STATE OF MICHIGAN
MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES
CERTIFICATE OF NEED COMMISSION

COMMISSION MEETING

BEFORE THOMAS MITTELBRUN, III, CHAIRPERSON

333 South Grand Avenue, Lansing, Michigan

Tuesday, March 27, 2018, 9:30 a.m.

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Lansing, Michigan

Tuesday, March 27, 2018 - 9:36 a.m.

MR. MITTELBRUN: Good morning. My name is Tom Mittelbrun. I'll be filling in today. We'd like to call the meeting to order. First item, review of the agenda. Need a motion to approve the agenda.

MS. BROOKS-WILLIAMS: Brooks-Williams. So moved.

MR. FALAHEE: Falahee. Support.

MR. MITTELBRUN: All in favor of approving the agenda?

(All in favor)

MR. MITTELBRUN: I would also like to welcome Amy McKenzie, our new commissioner. Thank you for joining us. We have one commissioner on her way. She'll be here shortly -- oh. I'm sorry, Denise. You snuck in on me. Oh, you even made the motion. Next, are there any declarations of conflict of interest? Seeing none, next item, review of the minutes of February 8th, 2018. If there are no comments or questions, we need a motion to approve the minutes.

MR. TOMATIS: Move.

MR. MITTELBRUN: Commissioner Tomatis moved.

MS. BROOKS-WILLIAMS: Brooks-Williams. Support.

JUDGE ROBBINS: All in favor?

(All in favor)

MS. ROGERS: This is Brenda. Just a friendly

reminder that as you speak today, please identify yourself each time before you speak and please speak into the microphones, if you can, assuming they keep working. We are recording the meeting. Thank you.

MR. MITTELBRUN: Next item on the agenda, Shock Wave Lithotripsy. Brenda?

MS. ROGERS: This is Brenda. If you'll recall at your December commission meeting you took proposed action on the draft language. Public hearing was scheduled and was held on January 28th. We've received two pieces of testimony, both in support of the -- well, one in support of the draft language and then the other just addressing access to care.

So based on the testimony received, the departments recommend -- can support you taking final action on this language today and moving it forward to the Joint Legislative Committee and the governor for the 45-day review period -- thank you -- with no changes.

MR. MITTELBRUN: Okay. We have one card for public comment. Mr. Shaski from Sparrow.

JOHN SHASKI

MR. JOHN SHASKI: Hi. Good morning. John Shaski, government relations officer for Sparrow Health System. I just want to say thank you to the commission and the department for their deliberation on this topic. As you're

aware, Sparrow's been very engaged on this issue for close to three years now and we are supportive of the proposed language that would allow consistent high volume facilities to convert from mobile to a fixed unit. And again, we appreciate the work that's been done by the commission and the department and we are hopeful for final action today. Thank you.

MR. MITTELBRUN: Any other comments? Okay. With no other comments, Brenda, action will be taken?

MS. ROGERS: Commission discussion.

MR. MITTELBRUN: Any discussion by the commission?

MR. FALAHEE: This is Falahee. Just to move this along, we've discussed this ad infinitum. I don't think we need to discuss it for another three years, three months or three minutes. So I'll make a motion to approve the language in front of us today and then to send it to the Joint Legislative Committee and to the governor and to the necessary 45-day review period.

MS. CLARKSON: Commissioner Clarkson. I'll second.

MR. MITTELBRUN: All those in favor?

(All in favor)

MR. MITTELBRUN: Motion passes. Next, Bone Marrow Transplantation. Brenda, draft language?

MS. ROGERS: Again, this is Brenda. You do have

draft language in your material. At the February meeting where you had your planning meeting, you asked the department to draft language to remove "stem" from the definition of BMT service, which would include infusion of cell therapy products such as CAR-T, chimeric antigen receptor T-cells, to be limited to BMT services. In drafting that definition, the department realized that this would be adding new services to CON and CON standards are not retroactive.

So language was developed along with removing the word "stem" from BMT to accommodate existing BMT programs applying to CON to perform expanded cellular therapy products. So any existing BMT service that chooses to provide these cellular therapy products must file an application first should the commission decide to move forward with the proposed language as drafted. Thank you.

And if the commission does take action to propose action onto this today, if you take action with no changes, then it will be moved forward and public hearing will be scheduled and then brought to you in June. If you take action today with changes, it would still be the same process because this is the first step of the change to the standards. Or if you decide to take no action as far as the cellular therapy products and leave the language as it currently is, then the standards would get scheduled for the

next review period.

MR. FALAHEE: This is Falahee. Brenda, can I ask you a question? So we have in our packet the yellow highlighted language and then I'm trying to figure out we also have a proposed amendment in front of us.

MS. ROGERS: This is Brenda. The proposed amendment in front of you I think was passed out not -- it was not passed out by the department.

MR. FALAHEE: Okay. That's what I wanted to know. Okay. Thank you.

MR. MITTELBRUN: Okay. For public comment -- and just a reminder, please keep your comments to three minutes or less -- first is Melissa Cupp from RWC Advocacy.

MELISSA CUPP

MS. MELISSA CUPP: Good morning. I'm Melissa Cupp from RWC Advocacy. I'm here this morning on behalf of Henry Ford Health System. Barbara Bressack apologizes for not being able to attend today's meeting, but asked that I provide these comments on her behalf. Henry Ford Health System appreciates the support of the CON commission to update the BMT standards as described at the February commission meeting.

However, based on discussions with the department, we understand why the definition update can't be as simple as we had originally envisioned. We appreciate the

department's suggestions and inclusion of the language to create a mechanism for existing providers to apply under the new standards once they become effective. We also appreciate the department's commitment to implement a grace period for existing programs to obtain CON approval without interrupting patient care. We completely agree with the premise behind the department's revised definition of BMT services and appreciate the work they put into their proposed revision.

However, we believe the definition should be narrowed even further. It certainly was not our intention to have existing therapies that are commonly provided today safely in an outpatient setting included. I believe Doctors Uberti, Yanik and Williams will address this more specifically in their comments, but we support the proposed amended definition provided to you this morning, which is what you referenced, Commissioner Falahee.

It looks like this (indicating). As we explained at the last meeting, CAR-T therapy is an extremely expensive, extremely dangerous cancer treatment that must be regulated by Certificate of Need to ensure the citizens of Michigan have access to the safest setting to receive this treatment. This is a brand-new therapy and because of all of these factors, it is prudent to proceed in a cautious manner. Once these treatments have been studied more,

fine-tuned, complications reduced and become more standard of care, then perhaps it will be appropriate to make additional modifications at that time. Thank you for your time and I'm happy to try to answer any questions you may have.

MR. FALAHEE: This is Falahee. Melissa, I missed the February meeting, but I have a lot of questions that maybe the subsequent witnesses can answer as to what's right or wrong with what's projected on the screen, what's right or wrong with what's being handed out, and why we would do this now versus wait until we just go through the regular review cycle. What's the rush?

MS. MELISSA CUPP: So I think a couple things. One is keep in mind we are in the regular review cycle right now, so this is kind of the opportunity to do it. My understanding -- and I agree with you that the doctors who will come up and speak will probably be able to answer this from a better substantive perspective, but I can talk about just kind of the differences between this language and what's on the screen, which is specifically "natural killer cells," "dendritic cells," "mesenchymal cells" are all deleted.

And Beth can maybe speak to where all that came from because I kind of know, but I don't want to misstate. But through conversations that I've participated in with the

existing providers, when they saw that they were concerned that it grabbed on to too much stuff, for lack of a better term, and wanting to keep this definition narrow. And I guess it would also make sense to point out, and this was something that the department added and that we agree with, is that this is limited even further to say it's CAR-T cells used to treat a hematological malignancy.

So it's not even CAR-T cells used to treat anything, it's just hematological malignancies which is what bone marrow transplant treats today. So we tried to make it as narrow as we could, but still incorporating what we truly do believe should be covered under these standards.

MR. FALAHEE: Thank you.

MR. MITTELBRUN: Any other questions? Thank you.

MS. MELISSA CUPP: Thank you.

MR. MITTELBRUN: Next, Dr. Philip Stella, Trinity Health.

UNIDENTIFIED SPEAKER: I don't think he's here yet.

MR. MITTELBRUN: Joseph Uberti, Karmanos?

JOSEPH UBERTI, M.D., Ph.D.

DR. JOSEPH UBERTI: I'd like to thank, first of all, the commission for allowing me to come up and speak again. I'm Joe Uberti. I'm head of the transplant and heme malignancy program at Karmanos Cancer Center. I do want to

focus how we've asked the language to change for this. And again, we wanted to narrow the focus of what we consider CAR-T cells. We currently have a project that would fit in this definition called PROVENGE that every urologist uses, every oncologist who treats prostate cancer uses right now. It's a product that's safe to give in the outpatient setting. If you look at it, this would be included in this definition.

We did not want to include that product in our definition. So by narrowing it a bit to look at CAR-T cells, it will eliminate some of the other cells, cellular therapy that are given safely in outpatient settings that are already being given right now in the state of Michigan and around the country, and those don't have to be included in this definition.

Remember we wanted to include the CAR-T cells because that was really the therapy that has most of the toxicity associated with it. All the investigational trials for these therapies were completed in stem cell transplantation programs and they did that because the infrastructure, the quality, the safety measures were all built into the stem cell transplantation programs and because of that, we think it should be continued to be managed with a transplantation program because that's the safest way that these patients get through this procedure.

This is a very difficult procedure. It's a very expensive procedure. It does require all the expertise that's involved in the stem cell transplantation program. And in fact, the companies mandate that it has to be done at a transplantation program. So for now, the two commercially available products have to be done through transplantation programs and we believe that should be incorporated at the CON as part of the BMT focus.

And the reason is that there are companies out there who are saying that they can make a product that's safer, that doesn't need this quality assurance that we have in transplantation programs, that hasn't been FDA approved. I know it cautioned us to allow that to occur until we have a greater time to evaluate the safety of these products. Some of these companies have already had their studies stopped because of excess deaths.

So to say these products are safe at this point without FDA approval, without further evaluation for their quality and safety measures, I think is very premature. I think it's up to the CON commission to prevent that from occurring, but by allowing that to occur through transplantation programs. Now, if it does turn out that these products become available and are safe to give, then we should change our standard just like we do on a yearly or six-month basis to include those products to be given in

other centers and the transplantation programs. And I really think that would be the best way to keep the quality and safety of our patients in the state of Michigan. You know, we've heard before that there's lack of access to these therapies and we've heard that with Bone Marrow Transplant, but we've never heard any credible evidence that by limiting it to high quality centers who lack access to patients who need these therapies.

Right now the lack of access to using CAR-T cell therapy isn't we don't have centers that do it. We currently have through our center, but the insurances haven't approved it. Medicare and Medicaid have not found a way to reimburse it. So most of our patients can't get this therapy right now because of insurance issues, not because there's a lack of facilities that are able to do this safely.

So I would encourage the CON to look at the revised definition, use that as our definition to maintain a safe product for our patients in stem cell transplantation programs. If a product comes on FDA approved that is safe to give patients outside of a transplantation program, we can change the criteria. But I think, you know, we can change criteria easily. We can't change the death of a patient easily and we want to try to avoid that at all costs. Again, I would like to thank you for inviting me

here and I'll be happy to answer any questions.

MR. MITTELBRUN: Go ahead.

MR. FALAHEE: Falahee with a question. Welcome back, Dr. Uberti.

DR. JOSEPH UBERTI: Thank you.

MR. FALAHEE: I think this might be the 50th time you've presented here. In states other than Michigan that provide this CAR-T, are those also done only in transplantation centers?

DR. JOSEPH UBERTI: They are. Remember, the two companies currently that have commercial products are requiring they be done at FACT accredited transplantation programs.

MR. FALAHEE: Thank you.

MR. MITTELBRUN: Any other questions? Thank you.

DR. JOSEPH UBERTI: Thank you.

MR. MITTELBRUN: Next, Philip Stella, Trinity Health.

PHILIP STELLA, M.D.

DR. PHILIP STELLA: I'm Dr. Philip Stella from Trinity Health, representing Trinity Health. I'm the medical director for the cancer center, the cancer program at St. Joe's, Ann Arbor, and also a principal investigator of the Michigan Cancer Research Consortium, MCRC, which is an NCI-designated research group. And I'd like to

respectfully disagree with my good friend Joe Uberti. Joe and I go way back and very good friends and most of the time we do agree on things. But CAR-T cells are very different than an organ transplant like bone marrow transplant. I mean, it is a immunotherapy and I think Joe would clearly agree with that. Just by its nature it's very different. This is a technology that's in its infancy right now. It is approved for two indications, but will definitely have broader indications as we go forward.

How that's going to develop is unclear at this point. This is very similar to what we saw with other immune therapies that are commonly used today such as all the checkpoint inhibitors that have been used. And at first they were just at a few centers, it's all this immune related toxicities that were associated with that, and it was different than what most oncologists were used to doing and seeing.

But now I can tell that -- as you see on the commercials, that every place has -- every oncology program is giving immune therapy. This is an extension of that. Not only blocking one area or enhancing one area of the immune cascade, but multiple areas of that. And we're going to see an evolution of the CAR-T cells as it goes on. I think it would be bad policy to represent this immune therapy as a bone marrow transplant. And as the indications

grow, and they will grow just as we've seen with the checkpoint inhibitors, they will grow and they will grow rapidly. There's 200 trials in solid tumors. It's not just hematologic indications for it. You're going to see it in all sorts of other things. And it would be, I think, inappropriate and bad policy for the CON commission to classify this in the same category as bone marrow transplant.

If you wanted to look at it in a completely separate -- and I understand you do have the capability of looking at it in a separate process, that we wouldn't disagree with. But to label it as a transplant and to limit it to transplant centers would be, I think, bad policy. The cost is a lot of money right now, as we're going to see, but many of the checkpoint inhibitors that you see advertised on TV such as KEYTRUDA and things like that, Chance to Live and OPDIVO, and things like that, they're --

MR. MITTELBRUN: Dr. Stella, I just want to interrupt you a second. I don't think you're in a room -- but your time is limited to three minutes and I heard the alarm go off, so if you could, just wrap it up.

DR. PHILIP STELLA: Okay. So there are many things that cost a lot of money and there's other drugs or costs in that range. The cost of this will come down and I think because of an access issue you do not want to limit it

to this, but limit it to those centers that have the capability of doing these kinds of procedures, which is an ICU and access to IL-6 basically. So we would strongly support not limiting it to the transplant centers, but keeping it available to other high tech centers around the state because the indications for this definitely will increase. Happy to take any questions and thank you for your time.

MR. MITTELBRUN: Any questions?

MS. BROOKS-WILLIAMS: Commissioner Brooks-Williams. Good morning, Dr. Stella. If you could, so the physician prior to you said that there is nowhere else right now that the CAR-T cells are being used outside of a bone marrow transplant program. So if we were to say that it could be done broader than that, what would be the criteria that you would --

DR. PHILIP STELLA: Well, as I mentioned, you know, these patients need to be in an ICU and you have to have access to a drug that helps prevent some of the toxicity to that. There's nothing inherent as to a special room or special, you know, flow systems that you would need in a transplant program, so it's very different. So you -- all you need is somebody who's trained in this kind of techniques and what to watch for, but that's been the case with immunotherapy and all the ones that are commonplace

right now. So I don't think -- the reason why it was started in the transplant centers is because it was a hundred patient trial worldwide. So how much experience do they have individually in any of the transplant centers? It's all about the learning curve, but we are used to that in oncology because all the new drugs come out and you need to have training as to drugs come out and how to give that appropriately.

