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

COMMISSION MEETING

BEFORE JAMES FALAHEE, CHAIRPERSON

333 South Grand Avenue, Lansing, Michigan

Thursday, June 13, 2019, 9:30 a.m.

COMMITTEE MEMBERS:	THOMAS MITTELBRUN, III, VICE CHAIRPERSON DENISE BROOKS-WILLIAMS J. LINDSEY DOOD TRESSA GARDNER, D.O. DEBRA GUIDO-ALLEN, R.N. ROBERT L. HUGHES MELANIE LALONDE AMY L. MCKENZIE, M.D. STEWART C. WANG, M.D., Ph.D.
MICHIGAN DEPARTMENT OF ATTORNEY GENERAL:	MR. CARL HAMMAKER (P81203) Corporate Oversight Division PO Box 30736 Lansing, Michigan 48909 (517) 335-7632
MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES STAFF:	TULIKA BHATTACHARYA BETH NAGEL TANIA RODRIGUEZ BRENDA ROGERS
RECORDED BY:	Mary J. Johnston, CER 6744 Certified Electronic Recorder Network Reporting Corporation Firm Registration Number 8151 1-800-632-2720

TABLE OF CONTENTS

		PAGE
I.	Call to Order	3
II.	Review of Agenda.	3
III.	Declaration of Conflicts of Interests	5
IV.	Review of Minutes of March 21, 2019	5
V.	Megavoltage Radiation Therapy (MRT) Services/Units Public Hearing Summary.	6
	A. Public Comment	
	B. Commission Discussion	7
	C. Commission Final Action	7
VI.	Bone Marrow Transplantation (BMT) Services Standard Advisory Committee (BMTSAC) - Final Report and Draft Language.	8
	A. Public Comment	18
	B. Commission Discussion	
	C. Commission Proposed Action.	
VII.	Psychiatric Beds and Services Workgroup - Final Report and Draft Language	36
	A. Public Comment.	50
	B. Commission Discussion	43
	C. Commission Proposed Action.	
VIII.	Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services/Units Services - Draft Language.	64
	A. Public Comment.	
	B. Commission Discussion	
	C. Commission Proposed Action.	

IX. Legislative Update. 66
X. Administrative Update 68
A. Planning & Access to Care Section Update
B. CON Evaluation Section Update
1. Compliance Report (Written Report)
2. Quarterly Performance Measures (Written Report)

XI. Legal Activity Report (Written Report). 69

XII. Future Meeting Dates. 70

XIII. Public Comment. . . . . .

XIV. Review of Commission Work Plan. 70

XV. Adjournment 72

Lansing, Michigan

Thursday, June 13, 2019 - 9:32 a.m.

MR. FALAHEE: So let's call the June meeting of the CON Commission to order. We have six commissioners present so we have a quorum. We have more on the way we are told so we'll start in being respectful of everyone's time. I'll welcome everyone to the June meeting of the Commission. Heads up. To my right three out of the four people are walking or sick or injured, wounded and I think Tulika who just walked in with crutches, I think it was that last Bronson Certificate of Need application that we filed that did her in, that caused her to drop so I apologize for that. No. Thank you all for being here in spite of being sick.

So let's get the meeting together. In front of us as the Commissioners you have at your place as always the most current updated final agenda. Entertain any comments about it. If not, I would entertain a motion to accept that agenda as presented. As a reminder, we have a new court reporter with us today so our veteran reporter is not here so we can be somewhat lax in not identifying ourselves. She knows who we are. She does not so make sure you identify who you are that's speaking so we can have it on the record. I would entertain any comments about the agenda or a motion to approve.

MS. GUIDO-ALLEN: Guido-Allen; motion to approve

agenda.

MS. LALONDE: Lalonde; second.

MR. FALAHEE: Motion on the floor to accept the agenda. All in favor say aye.

ALL: Aye.

MR. FALAHEE: Any opposed? Okay. Move forward.

(Motion carried at 9:34 a.m.)

MR. FALAHEE: Next, Declaration of Conflicts of Interests. We all know the requirements about Conflicts of interests. Does anyone at the Commission meeting, at the Commission have any conflicts of interests they wish to declare at this time? Great. We'll move on from there. Let's move on to the review of the minutes. Back in March, it seems like it was only yesterday, but the minutes for the March 21 meeting are in front of us today. I ask if there's any comments about those minutes. Otherwise, if there aren't any comments, I would entertain a motion to accept the minutes as presented before us.

MR. MITTELBRUN: Mittelbrun; motion to accept the minutes as presented.

MS. GUIDO-ALLEN: Guido-Allen; second.

MR. FALAHEE: Motion on the floor to accept the minutes. All in favor say aye.

ALL: Aye.

MR. FALAHEE: Opposed? That motion carries.

(Motion carried at 9:35 a.m.)

MR. FALAHEE: Next we move into the first of a few substantive items and then the always important administrative items as well. But we start with the MRT, the megavoltage radiation therapy. We are going to turn it over to Brenda to talk about that. So Brenda, please.

MS. ROGERS: This is Brenda. Do forgive me if I start coughing. I am no longer contagious. I do promise that. So at the March commission meeting we took proposed action on the MRT services. A public hearing was held on April 25th. As a result of that public hearing there was testimony received from three separate organizations. Testimony was all in support of the language that you move forward. So today the department is recommending the Commission to take final action on the language as you moved it forward in March.

If you do take action, final action today, it will be sent to the joint legislative committee and the governor for the 45 day review period. Thank you.

