the final edits are as follows: one, language was added to Section 2(n)(vi) of the Hospital Bed standards under the "Excluded Hospitals" to include the exclusion for hospitals as defined under MCL Section 333.21501(1)(I) as well as approved under MCL Section 333.21551 to delicense 100 percent of the beds; 21501, it just calls out REH. The concern with the workgroup was calling it out in the same way that may differentiate it from a hospital designation as it is. So that's why the reference is in there without calling it as an REH. And then 21551 was to, is -- requires them to delicense 100 percent of the beds, so that was why that was included as well. Part two, additional language was added to Section 6(3)(h) of the Hospital Beds standards to clarify that excluded hospitals as defined under Section 2(n)(vi) of the Hospital Bed standards shall not apply for additional beds until receding, the receiving hospital has relicensed the beds as required in section, MCL Section 333.21551(7). So as stated, 21551 requires them to relicense their beds before applying for additional beds, so that was called out in Section 6.

And then the last part, language was added to the Hospital Beds standards' project delivery requirements in

Section 9(a) through (c). The Section (a), the language will ensure that the Department is notified for a hospital designation as required in MCL Section 333.21513(h). Section (b), the language will require hospitals to notify the Department if they do not meet statute requirement requirements or permanently delicense their beds as required in 333.21551. And then lastly, Section (c), the language requires the REH to maintain the compliance as applicable in MCL Section 333.21551. So, again, those sections kind of reference all statute language, so we just basically called it out in the standards. And then,

"Thank you for allowing me to serve as the Chair of the workgroup. It was a pleasure to work together with these individuals to resolve the REH issues. Respectfully submitted, Chip Falahee."

DR. MCKENZIE: Thank you, Tiffani. So I know Commissioner Falahee is not here. I was able to speak with him and he did say they had great participation during the workgroup. I think Commissioner Falahee leading this, his expertise, you know, was very helpful in navigating that. But really they had good consensus with this across the board so no real disagreement. So do we have any public comment?

MS. STANTON: We do not. We have not received any blue cards.

DR. MCKENZIE: Okay. Great. So we have the proposed changes before us and the Department is supportive of the language that has been drafted. Is there any Commission discussion or questions? Okay. If there's no discussion, what we have before us is we're taking, again, proposed action on language before you and that draft language will go out for public hearing and we will have the opportunity to get public comments on that and it will also be forwarded to the JLC and then will come back to us on our September agenda for final action. So I'm open to taking a motion to move that proposed language forward.

DR. ENGELHARDT-KALBFLEISCH: Commissioner Engelhardt-Kalbfleish. Motion to move the Hospital Bed language forward for public hearing and comment and to the JLC.

DR. MCKENZIE: Thank you.

DR. DELANO: I second.

DR. MCKENZIE: Great. Commissioner DeLano seconded. And all in favor?

ALL: Aye.

DR. MCKENZIE: Any against? Great. Thank you so much.

(Whereupon motion passed at 10:14 a.m.)

DR. MCKENZIE: We are moving through our agenda efficiently and I appreciate your participation and help

with that to the Commission. Okay. Our next item on the agenda is our MRT services. We had an informal workgroup and we also had a public hearing summary and draft language and that is going to be summarized by Tiffani Stanton from the Department for us.

MS. STANTON: Okay. So there was two drafts included in the standards or, I'm sorry, in your electronic binder due to Chip's concern or the concerns that were addressed at the March 2024 meeting from the Commission. We didn't -- there wasn't a clear position on the driving mileage from 90 miles to the 45 and the change that was proposed from the workgroup. So we still have the final action items that were taken as proposed action at the December 2023 meeting which include the change from the driving mileage from 90 to 45. So after the March meeting we are now presenting a proposed action draft that just removes that allowing a future workgroup to review the concerns around it as there's been many positions presented. So we are offering proposed action and final action if the Commission so chooses to do on either of the standards that are presented.

DR. MCKENZIE: Thanks, Tiffani. This is Commissioner McKenzie. I am going to try to clarify this a little bit because it was very confusing for me and then Tiffani and Beth can tell me if I've got it right.

So MRT workgroup came back with a number of recommendations. Of all of those recommendations, one of them was to change the driving mileage from or the mileage from 90 to 45 miles and that raised a number of concerns that we got public comments. So we took initial action. We were set to potentially take final action in March, but this issue around the mileage came up and there was a lot of discussion and really we decided to table it and go back to the Department and say, well, do we have to take action on this? Is there something else the Department can put forward? And so what they did is they came back and they said, "well, we can keep all the language of the other changes the same and then include the 90 miles for you, Commission, to also entertain." Okay? So we have two proposals before us. Language is identical in terms of the recommendations from the workgroup. The difference between them, one is 45 miles, one is 90 miles. And what's before the Commission right now is on the 45 mile we have to make a decision of yes or no. So we have final language before us today to say yes or no to the 45 mile and then we also have initial language before us to say, yes, we'd move this forward with all the prior language, but we're changing it to the 90 mile. So those are the two things that are before us. We do have to make a decision on final action yes or no on the 45 mile, and then if we wanted to, we can move

forward the initial language on the 90 mile. So that's my understanding. Did I get that right, Beth?

MS. NAGEL: I think you hit the nail on that one. Perfect.

MR. CONNOLLY: Good job.

DR. MCKENZIE: Usually I provide that clarification before we go into public comment so the Commission is, is very clear because it was confusing to me when I read through my binder. So thank you for that.

MS. STANTON: And for the proposed action on it, too, we would be punting it basically for the next review cycle or a future workgroup or SAC to kind of review as there was many positions that were brought forward.

DR. MCKENZIE: Okay. Thank you. Okay. So I imagine we may have some public comment on this one?

MS. STANTON: Yep. There's -- we have Kelly Jefferson from OSF.

DR. MCKENZIE: Thank you.

MS. STANTON: Thank you for making the drive down.

KELLY JEFFERSON

MS. KELLY JEFFERSON: Pleasure to be here. Good morning. I'm Kelly Jefferson. I am the president at St. Francis Hospital in Escanaba, Michigan. St. Francis is a very busy, 25-bed critical access hospital in Delta County. And what we do is we strive to improve rural access to

specialty services that we can safely offer within our community including oncology and cardiovascular services. We were recently approved with a, for a cath lab which will be opening in July allowing us to be only the second provider in the UP of that particular service. Last year we performed 235 new oncology consults and administered over 2,000 chemotherapy infusions. We partner with Green Bay Oncology and we've had that longstanding relationship for over 30 years serving patients in Delta County and we would like to expand this partnership to include MRT services so that we can best serve our patients with a comprehensive cancer care program.