But there's nothing inherent about the training that it has to be at a bone marrow transplant center. They're just allowing it to be used in centers that had done the original trials and many of them have not had much experience in that.

MS. BROOKS-WILLIAMS: Thank you.

MR. MITTELBRUN: Any further questions? Commissioner Falahee?

MR. FALAHEE: Right. Falahee with a follow-up to Commissioner Brooks-Williams.

DR. PHILIP STELLA: You're not related to Mark Falahee, are you?

MR. FALAHEE: I plead the fifth amendment.

DR. PHILIP STELLA: My condolences on your dad.

MR. FALAHEE: Thank you. Thank you. Appreciate it. I understand, and that's the reason I asked Dr. Uberti the question I did and you raised another issue, CAR-T like

anything will evolve as you said and it may be used for other procedures, whatever, maladies. So what if the commission did nothing at this point? Right now CAR-T as it currently stands based on those that make it or whatever require it to be used only in transplantation centers. But as it evolves and gets better and is potentially used elsewhere, if the commission was silent that would allow that development to occur unless I'm way off base. What's your opinion of that? Does that make sense?

DR. PHILIP STELLA: In my mind, yes, absolutely. You know, PROVENGE is a drug that's been used for prostate cancer since 2010 and it's adaptive cellular therapy, too, and that's being done in the community all the time. It's not used very much because the indications are very limited.

In this case right now you have very limited indications, but as the data evolves in a rapidly changing field, those centers that are able to do the kind of research, they'll be participating in that and be able to get that kind of experience with it that are highly regulated by the nature of the trials. We do a lot of trials at St. Joe's.

And so I think there will be limits on the -- by the way, the costs, they'll naturally come down and the toxicities. We've seen this happen in all of therapies in terms of the immunotherapies, too. As it becomes more

commercialized and things, the costs will come down. How far? I don't know, but it will. And I think you're absolutely right by not acting on this. It's certainly not putting it in the same realm of transplant centers. It would be a very appropriate thing. I can tell you we do not do transplants at St. Joe's for a reason and it's really, I think, a ethical reason because we are in the same -- we're 40 miles from Karmanos and we know the guys at Karmanos are very good.

We're in the same town with the University of Michigan. We chose, even though we are highly specialized in doing studies, not to do transplants because it wasn't serving a community need. You know? So we respected what the transplanters do, but I think in this case it would be bad policy to put it in that same category as transplants. Thank you very much and for your time. Is there any other questions?

MR. HUGHES: Yeah. Commissioner Hughes. Well, you brought up the whole cost thing based on the other states doing it at the transplant centers and the insurance companies wanting it there. But would you care to add any comments about what you thought the potential impact on the cost of this procedure would be going forward if it was allowed to be done in places outside of transplant in terms of staffing, the expertise, the systems, all that type of

thing?

DR. PHILIP STELLA: Yeah. I think the incremental cost to an institution doing this is not great. The real cost is in the cost of the drug; right? And I think it's necessarily going to have to come down. To do it, you'll just need an ICU, you need access to IL-2, you need people who are experienced with it, and the best way to get that is to do -- to be in the clinical trial with all the regulations that are intended to that.

So you don't need a specialized facility for that. The truth of the cost is in the cost of the drug. And if you ask me to comment about that, I would tell you that the cost of cancer drugs in general have to come down, but that's not to -- it's -- putting it in the realm of transplants is -- it's just going to decrease the potential access to it. It's going to do nothing about the cost of it.

The cost will be driven by the indications that are out there. Right now they're limited, but they will grow for sure. And you wouldn't want your patient in the UP to have to come all the way down to a transplant center when it could be easily done in a center closer to them that has the expertise and the appropriate support systems within that center to do it when they could get it closer.

MR. HUGHES: Yeah. I don't think there's anybody

in this room that would argue that the cost of specialty drugs isn't outrageous, but the cost can be even worse based on where those drugs are administered. And I was just trying to get to the bottom of if it's being administered here instead of another place, if that would have an impact on the cost.

DR. PHILIP STELLA: Yeah. I don't think so because the cost -- the main cost driver is the drug company. I mean, Joe will be the first to tell you that he's going to -- he'll do anything to have access to an ICU, they'll have access to IL-6 and they'll be able to do it. But the cost of the drug company -- this is not going to affect the cost of the drug, which is the real main driver here, not the facility fee associated with that other than the ICU stay and that kind of thing.

Does that answer your question? Listen, there's no one -- I was -- have been very involved with the costs. At American Society of Clinical Oncology I was the government relations committee chair for that. I've worked with Congress on the cost of drugs. I've worked at the state level on the cost of drugs. And it is frankly outrageous and I think something needs to be done for that and how to do that is critical. But on the other hand, how do you say to a patient who -- where you can see these remarkable responses to this therapy and not provide it for

them? The cost issue is a bigger issue that I, as you and probably everyone on this commission, really would like to have a way to address. And we can talk a long time about doing that. But we're in the position of saying we want to provide the care for these patients in the most cost effective way and a high value way, but it doesn't really matter whether it's done in a transplant center or at another center who is capable and has the technical expertise to do it.

MR. MITTELBRUN: Any other questions by the commissioners? Thank you, sir. Next we have Arlene Elliott, Trinity Health.

ARLENE ELLIOTT

MS. ARLENE ELLIOTT: Good morning. My name is Arlene Elliott. And I'm not sure I can really follow up after Dr. Stella since he also spoke for Trinity Health. I wasn't sure if he was going to be here. I just did want to reiterate a couple of his points. That Trinity Health's perspective, you know -- Trinity Health does not offer bone marrow transplant. We've never provided testimony regarding bone marrow transplant in the past.

This time we really felt like we needed to and primarily it's because the bone marrow transplant standards exist because the commission is regulating an organ transplant. And then as soon as we start adding in this

immunotherapy, we're not regulating just organ transplant, we're regulating an entirely different service. The look is that we're adding apples and oranges here, and we just wanted to bring forward that we feel like the existing standards for bone marrow transplant do a good job of regulating bone marrow transplant.

The transplant of an organ is allowed by statute by the commission. And if the commission really wants to look at some of these immune therapies that are allowed by CAR-T and other novel treatments, that maybe the commission would like to use its NEWTAC mechanism to look at that. And then, you know, why would you just regulate the immune therapies that are for hematological carcinogens?

Why wouldn't you be looking at all of the immune therapies if that's what the commission is interested in doing here? So we feel like this is mixing apples and oranges, and would recommend that the commission maintain the current standards which are solely focused on bone marrow transplant as an organ.

MR. MITTELBRUN: Any questions? Thank you. Next we have Stacy Leick from EAM. I apologize if I mispronounced that.

STACY LEICK

MS. STACY LEICK: Good morning. My name is Stacey Leick and I'm here representing the Economic Alliance

for Michigan. I want to start by saying thank you for all the work and service that you do on the commission keeping it the best CON in the country and I appreciate it very much. In the past, the commission always has a deliberate process with public input ahead of taking proposed action on policy change to the standards. The EAM would like you to maintain that practice for nontechnical changes. We want to ensure the changes address the necessary issues and do not create new ones within the standard.

The proposed BMT standard addresses the questions related to CAR-T therapy and are very important for you to consider. Not only will you be deciding if and how CAR-T cell therapy should be regulated, but these decisions will likely set precedent for how other adopted cell therapies are also regulated. So these are the questions we would like for you to consider in your decision. One, should CAR-T cell therapy be regulated by CON?

If so, should it be regulated under the BMT standard? Does removing the word "stem" from the BMT standard adequately address the incorporation of CAR-T therapy into the standard? And lastly, does the change include or exclude other existing or future therapies that may not be needed to be regulated by CON? Again, we urge the commission to take this language to a work group or a SAC where it can be evaluated and debated to ensure that the

standard is clear and well-defined. Thank you for your time.

MR. MITTELBRUN: Any questions? Thank you very much. Next, Greg Yanik, University of Michigan.

GREG YANIK, M.D.

DR. GREG YANIK: Thank you to the commission. I'd also like to say that I'll start to say I disagree with my good friend Phil Stella and agree with my good friend Joe Uberti. Yeah, I just want to start by saying this, though. On February 1st of 2018 the New England Journal of Medicine published two articles back to back and the first articles was on the efficacy of CAR-T cells in acute leukemia.

The second article looked at the long-term follow-up for patients receiving CAR-T. Both articles point out key issues. The key issue in the first article is the fact that there was high toxicity. 70 percent of patients in that first -- in the acute leukemia article getting CAR-T cells developed a syndrome called cytokine release syndrome. 40 percent of patients developed significant neurotoxicity.

These are highly toxic gene modified cells. The second article talking about the long-term follow-up for CAR-T was really interesting because the long-term follow-up looked at a median follow-up of 29 months. There isn't a long-term follow-up of CAR-T patients. We have no idea what

the long-term effects of CAR-T are yet. This therapy is clearly in its infancy. And thus I ask the commission to think about this; that we should establish quality first, service first before we allow universal access. And I don't feel that the quality for this service has been truly established yet within the state, within the nation or even internationally. I also want to address a couple points that were brought up so far by other speakers and by Dr. Stella's point about checkpoint inhibitors.

CAR-T cells are not the same as giving checkpoint inhibitors. CAR-T cells are genetically modified cells that require processing by cell therapy units that are typically within -- imbedded within bone marrow transplant programs. Checkpoint inhibitors don't require any process. Two, in terms of the costs, there are significant costs. There's significant costs to upgrade the cell processing laboratories to administer CAR-T cells.

At our own center, the costs will be tremendous. We have a large proposal going in to the leadership of the University of Michigan that is daunting in terms of the cost. By expanding this CAR-T therapy now, we will be allowing for duplicity of costs that could be tremendous. And then next, now, I read the Trinity Health memo talking about the fact that the definition of BMT is universal. It may have been universal in 1984 when the definition was

first put down in terms of stem cells. It's no longer. And in fact, I've referred to a New England Journal article from March 8th of 2018, so just three weeks ago, that stated the following: "The term 'stem cells' is now being used to describe a wide variety of cells in terms of blood cells that are being administered to patients." So the term "stem cells" is now muddied. Bone marrow transplant physicians have the expertise and we actually have the cell processing facilities to limit the duplicity of costs.

I ask the commission to simply think quality first before we expand access. Thank you. Oh. By the way, I just want to say the question got brought up on a working group. The statute of limitations, by the way, for regulating CAR-T runs out August 30th. That's one year from when the first FDA approved product went out. So if we establish a working group, that means that that working group has to have its fully deliberated with a proposal to this commission and the commission vote before August 30th. Time is running short. I don't think a working group will suffice.

MR. MITTELBRUN: Any questions by the commission?

MR. FALAHEE: Yeah. Dr. Yanik, thank you again for being here. So we have the dueling physicians. Who are we as a CON commission then to decide which side of the duel to go on? I mean, what would happen if we just, as I asked

Dr. Stella, just let it go knowing that right now CAR-T as it is now is used only in transplantation centers based on what the manufacturers require? And if it gets expanded, clinical trials and all that can assure the quality. I'm just -- I'm throwing the question out open ended to see what your opinion is. But I have issues with -- the previous speaker said lack of a deliberative process, we have new technology, we haven't sent it to a NEWTAC committee and we have dueling physicians. Where are we -- as a commission, how can we decide where to go on that curve?

DR. GREG YANIK: You know, a recent white paper from the International Society for Cell Therapy, ISCT, had a line in there stating, in essence, I'm paraphrasing, "Now more than ever regulatory harmonization is needed for these services." That New England Journal article I referenced in March actually was focused on, in part, regulations for cell therapy services stating again how much they're needed.

I think everybody realizes that this could become a wild west for gene therapy, for cell therapy services unless somebody at some level, a state level, a national level, an international level, starts putting down strict guidelines and regulations. I think it behooves our state to become a model for other states. In looking and talking to other CON states, they're not even sure how to handle this. I think we can be a model for other states, for other

CON states or even non-CON states, in terms of how to look at this. Clearly regulations are needed as defined by some of these other groups.

MR. FALAHEE: Follow-up on that, though. In other times when we've had different opinions from physicians, we've formed either working groups or a Standard Advisory Committee, a SAC we call it, to hash those out, to have a deliberative, open-ended series of discussions back and forth, back and forth. Would that be something you would support here if we decided to do something like that?

DR. GREG YANIK: It could be done provided you gave that SAC, that working group, a defined timeline. Meaning we're expecting you to come back by June 1st, June 30th, whatever, with exact recommendations. So provided that there was a set timeline -- and the reason I state that is you have to recognize that there's an August 30th timeline because typically it's a one-year statute of limitations for when a service can be regulated and that year will be August 30th.

So provided you give us a strict timeline, then something could be done. You know, there's so many issues with CAR-T therapy and I have imagined that every commissioner here -- head is spinning from hearing this. The terms -- just looking at the terms here, "mesenchymal stem cells," all these terms, what do they all mean and

stuff? Yes, it's a loaded topic and that's why now more than ever somebody actually has to put their foot down and say, "All right. We're going to establish some local or even statewide standards for who can do this." And again, as many people have thought and worried about the federal government in other areas, that this truly could become a wild west for, quote, "giving genetically modified cells."

Now, I appreciate what Dr. Stella said about checkpoint inhibitors being done at centers that don't do transplants, but this is not giving checkpoint inhibitors. These are genetically modified cells that require processing by BMT-type laboratories. This is not something that can be easily done like giving a checkpoint inhibitor.

MR. MITTELBRUN: Commissioner Mittelbrun. Doctor, since you brought up the timing and the August 30th and June, what would happen -- I mean, it's not being done except for at, you know, small number of facilities -- if we missed the deadline and we didn't address this, just as an example, until next year? What would be the ramifications? Are the people that were already doing it grandfathered in? I mean, what would be the downfall of us missing this deadline?

DR. GREG YANIK: Knowing the state charter, I do think that centers already doing it would be grandfathered in. But I think if you miss the deadline, Commissioner

Mittelbrun, I don't think you could then regulate it after that one year, at least as to my understanding --

MR. MITTELBRUN: Is that the --

DR. GREG YANIK: -- of the rules. If I'm wrong, correct me.

MR. POTCHEN: This is Joe. Historically we've taken the position that the implementation of standards are prospective, not retrospective, so you go moving forward. So if something occurred within that window period, we wouldn't be regulating that or addressing that.

MR. MITTELBRUN: Any further questions? Thank you, Doctor.

DR. GREG YANIK: Thank you.

MR. MITTELBRUN: Next we have Stephanie Williams from Spectrum.

STEPHANIE WILLIAMS, M.D.

DR. STEPHANIE WILLIAMS: Commissioners, thank you for this opportunity to address you. I'm Stephanie Williams. I'm the director of the bone marrow transplant program at Spectrum Health Systems in Grand Rapids. And I want to come out in surprisingly support with Dr. Uberti and Dr. Yanik on both the wording of this and the comments that they had made. This is a very exciting time in cancer therapy to have these new types of immune therapies. CAR-T cells are a very different type of immune

therapy and I just want to respectfully disagree with my esteemed colleague, Dr. Stella. These are proliferating immune effector cells that are being infused into patients. And as Dr. Yanik said, there's a lot that we need to learn about the long-term effects of these particular agents. They also require specific type of processing that bone marrow transplant programs have been doing in order to collect the cells, then ship them to the manufacturer and then receive the cells.