MR. FALAHEE: Thank you, Brenda. Any questions about that? In terms of cards, so far I only have one card on MRT and David, just confirm, you don't need to speak. You're just -- Spectrum is in support?

MR. WALKER: That's correct.

MR. FALAHEE: Thank you. So I don't have any

cards, other cards on MRT unless there's anyone out in the audience that would like to speak. So no public comment. Then we'll move that into any Commission discussion. Does any member of the Commission have anything they want to ask about, question about or talk about the standards before we put it up for a motion? Okay. I would entertain a motion regarding what the Commission would like to do regarding these standards.

MS. BROOKS-WILLIAMS: Commissioner Brooks-Williams. So our options are?

MR. FALAHEE: The options are we could throw it out completely and reject it. The other option is we would accept it as approved and then as Brenda said, this would be for final action because it's already gone out, as Brenda said, for public hearing. So we would accept it, take final action and then since it is final action, it would be forwarded to joint legislative committee and the governor for their 45 day review period.

MS. BROOKS-WILLIAMS: So I move that we accept it as a final action and move to the joint legislative committee for the 45 day review.

MR. FALAHEE: And the governor as well, I bet.

MS. BROOKS-WILLIAMS: And the governor as well.

MR. FALAHEE: Any support for that motion?

MR. WANG: Wang; second.

MR. FALAHEE: Thank you. Any discussion? We have a motion on the floor. All in favor of the motion please say aye.

ALL: Aye.

MR. FALAHEE: Any opposed? That motion carries. Terrific. Thank you.

(Motion carried at 9:38 a.m.)

MR. FALAHEE: Moving right along, we get into the Bone Marrow Transplantation Services standards advisory committee which is a mouth full otherwise known as BMTSAC, otherwise known as CAR-T, otherwise known as I think IECP. You name it, we've got an acronym for it so I apologize for that. Let me turn it over to Brenda or Beth. If you want to tee it up and introduce Dr. Stella who I know is -- Brenda or Beth, you want to comment on anything?

MS. ROGERS: This is Brenda. I don't really have any comments, per se, but I would like to thank the SAC for all of their hard work that they did on this subject matter. I believe Dr. Stella is going to be giving the presentation to the Commission. Thank you.

MR. FALAHEE: And we'll bring Dr. Stella to the podium. I again want to thank Dr. Stella. Doctor, you barely a year go in March after we had the first discussions about CAR-T and we had physicians on either side of the issue. I approached him after the meeting and said your

penalty, you guys, for doing this was to be appointed as the co-chairs of the SAC and they were and they did a great job, so did the other members. Knowing Phil and Joe you won't be surprised to know that they are super achievers. They didn't wait for the six month period to get over.

They got done early. I appreciate Dr. Stella being here. I know this is clinic day for him, but I told him it would be important for him to be here if he could at all so we as commissioners can hear about it and we can ask him any questions. As we ll know, normally witnesses are held to three minutes, but in cases of this and our next speaker, that three minute rule does not apply. So Phil, Dr. Stella, the floor is yours. And again, thank you very, very much.

DR. STELLA: Thank you. You have in front of you I believe the review of our SAC and also the draft language that you'll be entertaining a little bit later. This is -- our charge basically was to look at CAR-T cells based on the toxicity and expense associated with these therapies should they be under the CON regulation. So there was a number of things that we discussed. We had a great panel that included those that were part of bone marrow transplants programs and were doing these CAR-T treatments and we had some representatives from the community of community physicians and oncologists that had a stake in immune

therapy.

We also had members from insurance and other stakeholders as part of the panel. So it was a very good one. Part of the time we were talking about educating about the CAR-T cells. You should know that this is a rapidly changing field. While we were in deliberations, Medicare came out with a statement that really helped us in our process. They talked about -- in their statements, it was a recommendation that's waiting for some feedback about the policy for coverage for CAR-T type therapies.

In that statement they talked about something we were in the midst of discussing, the accreditation by FACT which is an accreditation body for looking at -- in the past it was always bone marrow transplants so the transplanters on the committee were very comfortable with FACT accreditation. This is a multidisciplinary accrediting body that does this and has been doing it for years for the bone marrow transplanter. With the advent of some of these very powerful immune therapies, they develop within FACT an immune effector pathway that is separate from bone marrow transplant recognizing that these are different therapies.

So this fit very nicely with what the panel was discussing in terms of this was very -- this is very complex therapy that requires a multidisciplinary team basically hospital based to insure safety with these drugs because

many of them need to be admitted to the intensive care units and things if they have certain types of toxicities. So these therapies as they currently stand are going to need really the kind of treatment that is done in a facility as opposed to a totally outpatient program. Some of the treatments, however, can be done as an outpatient.

We thought that these immune effector strategies were different enough from bone marrow transplant that instead of putting a CON under the transplant, doing this under this transplant CON, it probably should have its own CON. We did feel for purposes of tracking and insure safety, that it should have a CON and that there was a compelling interest in making sure we could track these programs and make sure they were fulfilling their obligations in terms of the safety and the criteria that was needed.

We felt that the FACT accreditation which is a very laborious, very intricate accreditation that you have to go through was sufficient for to prove this institution or facility was going to be able to do this in an appropriate matter. This had to do with pheresis of the cells and collecting the cells and then administering them after they'd been manufactured with a company. So that if an institution or group had decided that they wanted to do this immune effector type therapies typical for -- a typical

example would be CAR-T cells. But if they wanted to do that, they first needed to get FACT accreditation.