State cancer profiles show that Delta County has one of the highest cancer incidents in the Upper Peninsula. Patients must drive long distances often to Wisconsin for radiation therapy which is costly and burdensome. Traveling multiple hours daily for a 15-minute treatment for up to six weeks in a row is a lot to ask for very sick patients. The Certificate of Need Commission recognized over a decade ago the geographic access to MRT services in the UP is a concern and in response they changed the standards to modify the demonstration of need in the UP to focus on distance rather than volume. Since those changes, there's not been one single application for a new MRT service. Geographic access continues to be a concern in the Upper Peninsula given the

fact that we only have two current radiation units: one in Iron Mountain and one in Marquette. In the UP, the current Certificate of Need standards only allow for the initia-, initiation of a new service if the proposed site is outside of the 90-mile marker. Currently six hospitals in the Upper Peninsula qualify to, to submit an application for a new radiation unit but none have done so.

We worked with the Department and the MRT workgroup over the past two years to address challenges and what came out of that was the proposal that's here for you today. The proposed changes reduce the 90 -- the mileage requirement from 90 to 45 miles making that 90 miles round trip. This changes though -- this acknowledges that 90 miles is a long way to drive -- and in two-lane roads in the winter when that could double; right? And it is true that this could add to the number of overall units that could be called to fight for in the Upper Peninsula. But given the fact that six of the seven facilities that would qualify to be able to apply under the new language have not done so in the past ten years, it's very unlikely that there would be multiple app-, applications and multiple approvals. So with that, I just ask for your support in supporting the final approval of the changes presented today and I'll accept any questions.

DR. MCKENZIE: Any questions from the

commissioners? I have a question.

MS. KELLY JEFFERSON: Sure.

DR. MCKENZIE: My understanding in looking at this -- and for those who were here at the March meeting, there was a map that was put out which showed I don't remember how many potential facilities, but many that could apply in the UP.

MS. KELLY JEFFERSON: Sure.

DR. MCKENZIE: Oh, thank you. Perfect. Did Chip do this map?

MS. NAGEL: Yeah.

DR. MCKENZIE: So I think that this was what raised the concern. And so my understanding in the outstanding piece of this is that this is a mileage requirement only without any volume requirement --

MS. KELLY JEFFERSON: Right.

DR. MCKENZIE: -- for a proposed initiation; is that correct? Is that your understanding of what one of the key concerns is?

MS. KELLY JEFFERSON: Yes.

DR. MCKENZIE: Okay. All right. Thank you. Any other questions from the commissioners?

DR. FERGUSON: Just a clarification. The existing standard is mileage only, no volume required.

DR. MCKENZIE: Mileage only. Like with outbound,

correct.

DR. FERGUSON: We have to decide about the mileage. Because we all --

DR. MCKENZIE: That's right. It's purely mileage. Right. And the existing -- that's a great clarification. That the existing standard was 90 miles, no volume requirements. This would change it to 45 miles and no volume requirements. Thank you.

MS. KELLY JEFFERSON: Thank you.

DR. MCKENZIE: Any other public comment that we have?

MS. STANTON: Yes. John Bartlett from Marshfield Clinic.

JOHN BARTLETT, M.D.

DR. JOHN BARTLETT: Good morning. Thanks, Dr. McKenzie, for having me down here. I am Dr. John Bartlett. I wear multiple hats like many of you do and I'm here to address this on behalf of not just my patients that I take care of as a primary care provider, my family that lives in the UP, but also as a chief medical officer for the Marshfield Clinic in the Michigan region.

So my multiple hats, I'm a primary care provider for over 20 years in Marquette, Michigan, on the top of that map. I've been the board chair of that hospital when it was Duke LifePoint and Marquette General. I'm the chief medical

officer for Marshfield Clinic for the Michigan region. I've been a quality director for years. I'm a dad, I'm a bonus dad, a son, basketball coach, baseball coach.

In my hat as a primary care provider I will tell you that patients in the UP have no trouble driving for quality care. My first day 23 years ago it was a snowstorm. I had two 80-year-old, a husband and wife, from Newberry which is about way over there about almost three hours from Marquette and they were my 8:00 and 9:00 o'clock physicals and I said no way are they going to come. Well, they got there the night before and stayed in a hotel because they knew it was going to be a snowstorm. So they're hardy.

When -- I know Marshfield Clinic has spent a lot of time working at getting a connection to clinical trials in the UP. When people are thinking about quality care in the UP, they want to go to somewhere where they're going to get quality treatment. They're not afraid to drive for that.

As the chief medical officer what's been interesting -- I've only been in that role for about a year and most of my cohorts from Marshall Clinic as you know are in Wisconsin. Wisconsin is a non-CON state. So I've learned a lot about the differences between Michigan and Wisconsin not just in other areas, but in the CON realm. I don't know how many of you know what happened with HSHS in

Eau Claire. The hospital closed basically because of the struggles with some of this. It's so difficult to recruit and retain good providers for these types of services. And then in my role as a son, I called and asked my mom on the drive down here. I drove down also. Got here at 3:00 a.m. It's a long drive. But I asked her -- you know, I told her about this proposal and she said, "why would they do that?" My mom lives in Rapid River. I was born at OSF. She lives right there. She said, "I'm going to go to Marquette or I'm going to go to Marshfield where I can get clinical trials." If you -- if you make this happen, there could be 11 different MRTs in the UP and that dilutes it too much.

So I was going to show you my hand. So you guys do a hand this way. I do it this way. If you're going to make more MRT in the UP, you don't need three on the palm. You need one on the finger or one on the wrist.

MS. STANTON: Thank you.

DR. MCKENZIE: Thank you very much. And I want to thank both of our commenters for the drive down. I know that's quite a commitment to come and give your comments. Any questions? Thank you. Any further public comment?

MS. STANTON: That was the last one.

DR. MCKENZIE: Okay. So hearing that we'll open it up for Commission discussion. And, again, what we have before us is the final draft language on the 45 miles that

we need to vote on today, either yes or no, and then a companion. So if we say yes, then we don't need to deal with the initial language. If we say no, then we've got initial language tied to the 90 miles. So I'm going to open it up for discussion. Any thoughts?

MS. GUIDO-ALLEN: Tell me again if -- Guido-Allen. Where are the -- is there two existing?

DR. MCKENZIE: There are two.

MS. GUIDO-ALLEN: And are they on, in the palm or the wrist or the finger?

DR. MCKENZIE: So that's a good -- so I'm not a UP expert so I'm going to turn to our speakers. We've got one in Marquette which is up on kind of the palm area and Iron Mountain which is --

MS. GUIDO-ALLEN: All the way over.

MS. STANTON: Right here.

DR. MCKENZIE: That's what I thought, in the Iron Dickinson point that's down.

DR. JOHN BARTLETT: So -- can I talk from here or do I --

DR. MCKENZIE: Yes, please. It'd be better if you could come up to the microphone. Thank you.