So a chain of custody which we are used to in the transplant world has to be maintained for these particular cells. So we believe that by adopting this definition that this will help in terms of the quality and safety that we offer patients here in Michigan. So once again, we come out in support of this particular language. I'm happy to answer any questions if there are any remaining.

MR. MITTELBRUN: Any questions? Thank you very much.

DR. STEPHANIE WILLIAMS: Thank you.

MR. MITTELBRUN: Next is Tim O'Rourke.

TIM O'ROURKE, M.D.

DR. TIM O'ROURKE: Thank you for allowing me to speak. I'm Dr. Tim O'Rourke. I'm from Cancer and Hematology Centers of Western Michigan in Grand Rapids. I think it is premature for us to regulate CAR-T cells by the

CON mechanism. The reason I feel this is sort of echoing what Dr. Stella said. First of all, the pattern and severity of toxicity of CAR-T cells is significant, I agree, but this field is in its infancy. We can expect the technology to change and we can expect perhaps that toxicities will be different. There may be other cellular therapies that are developed not encompassed by their definitions.

I would say that our own practice has been involved in PROVENGE, which has been cited, which is a cellular therapy. It's well-tolerated. We are actually the first institution or practice in the state of Michigan to offer the service and have done over 70 cases. At one time we had a FACT-approved BMT program for treatment of breast cancer back when that was an accepted therapy.

When that changed, we stopped our program and we refer to Stephanie and our friends at Karmanos and Ann Arbor. So I think the physicians and practice are responsible. Managing life-threatening toxicities is what we do. Everybody is going to have to adapt to this. We understand what the requirements are for taking this on and we have not done so, so far, and this area is regulated. The current therapies can only be given in transplant centers and the FDA has established rules for safety, the REMS Program, and the manufacturers are restricting it as

well. So we think the current restrictions are adequate for patient safety. We think the field is in its infancy. And we don't know what the future is going to hold and we don't want to say at this point that it might not be a therapy that we could offer to our patients sometime in the future. As far as costs, I agree that the cost of this is driven mostly by the cost of the drug, but I think practices such as our own do have a record of providing services in a more cost effective fashion, so I don't think that our participation in that would affect cost if it ever came to that. I'll take any questions.

MR. MITTELBRUN: Commissioner Mittelbrun. I don't know if I have a question, but if I heard you correctly, you said you didn't feel it should be regulated by CON or the CAR-T?

DR. TIM O'ROURKE: Well, we would be. It's not regulated right now I'm saying.

MR. MITTELBRUN: Right; right. And so as I listen to all this and how complicated and dangerous it is, and when we just had our previous discussion, I hate to get ourselves in a position where we don't regulate it and then somewhere down the road we say, "Aw, shucks, we should have done, you know -- we should have had that under our umbrella."

DR. TIM O'ROURKE: Well, I guess what I mean to

say is that it's regulated currently by the requirements of the manufacturers that it be done in a stem cell center and by the FDA.

MR. MITTELBRUN: But I guess we don't have control of those manufacturers and we don't know what will change with them going forward?

DR. TIM O'ROURKE: No, we don't.

MR. MITTELBRUN: Right. Okay. Any other questions? Comments? Thank you very much. Next, Malcolm Henoch from Beaumont Health.

MALCOLM HENOCH, M.D.

DR. MALCOLM HENOCH: Commissioners, good morning. My name is Dr. Malcolm Henoch. I'm the senior vice president and associate chief medical officer for Beaumont Health. Thank you for the opportunity to address you this morning and through the written comments we've submitted. Thanks also to health systems and physician groups who with Beaumont Health encourage you to not adopt proposed changes to existing standards regulating bone marrow transplantation in Michigan.

My brief oral comments this morning offer you a reasoned clinical perspective. As a physician, I'm not equipped to speak on the legal and procedural concerns which bear on the proposed changes. A growing number of new blood cell therapies are in various phases of development,

clinical trials or commercial production. These therapies will offer treatments for an expanding number of cancer and non-cancer conditions affecting many citizens in Michigan. These therapies have in common the use of a patient's own immune system to retard, stop or eliminate a specific disease. These immune therapies are sometimes referred to as "precision medicine." You've heard us refer to them with names such as CAR-T, IEC, or ACT.

They are distinct from bone marrow transplantation which falls within the acceptable definitions of a organ transplantation. These therapies do not. In each of these new therapies, blood cells are gathered from a patient with a serious disease. From these cells, immune cells are selected and trained to defend the patient against this disease. Those precision-trained cells are returned to the patient to treat the disease.

Cancer conditions including certain types of prostate cancer, leukemia and lymphoma currently have FDA-approved cellular therapies. Therapies for other cancers, and non-cancer conditions that respond to precisely trained immune cells including possibly multiple sclerosis, systemic Lupus, Crohn's disease will likely come to market in the next decade. The FDA will review each one of these. These therapies will arrest or eradicate disease for appropriately chosen patients. They will succeed where

other treatments will not. They will extend lives of patients, improve the quality of life for these patients, and reduce the expense of chronic progressive disease for these patients. Restricting access to these therapies to only four hospitals across the entire state of Michigan will do a great disservice to the citizens of our state. Thank you very much for the opportunity to provide these comments.

MR. MITTELBRUN: Any questions? Commissioner Hughes?

MR. HUGHES: Just the previous speaker had mentioned that this treatment was dictated by the manufacturers and the FDA to only be done at transplant facilities. And why do you think that is compared to what you're saying? Could you address that, please?

DR. MALCOLM HENOCH: I believe that -- as you said, that there are several levels of oversight for the current existing therapies. The first of these is the Food & Drug Administration. Another one of these is the FACT, a national and international body which offers accreditation for cell therapies. In fact, and I believe, the statements you heard earlier this morning are not quite correct. FACT does, is, has developed its own set of criteria.

Those criteria for immune therapies do not require an institution to be in the business of delivering bone marrow transplantation. It certainly is the case that

manufacturers are appropriately -- because of the newness of this therapy, are appropriately monitoring and managing where these therapies are offered, and it's not surprising at this point that institutions that have had experience with bone marrow transplantation might be some of those places where they would first look to offer those therapies.

MR. HUGHES: I'm sorry. And it just might be surprising because they're better equipped with administering it or dealing with complications along the way? Or if -- just if you could help the uneducated here, that'd be great.

DR. MALCOLM HENOCH: I think you've already heard this morning the common concern is reactions to these therapies. The techniques and technologies for bone marrow transplantation are different than for these. These do require some expertise in collecting cells, a process called leukapheresis. It is cells that are extracted need to be managed carefully. Bone marrow transplantation centers have that expertise. Other centers are in the business of collecting cells through this process of leukapheresis as well.

MR. HUGHES: Thank you.

MR. MITTELBRUN: Any other questions? Thank you.

DR. MALCOLM HENOCH: Thank you very much.

MR. MITTELBRUN: Next, Sean Gehle from Ascension

Michigan.

SEAN GEHLE

MR. SEAN GEHLE: Good morning, Mr. Chairman, and members. I'll be quick because I don't have a clinical background and so I won't add to the dueling physicians, but I've heard a couple of things that I just wanted to reaffirm. My name is Sean Gehle. I'm here on behalf of Ascension Michigan. We are concerned about regulating CAR-T cellular therapies within the CON bone marrow transplantation standards for many of the reasons that you've heard from Dr. Stella, Dr. O'Rourke, and others.

I think you, Commissioner Mittelbrun, and Commissioner Falahee have both brought up the complexity of this question and we agree and would suggest that this be further evaluated by either the NEWTAC committee or whatever body you feel is appropriate. I have heard -- and I'm just asking because I have heard -- that the manufacturers have indicated that they plan to open this up beyond BMT centers in 2019, 2020.

I don't know if that is something that is important in this debate. I've heard a number of comments about the limitation to the BMT centers, but that is something that I've heard and would offer or ask the experts whether or not that's something that they're aware of as well.

MR. MITTELBRUN: Any questions? Thank you.

MR. SEAN GEHLE: Thank you.

MR. MITTELBRUN: And last, Patrick O'Donovan from Beaumont Health.

PATRICK O'DONOVAN

MR. PATRICK O'DONOVAN: Good morning. My name is Patrick O'Donovan from Beaumont Health. I will not be adding to the clinical debate either. I want to talk a little bit more about the procedural issues, both as it relates to the language that you received in your packet to the department as well as what you received today. Beaumont Health opposes the proposed BMT language that would incorporate and regulate CAR-T cell therapies within the BMT standards.

In addition to the patient access and quality in the past that have already been discussed, we also do not believe that the proposed approach to regulation of CAR-T cell therapy. should you want to move forward with that, is in compliance with Part 222 of the Public Health Code. BMT and CAR-T therapies are substantially different as you've heard today.

BMT is an organ -- extrarenal organ transplant, and is referenced in Section 22203 as extrarenal organ transplantation in the statutory listing of covered clinical services. CAR-T cell therapy is not organ transplant and

thus to be regulated, should be regulated as a new service. Before regulating a new service under CON, Section 22215 indicates that the commission must first determine that such regulation is necessary to achieve the goals of health care quality, cost, and access. No deliberative process of any kind has yet taken place to justify the need to regulate this therapy. To determine whether regulation is necessary, the commission has the option to evaluate this new technology through the new medical technology advisory committee in 22241.

If after careful review the commission determines that CAR-T cell therapy should be regulated, Section 22215 requires the commission to develop CON review standards that establish the need for the covered clinical service. The usual process to establish review standards is through the Standard Advisory Committee described in Section 22215. No Standard Advisory Committee has been established for CAR-T cell therapy.

However, in contrast, just last meeting the commission did establish a SAC to review the MRT weights and volumes. If a SAC is established to evaluate that relatively narrow issue, it should also create one to establish the need for an entire new technology and service. As proposed, what's in the standards now before you, for CAR-T cell therapy there are no quality standards, there are

no minimum volumes, and there is no need projection methodology, so these would all need to be studied. So given that CAR-T cell therapy is a new service and has not yet been studied appropriately, we would ask that the new language not be adopted. Even those who are proposing the changes agreed that -- the need to move cautiously, so we would ask the same of the commission. Thank you.

MR. MITTELBRUN: Any questions? Thank you. Next is commission discussion. Who would like to start?

MR. FALAHEE: I'll start. This is Falahee. Let me direct this to either the department or Mr. Potchen. Mr. O'Donovan just threw a bunch of 222's at us and I saw Joe looking at his laptop quickly skimming what Patrick was talking about. Joe, do you have any comment one way or the other about those issues?

MR. POTCHEN: Generally, yeah. I'm looking at 22241, and you've heard this mentioned already. This is Joe. And the testimony was correct in the extent that you have 12 -- the NEWTAC review period ends 12 months after the FDA approval, so that is the opportunity for the commission to look at new technology. And I'm understanding that was sometime in August of last year, so that's what the statute provides. However, at any point the commission can determine whether there are services that want to come under its umbrella. So that's the two different points here.

MR. FALAHEE: This is Falahee again. So I didn't quite get -- so the NEWTAC, it's too late for that, is that what you're saying?

MR. POTCHEN: Well, I'm not sure.

MS. NAGEL: Well, I wouldn't say what Joe is saying, but we have 12 months from the FDA approval for the NEWTAC to review and bring a recommendation back to the department. However, 22215 says that if determined necessary by the commission, you can revise, add or delete any one of the covered clinical services. Yeah, so it's --

MR. POTCHEN: I'm sorry. And that's what I hope I said. That's what I was trying to say. But the point of the NEWTAC section of the code is that you cannot acquire new technology before the end of this review period. That's the limitation.

MR. FALAHEE: Right. Okay.

MR. POTCHEN: Once the review period is done according to the statute, it looks like you can acquire this new technology. However, that doesn't prohibit the commission from developing standards under new service under 15. Is that hopefully clear?

MR. TOMATIS: Commissioner Tomatis. I'm a little confused. I am absolutely overwhelmed by the opinion of the experts that are completely opposite; the people who said that this new technology should be spread to other centers

that don't have transplantation and the people who said that this is too early because all these technologies are going to evolve and would be many, many more just one year from now. Then my question is are we too early to address that or should we leave a committee or experts to clarify that to us? Because these people are very respectful. I was very impressed by the quality of their testimony and it was completely opposite. This is why I'm not confused, I am overwhelmed.

MR. HUGHES: I second it. Oh. I was going to say that Dr. Tomatis probably knows more in a day than I knew in an entire lifetime and if he's confused, it makes me feel better. So I would second what he was saying.

MS. BROOKS-WILLIAMS: Commissioner Brooks-Williams. So also being very confused, I guess, like everybody else, but I took notes so I'm going to try to recap what I think I heard to ask the department just in terms of what our options are; right? So it sounds like there is something that August triggers -- right? -- in terms of being that 12-month cycle.

So the "are we too early" question would be if we acted today -- and the only reason why I would say and I'm trying to figure out what paths we could take, you might act today -- is you say you follow what at least the manufacturer and the FDA says today, is that if you're going

to use the technology, that you do it in a center that, you know, equates to what they think is the right environment. For us right now, that would be a bone marrow transplant facility. So you could act on the language, I guess, with that concept in mind. You're simply following what the manufacturer and the FDA says. You always have the option later, I guess, to deregulate, to modify the language if you determine that that language changes.

And so when that language changes, then you could change accordingly. But if you didn't want to just say -- okay -- because we're confused and we don't know, we do nothing and you ignore some of the feedback I think that both sides are saying, that it is complicated, high-risk intervention for patients, there is a way, I think, to respond to both sides which is you simply say we're going to link language to what is the current standard and acknowledge that that could change.

It could change before June, August or whenever, but we certainly can change when it changes as opposed to doing nothing and leaving it open. And let's say the language doesn't change and then we've missed the opportunity to link it to those bone marrow transplant facilities. That's at least part of what I'm making out of the notes that I have and I'm just wanting to check if I'm accurate. If we were to -- and I can't do that alone;

obviously everybody has to agree. But if we were to adopt the language of this proposal that we received at our seats, that really is doable, and if we had to change it later because the manufacturers and the FDA modified their definition, we could do that still; is that right?

MS. NAGEL: (Nodding head in affirmative)

MS. BROOKS-WILLIAMS: Okay.

MR. MITTELBRUN: So just a clarification referring to this language --

MS. BROOKS-WILLIAMS: I'm referring to the dates, yeah.

MR. MITTELBRUN: -- as opposed to that one?

MS. BROOKS-WILLIAMS: Yeah. The narrower language I'll call it.

MR. MITTELBRUN: Yes.

MS. BROOKS-WILLIAMS: Yes.

MS. GUIDO-ALLEN: Commissioner Guido-Allen. So I also took notes because, like he said, the testimonies were very well done today and very confusing because they are so disparate, you know; two-sided. So some of my notes are, you know, that the CAR-T service is regulated by the FDA via the REMS Program and it also is restricted to transplantation sites based on manufacturer requirements. So it's really already quite regulated. What we don't know as a commission is is regulation necessary. We don't know

that yet. CAR-T is not extrarenal organ transplantation. It's immunotherapy. It is a new service with new technology. And, you know, I do support the statement that at least one person made, that it may be premature to regulate as a commission. I would recommend that we have some experts come together in whatever forum, whether it be the new medical technology advisory committee or a SAC, to really review what we stand for which is quality, access and cost for this particular therapy.