This is something that the pharma companies that are producing these products require anyhow, yet in the Medicare proposal for coverage they were suggesting that a group should have FACT accreditation in that proposal for Medicare. That was our feeling on the group that to assure the safe delivery of these products, that FACT accreditation was crucial. We did not believe that it should be limited to a certain number of sites because this is going -- the indications right now are for lymphoma, ALL and patients who had previous treatments. The new indication would likely come down assuming for multiple myeloma.

That's going to expand the use of this. As this area evolves, what's going to happen is they're going to certainly have more indications for this in the future, so we did not want to limit access. There was a strong feeling amongst those that were doing immune effector therapy as well as those from the community. So the bottom line is we indicated that in our recommendations and as reflected in the proposed document you have that it would not be limited in terms of the number of sites, but the sites who are interested in doing this needed FACT accreditation before proceeding.

This is an -- accreditation runs to over 300 pages

and a number of things. It is very onerous. It's not something that Mom and Pop operation is going to do on their own and you really do need the help of an institution or hospital system to be able to do this. Because when they come in and do the FACT accreditation, it's not only looking at the pheresis or the collecting of the cells but also your ability to handle the toxicities. So what you have in front of you in terms of the draft language reflects that the only criteria is that they meet FACT accreditation, but don't get me wrong. That is one heck of a criteria because it is a very, very stringent and difficult to achieve and, frankly, a costly type of accreditation to do.

You have to have five per year of these CAR-T cells patients per year to apply for FACT. Some groups with FTA approval will start to do this, but you have to do five and then apply for FACT accreditation and then you have to do five over three years to be fully accredited. So in the language it's talking about applying for FACT accreditation in this process, but the accreditation will come later. Most groups I think including our group at St. Joe's Ann Arbor will get involved with this with clinical trials where very, very stringent approval process going on through IRB and the like.

It will require a great deal of infrastructure to meet the FACT accreditation and to be able to do the

clinical trial which will get us involved and be able to help us get the five patients to apply for FACT accreditation. So that's basically it. There's other areas in immune effector therapies to apply to, CAR-T being one, but as an adoption of cells to stimulate or to increase the immune response to these malignancies. We took out some of those class of drugs including vaccines and including something called Provenge which is already on the market and a number of places are doing it.

It doesn't have the same consequences as the immune CAR-T cell therapy. So with that, you have the language. You have our statement and the language of the proposal and I'll be happy to take any questions.

MR. FALAHEE: Thanks, Dr. Stella. I appreciate it. Excellent explanation. Any questions of Dr. Stella?

MR. HUGHES: Yes. Thanks for your report. Is there anybody currently that has that accreditation?

DR. STELLA: Yes. The bone marrow transplant programs do have this. They have it for their transplant, but it's interesting. The audits that are done are done separately so they have been working with FACT for the transplant arm. The immune effector arm is looking at this adopted immunotherapy treatments. They already have that accreditation or they are applying for it and getting it. So the four bone marrow transplant programs.

MR. FALAHEE: Other questions? Commissioner Dood.

MR. DOOD: You mentioned FACT has been around for awhile and doing a good job. You anticipate that they will continue to be around for the foreseeable future and if they weren't, is there some backup we should have in these regulations?

DR. STELLA: Well, in terms of the bone marrow transplant they have been around a long time. And now you'll have it ensconced in Medicare policy if the final wording is approved, that it will have to get FACT accreditation. So I think given that, they're likely to be around for some time.

MR. FALAHEE: Commissioner Dood?

MR. DOOD: And you're okay that people would do this on an unlimited basis up until receiving accreditation? So you could do 50 in Year One, 50 in Year Two, 50 in Year Three, not get accredited and then what would happen?

DR. STELLA: That could happen, but you'll never convince one of the drug companies that are into this to do that. Basically they do require FACT accreditation now or that you -- they will come in and look at your facility, look at your pheresis capabilities, the safety, look at your ICU. They'll even talk with your CEOs and your executives on that side to make sure that you have the commitment, the institutional commitment to make sure that these drugs are

provided safety. These companies are not just letting this out. They've been very careful.

Of course, they started out in bone marrow transplant centers just because they were familiar with pheresis and there were some similarities, but FACT itself recognizes that there is significant differences between the two and that's why they developed an entirely different pathway.

MR. FALAHEE: Phil, I've got a question. Full disclosure, I have a nephew based in Boston that Dr. Stella happens to know. His business is inventing these therapies, so I've learned a lot from him over the last year. Help me understand. So what goes through an IRV process but then you mention the number of 5 and then you need to apply, so walk me through how that would work and it relates somewhat to Commissioner Dood's question about at what point do you need to get the approval or apply for the approval. Help me understand how that works.

DR. STELLA: So you have to have five so they can come in and assess how well you've done with those five, but you really have to set up structure to do those five and then you have to convince the drug companies not only to do it on a research basis which is an even higher level of oversight for the drug company and the FDA as well. Because the FDA has reporting requirements through all this for the

FDA approvement. So you do five. They want you to have some experience in it beforehand, so you basically have to set up the entire infrastructure that will allow you to get the FACT accreditation. Their number is five. They want to see how you do with that.

But recognize that beforehand you are going through a very rigorous process. You have to meet all the drug company requirements for safety and ability to do this whether on study or not. And then you have to meet the FDA requirements. The FDA requirements for ongoing reporting on every patient. That actually goes beyond even FACT accreditation.

MR. FALAHEE: Thank you. That's very helpful. Other questions of Dr. Stella? Commissioner Dood?