DR. JOHN BARTLETT: So, yeah, Marquette is where I live right now. I drive to Iron Mountain once or twice a week. It's about --

MS. GUIDO-ALLEN: Can you go closer and point?

MS. STANTON: Right here.

DR. JOHN BARTLETT: Marquette's up there. Iron Mountain is here. Escanaba is here and Gladstone. So it's actually 49 miles if you need to. You didn't draw that way, but that's, like, 60 miles.

MS. NAGEL: Hang on just a second. We have to have you near a microphone. I'm sorry.

DR. JOHN BARTLETT: Oh.

MS. NAGEL: For the court reporter.

DR. JOHN BARTLETT: Okay. So it's 49 miles from OSF to Dickinson County Hospital and Marshfield Dickinson. Marquette's up on Lake Superior. So those are all very close. There's Rapid River where my mom lives, just north of Escanaba. You know, yes, there's some snow up there but I've been driving there twice a week. I've had to not go once in a year. And especially the Iron Mountain/Escanaba area, they get less snow than Lansing.

DR. MCKENZIE: And so I think, you know, that some of the discussion is that while the 90 miles has been in place, there were opportunities for additional units, right, in some of that more outlying areas but no one has applied. So are we going to end up moving to the 45 and potentially end up still, you know, having a consolidation, you know? So I think that's kind of the argument that's on the plate.

Right? I mean, anybody can apply. So, but open for ideas, thoughts about how we move this forward or a motion to either move forward with final action or take initial proposed action on the 90 miles.

MR. CONNOLLY: Marcus from the Department. I'm not sure. Kelly, did you have a comment? I seen you get up. I don't want to -- don't want to overlook your --

MS. KELLY JEFFERSON: I just wanted to make sure I was ready to answer any questions for you, though, so thank you.

MR. CONNOLLY: Okay. All right. Just making sure that you didn't --

MS. KELLY JOHNSON: Thank you. I appreciate that.

DR. MCKENZIE: Oh, it looks like we have another public comment so we have another blue card coming in.

CARRIE LINDEROTH

MS. CARRIE LINDEROTH: Good morning. My name is Carrie Linderoth. I'm with Kelley Cawthorne. I do a lot of work with the Marshfield Clinic folks and have delved into this issue. I just also wanted to draw the Commission's attention to a letter that's in your packet from a number of facilities across the UP. So I think sometimes these issues are very challenging because it's a have versus have nots conversation and that's a difficult position for the Commission to be in. But I would like you to take a look at

that and see that there are other facilities that weighed in on this issue and ask the Commission to pause on reviewing this language. I don't think it's a bad option to consider putting together a workgroup to discuss this. I think with the current language that's there, you're right, no one has applied to it. But we're talking about essentially removing CON for MRT in the entire UP because they, there are so many people that would be eligible to do it and that kind of puts that planning area at a disadvantage compared to how we treat the rest of the state.

And so I think we really need to look at the quality element, look and see what the other facilities would like to do and consider the cost of bringing a program like this online in addition to the cost it would pose to the communities of the existing providers. So I, I would just urge caution in moving forward with this because there is no volume requirement for it and if we could kind of come together with the providers in the UP to have this conversation, we can probably come up with an alternative to just completely removing the volume requirement entirely. So just ask you to consider that and pause in that regard. And I'm happy to answer any questions. I also need to add I grew up in that area. I'm a Yooper myself and I have to echo what the doctor said earlier. We drive all the time. Most of the time our family is further than 45, 45 miles.

And so just take into consideration it's a different population. And so I'm happy to work with anybody on the details about this, but I think we should pause.

DR. MCKENZIE: Any questions? Okay. This is Commissioner McKenzie. I was sidebarring with Assistant Attorney General Brien Heckman on our options here because I think this is a difficult one for the Commission; right? We have differing opinions and --

MS. STANTON: We did get another.

DR. MCKENZIE: Oh, we have another comment?

MS. STANTON: Yes.

DR. MCKENZIE: Okay. We'll let that comment move forward and then I'll make my comments about our options, so thank you.

MS. STANTON: Yeah, thank you.

MELISSA REITZ

MS. MELISSA REITZ: Good morning. Are we still -- yeah. Morning. Melissa Reitz with McCall Hamilton. Sorry. I just wanted to add a couple of things. Carrie pointed out a letter in your packet and I just wanted to also point out a new letter that came in this morning from one of those facilities that were included in the original letter adding their support to the reduction to, to the 45 miles. So I just want to make sure that everybody have a chance to see that because it did come in rather late.

And then I'd also just wanted to say that there was a workgroup. This was a charge that was published. It was discussed at several Commission meetings. The workgroup had -- it, it's open. Those meetings are published on CON web site. Everyone is encouraged to participate. If this proposal received unanimous consensus with that workgroup -- and, and then the other thing that I just wanted to also mention or, you know, point out is that my name was mentioned. Out of the seven hospitals that would be able to apply under this proposal, six of them could apply today and they have had the last decade to do so. So I think that although there is the theoretical potential for seven new MRT that's under this, if past behavior is any indication of future expectations, we won't see. I mean, we, we agree that it'd be wonderful to have one in the Sault or somewhere on that side and one over here, but unfortunately it takes more than a change in the CON standards to, you know, have applicants feel that they have all of the resources available to implement these services successfully. So happy to answer any questions.

DR. MCKENZIE: Any questions from the Commission?

MS. MELISSA REITZ: Thank you.

DR. MCKENZIE: Okay. So I'll go back to what I was stating previously and I think Melissa's comments were helpful in that a workgroup did look at this. One of the

things that we were talking about is, you know, could we, you know, pause on the language as was asked and not take action at all today and that is an option. We can ask for a workgroup to go back and look at this again given the, the difference in, you know, opinion here. So we have a couple options before us. One is we can call a vote on final action if, you know, and that may pass or not pass. We have the initial language that's there for us on the 90 miles. If we want to move that forward, we would not be taking final action today and then we would get more public comment and hear about that in September. So that still gives time for that to move forward. But we would -- Beth, we do have to take a vote on the 45 mile; is that right?

MS. NAGEL: So you're taking a proposed action. There will need -- there does need to be at some point --

DR. MCKENZIE: At some point.

MS. NAGEL: -- a final action on the proposed action. And I will add one thing, too. I know we, we've talked a little bit about adding another workgroup to, to look at this. We haven't gotten on the schedule yet to -- you'll review our work plan later on the agenda. It is jam packed. By the time we would be able -- we estimate we'd be able to have a workgroup look at this, it's very close actually to the next time the CON standard comes up for a review which is 2026. So our recommendation is that if the

Commission does not want to -- wants to have experts to look at this issue, that it will be in 2026.

DR. MCKENZIE: Go ahead, Commissioner Ferguson.

DR. FERGUSON: Oh, I was going to go someplace you may not be ready to go. It looks like you got another idea from Brien.