I did a lot of research, I brought a bunch of the articles, because I was really unfamiliar with CAR-T because it is so new. But just from the National Cancer Institute, there are now over 180 clinical trials looking at CAR-T which means, you know, as one of the speakers said, it's going to evolve to probably way beyond just cancer diagnoses. And I think we have to be diligent and do our due process to make sure we make the right decision for the citizens in Michigan.

MS. CLARKSON: This is Commissioner Clarkson. I agree with Guido-Allen.

MR. MITTELBRUN: Commissioner Mittelbrun. I can't help think this all started with removing one word, "stem." So in order to meet the timing requirements as been discussed if we were to bring those experts together, is it possible in the time frame we have to deal with to meet the

deadline?

MR. FALAHEE: Falahee. Well, what is the time frame? I don't understand and I don't know which 222 I'm talking about. Help me out.

MR. POTCHEN: 22241 is the NEWTAC review period 12 months after FDA approval. I have heard it was August of last year. So that's just the NEWTAC review. That doesn't stop the commission from determining whether to regulate it. That's done under a whole separate section. That's all I'm saying.

MR. FALAHEE: Falahee again for Mr. Potchen, a hypothetical. If we don't have enough time to appoint a NEWTAC to get answers by August, then one of the other options could be appointing a SAC to look at the entire issue and to deal with the differing points of view on the issue?

MR. POTCHEN: Yes.

DR. TOMATIS: Commissioner Tomatis.

MR. POTCHEN: Let me just say with an understanding that the restriction will be no longer there. In other words, there's a restriction in place today under the statute here. It's called the NEWTAC review period. And that's what -- I'm sorry. I'm in the wrong section here. 22241 means -- and I'll just read it specifically.

"The period ending 12 months after the date of

Federal Food & Drug Administration approval of new technology for a commercial use shall be considered the new technology review period. A person shall not acquire new technology before the end of the new technology review period."

And then it gives a couple "unlesses," like basically unless the department says it's okay and various other things.

MR. FALAHEE: So -- Falahee. So if I heard you right, Mr. Potchen, what that means is as of August 2 of this summer, an entity could begin to use CAR-T in Michigan?

MR. POTCHEN: (Nodding head in affirmative)

MR. FALAHEE: Okay. And that would be true even if the NEWTAC was in place or not?

MR. POTCHEN: What the committee is looking at; right.

MR. FALAHEE: Right.

MS. GUIDO-ALLEN: Guido-Allen. Let me just repeat one more time that it is restricted by the manufacturer and by the FDA.

MR. POTCHEN: Right.

MR. FALAHEE: Right. No, I understand.

MS. GUIDO-ALLEN: That regardless of what we do.

MR. FALAHEE: Right. I understand.

MR. POTCHEN: Correct.

MS. BROOKS-WILLIAMS: Brooks-Williams. So I go back to my original thought -- right? -- which said if our concern -- which I'll say this is my concern -- right? -- is that if we do nothing with the language that evolved out of changing the word "stem," that as I understand it no one would be able to just magically, you know, enter into delivering the service come August. But we have as a commission essentially -- we would have left it open where at any point after that that you could enter, you would enter.

And let's just say that -- I'm assuming if the manufacturers and the FDA continue to restrict it to a particular site or whatever, then obviously there wouldn't be a need for us to consider it. But if from a cost, quality, all these unanswered questions that we have, we have concern, what is the risk of introducing the language that we can remove at some future point if we decide it's unnecessary because there is a window of time that we have to do that?

That's all. So I think it's more a protective measure because of the confusion that we're expressing. Because otherwise you're saying that you're not going to act, you're just going to let the clock run and then you no longer have the ability to have a -- sort of a restriction guideline because the window of time simply passed. And so

I don't disagree at all with -- I think you could do it both in. I think it is totally appropriate to have further study and further dialogue, but I don't think you have to do that absent of the language provision at the same time. So you could do both because otherwise you're kind of guessing and hoping that it can all be done by June. That's kind of the only win-win. If you send out a SAC or a work group or whatever, they'd have to finish by June in order for you to act before August.

DR. MCKENZIE: This is Commissioner McKenzie. I don't disagree with that approach. I have concerns about not looking at this issue because of what we heard, that the drug manufacturers are going to be opening this up in 2019 and 2020. So if the commission doesn't act and you miss that period, my understanding was that it's not retrospective, we can't go back, that we're moving forward prospectively.

And I don't know if we pull together a SAC now will we be able to get those recommendations and have this issue finalized by August. With CAR-T currently, from the great testimony that we have, we know that there's high risk to patients, so I have concerns about quality. We know that, you know, there is a balance to access and quality, but just letting free reign in this space I think we may have some concerns with quality. I agree with the speaker

that -- I think it was from U of M -- that mentioned that we really need to master this. I -- also, there's a balance with that; right? We don't want to inhibit things as they're coming out. There may be further development. These things may become safer. I do think that adding some provision to this language doesn't prohibit the commission from going back and relooking at this and loosening it while we pull together a SAC and look at the issues that are forthcoming with further studies.

MR. FALAHEE: Falahee. And that raises a question I had. If we approved language today that was very limited, close to what we have in front of us this morning, we could -- and I guess I'll address this to Mr. Potchen or the department -- we could approve language and appoint a SAC to look at the issue in further detail to address the competing opinions we had today. Could we do that?

Because that gets to the issue of the differing opinions. It gets to the quality issues. It gets to the access. To Commissioner Hughes, it probably doesn't get to the cost. Bob, I'm sorry. But it at least answers in my mind a reasoned, deliberative process to look at this so that if we approve language today and can and do appoint a SAC, we can then look at what the SAC sends back to us. It won't be done by August. It takes two or three months to even put the SAC together and it's got a six-month life.

But it can come back to us and say, "Look at it. We had physicians back and forth and here's the consensus decision for what's best for quality, access and maybe cost." That's why I asked the question.

MR. TOMATIS: Commissioner Tomatis. I would agree with that.

MR. POTCHEN: I guess the best answer I can give is nothing -- that's very innovative thinking. But I can't see anything here that prevents that, and I'm looking at your bylaws. "If the commission determines it's necessary, it may appoint a SAC to assist in the development of proposed CON review standards in accordance with Section 22215." It's innovative thinking and, again, I don't see anything stopping you from doing something like that.

DR. MCKENZIE: This is Commissioner McKenzie again. The other reason that I think --

DR. TOMATIS: Commissioner Tomatis.

MR. MITTELBRUN: One at a time.

DR. MCKENZIE: I'm sorry.

MR. MITTELBRUN: Commissioner Tomatis?

MR. TOMATIS: I think that this is too early for us to leave that open to be done in any other place when we don't know exactly what are we regulating. Let's get a SAC, let's do the due process, and then with the opinion of the experts let's then write the regulations.

MR. MITTELBRUN: Commissioner McKenzie?

DR. MCKENZIE: The other benefit of I believe having a SAC looking at this issue was this is very specific to hematologic malignancy which was brought up. The CAR-T therapies may evolve into treatment of further malignancies, and so I believe that there's probably a need to pull together a SAC regardless, even if we institute the language here today under --

MS. GUIDO-ALLEN: Guido-Allen, a question. Is there any site that is performing CAR-T that is not a BMT transplantation site today?

MS. ROGERS: This is Brenda. From the information that we were able to find and do the research on, it is true. You do have to be approved through the manufacturer, there's the REMS through the FDA, et cetera. And right now there's two drugs, the KYMRIAH, and there was a second one that was approved in October.

And I believe -- and they can correct me if I'm wrong, but I believe the University of Michigan has been approved for the KYMRIAH, and then Karmanos has been approved for that second drug which was approved in October. So right now there's only two facilities that have been approved according to the web sites to perform CAR-T therapies.

MS. GUIDO-ALLEN: So it's not widespread?

MS. ROGERS: Not at this time.

MR. MITTELBRUN: So Commissioner Mittelbrun. I think it may have been our last presenter that talked about -- or at least one of the presenters talked about the fact it was going to be opening up to other facilities. And I realize, you know, the manufacturer has requirements. And I'm not disparaging the manufacturers, but they have different motivations. And I realize the FDA, of course, you know, it's their regulation.

So, I mean, I'm kind of hearing that -- and you can correct me if I'm wrong -- but it sounds like as a commission we want to get out in front of this or at least in my opinion it is, we want to get out in front of it, make sure we're ready to go and we can make changes as necessary.

MS. GUIDO-ALLEN: Guido-Allen. One more thing. I just want to reiterate that CAR-T immunotherapy is not extrarenal organ transplantation, which is our BMT definition. I just want to reiterate that. This is a new service.

MR. MITTELBRUN: Okay. Commissioner Brooks-Williams --

MS. BROOKS-WILLIAMS: Commissioner Brooks-Williams. I'm going to take the first stab at this -- right? -- and make a motion. I move that we accept the proposed amended definition dated 3-27-2018, which was

presented to us today, and that we seek a SAC that would look at the bone marrow transplantation CAR-T relationship and have the SAC bring back additional clarifications, if any, that might support and/or modify the language.

MR. MITTELBRUN: I have a motion. Is there a second?

MR. FALAHEE: Falahee will second just to generate some discussion.

MR. MITTELBRUN: There's been a second. Commissioner Mittelbrun.

MR. FALAHEE: So here's the discussion. This is Falahee again. What would happen if we didn't adopt any language today and just appointed a SAC to look at the issue? I don't know what help the language provides given FDA and what manufacturers require now. I don't foresee a huge growth in this and that's why I'm asking.

MS. BROOKS-WILLIAMS: So I'll tell you why I'm linking them. So what I heard -- and it is probably more protective, as I said earlier, than it's that I can tell you definitively why; right? But if you're hearing that they're going to open it up in '19 or '20 -- right? -- we're also hearing, though, that it's -- it's the same -- to me it's the same argument as the bone marrow transplant. Why do we continue to regulate it? I'm not opening that up for discussion; right? But if you really then look at the cost,

quality, access question, do we want it to just be open because the manufacturers and FDA open it up? I don't know the answer to that. So the language for me says you don't miss the window to have it linked to the bone marrow transplant programs going forward just because we've heard from some in testimony that they have the resources, the access, the volume. I mean, you wouldn't want it to be one here, one there, I'm guessing -- right? -- from a quality perspective.

You'd want to have some aggregation. So for me proposing the language is because the window would run out to have the language in before the SAC would come back. So it's more protective and you can drop it if the SAC brings you something that suggests it's unnecessary.

MS. GUIDO-ALLEN: Guido-Allen. My thoughts about your question is that we don't run any risk. I did research for nine years in cardiovascular drugs and devices and the FDA is not a fast moving animal to say the least, but they are very protective. Their human rights component is very strong. In the stage where CAR-T is and the other immunotherapies, I find it very hard to believe that they would open it up before we have a SAC set and really some due diligence, which the citizens of Michigan really deserve.

MS. BROOKS-WILLIAMS: If I could just add then?

So that actually supports what I'm saying. So then there's not harm in the language one way or the other. I guess the focus is really on do we think we need a SAC? Yes. So the language is just -- again, like I said, it's a protective piece. If I'm wrong or we're wrong, then I would agree with you, the language is going to fall off when the SAC comes back anyway because -- so I wouldn't -- I'm simply linking it to the narrow language to suggest that maybe it could matter down the road and we would have missed that opportunity, because I agree with you in the short term it doesn't have any major effect one way or the other.

But it could -- if for some reason your SAC came back and said you wanted to regulate in a more restrictive way, you wouldn't be able to act on that because you'd be outside of that 12-month window. That's all I'm saying.

MR. HUGHES: Just to make sure I understand something. If we go with just the SAC and let's just say they come back and say, "Yes, it should be under BMT" for some reason, would people that have jumped in between now and then be subject to that? Is there any disadvantage of them getting in before that happens that we can't take it away or is there any negatives to that?

MS. BROOKS-WILLIAMS: You can't retrospectively apply it.

MR. POTCHEN: The implementation of standards is

prospective. So if something occurred before, you would decide to -- before you determine that it fall under a covered service, you would not be regulating that.

MR. HUGHES: So they'd be able to continue going forward?

MR. POTCHEN: That would be correct.

MR. FALAHEE: This is Falahee. And for Commissioner Hughes, that's my -- my initial thought was put this language in plus the SAC to protect that from going on. If I knew that wasn't going to --

MR. POTCHEN: I stand corrected. Apparently the department may have a different view.

MR. FALAHEE: I'll be quiet.

MS. NAGEL: I'm sorry if I missed what you were saying. But the answer to the question if a service becomes regulated and there's already someone performing the service, that's a situation that we've run into many times in Certificate of Need. For example, the example that comes to my mind is when we had neonatal intensive care unit standards and then we began regulating special care nurseries.

The department gives a window of time for all special care -- anyone who wants to continue performing special care nurseries to catch up to that standard and apply. And then after a certain point, once it's regulated

and -- we've said, you know, "By January 1 if you don't have a Certificate of Need for a special care nursery, then you are out of compliance with the standard." So there's the ability to do the same thing here using the same standard. So if we started regulating CAR-T therapy and there are people using it, we would say, "You have until this date to come up to the standard and apply under that standard."

But I will say there is also an example of CON permanently grandfathering as well. That's also an example. In the past for open heart surgery when the Certificate of Need started regulating open heart surgery, there were many that were already performing it and so there are a handful today that are still grandfathered and not under any standard.

MR. MITTELBRUN: Commissioner Mittelbrun. Does that make you feel any better? I think we're all trying to -- I think some of the comments, we're trying to protect ourselves; right? We're trying to cover ourselves and that's a good thing. Does that provide comfort, I guess, in what we're talking about, what we're trying to accomplish?

MS. BROOKS-WILLIAMS: Right. I think I still -- I mean, the motion as I made it, I'm comfortable with it, and obviously it gets voted up or down and we can move on to one that makes more sense to others if it doesn't, you know, go forward.

MR. MITTELBRUN: Okay. If no further comments, we'll end discussion. Show of hands, please. All those in favor? Four. All those opposed? We have a tie, so it does not pass.

MS. BROOKS-WILLIAMS: Some people abstained.

MR. MITTELBRUN: So I guess I would ask for other proposed action for consideration.

MR. FALAHEE: Okay. This is Falahee. What I'll recommend is that we appoint a Standard Advisory Committee, shorthand of SAC, to look at the issue here. I don't have any idea what the charge would be. In my head I think the charge would be encompassed many of the competing professional opinions we had today to look at whether CAR-T should be limited to BMT, not limited to BMT, issues like that.

But I think the first and foremost is that we appoint a SAC to look at the overall issue and to grapple with the issues as we heard them today, and that we instruct the chair and vice chair to work with the department to appoint that SAC.

MS. CLARKSON: This is Commissioner Clarkson. I'll second that motion.

MR. MITTELBRUN: Any discussion?

MR. TOMATIS: Tomatis. I support this strongly. We are going to make the decision basing science to those

who know and then we can make a decision. I support that.

MR. MITTELBRUN: Brenda, did you have a comment?

MS. ROGERS: Yeah. This is Brenda. I just need a clarification on the motion. So this is limited to just CAR-T then, Chip, according to what your motion stated?