MR. DOOD: Relating to that, is three years enough time for someone to attain accreditation or would they be back to the drawing board if they had one minor stumble in terms of the timing?

DR. STELLA: They would have to go back to the drawing board. You have to have FACT accreditation to continue on with that. You apply after five and then you have three years of follow up that they do to get the final accreditation. But you really would have to go back to the drawing board on that. There's some good things about that. Because you want to have a certain number of these that

you've done so that you can do these safely. You don't want to have just one every year. You want to have enough volume so everyone is familiar with these patients and how to treat them. So five is what FACT came up with.

MR. FALAHEE: Dr. Stella, thank you. If you can stick around, I've got at least three or four cards from people that want to talk. Frequently we, as commissioners, will say duh, we don't know, let's bring Dr. Stella back to maybe answer that. So if you could stick around, that would be great.

DR. STELLA: I just want to recognize Joe Uberti, my co-chair, and all the panel members that were very helpful. It would hearten your soul to hear the discussion. It wasn't one about haves and have-nots. It was understanding that this is a very complex medical treatment that is moving and changing very quickly as we speak and how to do this safely was a prime consideration of the panel and then to make sure the patients had access. By the way, the costs will come down with time. Thank you.

MR. FALAHEE: Thank you. I've got a few cards. We'll start with David Walker from Spectrum, please. I usually take the cards in the order in which they were received so next up would be Tracey Dietz and then I've got at least one other here.

MR. WALKER: Thank you very much and good morning.

My name is David Walker. I'm here on behalf of Spectrum Health. I appreciate the opportunity to provide comment today on the CON restandards for immune effector cell therapy. First of all, Spectrum Health would like to thank BMTSAC for its diligence, cooperative attitude and attention to detail during their deliberations. The group of medical experts and representatives from purchasers, payers and consumers of health care were extremely thorough in their review and, in our opinion, have produced an exceptional recommendation in the uncertainty surrounding immune effector cell therapy.

Allow me to offer a few improvements for the Commission to consider. First I believe the Department may make a recommendation similar to this, but there are some specific lines in the language. 150 to 151 that should be updated to be consistent with the requirements included in the initiation section. This update will allow important medical research to continue. We also would recommend removing Line 159 through 160 which is Section 7, 3C which would prohibit providers from denying IECT services to patients with the inability to pay. While we recognize that this language is included in every other CON standard, IECT is not like every other CON service.

One of the very reasons it is critical to regulate IECT under CON is help control costs, control financial

sustainability of systems offering IECT. Not every patient should be treated regardless of ability to pay. The cost of treatment ranges from 378,3- to $475,000 for the medication alone. The hospital administration -- admission, excuse me, on top of that depending on complication could add hundreds of thousands of dollars in charges on top of medication. Total cost could approach $1 million. Supporting a patient requiring IECT should be sustainable -- would not be sustainable if insurance coverage or financial assistant through the pharmaceutical company were not possible.

For the workup prior to the IECT and follow up care could be costly. It's not always in control of the health system such as outpatient medication or other services provided outside of the hospital setting. The patient will need to be compliant with all care to assure survival outcome and potential is maximized. Even if the hospital were to provide certain care for the procedures and specialty care, this would not ensure their ability to obtain coverage for all necessary services. Although this provision is just an oversee on standards, it is not required by law.

MCL 33.22215(5) allows the Commission to include this provision, but it is not a requirement. We understand a desire to encourage care of provided services for the most needy. Spectrum has a long history of doing exactly that.

In Fiscal Year 2018 we provided over $480 million in community benefit. However, this requirement for this service in particular puts tremendous burden on the hospitals providing the services and could, in fact, discourage providers.

Again, thank you very much for the opportunity to speak on the CON restandards for immune effector cell therapy. I'd be happy to answer any questions commissioners may have, although I am not an IECT cell therapy expert.

MR. FALAHEE: Any questions for Mr. Walker?

MR. MITTELBRUN: I have one. David, I guess I'm a little confused. As you mentioned, those lines you want to remove are included in the other CON standards. What makes providing access to care for this particular item different than all the other ones, especially bone marrow transplant? Because I've been around a long time and I've dealt with bone marrow transplants for a long time in terms of paying for them and dealing with other things. I don't see this as any different than bone marrow transplants and I'm a little surprised by your recommendation.

MR. WALKER: Sure. And I certainly appreciate the question. I think what's different is that this is an extremely expensive therapy and treatment. With costs approaching $1 million, it may not be viable for some systems to be financially sustainable to be able to cover

that cost if the patient was unable to pay.

MR. MITTELBRUN: Once again, I relate this to bone marrow transplants. It was very similar when those started being utilized and the process they had to go through. They were very, very expensive because I used to pay those claims. Thank you for your comments, but I have to disagree.

MS. GUIDO-ALLEN: This is Guido-Allen. I'm a little concerned about your request to remove that. Again, with bone marrow transplant, what is the difference -- have you done an analysis on the difference between BMT and this therapy as far as cost given looking back at when bone marrow transplant was still relatively new?

MR. WALKER: No, personally I have not done an analysis. This is a recommendation that I believe -- that is solely focused on the impact of the treatment, the medication and the treatment adjusted cost. It does far exceed what BMT is, which is around about -- depending on if you do it in an auto and allo and I believe some of our medical experts could speak to this better, but it's about half that.

MS. GUIDO-ALLEN: Thank you.

MR. FALAHEE: Other questions? I'll just add my two cents worth. I am strongly against taking this language out. I think it's wrong to take it out. I think it sets up

potentially two levels of care depending on how much money you've got and this commissioner will not let that happen. Denise Brooks-Williams.