DR. MCKENZIE: We were just discussing kind of some of the comments that Beth was making, so, so he was clarifying that for me.

DR. FERGUSON: If you're looking for a motion, I'll make a motion to adopt the changes inclusive of the 45 mile standard.

MS. NAGEL: So that's final.

DR. MCKENZIE: That's final action.

DR. FERGUSON: Call for the vote and final action --

DR. MCKENZIE: That's on final action.

MS. GUIDO-ALLEN: Can you repeat that? Can you repeat your motion?

DR. FERGUSON: I'd like to go ahead and vote on this. Right? So motion to adopt the language inclusive of the 45-mile standard that, that is submitted to us for final action today. We've been kicking this down the road. We might as well vote on it and --

DR. MCKENZIE: And so that final action would move

forward the language to the JLC as well as the Governor and there's a 45-day review period, but then after that 45-day review period, there's -- I think there's still opportunity for the Governor to opine on this and, and other things, but after that 45-day review period, the language would go into place. So just for clarification.

DR. FERGUSON: Just feels like we're spinning.

DR. MCKENZIE: Yes.

DR. FERGUSON: Like vote it up, vote it down.

DR. MCKENZIE: Yep.

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

DR. MCKENZIE: Okay. So we have a motion as well as support. So I think we're going to do a roll call vote on this. So, Beth, would you like to go through kind of the, the roll call or Marcus or --

MS. NAGEL: Tiffani?

MS. STANTON: Okay. Commissioner Guido-Allen?

MS. GUIDO-ALLEN: Support.

MS. STANTON: Greg Salwin?

MR. SALWIN: Support.

MS. STANTON: Mark Delano?

DR. DELANO: Support.

MS. STANTON: Kondur?

DR. KONDUR: Support.

MS. STANTON: And then have you --
DR. ENGELHARDT-KALBFLEISCH: Support.
MS. STANTON: -- and Daniel Velez?
MR. VELEZ: Support.
MS. STANTON: And, Dr. Ferguson, I have yours.
DR. FERGUSON: Support.
MS. STANTON: That's all in favor so the motion will carry.
DR. MCKENZIE: Thank you. Yeah, I was going to say, for me I support.
MS. STANTON: Sorry.
DR. MCKENZIE: That's okay. I support as well.
MS. STANTON: Sorry. That is my fault.
DR. MCKENZIE: No worries. Okay. So the motion carries.
(Whereupon motion passed at 10:39 a.m.)
DR. MCKENZIE: Thank you very much. Appreciate the motion and appreciate you helping us get out of the spin here, so -- okay. Thanks for the discussion and all the public comments on that and we appreciate our speakers coming down on, on that as well.
Okay. Our next item up for review is on BAMF. And we heard a little bit about this at our last Commission meeting with a request for a pilot program extension. And I think Justin is going to be reviewing the background on it.

MR. EASTER: Yeah.
DR. MCKENZIE: Oh, sorry. Hold on just a moment.
MS. NAGEL: I'm so sorry to take us backwards in any way. I do have a question for Brien. Procedurally do we need to take action --
MR. HECKMAN: Yeah, good --
MS. NAGEL: -- on the proposed action to down vote it or --
DR. MCKENZIE: Oh, we do?
MR. HECKMAN: Yep. Good catch, Beth.
MS. NAGEL: It's Tulika. Tulika caught that.
DR. MCKENZIE: Okay. So we're going to back up just a moment. So because we had two separate proposals at the request of the Commission, right, one for 45 and one for 90 and the 90 was the initial, since we approved the 45, I will take a motion now on the same language with the 90-day. And we, we have to put that forward and then vote it down or do we have to put forward a motion rejecting that? I've never done that before so I need some guidance here.
MR. HECKMAN: To clean it up, just vote to turn it down.
DR. MCKENZIE: Okay. So I will take a motion to turn down the initial proposed action for the 90 days.
MS. GUIDO-ALLEN: 90 miles.
DR. MCKENZIE: 90 miles. Sorry. Thank you. So

what is on the floor or what I am requesting is someone to propose that we turn down the initial proposed action with the 90 mile language for MRT.

DR. ENGELHARDT-KALBFLEISCH: Commissioner Engelhardt-Kalbfleisch. Proposal to turn down -- or motion to turn down the language for the 90 miles.

DR. KONDUR: Commissioner Kondur. Second.

DR. MCKENZIE: Thank you. All in favor?

ALL: Aye.

DR. MCKENZIE: Any against? Okay. That motion passes. Thank you.

(Whereupon motion passed at 10:41 a.m.)

DR. MCKENZIE: Thank you, Tulika and Beth, for keeping me straight here. Okay. Now we will move on to the request for pilot program extension for BAMF and Justin's going to be providing us with some of the background on that.

MR. EASTER: Justin from the Department. At the March 2024 Commission meeting, the Commission asked the Department to provide language that may extend the pilot program as outlined in Section 10 of the PET standards. Provided in the binder is a copy of the BAMF time line background from former advisors. Also in the binder is a copy of the proposed language in Section 10(6) updating the expiration date to September 1st, 2025, assuming the

language will be in effect February 2025. Proposed action from the Commission will require a motion, a second, and a vote to approve. The Commission's proposed action will move the language to a public hearing and to the JLC, and a report and language for final action will be brought back to the CON Commission at the September meeting.

DR. MCKENZIE: Thank you, Justin. Do we have any public comment on this?

MS. STANTON: We, we do.

MR. EASTER: Yes.

MS. STANTON: Go ahead.

MR. EASTER: Okay. Dr. Gulani?

DR. DELANO: Delano.

MR. EASTER: No, for public comment.

MS. STANTON: Yeah.

VIKAS GULANI, M.D.

DR. VIKAS GULANI: So I'm Vikas Gulani. I'm from the University of Michigan. I'm the chair of radiology at the University of Michigan. Pilots are designed to test the efficacy of novel investigational approaches for a limited time, hence the word pilot. And also refers simply to the approach of using the same chemical balance of two wave phases: one for therapy, thera, and another according to diagnostics. And this approach while exciting has been around since the 1950s for iodine treatment and more

recently for neuron brain tumors and these were for neuron tumor diagnosis and treatment, good therapy needs for treatment. Excuse me.

So the service, the -- this is not a novel or investigational thing anymore. This is a pretty standard way of approaching this. BAMF has no long -- no doubt that helped many patients, however, many groups in the, in the region, ourselves included, offer the same treatment and also the same imaging services. Duplicate of health care services create an over supply and lead to over utilization. They run counter to the principles of Certificate of Need and which is balancing cost, quality, and access. Creating a special case I think will really bend this principle. So I would suggest from the University of Michigan that we stick to our principles of Certificate of Need.

DR. MCKENZIE: Thank you very much. Any question from the Commissioners? Okay. Do we have any other public comment?