MR. FALAHEE: Of course I didn't mean that, no.

MS. ROGERS: Okay.

MR. FALAHEE: It's all those long words that we've been talking about today.

MS. ROGERS: So it's the immunotherapy services or the cellular -- as we've kind of described it in the document, cellular therapies?

MR. FALAHEE: Yes; correct. All of the above.

MS. ROGERS: Okay. So as far as the chair and vice chair as far as seating the SAC, then are you also delegating to the chair to draft the charge based on today's discussion then?

MR. FALAHEE: The chair working with the department.

MS. ROGERS: Okay. All right.

MR. MITTELBRUN: Any other discussion by the commissioners? All those in favor? All those opposed? Passes. Motion passes.

MS. GUIDO-ALLEN: Can we take a two-minute bathroom break?

MR. MITTELBRUN: We'll take a bathroom break for ten minutes or any other break that's necessary.

(Off the record)

MR. MITTELBRUN: Okay. Due to travel arrangements, we're going to mix up the agenda a little bit. We're going to move to Cardiac Cath Standard Advisory Committee final report, the draft language.

MS. ROGERS: This is Brenda. Before Dr. David speaks, as we stated in the cover memo, so you saw some language that the department proposed in Cardiac Cath that the SAC did not make recommendation for. So instead, we were talking about procedurally, instead of jumping back and forth between Cardiac Cath and Open Heart, we're going to stay focused on Cardiac Cath.

But keep in mind what you do with the Cardiac Cath language as far as the department's recommendation in that is tied to the language that's being proposed in Open Heart Surgery. So we're kind of doing them in the reverse order, but I just want to make sure that the commission is aware of that those two pieces, the department language in Cardiac Cath as well as the Open Heart Surgery language, are tied together. Thank you.

MR. MITTELBRUN: Dr. David is going to provide us his report. He was the chairperson of the SAC. Thank you very much for your hard work.

PRESENTATION BY SHUKRI DAVID, M.D.

DR. SHUKRI DAVID: Thank you for the opportunity to present this morning. I do want to take a moment to thank Brenda, Beth, Tulika and the entire team for their hard work as well. And I do want to recognize the members of the Cardiac Catheterization SAC committee. Myself, I'm the chair of cardiology for the St. John Providence Health System.

We had Ernest Balcueva, from the American Heart Association; Dr. Ibrahim Shah, chair of cardiology at McLaren; Dr. Kristopher Selke, he is the chief of interventional cardiology and director of the cath lab at Mercy Trinity; Dr. Madder is the chief of interventional cardiology and the cath lab at Spectrum Health; Dr. Hitinder Gurm, he is the associate chief of cardiology at the University of Michigan; Dr. Simon Dixon is the chair of cardiovascular medicine and service at William Beaumont Hospital Health System; Dr. Schreiber is the president of the heart hospital at the Detroit Medical Center; Dr. Henry Kim is the division head of cardiovascular medicine at Henry Ford Hospital; Dr. Sunita Vadakath is from Mid-Michigan Health and is the cardiovascular service line director; Lynne Carter is from Blue Cross and Blue Shield as the associate medical director -- Dr. Lynne Carter, I apologize; and Michele Davis from the Electrical Workers'

Joint Board of Trustees as -- representing the purchasers. And so we are not going to be as controversial as the last discussion. You folks dealt with one issue regarding therapy in bone marrow transplantation. I am going to address several issues, so I hope we'll be out sometime tomorrow afternoon. So we had dealt seven difficult charges.

One was to determine the section 10(5)(I), the applicant hospital initiating electrical PCI, as percutaneous coronary intervention, basically balloon angioplasty and stenting without open heart surgery standby. In the past you could not do elective coronary interventions or PCI without having open heart surgery; were only allowed in the state of Michigan if it was an emergency, a ST elevation myocardial infarction.

So this relates to elective PCI. We talked about a credentialing body coming in and overseeing data, quality, and making sure that folks that were doing these procedures were doing them appropriately, that there was standards behind the quality metrics and that they were doing what they were supposed to do and had some peer review process. And it was felt that we should not police ourselves entirely and therefore we should bring in an outside organization to do this, whether it's through the American College of Cardiology or several other external organizations. So

there was a lively discussion and basically a motion was made by Dr. Selke and seconded by Dr. Schreiber to modify this so that we did not have to have these oversight organizations review these programs if there was a parent hospital. And so the motion was defeated six to five that the standards remain, that we have an external review of these projects.

The second charge was to determine if pacemakers and implantable defibrillators should be allowed to be performed in ambulatory surgical centers or only in licensed hospitals. Now, currently CMS has said that you can't perform implantable defibrillators and pacemakers in ambulatory surgical centers, that there is payment. There are a few centers throughout the state of Michigan that are doing this.

There was vigorous, lively debate as intense as this morning's discussion. Basically it was felt to distill it down; that there were safety concerns. When you put in a defibrillator, there is a maybe one percent risk of when you put the line in that you can develop what we call a pneumothorax or a tension pneumothorax. And if you're in an ambulatory center not connected to the hospital, there could be a risk of needing a chest tube, needing an emergency thoracotomy, needing other procedures. There was a relatively small risk; there was a risk. After extensive

discussion back and forth, we brought in an electrophysiologist, Dr. Dipak Shah, who is the director of the atrial fibrillation center, who did make a case for doing these procedures in an ambulatory care center, but could not really provide data, larger data, from around the country to support the safety measures. It was felt that the standards remain that these procedures and devices should remain in licensed hospitals.

The third charge we have was to talk about definitions to determine if provisions are necessary for coronary interventions, diagnostic caths, elective coronary interventions PCI without open heart surgery to now include electrophysiology. What are we talking about? We're talking about right-sided ablations. These are what the electrophysiologists deem as simple ablations.

The majority, I think the vote -- so this discussion came up, Dr. Schreiber motioned, Dr. Selke seconded, and it was an 11 to zero in support, and this motion carried to allow right-sided atrial flutter ablations and those types of arrhythmias that are considered low risk to be performed in facilities that do not have onsite open heart surgery.

The fourth charge was to determine if it was appropriate to exclude patients with cardiogenic shock from Section 10(5)(c), which is basically when patients come in

with a myocardial infarction or heart attack, it's treated as an emergency. Response times are -- appropriate response time to treating these patients is paramount to the patient's recovery. We have what's called a door to balloon time, from the time the patient hits the door in the emergency room until the balloon is across the occluded artery or the blocked artery, that we measure that time and that time is 90 minutes.

And there are lots of variables; door to balloon, door to table, et cetera. We monitor it. Some patients come in with cardiogenic shock. They're very sick and they require other treatment modalities. For example, a patient that is in shock with a low blood pressure, the first thing to do is stabilize the patient, so you put in -- a heart pump in, a balloon pump or a left ventricular assist device.

Those things take time and that pushes the door to balloon time out beyond the 90 minutes. So hospitals are graded based on their door to balloon times and most of us have a target of 85 to 90 percent of the time hitting the 90-minute window. We wanted to take cardiogenic shock and extremely ill patients out of that equation and currently it exists in it. It was unanimously approved that cardiogenic shock patients would be excluded from the standard. The Certificate of Need looked at charge five, which was to review Section 11 to determine if it was appropriate to

incorporate additional interventional procedures that are performed in the cardiac catheterization laboratory but are not currently identified or weighed. So what we talk about are wheels in and wheels out. When these patients come into a lab, it takes usually about an hour, let's say, to do a cardiac catheterization, so we give that one procedure equivalent.

But some new technologies that we have, for example, transaortic valve replacement, a mitral clip, a very complicated patient who has a completely occluded artery called a CTO, sometimes that could take four hours of work but really only currently weighed at one or one and a half procedure equivalents. So Dr. Dixon took that charge on and did a phenomenal job.

And we reviewed all of the various charges from diagnostic caths to therapeutic, to peripheral work, complex therapeutic, and others that would require some as long as six hours and came up with this language that satisfied the committee and it was unanimously approved. Charge six, consider a revision to clarify Section 4(13)(a) and (b) applicants, initiate PCI services, elective PCI services.

We wanted to be sure that when you start an elective, hospitals -- there are right now two ways of doing a coronary angioplasty in the state of Michigan. If you have open heart surgery and it's an elective procedure or if

you come in with a myocardial infarction, we call it ST elevation myocardial infarction. The state of Michigan, I think several years ago, adopted a CON that allowed you to perform elective PCI with certain modifiers. There were reasons why you couldn't do electives if it's approximal. These certain characteristics, if it's a shock patient, if it's a patient that's got calcifications in the arteries, a complicated bypass, et cetera.

What this wanted to do was just make sure that we had enough experience to initiate these programs. So a motion was made by Dr. Selke and seconded by Dr. Gurm to add the requirement that a minimum of 36 interventions be performed in the most recent 12 months prior to the application date and it carried 12 to zero. And again, it was just assuring that we had enough sufficient experience and we monitor volumes of the physicians and other standards within this structure.

And the last charge was to consider requirements for replacing cardiac catheterization services from one existing licensed hospital to another. A motion was made by Dr. Shah, supported by Dr. Gurm, to make this addition and the motion failed with one support and nine "no." Dr. Gurm, I think, was going along with what you were saying, one of the councilmen, which was just for purposes of discussion supported it, but it did not get the support. And it's a

really complicated situation, but I think it came down to this: If you've got a cath lab on Six Mile and you've got a vibrant community on Twelve Mile, can we shut that service down and move it here though it might be in the same service area and your patients might not be impacted? The concern was that there would be some impact to those that are serviced there, though there are -- there will be debate and discussion and I anticipate more commentary will come as it relates to this.

But that was the reason why this motion for support got a "no." So I'm happy to take any questions that you might have.

MR. FALAHEE: Doctor, thank you very much for the time you put in on this and everyone else. As those physicians who have by now left the room, they will find they, too, will be putting in time on the next SAC we form. So I've already hit up two of them to be the chair and vice chair.

DR. SHUKRI DAVID: It was six months, but I'll tell you, the team that we had was a fantastic team and they represented the state of Michigan well, which is as you alluded to; quality, access -- and cost was way down there, but it was really quality and access.

MR. FALAHEE: I have a question on your first charge, what you first talked about. If you could rehash

that for me again briefly, please? I'm sorry.

DR. SHUKRI DAVID: Yes. It was an elective PCI, that's coronary intervention, without onsite open heart services. So you have an external body -- Alice, help me with the name of the body that's currently working in Michigan.

MS. ALICE BETZ: Corazon.

DR. SHUKRI DAVID: Corazon. So I'll give you an example. Providence Hospital in Southfield, that's our open heart surgery program, so we really never needed Corazon in the past. When we started doing elective coronary interventions in Novi at Providence Park Hospital, though the same operators are there, the same QA process is there, the argument is, "Why are you paying an external agency to come in and monitor your work?"

And quite honestly, I can understand the argument that it's unnecessary, it's duplicative and redundant to be doing that. And there were passionate arguments. As you can see, it was five to six. But I personally felt, and others, at least the others in the room that felt that, look, I think it's important that we have an external reviewer to monitor the quality, to police especially low-volume centers, that it can't just be your initial organization. And they provide valuable data as far as database, as far as monitoring, as far as QA. I forgot the

schedule. I can't recall it directly. But they do -- once they credential you as a PCI organization, then you have a review I think at three months, at six months, at one year and then at two. And I think the cost is $25,000 -- but I could be wrong -- per year once they review you. It's a one-time fee and then there is an ongoing fee.

So the argument was why duplicate it if we've got, you know -- for example, Beaumont has Royal Oak but they also have Botsford, of course, that doesn't have open heart surg- -- is it sufficient for Beaumont physicians to QA another facility or not? It was felt at least by the physicians around the table, the experts, that it's a good idea to do it. It may be redundant, it might cost you a little bit of money, but it's better for patient outcomes and quality.

MR. FALAHEE: Thank you very much.

MR. TOMATIS: Commissioner Tomatis. Do I understand clearly this is only for replacement?

DR. SHUKRI DAVID: I'm sorry?

MR. TOMATIS: It's for replacement, not new units?

DR. SHUKRI DAVID: No. This is to initiate a new program, so a new program. So hospital X wants to start doing elective coronary interventions. You can't do it now without having open heart surgery, so in order to do that, you need to meet the minimum requirements of volumes and you

also need to have an external reviewer to make sure that your quality and standards are adequate.

MS. ROGERS: And this is Brenda. And that was actually already in the standards previously, so the SAC elected to maintain that within the standards. And then if you look at your draft language, the only thing added to that particular subsection was to make it clear that it had to be maintained on an ongoing basis.

MR. MITTELBRUN: Any other questions? Thank you, Doctor.

DR. SHUKRI DAVID: Thank you.

MR. MITTELBRUN: Under public comment we have Alice Betz, Michigan Chapter of American College of Cardiology.

ALICE BETZ

MS. ALICE BETZ: Thank you, Commissioner. I'm Alice Betz, executive director of the Michigan chapter of the American College of Cardiology and I'm representing our president, Dr. Akshay Khandelwal. As Dr. David mentioned, the current standards indicate that pacemaker and ICD implants can be performed in a licensed operating room and that the Cath SAC was charged to clarify whether that licensed operating room must be located in a licensed hospital. And the SAC clearly decided that those procedures are indeed only appropriate in an operating room in a

licensed hospital. Following the SAC's conclusion, however, one of our members raised the question of whether that licensed hospital must have a cardiac cath service. The department concurs that the proposed language is not clear on this question and the SAC did not debate that issue. So we ask the commission to specifically solicit public comments on this issue so that interested parties, especially electrophysiologists, can provide input on whether these implants should be limited to hospitals that have a cardiac cath service. Thank you.

MR. MITTELBRUN: Any questions? Thank you. Next, Tracey Dietz, Henry Ford Health System.

TRACEY DIETZ

MS. TRACEY DIETZ: Thank you for giving me the opportunity to provide feedback. I'm Tracey Dietz with Henry Ford Health System. Henry Ford appreciates the amount of work, time and effort that the SAC put into this as well as the department, and generally support the recommendations that have come forth from the group. The exception that we have, though, is we would like to ask or have a little bit of concern around the replacement language that was mentioned that the department added.

And we truly understand and appreciate the reason for that addition was to bring some consistency between the standards of Cardiac Cath lab and Open Heart Surgery

services. So we do appreciate the effort and time that the team took to consider that language to bring that consistently between the two. The Cardiac Catheterization SAC considered similar language, as the doctor had mentioned, and rejected it. So Henry Ford Health System would like to try to understand the differences between that proposal and the proposed language that was added by the department.

That language was also just released on Thursday, so we're asking for some opportunity and some time to take to evaluate and really understand, again, the differences between the charge versus the language that was proposed and generally the impact for the state of Michigan. The other proposed changes that they suggested through these charges that they worked through really aren't time sensitive, so we don't feel that the delay will have any significant, negative or any impact at all for us as we provide these services.

And so what we're asking is if the commission could delay the vote until June -- the June meeting, so that it gives everybody in the state some time to take a look at that new replacement language and just better understand, like I said, those differences and what that impact will be for all of us. Any questions?

MR. FALAHEE: This is Falahee. Not so much for

questions for you, but for the department. So we're hearing take some time and all that. But question: If we approve the SAC recommendations and send it to public hearing, at that public hearing if people had issues or questions about the language, they could use that forum to present those issues; right?

MS. NAGEL: Yes, that is correct.