MS. BROOKS-WILLIAMS: So I guess I'll ask the question a little bit differently. If we leave it is, is it your concern that you wouldn't be able to accommodate those that are unable to pay through the charity care process? Because I'm assuming that that's what's being used for the other standards where the language is in. So maybe more education on the why. I understand the cost, not the cost but why there's the concern. Is it because you feel the demand will be so great and with the demand, that population is going to be more biased toward being uninsured?

MR. WALKER: I honestly that. I think that most patients that come for this treatment will have commercial insurance. I would guess, but I am not an insurance expert by any means and I would hate to misrepresent that. But my guess is it will be a small number that comes without the ability to pay, but I have not done an analysis on that either.

MS. BROOKS-WILLIAMS: I was just trying to understand personally. I was just trying to understand the motivation for the suggestion to take it out. If there was some data behind that, that would say why it was your concern.

MR. WALKER: I do not have any data in front of me on that.

MR. FALAHEE: Anybody else? Okay. David, thank you very much.

MR. WALKER: Thank you very much. Appreciate the time.

MR. FALAHEE: I have two cards from Tracey Dietz. Tracey, I don't know if you want to testify or not.

MS. DIETZ: I'll be brief, yes.

MS. ROGERS: This is Brenda. Just before the next speaker, just to let the commissioners know, the other suggestion that Mr. Walker made regarding Lines 150 and 151, that has to do with the IRB language. We had it in the initiation section but forgot to update it in the project delivery requirements, so the language you actually have in front of you has that correction already in there. Thank you.

MR. FALAHEE: So the Department knew what Mr. Walker was going to say. Okay. Thank you. Proceed.

MS. DIETZ: Thank you. Hi, I'm Tracey Dietz representing Henry Ford Health System. Thank you for the opportunity to speak and make some comments in regards to immune effector cell therapy. I'm not going to go into my detail in regards to the support of FACT accreditation and restandards, but we also support that. One of the things

that I'm not sure I heard today but I wanted to make sure to point out is while the manufacturers producing these drugs currently today require FACT accreditation, we are not sure what will happen in the future.

So that's one of the reasons we feel it is so important for these standards to be inclusive of FACT accreditation. It ensures that we'll continue to focus on the high quality care that FACT then allows for and drives. The other comment, quick comment we want to make is we are in support and agreement with those changes to Line 150 and 151. Any questions?

MR. FALAHEE: Any questions? Thank you very much. I see him sitting over there next to Dr. Stella, Dr. Greg Yanik, who must be a CON crazy person because he's here even though he didn't have to be. Greg, the floor is yours for at least three minutes.

DR. YANIK: Thanks, Chip. Thanks, Commissioners. I was in CON withdrawal so I thought I'd come down. This is Greg Yanik, University of Michigan. I just want to start by just saying that this is an incredible group. Phil and Joe Uberti just did an outstanding job pulling everything together. It's just amazing and I just want to thank them. I also want to state for the University of Michigan, for myself and the University of Michigan, we strongly 100 percent support the SAC recommendations that came out in the

document in front of you. I don't even need to use all my three minutes. To quote Mark Twain, if I only had more time, this letter would have been shorter.

But certainly the document that you see insures quality by mandating the FACT rule. It also will insure access. You can ask -- in fact, I thought I'd really come up here and just give you guys a chance to ask me questions. Because our centers now have 55 referrals for CAR-T therapy. We've done over 30 commercial CAR-T therapies, so the questions I've already heard, maybe you guys could ask me and I could address. The question from Commissioner Dood is three years enough? Will FACT be around? What percentage of 50 in the first year? Talking about our payer coverage and how often we receive denials.

I figure if you guys just ask me those questions, I could probably go over a lot of those things.

MR. FALAHEE: Thanks. Questions? Commissioner Dood.

MR. DOOD: Would you like to supplement or offer a different opinion on any of the questions I asked previously or would you agree with the earlier answers?

DR. YANIK: Actually, I echo a lot of what Phil said, Dr. Stella said. Three years is enough. Centers will apply for the CON approval to do this when they know they've got the foundation in place, the building blocks in place to

do it. Three years is actually more than enough from that standpoint to get FACT accreditation. FACT is actually becoming the JACO (phonetic) of cell therapy services. It actually was first founded in 1997 and now is accrediting hospitals, transplant and cell therapy programs around the country. Dr. Stella is correct. There's two different pathways for accreditation.

They accredit both transplant programs and they accredit cell therapy programs. You can be accredited as a cell therapy program without being accredited as a BMT program and visa versa. The accreditation is getting more stringent every year. It's now actually been recognized by multiple governing bodies and also by most insurers as a mandatory requirement. I actually do feel it is here to stay, almost like JACO. It's here to stay for the long run. What if the center did 50 in the first year and how would they ensure quality? One of the things that they've actually put into place is there is now a national data reporting site called CIMBTR.

All of our data -- FDA mandates that all of our data has to be put into that. And it gets published. You can see it as commissioners. If our center did say 50 next year and 40 of those patients died within two or three months, you'll quickly pick this up 'cause we have to report it in this national clearing house. So all insurers, all

payers would be able to see that also. Yes, you could do 50 in the first year. If your quality was marginal in those 50, oh, it would quickly get picked up 'cause it's readily visible because it's mandatory reporting of your outcomes. So that's actually a nice safeguard to have.