MR. EASTER: We do. Jeremiah Johns from BAMF.

DR. MCKENZIE: Okay.

JEREMIAH JOHNS, M.D.

DR. JEREMIAH JOHNS: Dr. Jeremiah Johns, vice president, Medical Affairs for BAMF Health. Thank you for having us. We are submitting a summary of some of the accomplishments that we've been able to achieve thus far in

the CON along with letters of support from Corewell Health East, Beaumont Chair of Radiation Oncology Dr. Craig Stevens as well as Dr. Norm Beauchamp with Michigan State University, Executive Vice President of Health Sciences. Unfortunately, those letters arrived too late to make your prehearing packet, so I apologize for that.

You know, we support the language as has been mentioned to extend the deadline for application for new pilot programs. So the pilot program is not exclusive to BAMF Health. Anyone can apply for it and could do so if, if they wish. Extending the application deadline to allow for a new pilot program would also be available to anyone.

We are asking for an extension because we opened our doors in August of 2022, fully operational -- both operational in May of '23, the deadline extended -- ended in September. In a bipartisan effort, the Michigan legislature has appropriated funds to help build an innovative site such as this in the Detroit area. That was not finalized until December of '23.

Advances in molecular imaging and radiopharmaceutical therapy do promise to bring great benefit to Michigan patients as have been previously mentioned, but the infrastructure to provide that complex care does not exist. BAMF Health is focused on novel imaging and radiopharmaceutical therapies of which there are

approximately 90 current candidates in active clinical trials, many of which don't even involve oncology. So this is an area where much great work does need to be done. We're partnering with other health systems including University of Michigan where we're actively enrolling patients in a trial related to cholesterol and hypertension with others on the way as well. Further access to Detroit patients is limited to our facility in Grand Rapids; social determinative health issues, transportation, and things limit their access. Thank you.

DR. MCKENZIE: Thank you very much. Any questions?

DR. FERGUSON: Commissioner Ferguson. So thank you for the information here and thank you for the information at the last meeting. I guess what I'm still trying to or wrestle with my mind is understanding that working with novel agents takes more time and resources, absolutely. But it sounds like so 20 percent of your patients are in clinical trials, so 80 percent presumably are not. And then of that 20 percent in clinical trials, presumably some chunk of those are on FDA approved agents and are in some form of clinical trial. We still do clinical trials on agents. So what percentage of your patients are out there and what we need a pilot for? Because what I'm hearing is that vast bulk of your patients

could be done at other research institutions in the state, whether it's U of M or even non-research institutions that are providing many of the similar services. So I'm trying to figure out, like, you're asking for a big exemption for what sounds like a very small chunk of your patients.

MR. JEREMIAH JOHNS: So the pilot program is for a comprehensive, fixed PET referral center and the comprehensive part is the key. So your question being that many of the clinical trans that we're doing are very difficult to do when you're not doing it in the comprehensive center with the availability of the cyclotrons paired with the imaging facility. Many of the dual combination imaging and therapeutic investigational drugs benefit from being able to have the facility paired in a comprehensive way and it's very difficult because of the time constraints necessary due to the trials to do them within traditional health system setting. The capacity is very difficult, the time constraints on the machines, and patient scheduling.

DR. MCKENZIE: Other questions from commissioners? Thank you very much. I think I've seen additional public comment come in, so thank you.

MR. EASTER: Anthony Chang from BAMF.

ANTHONY CHANG

MR. ANTHONY CHANG: Thank you, Commissioners.

First I want to appreciate your time and understanding of these, how important this project is.

So I want to emphasize several point. Number one, this is extension for a pilot project. This is not specific to BAMF. And also, this is actually allowing us to have solid data to actually explore how to set up rational and reasonable rules for future approval of the PET and for future technology.

Yes, we heard previous about -- a person talk about that there now has been exist for since 1950s, but we have none in our census until 2022. There's only one job available for thera, that's iodine therapy. And until 2022, the first -- until 2022, the prof-, the profit (indiscernible phrase) approved, the whole field is booming. Currently there's 89 diagnostic PET drugs that's in clinical trial right now ready to get into the, into the market for a wide variety of disease in neurology, and oncology, and radiology. This is a world we haven't seen before. This is the data we don't have before, and this is an experience we don't have before. Even with all the, all the academic center has the capability can do these kind of clinical trial, but it's very, very hard for them to have capacity to conduct this kind of large amount of clinical trial while they're serving their patients for routine care. And therefore, we're actually asking for this pilot program

allowing us to officially conduct these kind of program for these kind of novel tracers, not only pharmaceuticals, for a wide variety of disease. So we have solid data to put it in front of a CON committee in a few years so we can make a solid decision how to regulate these kind of a PET centers for the new world over here. So that's why I want to bring it out to the commissioners for consideration. Thank you. I'm wondering if you have any questions.

DR. MCKENZIE: Thank you. Commissioner Ferguson?

DR. FERGUSON: I'm still working on the same point here that I'm struggling with the idea that I understand to make your -- I'm guessing to make the model work you need to provide services to a whole lot of patients who aren't part of investigation.

MR. ANTHONY CHANG: Yes.

DR. FERGUSON: And I guess my question is, is that for that 80 percent or whatever chunk, 90 percent of your patients, ends up functionally a little bit of an end around. I know that it's probably a basis that you need to make it work. I guess my ask of you is, is there a way for you to have a viable business entity doing the important investigational work that you're doing, right -- and I thank you for that work. That's really important work.

MR. ANTHONY CHANG: Yeah.

DR. FERGUSON: But is there a way to do that that

doesn't frankly disadvantage everybody else to have to play by the traditional rules of getting their CONs and their PETs and running, you know, their diagnostics in their existing facility? Because it is a, it is a service that's provided by a lot of facilities now. Not the research side, but the, the other. I want to be real clear about that.

MR. ANTHONY CHANG: Yeah.

DR. FERGUSON: Is there any way to make that work? Because I'm, I'm feeling really torn.

MR. ANTHONY CHANG: Yeah. So that's actually exactly the question or problem we're trying to solve. I mean, yes, conventional facility using those same conventional PET services, they can do these kind of things. But the issue is they don't have capacity to do these kind of things. Conventional PET scanner can scan about, for a large hospital sees them, they scan about 20 patients a day. That's basically about 10 hours operational or more. And you can see right now majority of PET services is actually two to four weeks ahead, some place eight weeks aside. For you to conduct these kind of clinical trials, especially for fac-, patient running clinical trials, each patient you going to stay in the clinic for about eight hours because you need to start to collect a lot of the fundamental clinical informations. So there -- the current facility and the current infrastructure just don't have those kind of

capacity to, to be able to conduct these kind of, these kind of stuff. Especially not a one or two drug enter the market, this is about eight new drug and see a increase and trying to get out to market it right now. And therefore we, we either request the special rules to change the CON law which is request to extend a pilot program, give us more time to actually test these kind of things and offer solid data so we can make the reasonable judgment for the future to adopt a new type of medicine. That's all we're asking. And, again, I want to emphasize this is not specialized, specialized to BAMF. This is everybody in the state of Michigan can actually apply for this if they want to get involved in this mission and to make these things happen.