MR. FALAHEE: So we wouldn't necessarily have to delay it to get to the same result?

MS. NAGEL: Yes. You'd take proposed action, then a public hearing, and then you could take final action in June or not.

MR. FALAHEE: Right.

MR. MITTELBRUN: Any other questions? Thank you.

MS. TRACEY DIETZ: Thank you.

MR. MITTELBRUN: Next, David Walker from Spectrum.

DAVID WALKER

MR. DAVID WALKER: Good morning. My name is David Walker and I am here on behalf of Dr. Ryan Madder, medical director of the Spectrum Health cardiac cath lab and a member of the Cardiac Care SAC. Dr. Madder is in the lab today and regrets not being able to attend in person. Spectrum Health would like to thank the SAC led by Dr. David for all their hard work as well as thanks the department for everything they do and have done for this, for the SAC.

Spectrum Health does have some concerns with the department's recommendation to include the replacement language. This issue was discussed during the SAC's deliberations and was soundly rejected by a one to nine vote. To be clear, nine members of the SAC voted against including replacement language in their recommendations.

From a patient safety perspective, Michigan has numerous high-quality cardiac catheterization services. This is because these services have built up the volumes necessary to develop high-quality programs. Should a service be allowed to move into an area where an existing service is already located without the requirement to project need in that area, it may dilute the cases in the area reducing volumes which in turn could negatively affect patient care.

Proposing such a large replacement zone, an entire health service area, only exacerbates the concern. We understand that the department has the prerogative to recommend language to the commission. However, given the strong opposition by the SAC, Spectrum Health respectfully requests the commission adopt the SAC's recommendations without the replacement added.

Dr. Ryan Madder and Spectrum Health thanks the commission for the time to discuss our concerns with the replacement language included in the draft standards and I

would be happy to answer any questions.

MR. MITTELBRUN: Any questions? Seeing none, thank you very much.

MR. DAVID WALKER: Thank you.

MR. MITTELBRUN: Commission discussion?

MS. BROOKS-WILLIAMS: Commissioner Brooks-Williams. So the one request about delaying, the answer was basically if we did not delay and it went out for public comment, the question about the department's language versus the SAC's recommendation could be clarified during the public comment period. Was that what you had asked, Commissioner Falahee?

MS. NAGEL: Well, we could clarify it now as well. I think I interpreted the request to delay that others could have more time to look at it, but I think part of the discussion, that that mechanism is in place as well.

MS. BROOKS-WILLIAMS: Okay. And so therefore would you like to share?

MS. NAGEL: I would love to. Thank you. As Brenda mentioned earlier, this is connected to the Open Heart Surgery standard. In January of 2017, at that planning meeting, the department brought a concern to the commission that Open Heart standards and Cardiac Cath do not have any replacement language, something we noticed that all the other standards have some sort of replacement language;

that if you could move all of the other CON covered clinical services, why couldn't you move these two? So the commission asked the department to come back with language specific to Open Heart Replacement and the commission asked the Cardiac Cath SAC to also review Cardiac Cath replacement language.

So the end result is that it put us in an interesting position where the Cardiac Cath SAC rejected replacement language, but it's still the department's prerogative to bring back to you the recommendation that you asked for in January pertaining to Open Heart Surgery. So in our draft, what we came up with was tying the two together; that if you had an Open Heart Surgery program and you wanted to replace that, you also had to replace your Cardiac Cath at the same time.

Both of the previous locations of those services would need to shut down before the new one opened so there was no incremental increase in the number of those services, but a full replacement. So in order to provide you language in Open Heart, we needed to insert something in Cardiac Cath as well. We would normally not provide you language that a SAC had soundly rejected. But in order to fulfill our duty to bring back to you something that might work for Open Heart, we had to include it in Cardiac Cath as well.

MS. ROGERS: And this is Brenda. If I can add to

that, you can't have an Open Heart Surgery program without Cardiac Cath. So what the SAC initially looked at was open replacement language. So what we've done is restricted it in Cardiac Cath. The only way you can replace in Cardiac Cath if you are simultaneously doing it with the Open Heart Surgery program. So there is a limitation in Cardiac Cath. Not just any Cardiac Cath program can be replaced.

It's going to be replaced in conjunction with an Open Heart Surgery program by -- under the same ownership. So we did try to narrow it trying to respect the SAC's decision in its overall view of replacement, but, again, felt that if we're going to do this or make this recommendation in Open Heart, there still had to be a tie to the Cardiac Cath because you can't replace Open Heart without Cardiac Cath.

MS. BROOKS-WILLIAMS: Commissioner Brooks-Williams. Just one more question. So in the replacement language is it implied or explicit that if I'm moving an Open Heart program with the Cath lab, do they both have to be compliant or are there -- in order to move it, it has to already be functioning as the department's requested or required level?

MS. NAGEL: Yes. In the Cardiac Cath standard 5(3)(d) says that the existing Cardiac Cath service to be located must perform the applicable minimum number of

cardiac catheterization standards service set in the standard and the same language is duplicated in Open Heart. So both the Open Heart and the Cardiac Cath would have to be meeting all of the standards for volume.

MR. MITTELBRUN: Any other discussion?

MR. TOMATIS: Commissioner Tomatis. Please provide for me in the hypothetical case that the hospital decide to move the surgery to another place because -- go with them, but in the area where they were perhaps they will need catheterization. They have to apply as a new program?

MS. NAGEL: Yes. Replacement would be a one-for-one exchange. So if there's an Open Heart surgery program with a Cardiac Cath program and they move it to location B, location A is shut down. Now, if location A wants to implement Open Heart or Cardiac Cath, they would need to apply to implement and meet the standards for implementation.

MR. TOMATIS: Yeah, because you'll see they're unauthorizing to do catheterization and so on without Open Heart and perhaps the population where they were leaving that hospital was -- need the cardiac cath.

MS. NAGEL: They would have the option. There is the ability to open up therapeutic diagnostic, a diagnostic Cardiac Cath without Open Heart Surgery onsite, so they would have the ability to do that.

MR. TOMATIS: A new application.

MS. BROOKS-WILLIAMS: Brooks-Williams. I want to ask another question about planning area. Right? So the requirement for replacement, the language is on planning area, and that I'm assuming it has to -- there has to be need for it. So if I -- I think the example that was given by the Cardiac Cath SAC -- right? -- part of the concern that they would have would be the same concern that I would have, is that someone's not just seeking to replace to a area that has a higher pair (phonetic) mix, let's say, hypothetically, --

MS. NAGEL: Right.

MS. BROOKS-WILLIAMS: -- and therefore you abandon an area that, you know, could be left vulnerable. So what does the planning area do to protect that if that's kind of the only requirement that you have to have?

MS. NAGEL: That's a great question. And we proposed planning area, but in the other standards the replacement zones vary.

MS. BROOKS-WILLIAMS: Okay.

MS. NAGEL: And so it was just our recommendation --

MS. BROOKS-WILLIAMS: So you did that to try to give some geographical replication -- right? -- so that it's --

MS. NAGEL: Yes, so it couldn't move, --

MS. BROOKS-WILLIAMS: -- approximal?

MS. NAGEL: -- you know, across the state or something, but within a defined area.

MS. BROOKS-WILLIAMS: Okay.

MR. FALAHEE: This is Falahee. I've got a question about that same thing but when we get to the Open Heart Surgery section. So if I'm understanding correctly, there's language submitted by the department that in effect has been voted down by the SAC. If we go ahead and approve the SAC's report and send it to public comment, will the department's language be in or out of what we're sending out, out for public comment?

MS. ROGERS: This is Brenda. What you have in front of you today is all of the SAC recommendations including the department's recommendations. So if you accept the language as presented, you would be accepting all of the language; the SAC as well as the department. If you want to exclude something, then you would have to specifically, you know, make that as part of your motion.

And that's why we included it all in one document, so we didn't have to work on a couple of different documents for the commission to move forward. And, again, just to make it clear, yes, the SAC did not approve replacement, but what we tried to do -- and hopefully we've done and maybe it

does need some tweaking, but what we've attempted to do is keep it tied very specifically to Open Heart, so --

MR. FALAHEE: Right. No, I get that. So if we approve the language in front of us, including the department's language which is in blue on page 89 of our packet, that would still be open for public comment, the public could say this is a great idea, this is a lousy idea and here's why?

MS. ROGERS: This is Brenda. That is correct.

MR. FALAHEE: Okay. Then I'll -- Mr. Chairman, if I could make a motion?

MR. MITTELBRUN: Yeah. Is there any further discussion? Then commission action.

MR. FALAHEE: Okay. This is Falahee. I would move that we take the language in front of us, including the department's language, to approve the recommendations of the SAC and the language in front of us as it is here and to send it out to public comment. And I know there's somewhere else it needs to as well, the JLC.

MS. ROGERS: This is Brenda --

MR. FALAHEE: Yes. Also to the JLC, and with an eye toward a couple speakers. So they really want to focus on a couple questions about doing ICD's in hospitals without a cath lab, I believe, and there may be another question that was asked to be asked. Whatever those were, I would

encourage those on either side of the equation to make public comments about it during the public comment session or during -- in written testimony.

MS. GARDNER: This is Gardner. I second.

MR. MITTELBRUN: Any further discussion? All those in favor?

(All in favor)

MR. MITTELBRUN: Opposed? No opposed. Motion carries. Next we are going to jump to item X, Nursing Home and Hospital Long-Term-Care.

MS. NAGEL: No.

MR. MITTELBRUN: Oh. I'm sorry.

MS. NAGEL: If we could just quickly, then, because you've approved at least that proposed language in Cardiac Cath and it is tied to Open Heart, could we quickly go to that agenda item?

MR. MITTELBRUN: Well, I think we were going to jump to this due to someone having to catch a flight and it's going to be a quick --

MS. ROGERS: That was the Cardiac Cath.

MS. NAGEL: Oh. No, there's another one.

MR. MITTELBRUN: No. There's -- sorry. Sorry.

MS. ROGERS: Okay.

MR. MITTELBRUN: So anyway, item X. Did you have any comments from the department?

MS. ROGERS: No.

MR. MITTELBRUN: I did have one public comment card.

MS. ROGERS: Okay. This is Brenda. Just on the Nursing Home, just -- again, just a reminder that this was brought to you in December for setting the effective date of the new bed need numbers, and you did ask the department to take it back to Mr. Delamater to take a further look and making sure that the numbers are correct. He has provided an updated report for you and you have that in your packet.

And the department did work closely with HCAM on all of this and there are concerns, I think, out there. And so the department actually, and as you've seen in your material, is suggesting that possibly postponement indefinitely until we can get some better data as far as setting the effective date with the bed need. Thank you.

MR. MITTELBRUN: I do have one public comment card from Pat Anderson, Health Care Association of Michigan.

PAT ANDERSON

MS. PAT ANDERSON: Good morning. It's one more minute before it's afternoon so I'll still say "good morning." I am Pat Anderson with Health Care Association of Michigan and I'll just make this really brief. We have worked with the department on this issue, brought it forward in December and that, and we agree that we would like to

postpone this, using the bed need methodology. And we would request that a SAC be appointed to review the methodology and get it more in the line of what is happening currently. Thank you.

MR. MITTELBRUN: Any questions? Thank you. Any action?

MS. CLARKSON: This is Commissioner Clarkson. I would like to propose a motion. Motion to have the CON commission postpone indefinitely the Nursing Home and Hospital Long-Term-Care unit bed need report dated November 15, 2017, and related follow-up report dated December 27th, 2017, and that the commission establish a SAC in 2019 to review and revise the Nursing Home and Hospital Long-Term-Care bed need methodology by engaging Dr. Delamater to perform the necessary research.

MR. MITTELBRUN: Is there a second?

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

MR. MITTELBRUN: Any discussion? All those in favor?

(All in favor)

MR. MITTELBRUN: Any opposed? No. Motion carries. Now back to item VII on the agenda, Open Heart Surgery draft language. Brenda?

MS. ROGERS: This is Brenda. As we stated earlier, this was initially brought to the commission back

in 2017. I'm not going to restate all of that again. So basically the language that you have in front of you today would allow an Open Heart Surgery service to be replaced and, again, it's got to be meeting all of the volume requirements, et cetera, and tied to that is the replacement of its Cardiac Cath as well. So we tried to make it clear that it's your Open Heart program, it's your Cardiac Cath program that are being replaced simultaneously. So if there's any questions, we'd be happy to try and answer that.

MR. FALAHEE: This is Falahee with a very little question. Under subpart (e) you've got to be meeting the minimum number as stated in the current Open Heart Surgery cases, and then there's an "unless." And the "unless" is basically if you're moving everything to a new hospital at a new site; right? Is that, how I'm reading that, right?

MS. ROGERS: Okay. I'm trying to find where you're at, Chip. Sorry. This is Brenda.

MR. FALAHEE: 4(e).

MS. ROGERS: Yes; yes. Because right now Cardiac Cath can be moved, replaced if it's part of the entire hospital. So that, and the -- and in here --

MR. FALAHEE: So it --

MS. ROGERS: Yeah. So here, the same thing. So if it's part of replacement of the entire hospital, then it can be replaced without meeting the minimum volume. That is

correct. I believe that's the case in most of our other standards and that's the reason it was drafted this way.

MR. FALAHEE: Thank you.

MS. ROGERS: And then also just one more item, and it is in the language (c), we did try to -- that has been reworded, and it is correct up on the screen, just to make it clear, again, that you are simultaneously replacing both the Open Heart and the Cardiac Cath. We had it worded a little bit differently, but hopefully the way it's been reworded actually clarifies that. So thank you.

MR. MITTELBRUN: Any other questions for the department? If not, public comment. David Walker, Spectrum.

DAVID WALKER

MR. DAVID WALKER: Good afternoon. My name is Dave Walker and I'm here on behalf of Spectrum Health. I appreciate the opportunity to provide comment on the CON review standards for Open Heart Surgery services. Spectrum Health would like to thank the department for its work on this effort. However, we are opposed to the draft as currently written and allow me to provide a few considerations.

The language exempts programs from hitting the minimum volumes in part of the full hospital replacement. It would seem that a full hospital replacement would be a

scenario and the most money would be spent to replace an Open Heart Surgery service. I would argue that this opens the door for low volume programs to be replaced at the highest cost, which I do not think is in the best interests of the residents of the state. Similarly, when a hospital with an OHS service is being fully replaced, it can already replace the OHS program with the hospital so why is the provision necessary?

I believe it's one of the main reasons the Cardiac Cath SAC rejected by a one to nine vote similar language it was considering inserting into the Cardiac Cath standards. Allowing an OHS and Cardiac Cath program to replace anywhere in the same HSA is a huge geographical change. A program that services one community can move several counties away to an entirely different market. This would be a decrease in access for patients in the old community and would decrease in access for patients not able to travel which could increase mortality.

Again, thank you to the department for their efforts. I know that crafting the language for the CON standards is no easy feat. Spectrum Health would like to thank the commission for considering our comments today. I would be happy to answer any questions the commission has.

MR. MITTELBRUN: Commissioner Tomatis?

MR. TOMATIS: Commissioner Tomatis. Do you mean

that it should be -- that the move should be within the same service area?

MR. DAVID WALKER: I think that the service area is too large. For instance, up north a service area could be literally from, you know, Leelanau County all the way over to Alpena County. That's a huge area to replace such a --

MR. TOMATIS: I mean the same service area that there is another hospital will service cannot be so far?