In terms of the payer coverage and denials, I looked yesterday just to see on this issue. Up through March we've had 55 referrals for CAR-T therapy. We've treated 27 patients, this is through March, with commercial CAR-T products. So what happened to those other 28 that weren't treated? 16 actually either were too sick to get it or just said no, I don't want to get it so 16 of 28 refused. Of those remaining 12, 4 underwent the collection and they couldn't actually generate a product, so about 10 percent of the time a patient comes to us. We'll put everything in the queue. We can't make the CAR-T product. Their immune system just won't allow it.

So the remaining 8 patients, either the insurance coverage -- there's either insurance denial or the insurance denial dragged on so long that the patients died while trying to get coverage for it. So we're looking at roughly the -- of the 55 referrals, we've got 8 patients that were either flat out denied from an insurance standpoint or the patients died while trying to get insurance coverage. It's a battle for us to get insurance coverage. I would say the

toughest one, and this is being recorded so I'll probably be shot for saying this, but for us two thirds of our referrals are coming from CMS, Medicaid and Medicare.

The toughest one for us right now is Medicaid HMOs. It's really -- in fact every Medicaid HMO referral we've had so far for CAR-T therapy has been denied. So yes, the language there is appropriate, but as commissioners, I think we need to go back to CMS and say, guys, how do we insure this to our patients. Fortunately the leadership of Michigan Medicaid, Dr. David Neff, is an incredible advocate for this. We went up and he personally met with us. He's actually been able to step in in multiple cases and come up with some novel contracting to ensure that Medicaid patients have access to CAR-T therapy. Dr. Neff should be lauded for what he's done.

But the Medicare HMO premiums as a whole just stop this stuff. So yes, I appreciate actually what the gentleman from Spectrum said. The costs are enormous. I can comment on costs compared to bone marrow transplant. Typical autologous transplant costs about 200,000. Allogeneic transplant about 400,000. CAR-T therapy, depending on the product, anywhere from 373- to 475,000. Hospitalization costs can run max about another half a million. But then there's the costs of the monthly infusions of what are called I.V. gamma globulin that these

patients have to get that cost $10,000.

So if this therapy works, these patients are literally mandated to get once a month infusions of antibodies, a transfusion of antibodies for the rest of their life, so approximately 120,000 a year for the rest of their life. So I do appreciate that that is a big burden for hospital systems to bear if we can't get insurance coverage for them. So I would ask the commission, everybody out here to put pressure on CMS and say, hey, guys, we have to be able to get access to all patients.

MR. MITTELBRUN: Mittelbrun. Doctor, of the patients who are going through the therapy or have gone through the therapy and continuing on with what you just described, what is the success of the program? Of the therapy?

DR. YANIK: So for ALL patients, so acute lymphocytic leukemia -- so right now CAR-T therapy is -- there's two commercially approved products, I should say. One for a kid with acute lymphoblastic leukemia and one for large cell lymphomas. Right now our response rates for our leukemia patients are 80 percent and for our lymphoma patients are over 60 percent. Now what remains to be seen, Commissioner Mittelbrun, is the durability of these responses. Okay? Meaning that we've all seen that you're targeting a specific protein on your own tumor. You're

hoping that all 1000 tumor cells have that one protein.

If 999 do, you failed because the one that doesn't eventually turns into 2, 4, 8, 16 and before you know it, a year, two years, four years from now you may relapse. So because this therapy is still new, we're still looking at the durability of it, but for just front line response, for many of these patients as they'll testify, it's either hospice or CAR-T therapy. So we're looking at response rates for a group of patients that are incredibly sick with very minimal other options. It's just astronomical. For me, in my career, 25 year career as an oncologist, this is the biggest game changer that I've seen.

I should also -- in fact, one of the questions, I'll just give you a question to ask me. Doctor, what kind of patient value are we expecting here in this state? It does in fact cost a little bit. I said we've had 55 referrals. That's just in the last year. One of the reasons this had to be open to all centers to at least have the ability to do this, our center alone cannot -- even the four transplant centers alone cannot handle the potential patient volume. Just looking at the number of live cell lymphoma cases, multiple myeloma, follicular lymphoma, acute leukocytic leukemia, a rough estimate is about 500 cases per year in this state, at least right now, could be eligible for CAR-T therapy if it were accessible in all centers.

That's a sizeable number.

MR. FALAHEE: Never had a witness ask himself a question. That's a novel way to do it so congratulations.

DR. YANIK: I disagreed with my answer.

MR. FALAHEE: Your alter ego disagrees. Any other questions? Commissioner Hughes?

MR. HUGHES: I realize this is new and everything, but could you be a little bit more specific in terms of how you're defining success?

DR. YANIK: That's a good point. So Commissioner Hughes, so for leukemia trials, we define success as 30 days after the therapy are you in complete remission. We're not even mandating partial remission or how you're define that in leukemia. No, 30 days after the cells have gone in, you take a patient that had refractory disease and put them into complete remission. That's our definition of success for leukemia. For the lymphomas, typically the success with the response metric is done at 90 days or three months. It just takes longer to kill lymphoma cells. They're defined typically as a radiographic response by a PET scan or CAT scan. Are you seeing a 50 percent shrinkage or more in the number of lesions or in the number of PET applications?

MR. HUGHES: Do you have any benchmark further down the road?

DR. YANIK: In terms of what we're trying to

achieve?