DR. FERGUSON: Question for the Department in follow-up is, is there, is there any category of a research PET or a research CON as opposed to a pilot? Like is there an existing model that this would fall into?

MS. NAGEL: Tulika?

MS. BHATTACHARYA: So there is a provision to add dedicated research PET scanner, but it is for an existing service to add a dedicated research scanner. We cannot issue PET service in a new location, just a dedicated research scanner.

DR. FERGUSON: So maybe that's the exemption we should be granting.

MS. GUIDO-ALLEN: But they're not existing. They don't have a CON.

DR. FERGUSON: No. But maybe that's my -- but my point is maybe that's what should be granted is rather than a full pilot project is a way to grant a research scanner that only does research.

DR. MCKENZIE: I think the question that I'm hearing kind of tossed around is should we be extending a pilot or should the standards be opened. Was that something to, to kind of, like, hard coat this. I understand everybody's available, but I think that the term "pilot" makes the commissioners maybe a little bit, like, because it's not -- it feels like it's, it's something that's outside of kind of the ongoing hard coating within the standard. Am I understanding you correctly? It's like we're looking for something that -- you know, do the standards need to be opened I guess is the question to contemplate this type of activity in an ongoing way?

MR. CONNOLLY: Marcus with the Department. That is something that the Department has grappled with because when you say the word "pilot," it almost sounds like it should be an end and we've been talking about it internally. The next cycle is to look what we should do as far as the pilot program because those are some of the questions we have when we actually implemented it. So it's something

that we want to look at once it's back up for the review cycle to see where we would end it because obviously you can't have a pilot program that's ongoing. So that's what we're going to talk about internally, what we need to do the next cycle.

MS. STANTON: Tiffani from the Department. Just to add the date for the, that's being proposed for September '25. The PET standards are up for review at the October '25 public comment period to be opened for a possible SAC or workgroup in '26. The language in the standards currently have the pilot program I think it's through the statute through 2027, so that's where the allowance of that extension where we were pulling the date from, but also to fall in line so that language can be implemented by a workgroup or SAC in 2026, at the next review cycle.

DR. FERGUSON: Following up on the pilot. So if, if you're looking at whether or not the, the, the subset of pilot program or pilot offering at the next go around, can't believe you're going to take away a CON and make them shut down a fixed facility that's got millions and millions of dollars to build. All right. So presumably whoever is granted access to the pilot program would keep that access on a semi-permanent or permanent basis. Right? I mean, you can't ask somebody to build something, plunk down millions of dollars and then say, "oops, sorry, pilot program is

over. You have to shut it down."

MS. STANTON: Yeah. It'd be grandfathered in.

MR. CONNOLLY: Yeah.

DR. FERGUSON: Yeah. You wouldn't, you wouldn't allow new entrants.

MS. STANTON: Unless there was a change.

MS. NAGEL: That was the pilot portion of it. That, that's the variable.

DR. MCKENZIE: Any other questions from commissioners? Thank you very much.

MR. ANTHONY CHANG: Thank you. Appreciate it.

DR. MCKENZIE: Do we have other public comment?

MR. EASTER: Dr. Gulani.

VIKAS GULANI, M.D.

DR. VIKAS GULANI: So once again I want to reiterate that this isn't novel. This is done all over the country. We have two cyclotrons at our facility. We do research on a research scanner, we do clinical on our clinical scanners. This is a standard thing that's done around the country. And many, many, many universities and academic centers are doing this. We're doing this. A majority of the work as pointed out is Pluvicto which is no longer research. This is normal clinical treatment for prostate cancer. LumiThera which came out in 2021 is also treatment. And these are FDA approved approaches. So this

is not novel. Imaging of prostate cancer with, with gallium PET is not novel. It's pretty standard. We do this all the time. We are awaiting government approval for one more indications for these things. The studies that are requiring the cyclotron on facility are done together at U of M and other places. It's interesting work, it's wonderful work, it's going to help patients, but I don't see how this is a pilot program.

DR. MCKENZIE: Okay. I see that we're getting multiple comment cards from folks who've spoken and that's not typically, so I apologize. That, that was my mistake in allowing the comments to go back and forth. But I, I think we heard the positions from both, so -- okay. We'll let you have one response and then, and then that's it.

ANTHONY CHANG

MR. ANTHONY CHANG: I appreciate that. So I appreciate this. I mean, I agree with Dr. Gulani just said, Pluvicto with thera is novel -- it's not novel because it's become -- it carries FDA approved. I want to make -- they're making the point that we're talking about here. It's everything besides those. There's 89 drugs in clinical trial right, right now that's not for those. There's a lot of hospital practice Pluvicto, do the thera, but not every hospital is like U of M, have two cyclotrons and that which is one of the most prestigious universities in the world.

And in fact just four, four days ago when I attended international meeting in Toronto in this field, the U of M researchers and leader in their department talk about the serious capacity issues they are facing over there. Therefore, they cannot do enough -- they cannot do a clinical trial efficiently.

So that's exactly the same issue we're talking about over here from the, the same institution we mention those kind of things over here. We're here using brand new organiz- -- brand new organization in a way in pilot program to try to solve this issue, to learn about this novel tracer for other disease, what Dr. Gulani just mentioned. So that's the pilot program. It's not things has been approved by FDA and practicing. That's I want to mention.

MS. GUIDO-ALLEN: I have a question. A question for you. Guido-Allen. How sustainable would your model be if you were limited to only research? Only research? Not FDA-approved clinical care that can be provided at many other facilities?

MR. ANTHONY CHANG: So that will poten- -- the reason we are actually doing --

MS. GUIDO-ALLEN: How -- my question was how sustainable is your model if you removed all standard of care, clinical care, from your, from your BAMF Health?

MR. ANTHONY CHANG: It's not quite sustainable

because the question we're facing right now is how fast are these new things going to start to come out. So we're waiting -- the reason we asked for extension is because for the past two years we have that the new drug for clinical trial are not cranking in fast enough so we want more extension so we can have some time to, to value that.

MS. GUIDO-ALLEN: You're asking for an extension but you're also asking for a $20 million facility to be built in addition to the pilot facility that you're, you already built. That I think is what's weighing heavy on the commissioners here, --

MR. ANTHONY CHANG: Yep.

MS. GUIDO-ALLEN: -- because it is going around our standards.