MR. DAVID WALKER: I think that any type of replacement zone should be discussed by medical experts and I don't believe I'm in the best position to consider that. And if that was something the commission would consider, I would say maybe in a work group to look at the geographical relocation area.

MR. TOMATIS: We have to write some rules that everybody know what they can or cannot do and this is why I'm asking you how should we limit that they will move from Detroit to Grand Rapids or just we can seek -- what do you suggest?

MR. DAVID WALKER: Well, I think that some -- and I'm not sure about all the other replacement languages, but, you know, there are certainly some replacing -- I'm trying to remember -- some that are within 10 miles or initiating a new service is, like, surgical services is limited to 20

miles. So I think that somewhere in that range is probably, in my opinion, more appropriate than an entire HSA.

MR. TOMATIS: Tell me what we will use for other services.

MS. NAGEL: Are you asking what we would normally use in other services?

MR. TOMATIS: What other services, yes. We limit how far they can go. What we use?

MS. NAGEL: It varies. Some standards have a mile, a mile radius. Some use the planning area. But each standard kind of defines it.

MR. TOMATIS: Well, we would have to define ours?

MS. NAGEL: So right now in the language as it's written, it is defined as a planning area.

MR. TOMATIS: Planning area?

MS. NAGEL: Uh-huh (affirmative). And then the planning area is shown on -- I don't know what it is in your packet, but it's page 9, Section 11. So those are laid out in the standard.

MR. MITTELBRUN: Any other questions? Thank you.

MR. DAVID WALKER: Thank you.

MR. MITTELBRUN: Next, we have Stacy Leick, Economic Alliance of Michigan.

MS. NAGEL: Could we clarify just quickly more information to Dr. Tomatis' question?

MR. MITTELBRUN: Yes; please.

MS. NAGEL: Tulika?

MR. MITTELBRUN: Stacey's not on the clock yet.

MS. BHATTACHARYA: This is Tulika. And just in our view there is a correlation between the -- so in our view when we propose or when we review the relocation zones in the individual review standards, those are somewhat related to the methodology under which you project unmet need for initiation of service. So if you look at Surgical Services standards or CT standard or MRI, in order to initiate service you need to project or collect physician commitment forms within a mile radius. Let's say a 20 miles radius.

So when you think about relocation zone for existing service and the community served, we, you know -- we think about mile radius. So when you look at the methodology for initiating Open Heart Surgery services, it is based on MIDB data as charges for the entire planning area or the health service area. So that's why, when we were thinking about replacement zones, we thought about, you know, following the methodology for initiation which is the whole health service area, but not saying that cannot be changed. That was the --

MS. NAGEL: Yeah.

MR. MITTELBRUN: Thank you. Okay. Stacy, you're

up.

STACY LEICK

MS. STACY LEICK: Hi, again. My name is Stacy Leick. I'm with the Economic Alliance for Michigan. As previously stated in my public comment for the BMT standard, the commission in the past has always had a process, public input ahead of the commission taking proposed action on policy change to the standards. The EAM would like the commission to maintain that practice for nontechnical changes.

So again, we want to ensure that the changes address the necessary issues and do not create new ones. It appears the Open Heart Surgery standard and the Cardiac Cath standard needs language to change and address the issue of a full hospital moving from one location to another. While the intent of the proposed language is to allow a program to move along with the hospital, we are very concerned that a program would be able to move cities or counties away from where it originated.

The proposed draft language states that the proposed new site is within the same planning area and our concern is, as the previous speaker said, these planning areas encompass multiple counties and situations. And the thing is that some of these health care systems have multiple locations within those planning areas. So the CON,

what was originally issued, was based on the need of that service within that community. So uprooting it from one city and moving it over to another city, that does not address the need that was already previously stated. So we urge you to take this language to a work group or a SAC where it can have a deeper discussion of public comment to create a more precise and clear standard, especially for the planning area. Thank you.

MR. MITTELBRUN: Any questions? Thank you. Next we have Marlena Hendershot from Sparrow Health System.

MARLENA HENDERSHOT

MS. MARLENA HENDERSHOT: Good afternoon. My name is Marlena Hendershot. I'm the director of strategic planning at Sparrow Health System. Thank you to the commission for allowing me to speak in this public comment period. I'm going to read -- it's from Sparrow.

> "It has come to our attention that the Certificate of Need Commission will be considering revisions to both the CON Standards for Open Heart Surgery and Cardiac Cath at the March 27th meeting. These revision would add provisions for replacing both services to new geographic locations. I am writing today on behalf of Sparrow Health System to express our concern regarding these changes. Based on our initial review, we have the following comments regarding the

replacing language. Section 4(d) which states, 'The proposed new site is within the same planning area of the site at which an existing OHS service is located.' These proposed changes would result in a significant change in policy. Facilities will be allowed to move programs out of less desirable communities across several counties and place them in areas with an undemonstrated need. Most replacement provisions include a mileage limitation of 2-10 miles, depending upon the service, to ensure that a replacement does not change the population being served. This proposal provides the ability to replace anywhere in the Health Service Area."

For example, we are obviously in Ingham County, but we also have -- other counties in our planning area would include Ingham, Eaton, Clinton, Jackson, Hillsdale and Lenawee. So that is a huge planning area.

"Section 4(e) states, 'The existing Open Heart Service to be replaced performed at least the applicable minimum number of open heart surgical cases set forth in Section 8 as of the date an application is deemed submitted by the Department unless the OHS service being replaced is part of the replacement of an entire hospital to a new geographic site.' This includes a provision which would allow for the

replacement of an Open Heart Surgery program that isn't meeting minimum volumes. Based on the CON tenets of cost, quality and access, we are concerned that the proposed standard could encourage facilities to spend millions of dollars to replace an Open Heart Surgery program that may not be needed nor meeting minimum volume requirements.

The seated experts on the Standard Advisory Committee for Cardiac Cath Services debated this issue over 6 months of meetings and determined that was not good public policy. In fact, they voted a similar proposal down by a vote of 1 to 9. I am concerned we are considering this proposal absent the SAC's recommendations.

Based on our initial review, we as the Commission to support the recommendations of the Cardiac Cath SAC and remove the proposed language in both the Cardiac Cath and Open Heart Surgery standards related to replacement of those services to new geographic sites."

Any questions?

MR. MITTELBRUN: No questions. Thank you.

MS. MARLENA HENDERSHOT: Thank you.

MR. MITTELBRUN: Next we have Tracey Dietz, Henry Ford Health System.

MS. TRACEY DIETZ: I have no further comments.

MR. MITTELBRUN: Okay. Thank you. Commission discussion?

MR. FALAHEE: This is Falahee. I guess to the department, what's the genesis for this Open Heart Surgery language? Was there a specific request for it? Was it tied to the Cardiac Cath SAC? I'm just trying to figure out why is it here now?

MS. NAGEL: Yeah. At the 2017 commission planning meeting in January, both Open Heart and Cardiac Cath were the two standards that needed to be reviewed or the commission needed to decide how to review at that meeting. The department put forth recommendation to add replacement language in Open Heart and Cardiac Cath because, as we do for every standard that comes up, and we asked the commission to review, we found inconsistencies.

All the other standards for services had replacement language but Open Heart and Cardiac Cath did not. And so our question to the commission was, "Do you want to add them?" And so we said that we would come back with Open Heart Surgery language and we also -- it was concluded as part of the SAC's charge. And so we're coming back today, as the SAC has made their recommendation, and following up with the assignment we were given by the commission to bring you Open Heart Surgery service language as well.

MR. FALAHEE: So the options in front of us, if I'm trying to figure them out, one would be approve this, it would then go out for public comment much like the Cardiac Cath SAC, so anyone that had issues with this language could raise it then?

MS. NAGEL: Yup.

MR. FALAHEE: If we have issues with it now, we can raise it now. I'm just trying to figure out what our options are down the road. Or we could just say, nope, we're not going to approve this language, just vote that down? That's another option.

MS. NAGEL: Correct. However, it is tied to the Cardiac Cath language that you did move for a proposed action.

MR. FALAHEE: Right. No, I understand.

MS. NAGEL: Okay.

MR. FALAHEE: Just a comment. I, too, share the concern about being a planning area which is a wide area. All planning areas are wide, but you get further outside of southeast Michigan, they get wider and wider. And I share that concern. One of the things I always looked at when I see any standard -- Mr. Potchen knows this -- I figure -- I try to figure out how to game it, and you can game this one very easily and move from one area to a more higher payor rate or percentage area. So I, too, have concerns about

that and whether -- I'd be curious what public comment has to say because you could put it -- and I understand, Tulika, where you were coming from, but, I mean, some say ten miles, some say five. Is it two? I don't know the answer to that. But I think I would be much more comfortable if we had a mileage limitation there rather than an entire service area which can be six, seven, ten counties wide.

MR. TOMATIS: Commissioner Tomatis. I share your opinion. This is why I was asking him what prevent the big institution to buy one of the six noncompliant Open Heart in Detroit and move it to Traverse City as part of the planning?

MS. NAGEL: That would be in a different planning area.

MR. TOMATIS: Who determine what is the planning?

MS. NAGEL: The planning areas are defined in the standard on page 9 of your Open Heart standard.

MR. TOMATIS: Yeah?

MS. NAGEL: So they're listed there what they are.

MR. TOMATIS: I would feel more comfortable in my initial county or whatever it is.

DR. MCKENZIE: I share similar concerns about the ability to move within a planning area. In the area where I live, moving from Wayne to Macomb is a drastic difference and you could do that to improve your payor mix, but it

would leave those who are most vulnerable without access.

MR. MITTELBRUN: If there's no further discussion, we're looking for action by the commission.

MR. FALAHEE: This is Falahee. Let me propose a motion to approve the language that we have in front of us here and send it out to public comment and the JLC with a specific request of those during the public comment period. You've heard that at least some of the commissioners have concern about the planning area and being able to move within a planning area. Please let us know what you think about it; pick a number, two, five, ten mile; and give us the reasons for that during public comment. That would be my motion.

MR. MITTELBRUN: Is there a second?

MS. CLARKSON: Commissioner Clarkson. Second.

MR. MITTELBRUN: Second. Any further discussion? All those in favor?

(All in favor)

MR. MITTELBRUN: Any opposed? Motion carries. I think we're on number IX, Hospital Beds Standard Advisory Committee Final Report and Draft Language. Renee Turner-Bailey is our chairperson to provide a report.

PRESENTATION BY RENEE TURNER-BAILEY

MS. RENEE TURNER-BAILEY: Good afternoon. My name is Renee Turner-Bailey. I chaired the Hospital Bed Standard

Advisory Committee. I am a senior benefits consultant with the International Union, UAW, representing consumers on the SAC. I just want to take a moment before I get into my report presentation to thank the department. They're always so amazing in supporting the SAC's. This is not my first rodeo. And I just want to thank Brenda, Beth, Tulika, Tania, everybody for the work that you do in supporting the SAC's.

And I also want to acknowledge the members of the SAC which include Shannon Striebich from St. Joseph Mercy Health System; T. Anthony Denton, University of Michigan Health System; Margaret Klobucar, Ascension Michigan/St. John Providence; Patrick O'Donovan from Beaumont Health; Jane Schelberg from Henry Ford Health System; Dr. Robert Camp, Spectrum Health; Thomas Mee, McLaren Health Care; Jeffrey Garber, Mary Free Bed Rehabilitation Hospital; Jennifer Groseclose from Munson Health Care; Stephen Anderson, Blue Cross Blue Shield of Michigan; Richard Lindsey, Jr., from Ella M. Brown Charitable Circle doing business as Oaklawn Hospital; and Joel Clark, Economic Alliance, EAM, as a purchaser.

On March 16th, 2017, the commission addressed the questions that I'm going to go through. The Hospital Bed Standard Advisory Committee was approved at that time with five charges to consider. You have a written report, I

think, that was in your materials and I just want to take some time to go through each of the charges and to give you the results that are being recommended to you today from the SAC. The Hospital Bed Standard Advisory Committee, which I will alternatively refer to as the Hospital Bed SAC or the committee, met six times to address the charges from the commission.

The SAC agreed early on that two subcommittees would be helpful to help to address some of the issues that we were dealing with and those would be under charges two and charges four, which you will hear about more as I go through my presentation. We felt that this would allow for additional time and effort to gather research and information to address these charges. Charge number one was to, "Review and update or eliminate, if necessary, the language in Section 6(4)(f)." This language states,

> "Applicants proposing to add new hospital beds under this subsection shall demonstrate to the Department that they have pursued a good faith effort to relocate acute care beds from other licensed acute care hospitals within the HSA. At the time an application is submitted to the Department, the applicant shall demonstrate that contact was made by one certified mail return receipt for each organization contacted."

Following discussion during the committee meetings and with information from the department, the Hospital Bed SAC agreed that despite good faith efforts, no acute care beds are relocated from other licensed acute care hospitals within the HSA, nor is this likely to happen. To preserve the resources under this effort, the Hospital Bed SAC agreed to recommend elimination of the language in Section 6(4)(f).

Charge number two, "Review and update, if necessary, the language throughout Section 12, titled, 'Additional requirements for applications included in comparative reviews.'" The committee formed a subcommittee to review the language throughout Section 12. The subcommittee came to two conclusions and made recommendations to the SAC for submission to the commission. The first is that comparative reviews should include scoring for quality measures.

CMS star ratings is the recommended basis for this approach. And two, the points for a comparative review should be determined in a clear and understandable way. As such, the points you see on the slide illustrate the recommended scoring for the requirements for a comparative review. And these are -- this is the scoring that we're submitting for your consideration today. Charge number 3, "Review and update, if necessary, the space and lease renewal at hospitals." The SAC reviewed and made proposed

updates to the space lease and lease renewal by clarifying that requirements for approval apply to those situations where an applicant is proposing to acquire an existing hospital or renewal of an existing hospital lease. In addition, the proposed language changes make exceptions in certain cases and for certain types of facilities. With these changes, the hospital language referring to -- excuse me -- referring to lease renewal is now consistent with language in other sections of the CON standards.

And so what you see on the screen is the language that we are proposing. It's not the language. It's a summary of what we're proposing to the commission today. Charge number four, "Review the concept of replacing and relocating inpatient rehabilitation beds and update the standard, if necessary." So this was the most complicated of the language changes recommended by the Hospital Bed SAC and that is to charge number four.

Once again, in this instance a subcommittee was formed and the committee considered the recommendations and agreed upon language changes to submit to the commission. Over the next few slides I will discuss the critical points involved in the concept of replacing and relocating inpatient rehabilitation beds. The first change involves modifying definitions. The inpatient rehabilitation facility or IRF bed is defined as a Medicare-approved,

licensed bed within an IRF hospital or unit. The definition of replacing IRF beds means a change in the location of all IRF beds from an existing site to a site within the replacement zone. The committee also agreed upon criteria for developing a new licensed IRF site. The first criteria is that the applicant must demonstrate that it is operating under high occupancy. A facility operating under high occupancy will have a legitimate need to relocate beds due to space or capacity issues.

An applicant must also have demonstrated that the beds to be replaced are IRF beds that meet Medicare criteria, which I mentioned. The replacement of IRF beds in a hospital replacement zone will result in a hospital of at least 40 beds. The committee implemented criteria to ensure that a sufficient number of beds in an IRF hospital are relocated based on the size of the county.