MR. HUGHES: No, in terms of -- instead of 30 days out, six months or --

DR. YANIK: Oh, I see. Yes, that's a good point. Yes, at our six month overall response rate, what are the chances for leukemia patients? That you be alive and leukemia free six months later. Nationally -- and our center is pretty close to this -- nationally it's just over 50 percent. What's happening is in that interim between the 3 and 6 months we're starting to see some of those escaped clones, that one out of 1000 cells that didn't have that target protein and started to come back. That's why I hate to say it. A lot of folks are just advocating and just, oh, when I think of this, that you get into remission with the CAR-T therapy and then those patients go right to transplant to mop it up.

Think of the cost that would be involved there. Many folks would come to talk to you right now and say that this is what our program does. We do CAR-T therapy and then before you can relapse six months later, we recommend that you clean up the rest of the escaped clones up with the transplant, adding on more cost. Our center hasn't taken that tact yet, but many -- even the NIH, that's what they're advocating, that you should do transplant as a consolidation. So durability of response yet remains to be

seen. Nationally it's around 50 percent at six months. It seems to be holding.

Those patients that get out six months at that 50 percent mark, at that point in time, it's like you're either going to get the escaped clone or you're not. We haven't seen late relapses. We started doing CAR-T therapy in 2014. We treated 11 patients in 2014. We're not seeing relapses now in 2019 from patients treated earlier. Typically you relapse in that first 6, 12 months out, if you're going to relapse. At least from my experience.

MR. FALAHEE: Other questions? Dr. Yanik, thank you very much. We appreciate all the work you've done on this. Thank you. I don't have any other cards, but let me look at Dr. Stella. Phil, do you have any other comments you want to add?

DR. STELLA: (Shaking head negatively)

MR. FALAHEE: Okay. Thank you very, very much to everybody that participated in this SAC. Thank you, Commissioners, for many, many good questions. So I will turn it over to Brenda to give us the options we have before us and then we can have discussion and then take action.

MS. ROGERS: You do have the language in front of you today. As I mentioned earlier, the only suggestion that was made we've already included in that draft language in the project delivery requirements. If you decide to move

this action language forward, you'll be taking proposed action. A public hearing will be scheduled and then it will come back to you at your September Commission meeting for potential final action at that point and/or if there's comments that come out of public hearing and deem to make some changes that are substantial in nature.

Then again, the process just picks up and it would go out for another public hearing, et cetera. So that's your first option. You can always outright reject the language. I don't see that happening, but that is another option. You can also move the language forward with other suggested changes that aren't already incorporated into the draft. So that is another option for you as well. Thank you.

MR. FALAHEE: Thank you for laying out all the options. Any Commission discussion before we take action? Many good questions so thank you for all that. Any discussion? I'm going to entertain a motion. Anyone care to make a motion?

MS. BROOKS-WILLIAMS: I move that we move the language forward for proposed action and move to public hearing.

MR. MITTELBRUN: Second.

MR. HAMMAKER: Chip, if I may. In addition to -- because this is a new standard, if I could have you

specifically move that the Commission determines that establishing a CON standard for IECT is necessary as well.

MS. BROOKS-WILLIAMS: May I add that to the motion?

MR. MITTELBRUN: Second.

MR. FALAHEE: Thank you. It's not too often we deal with new standards. Any discussion amongst the commissioners regarding the motion that's before us? If not, all in favor of the motion please say aye.

ALL: Aye.

MR. FALAHEE: Anyone opposed? That motion carries. It will go out to public comment.

(Motion carries at 10:23 a.m.)

MR. FALAHEE: Again, to the physicians and everybody involved, thank you, guys, very, very much. Appreciate all the work you did on this. Thank again. We'll remember you so next time we have a SAC and we want to finish early, I don't care what the topic is, we'll call on you. Moving on to our next important topic, Psychiatric Beds and Services Work Group, I'd like to invite and introduce Dr. Laura Hirshbein to come up. When I spoke with her months ago, I could tell this is a person very committed to the topic and she came highly recommended and she delivered on all those recommendations so she is here to present.

And we chatted this morning and Laura said, Chip, I don't have any slides. I said thank you for not having slides. She's here to present to the commissioners and as we did with Dr. Stella, we can then ask her any questions. Dr. Hirshbein, the floor is yours. Thank you so much for all the work you and your fellow members did on this important topic. Thank you very much.

DR. HIRSHBEIN: First I want to thank, the Commission for giving me the opportunity. This has really been an honor and a privilege to be attempting to steer this work group. This is a work group rather than a SAC and so apparently the rules are quite differently. We had six meetings of the work group over the time between August of 2018 and March of 2019 and about 90 people participated in one or more of the meetings. So at times it felt like herding cats because people were very impassioned, had lots of things to say, lots of strong opinions.

We had great representation from across the state, from providers, from payers and people really, really invested in trying to solve as much as we can where everybody recognizes is a crisis in the mental health in the state. I especially want to Beth and Brenda for helping us stay on track and helping us stay focused. Because at times the conversation got derailed to things that are not the business of the commission, so it was helpful to have them

reminding us that we're not going to solve all the problems of the state with this one work group.

We were given eight charges and I submitted a report of what our responses were to the charges, but I wanted to hit a few high points because they were involved in more extensive discussion. We had -- in addition to the big work group -- we had three subgroups that addressed very specific issues that were more time consuming. So probably the thing we spent the most time on was addressing the bed need methodology. So for that I'm profoundly grateful that we had the assistance of Paul Delamater who used to be in Michigan, is now at the University of North Carolina so we group him up here once in the dead of winter and also had him participate via phone.