MR. ANTHONY CHANG: Yeah. So we're -- we -- the reason we asked that that facility built -- not that we're asking facility built. We're actually going to try to build a facility in, in Detroit to doing these kind of a things is because what we learned is for a lot of patients -- well, originally I think a Detroit patient will drive to Grand Rapids for this kind of novel study but for the past two years we actually learned that a lot of patients were not willing to do that, especially for what I said, those kind of phase studies, ones that they need to stay over one day even overnight so it's not efficient. And that's why we are

trying to --

MS. GUIDO-ALLEN: So you're saying --

MR. ANTHONY CHANG: -- ask for, ask for an extension and we're going to go through a lot of application process and the CON Commission can actually approve of those kind of things. So that's two different kind of steps. Here we are asking for extension.

MS. GUIDO-ALLEN: So you're going to build a facility regardless of the outcome of the Department's and the, the standards?

MR. ANTHONY CHANG: No. We're not, we're not going to do that. That's why we need to go through this kind of process. Yeah. We need to have a communicate why this is important for the Commission, with the commissioners and we're going to go through that process.

MS. GUIDO-ALLEN: Thank you.

MR. ANTHONY CHANG: Thank you.

DR. MCKENZIE: Other questions from commissioners? Any other public comment?

MR. EASTER: No more.

DR. MCKENZIE: I have a question for the Department. We have proposed language change to 2025 and Tiffani outlined the time frame that we could reopen the standard tied to that and that's how you chose the date, to contemplate what should happen going forward -- and, Marcus,

thank you for outlining that as well -- with kind of this pilot language. And if the commissioners were uncomfortable with that, that proposed extension, we heard how busy the agenda is. How quickly could this item -- could the Commission ask, like, feas-, feasibility of looking at this item earlier versus it having to wait until 2026 when the normal time frame would roll forward for MRT? I know that's a difficult question, but I think that's kind of what's on the table for the Commission to contemplate.

MS. NAGEL: It is a difficult question to answer specifically. I, I can say that we would have room in the 2026 to, to look at, to the 2026 work plan to look at this along with any other MRT issues to hold a kind of a, a workgroup just to look at this specific issue. I think we would be cutting it really close to 2026 actually. I think it would definitely be into '25. I couldn't say for sure to be honest. The work plan is -- as you'll see we had to add new pages to it. I mean, it's a, an extensive work plan. So I, I'm comfortable with saying we could look at it at its regular part of the review cycle. I cannot make any promises.

DR. MCKENZIE: So what I'm hearing is that the earliest that you would be comfortable committing to would be 2026, which would mean it would remain expired unless the Commission takes action today to extend it?

MS. NAGEL: That's accurate.

DR. KONDUR: Commissioner Kondur. Quick question. So if we don't extend the, the pilot program, what happens to the present patients who are in therapy?

MS. NAGEL: So if I could just -- I had Tiffani put the language up on the, the screen just to kind of clarify actually a question that Dr. Ferguson asked. The how this was written and accepted by a previous Commission is that this language that's in the standard, Section 10, the Commission has until September 30th of 2027, to accept this language as part of this standard. That's the pilot portion, should this language be included as part of the standard. Nothing happens to anything that's approved under this pilot. So that is the nature of the pilot if this language is worth having in the standards or not.

DR. MCKENZIE: So the existing facility and all the patients that are getting treated there, if the Commission chose not to do the extension, would still be protected under that ability to incorporate the language through the 2027. The only thing that would not be allowed is the addition of a new --

MS. STANTON: New applicants.

DR. MCKENZIE: -- applicant.

MS. NAGEL: That is accurate.

DR. MCKENZIE: Is that accurate?

MS. NAGEL: Uh-huh.

DR. MCKENZIE: Okay. Do the commissioners have other questions?

DR. FERGUSON: So we have to take action to actively extend or not extend or is no action the same as no extension? Do we need a vote?

DR. MCKENZIE: Well, I think -- go ahead.

MR. HECKMAN: I believe the packet has the proposal in it. So you'd want to reject the proposal.

DR. FERGUSON: Okay. So the proposal in the packet is to extend the pilot, so --

DR. MCKENZIE: Any other commissioner discussion or questions? Does anybody want to make a proposal?

DR. KONDUR: Commissioner Kondur. Want to propose extend the pilot project as proposed in the language.

DR. MCKENZIE: Okay. And this is initial -- is this -- this is initial proposed language?

MS. NAGEL: Proposed action, yes.

DR. MCKENZIE: Proposed action. So this would come again before the Commission before final action?

MS. NAGEL: Yes, in September.

DR. MCKENZIE: Thank you. So Commissioner Kondur is proposing to accept the proposed language the Department has drafted which would extend the pilot program through 2025, and that language would then go out for public comment

and to the JLC before final action which would come back to the Commission in September. And so we would get opportunity to get more public comment. Does anybody want to second that? Okay. We have a motion on the floor without a second.

DR. FERGUSON: I think we -- help me with the process here. Seconding it just gets it to a vote.

DR. MCKENZIE: Just gets us to a vote. It just gets us -- thank you.

DR. FERGUSON: I imagine we've got to vote, so I'll second it just to get it to a vote.

DR. MCKENZIE: Okay. Thank you. Okay. We're going to do a roll call vote and I'll turn it over to the Department to walk through that.

MS. STANTON: Dr. McKenzie?

DR. MCKENZIE: I'm trying to remember what's on the floor. Hold on. Okay. This is to accept. Yes, I will support.

MS. STANTON: Guido-Allen?

MS. GUIDO-ALLEN: No.

MS. STANTON: Salwin?

MR. SALWIN: No.

MS. STANTON: Delano?

DR. DELANO: Abstain.

MS. STANTON: Kondur?

DR. KONDUR: Yes. Accept.
MS. STANTON: Engelhardt-Kalbfleisch?
DR. ENGELHARDT-KALBFLEISCH: No.
MS. STANTON: Velez?
MR. VELEZ: Support.
MS. STANTON: Ferguson?
DR. FERGUSON: No.
MS. STANTON: So that's not enough for it to pass, so the motion will not carry.
DR. MCKENZIE: Okay. Thank you.
(Whereupon motion failed at 11:11 a.m.)
MR. EASTER: Didn't carry?
MS. STANTON: I'm sorry?
MR. EASTER: Didn't carry, yeah.
MS. STANTON: Yeah. It stay --
MR. CONNOLLY: Didn't carry.
DR. MCKENZIE: So the motion to extend the pilot program did not carry the language. So I do need another motion then to -- I guess the other alternative is to reject or to pull together to request the Department to put together a workgroup.
MR. HECKMAN: The down vote counted.
MR. EASTER: Yeah; yeah. That works.
DR. MCKENZIE: Oh, it does count? Okay. Good. Okay. So we are done with that item then.

MS. STANTON: The motion does not carry, so --

DR. MCKENZIE: Okay. Good. Thank you. Thank you for my process people for keeping me straight here. I appreciate it. Okay. So that item is closed. So the pilot program is not extended and we can close that item. Okay. Now moving on to our legislative update next.