To allow for phasing in of the replacement IRF beds, an applicant is allowed 36 months from the time of activation to the new site to retain up to 8 IRF beds at the existing site. To avoid the unintended consequence of replacement beds not relocating in a timely manner, any beds not transitioned within the 36-month time frame shall revert to acute medical-surgical beds. The committee clarified that the new IRF hospital shall be assigned to the same hospital group as the hospital group of the originating

hospital. The new IRF hospital shall not be subject to comparative review. Finally, if the new IRF hospital ceases operations as an IRF hospital, the beds must be disposed of. This would take place either by relocating the replaced beds back to the site of origin, relocating any IRF beds approved under high occupancy to the site of origin if they are to be utilized as IRF beds, or delicense any IRF beds approved under high occupancy if they are not to be used as an IRF bed.

Charge number five, "Consider any necessary technical or other changes, for example, updates or modifications consistent with other CON review standards of the Public Health Code." The department made technical recommendations to the language which the Hospital Bed SAC accepted and voted to propose for approval. And these technical changes were actually fairly benign to a SAC compared to, you know, some of the discussions you've had.

It's more clarification of titles, changing the name of the department, et cetera. And so the SAC is recommending that we accept those changes. Are there any questions?

MR. FALAHEE: Commissioner Falahee. Good to see you again.

MS. RENEE TURNER-BAILEY: Thank you.

MR. FALAHEE: I'm thankful for getting rid of that

first charge about looking for other beds. I think you may have been the chairman of the commission when you appointed Jim Ball and I to a SAC to look at this many years ago, Renee.

MS. RENEE TURNER-BAILEY: I'm sorry.

MR. FALAHEE: No; no; no. At the time there was pressure to do that. I'm glad to see it's finally being removed. I totally support that. I've just got questions about the IRF. So to set up a new IRF, you've got to be at high occupancy. All right?

MS. RENEE TURNER-BAILEY: Yes.

MR. FALAHEE: And then let's assume you're at high occupancy. And by that I think you mean, "Okay. We've got this much occupancy. We've got 28 beds that we need that we could get under high occupancy," and it's those 28 that under this language could move to a new IRF hospital, but it can't be 28, it's got to be at least 40; is that correct?

MS. RENEE TURNER-BAILEY: It has to be at least 40 to move to the new location. It is possible if an organization is operating under high occupancy to request beds under a high occupancy and then use them as IRF beds to move to the new location.

MR. FALAHEE: That's what I thought. Thank you. That helps.

MS. RENEE TURNER-BAILEY: Any other questions?

MR. MITTELBRUN: Thank you, Renee.

MS. RENEE TURNER-BAILEY: Okay. Thank you.

MR. MITTELBRUN: We have no public comment cards on that one. So commission discussion?

MR. FALAHEE: This is I think the third or fourth time I've been through the Hospital Bed SAC and each time it's been -- we've been lucky to have very good SAC participants, leaders of the SAC's, participants in the SAC's. We've been very lucky as a commission to have that. So thank you once again. It's not easy and it's complicated. I think you've done a great job. I would therefore recommend that the -- my motion would be to approve the language as prepared by the SAC and the department, send that out for public comment and to the JLC.

MR. HUGHES: Commissioner Hughes. Second.

MR. MITTELBRUN: Any other discussion? All those in favor?

(All in favor)

MR. MITTELBRUN: Motion carries. Next is item XI, a 10-minute presentation regarding St. Pio's Hospital from Mr. Palazzolo and two of those minutes will be allocated to Michael O'Dea for comment.

MR. JERE PALAZZOLO: Actually, if you don't mind --

MR. MITTELBRUN: Oh. You're doing it first. I'm

sorry.

MR. JERE PALAZZOLO: -- I'm going to do it and Bishop Boyea is going to speak for two minutes, and I think Mike requested with a card, if there's the opportunity to speak, public testimony and the like.

MR. MITTELBRUN: Okay.

PRESENTATION BY JERE PALAZZOLO

MR. JERE PALAZZOLO: Thank you very much. My name is Jere Palazzolo. I'm president of Catholic Healthcare International and I appreciate the opportunity to address the commission. We have submitted a Certificate of Need application for a very unique proposal which I think you may not fully understand unless we have the opportunity to come up and just address a few things about it. There is a hospital over in Italy called the Casa Sollievo della Sofferenza, the "Home for the Relief of Suffering."

It is a Vatican-owned hospital and it was started up by a very famous and very active contemporary saint, Padre Pio. Some people may know of him. We have, through some of the issues in the delivery of Catholic health care in our country because of the secularization trends and things like that -- have actually worked with them to develop a collaboration agreement to replicate that hospital model in the United States and actually in other areas around the world, too, as a model of fully faithful Catholic

health care delivery. The key focus here is the care of the most vulnerable and compassionate care of the sick and dying in the real tradition of the Catholic church over the years. So I wanted to start off with just the considerations that we would like to address to you that make us unique and make us want to request a special consideration. We know you don't have beds allocated for additional beds in the state of Michigan.

But we're asking you to make a special request outside of the norm to approve the project we're doing. First of all, it's an international collaboration with a Vatican-owned hospital. This has never been done anywhere else in the world, actually. It has a national profile, outreach, and affiliation and catchment. Essentially what we're doing is trying to create the model from scratch of what would be 100 percent full faithfulness to what we call the magisterium of the Catholic church.

The magisterium is the teaching authority of the church, which includes the bishops and the pope and all of the directives that they have within that. Again, going back to the basic of what the church has always taught, care of the suffering and the sick and the dying. It's a unique model that I had never heard of before. The "Home for the Relief of Suffering" I think tells you everything you need to know about what it is we're trying to do. We are trying

to relieve suffering of those people coming in to us both from a physical perspective, the highest quality of care it goes without saying, but also from a spiritual and emotional perspective and the like. It is, again, the emphasis on the most vulnerable.

It's the model of Catholic health care for the future. So, for instance, we have 650-plus Catholic hospitals in this country. They're all fragmented in different directions. They're run by different corporate structures and congregations, more corporate than congregation now, which is kind of the difficult issue. Well, this is going to be the model for them to emulate, to come back and affiliate with us. So we're setting up what will be an affiliation among hospitals.

We will also develop a medical school called the "School for the Relief of Suffering," which will be to form Catholic physicians or physicians who want to learn the basis for Catholic care to practice out in a secular world. That being not so much Catholic, but more the care of the vulnerable, the sick, and how to do it within a society quite frankly that is geared more towards secularism and more towards, you know, as some of us might call, the culture of death and things like that. So trying to arm them to go back out, but also be a place where they can come back to become strong, to be reinforced, to get their CME's,

but also to get strengthened and provide them support in their community. So both for the physicians, the hospitals to have that affiliation. The first thing we're going to build is a pilgrim shrine. Saint Pio, before he built this hospital, built an international network of prayer support, prayer groups. They're formally chartered prayer groups under the diocese wherever they are, 3700, 3400 of them around the world, about 125 in our country.

And the head of the Padre Pio prayer groups in the United States is on our board. We have already an infrastructure of support here and we're going to replicate the church, the Santa Maria delle Grazie church that Padre Pio said mass at, for people to come, pray with us and support. So this is going to be essentially a draw for pilgrims and tourists support and that type of thing.

And a very specific mission. We're not here as a big system coming in to capture market share. We are in to set up a very specialized, unique model that will frankly help the other hospitals in the area because it's going to bring in a basis of medical education in a unique way and medical delivery, but very much focused on the care of these most vulnerable people. So essentially, this is what we're asking of you. You know, to approve this. Nothing exists in the United States or in Michigan like this. It will be 100 percent funded by philanthropy. We will not take on

debt, so there will be no cost increase. If we can't raise the money, we ain't going to do it. But we're relying on providence to be able to do it. Padre Pio insisted on that. I have no idea how much time I've taken, so I don't know if I'm --

MR. MITTELBRUN: Tania's watching.

MR. JERE PALAZZOLO: Four minutes left? Perfect. Thank you very much. It will further enhance Michigan. Michigan is well-known throughout the country as a leader in health care. This will enhance that and it will actually provide a very, very positive impact both economically, culturally, jobs, housing, commerce and the like. So it's going to be a real positive enhancement both to health care as well as to the community and it will help existing providers.

So let me just run through it really quickly. Padre Pio, he was a miracle worker. He had the stigmata like Christ. He's the only priest in the church that ever had that. It's a clinic for the body and the soul, Vatican-owned, very unique. The prayer groups I told you about. They're already in existence. That (indicating) is a picture of a young Padre Pio. He died in 1968. That (indicating) was San Giovanni Rotondo when he went there in 1916 and this (indicating) was the church that opened up in '56, a 300-bed hospital which is now a 1,000-bed

international referral center. It was built in a community of only 3,000 people and now you can see 1,000-bed hospital, huge complex, and very world renowned, 150 journal publications, but they don't have a medical school. So that's another thing. The exchange programs and affiliations with us through them is something they've never had, which will really be something unique for the state of Michigan.

And basically he said this is not just supposed to be a model clinic. This is pushed to be the reminder of the love of God, through the call of charity. This (indicating) is our vision. It was said by Dr. Sanguinetti who built the hospital for him in 1950, six years before they opened; basically that the Casa Sollievo della Sofferenza would be the first link in a great chain.

"The model for many other, innumerable casas with the same name and above all the same spirit, which must bring love to all of humanity. A program which would make us tremble with awe, if it was not inspired by God."

It was basically a prediction that this would be a model that would be replicated around the world. We formed a Collaboration Agreement. This (indicating) was the collaboration program that we had. This is our model that we're talking about, built upon the "Loyalty to the

Magisterium of the Church" with the hospital, the medical school, and the Catholic network. We built a clinic as a first fruits down in the poorest of poor areas in Appalachia with the bishop in the Diocese of Lexington. And this is what we're proposing here under the leadership of Bishop Earl Boyea with Catholic Healthcare International, the Casa over in Italy. Again, I don't have time really to go into, but the Terri Schiavo Life & Hope Network is a -- you might remember the Terri Schiavo case down in Florida.

They're a part of our team because they have a unique program to be able to care for people end of life, brain damage and things like that. It doesn't, again, exist anywhere, but it's going to be a part of our program. And the Christ Medicus Foundation which is to develop physician practices and that. Bishop Boyea has donated land for us outside of Howell, Michigan, to build this and this is essentially -- that's the Casa Hospital.

That's the replica of the pilgrim shrine that we'll build and essentially the medical school, and that's the picture of our vision. I don't have time to go over this again. I said it before, you know what we're looking for. If you have questions, we'd be happy to ask. And this (indicating) is what Padre Pio basically said the first time he met with the people to build this hospital. "This evening my earthly Work has begun." He called it the most

important work he ever did. And bless you and all those who will help us to make it bigger. Thank you. If you have two minutes, I'd like to have Bishop Boyea say a couple of words.

BISHOP EARL BOYEA

BISHOP EARL BOYEA: Well, thank you very much, Jere. I appreciate that. If this is the work of God, well, then if it happens, it happens. And I'm just relying on God's grace in this matter, so we'll see where this goes. My primary -- I'm really looking forward to the possibility of a medical school more than anything else frankly on this. But any way in which we can serve those in need, the poor -- it's our tradition.

It's what we do. It's what we've always done and it's what all of our Catholic hospitals are doing, is to try to serve those in need. And so if we can advance that a little bit, I'm very happy to do that. Thank you.

MR. MITTELBRUN: Thank you.

MR. JERE PALAZZOLO: If anybody has any question, we'd be happy to -- I just appreciate the opportunity to come and share that which you wouldn't have gotten out of reading the application, I don't think.

MR. MITTELBRUN: Any questions? Thank you for your presentation.

MR. JERE PALAZZOLO: Thank you very much.

Appreciate it.

MR. MITTELBRUN: Legislative report. Mr. Lori?

MS. NAGEL: He is not here.

MR. MITTELBRUN: Okay. Assuming there was nothing to report then. Administrative update, planning and access to care section update. Beth?

MS. NAGEL: I will just let you know that we solicited nominations for the MRT SAC that you charged the department with forming at the February meeting. We are hoping to get started soon on the Psychiatric Beds SAC as well. That's it.

MR. MITTELBRUN: Okay. The CON evaluation section update. Tulika?

MS. BHATTACHARYA: This is Tulika. The reports are in your packet. They're kind of self-explanatory. I just want to touch base on the statewide compliance review plan for this year. So the department plans to and proposes to do the statewide compliance review for the following services in 2018: NICU beds, Special Care Nursery Services, Computed Tomography scanner services, and Open Heart Surgery services. We'll bring back the updates on how the compliance reviews are going and provide you summary reports at future meetings.

MR. MITTELBRUN: Okay. Thank you. All right. Compliance report, that's a written report, both written

reports, Quarterly Performance Measures?

MS. BHATTACHARYA: Yes.

MR. MITTELBRUN: Legal Activity Report?

MR. POTCHEN: This is Joe. We continue to assist the department in the development of standards and there is no active litigation.

MR. MITTELBRUN: Future meeting dates, same as already provided. No changes at this time. I do not have any other additional public comments or public comment cards. Review of Commission Work Plan, Brenda?

MS. ROGERS: This is Brenda. You do have the draft work plan in your packet. The only change to that, based on today's discussion, instead of taking proposed action on BMT language the commission agreed to seat a SAC, so that will be reflected on the revised work plan. Thank you. You do need to have a motion to accept if there's no discussion.

MR. MITTELBRUN: Any discussion? Motion to accept the work plan?

MS. CLARKSON: So moved. This is Commissioner Clarkson. So moved.

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

MR. MITTELBRUN: Any further discussion? All those in favor?

(All in favor)

MR. MITTELBRUN: Any opposed? Motion carries. Next, election of officers. We need a chairperson and a vice chair. I will take my prerogative and nominate Commissioner Falahee to serve as chairman. Any seconds?

MR. HUGHES: Second.

MR. MITTELBRUN: Any other nominations for --

MS. ROGERS: This is Brenda. Who was the second on that?

MR. HUGHES: I would second it as long as he buys everybody on the commission dinner at --

MR. FALAHEE: Right after you compete in the --

MR. MITTELBRUN: It's been moved and seconded. Any other nominations? Seeing none, all those in favor?

(All in favor)

MR. MITTELBRUN: Any opposed?

MR. FALAHEE: I abstain. I abstain.

MR. MITTELBRUN: You abstain. Next is vice-chairman.

MS. BROOKS-WILLIAMS: This is Commissioner Brooks-Williams. I nominate Thomas Mittelbrun.

MR. HUGHES: Second.

MR. MITTELBRUN: Any other nominations? Seeing none, --

MR. HUGHES: Nice job today, by the way.

MR. MITTELBRUN: -- all in favor? Thank you. Oh.

I've got to abstain. Sorry.

(All in favor)

MR. MITTELBRUN: All opposed? All right. Thank you. Any other business?

MR. FALAHEE: I just recall Mr. Hughes' comment, "never do a bad job well."

MR. MITTELBRUN: All right. Looking for a motion to adjourn.

MS. CLARKSON: So moved.

MR. FALAHEE: So moved.

MS. BROOKS-WILLIAMS: Support.

MR. MITTELBRUN: All in favor?

(All in favor)

MR. MITTELBRUN: Thank you everybody.

(Proceeding concluded at 12:52 p.m.)

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