MR. EASTER: Justin from the Department. Two bills for our Open Meetings Act, House Bill 4693, was introduced last year and House Bill 4817 also introduced last year and there's no movement on these bills currently. House Bill 4834 pertained to the Certificate of Need, was introduced last year as well, no movement. Twenty-nine bills that were introduced between the January and March Commission meeting in February, House Bill 5478 through 5498, to repeal the Certificate of Need program within Michigan, there's still no movement on this. We will continue to track these bills. The new bill that was introduced between these two meetings in April, Senate Bill 811 about slim beds, this bill was introduced on April 9 to expand access to mental health care patients. The bill was sent to Health Policy and currently no movement and we'll continue to track these bills as necessary.

DR. MCKENZIE: Thank you. Any questions? Great. Okay. And we will move to our administrative update.

MR. CONNOLLY: Yes. I do have -- this is Marcus

with the Commission. I do have an administrative update. Our liaison for the CON, Tiffani Stanton, she will be on maternity leave probably in the next few weeks until October sometime. So if there's any concerns or anything concerning the CON Commission, please reach out to myself, Justin Easter, or Katherine Tucker, and we'll be more than happy to assist you. So that's the administrative change right now.

DR. FERGUSON: Congratulations.

MS. STANTON: Thank you.

DR. MCKENZIE: Thank you. And do we also have our -- we have our Evaluation Section update from Tulika as well.

MS. BHATTACHARYA: Thank you, Dr. McKenzie. Before I give the reports, I would like to introduce Thomas J. Reese, TJ, our CON finance specialist. So it's about a month he started. The applicants will get to know and so he will be doing the finance review for all applications that we see, about 300 a year. So welcome aboard, TJ.

MR. REESE: Very nice to meet you all. Looking forward to work.

MS. BHATTACHARYA: There are two sets of report in this meeting because I skipped presenting at the last meeting because I presented the annual report. So for first and second quarter of February 2024 -- it has been a long meeting so I don't plan to go over everything. But just to

summarize, we continue to meet our deadlines for application reviews and decisions. As you can see emergency CONs has slowed down a lot compared to the pandemic level, but we still continue to receive service specific or situation specific requests for an emergency CON and appropriate to review and approve those. And then there were specific service or facility specific compliance actions or compliance letters with warnings that were sent out to a few facilities. That is in your packet. And this year we are going to do statewide compliance review for NICU beds and Special Care Nursery Services. We are in the process of completing our annual survey audit, but those e-mails to the provider will start to go out soon. I just wanted to advise the Commission that those are on our plate this year.

DR. MCKENZIE: Thank you, Tulika. I know that's a lot of work and appreciate all the work you, you and your team are doing. Next on our agenda we have our Legal Activity report -- and that's contained in your packet -- from Assistant Attorney Brien Heckman.

MR. HECKMAN: This is, as you know, Brien Heckman. As you can see from the legal activity report we don't have anything in litigation or subpoenas or anything, so thanks.

DR. MCKENZIE: Thank you. Next on our agenda we have open public comment. Do we have any public comment cards?

MS. STANTON: We do not.

DR. MCKENZIE: Okay. We'll keep this moving. Next we have our review of our Commission work plan which is contained in your packet and I'll turn it over to Tiffani.

MS. STANTON: Yes. So there was the two work plans that are being presented. So to start -- and I apologize for how small it is. The BMT we did present today for the proposed action. Our Cardiac Cath SAC did start last month. That will be ongoing through October. CT is up for public review or public comment this year for a possible SAC or workgroup next year. Our Heart, Lung, Liver SAC, we will be starting that nomination period later this month and the first meeting is anticipated for October. The Hospital workgroup we just discussed today as well as the proposed language. That'll come back for final action in September.

The MRI informal workgroup, that is starting later this month as well. MRT, we just discussed that as well. The NICU and Nursing Home, those will both be up for public comment at the October public comment period for a potential workgroup or SAC next year. Open Heart, that one was finalized earlier this year at the March meeting. Those were in effect in May, the standards that were proposed. Psych Beds, we have that tentatively starting, that workgroup starting in December. Based on how the schedule is, we will be having that, again, December.

The Surgical Services just concluded. We discussed that today. That will be back for final action in September. Litho is also up for the public comment for potential workgroup or SAC next year. And then the, at the March meeting we did discuss the county designation workgroup. We anticipate having that -- we did have to add that. That is not a normal review cycle so that was added on here and we are anticipating that to start in January between Psych Beds low charge. It was mainly the adjustment from an 86 -- or 80 percent to 60 percent for the, that. So hopefully we're hoping to get by with four meetings. Same thing with the county designation, to kind of fit them in. So we have that. That's why you'll see the two drafts in here. The, this goes into the 2025 year, and that's not counting any of the standards that are up for the review in October, any potential workgroups or SACs that may come out of those. Any questions on either of them as presented?

DR. MCKENZIE: If there's no questions, we do have to approve the work plan. So I'll take a motion.

DR. ENGELHARDT-KALBFLEISCH: Commissioner Engelhardt-Kalbfleish. Motion to approve the work plan.

DR. MCKENZIE: Thank you.

DR. KONDUR: Commissioner Kondur. Second.

DR. MCKENZIE: Thank you. All in favor?

ALL: Aye.

DR. MCKENZIE: Any against? Okay. Work plan passes. Thank you.

(Whereupon motion passed at 11:19 a.m.)

DR. MCKENZIE: Your future meeting dates are on your agenda. We have our next meeting which is September 19th. I think Commissioner Falahee will be back and we will enjoy having him back at the helm. And then we also have our, our end-of-year meeting on December 5th. So please make sure you mark those on your calendar. And we approved those dates in the past, so we don't need a vote on that. So last on the agenda, a motion to adjourn.

DR. ENGELHARDT-KALBFLEISCH: Engelhardt-Kalbfleisch. Motion to adjourn.

DR. KONDUR: Second. Commissioner Kondur.

DR. MCKENZIE: Thank you. All in favor?

ALL: Aye.

DR. MCKENZIE: Okay. I assume nobody's against.

(Whereupon motion passed at 11:20 a.m.)

DR. MCKENZIE: Thank you all for your time today. Really appreciate it. Drive safely and we'll see you in September.

(Proceeding concluded at 11:20 a.m.)

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CERTIFICATE

I, Marcy A. Klingshirn, a Certified Electronic Recorder and Notary Public within and for the State of Michigan, do hereby certify:

That this transcript, consisting of 84 pages, is a complete, true, and correct record given in this meeting.

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 25th day of June, 2024.

Marcy A. Klingshirn

Marcy A. Klingshirn, CER 6924
Notary Public, State of Michigan
County of Eaton
My commission expires: March 30, 2029