He talked to the entire work group about methodology and also led a small work group to discuss changes. I'm not going to be able to do justice to his math or his stats, but in general what he did was recommend that we shift from the old system that hadn't been updated really in more than 20 years of doing the methodology differently for adult and pediatric psych beds. The old methodology for adult beds was basically based on population and that's it. For the child beds, it was based on utilization of beds in one year kind of projecting forward and estimating what the need would be in the future.

What Paul's group did was basically say let's look at utilization, how often are people actually using beds and looking at more data points. Instead of one data point in one year, looking at data over a five year period to kind of get more of a trend, how is this looking over time. That very nicely captured that there's been a significant increase in usage of psych beds, certainly over a five year period and much more over a bigger time period. I think that was really helpful because it put numbers to what I think we were all seeing which is an explosion in the need for psych beds in the state.

He put -- his group put forward very specific recommendations that are incorporated into the proposed standard changes. Again, I am very grateful for Brenda and Beth for translating his math into actual standards. So it's there. I think I get it. It does a nice job of showing the trends. The numbers, there's a combination of looking at sort of need over time and also distributing beds to the different health service areas in the state, so that's more technical and probably these guys could address those kinds of questions better than I could, but I could do my best if people have questions about that.

The other thing we looked at from both bed need and also in terms of topic was the special pool beds. So in 2015 there was a recommendation to create a special pool of

a different kind of bed that wouldn't come out of the general psychiatric bed need but for special populations. We haven't gotten a chance to really see how that effects what our bed needs are in the state because none of those beds have gone online yet so we haven't really felt the effect. The bed types that were created in 2015 were gero psych, developmentally disabled and med psych and based on a particular percentage of the total bed need in the state.

So the group is recommending that we increase the percentage of the total bed need in the state from 5 percent for those bed types to 7.5 percent, again reflecting the higher -- what we are expecting is a higher need for certain kinds of patient populations. One of the things that came up over and over again through all our discussion and charges was that a bed is not a bed, that there are general issues with psych beds, but also some patient populations are harder to place or some patients are harder to take care of and so we needed to really accommodate that as much as possible.

So while looking at bed usage overall was really helpful and using Paul's new methodology to estimate future needs was very helpful, it was also really important to take a look at what are the patient populations that are particularly hard to place. So in addition to the developmentally disabled which everybody recognizes are

particularly challenging patients to place, gero psych and med psych, we're expecting ongoing demand for that. We also propose a new category of special pool beds.

So the percentage came up in the bed methodology numbers, but the specific outline of that came up in a different work group, the special pool work group, subgroup, where we discussed what a high acuity bed would look like. So we are proposing a new category of special pool beds that we are designating high acuity that would address the particular issues that we heard in the state around patients denied admission from emergency departments because they're high acuity, people who are either aggressive or assaultive or very, very sick, very, very psychotic.

This was one of the bigger challenges to try to put our hands this type of patient population. How do you define it? One of the things that's tricky in psychiatry is we don't have the same kinds of lab measures. You can't say, you know, with a score of, you know, 8 on hemoglobin and whatever. It's a lot squishier. So with a lot of extensive discussion we were suggesting to define a high acuity patient as demonstrating three or more moderate symptoms or two or more severe symptoms of a list.

They include confusion, irritability, boisterousness, poor impulse control, uncooperativeness, hostility, verbal threats, physical threats, attacking

objects. High acuity could also include patients who are unable to refrain from harming themselves in the moment or patients who have a history of assault on themselves or others in a psychiatric hospital setting. That's still, again, very squishy, but it is somewhat evidence based. It's based on particular scale of the positive and negative symptoms, scale of hands, excitability component as well as the Broset violence screening.

So based on those two screenings, we were trying to define this higher acuity population. The number of beds we were recommending would be 10 percent of the total bed need. Then the final subgroup looked at comparative review criteria and they did an amazing job of really kind of looking at how you would compare applications for systems in any of these populations and really focusing on access, quality and cost.

They refined criteria and streamlined and instead of the pre-existing system that was very confusing, you know, you get some points for this and you get some points taken away for this, it's much more streamlined and clear for assisted health systems to use to help evaluate their program, again with the idea that we want to try to make it easier for patients to get the healthcare that they need. I can absolutely take questions about that, but I did want to call out there were a few things that the group continued to

come up against that we're hoping that the Commission can then take to other organizations within the state.

The issue of cost and reimbursement came up over and over and over again. The reimbursement for psych beds is not good. For high acuity patients it's really terrible. So we're hoping that's not a conversation really that we can continue to have within the work group, but that was outside of the scope. There's some way to take that to another agency. I know there was a much bigger conversation about mental health with the My Pad initiative in the state a year or two ago. So we just wanted to echo concerns about that, that cost is a big issue as health systems try to figure out how to accommodate patients. So thank you.

MR. FALAHEE: Thank you very much. And thanks to -- I didn't realize it was 90 people that participated, so thanks to them and thank you for herding that group. Appreciate it. Questions? Denise Brooks-Williams.

MS. BROOKS-WILLIAMS: So in Recommendation 7 where we talk about the new occupancy requirements -- and maybe this is a question for the Department. Part of the dilemma you describe is you talked about the populations and I think some of the challenges that are added, knowing some of our facilities where when you have those challenging populations, it really starts to affect the occupancy. So I was just curious how you guys came up with 60 to 40. Was

there any science behind that? Having flexibility with the occupancy rate, I think having it lower makes sense. Just curious about how those numbers were selected and if there's a different way to approach them.

DR. HIRSHBEIN: That's a good question and I think Brenda and Beth could probably answer a little bit more. I will say the two things that came up a lot in discussions around occupancy were accommodating high acuity patients which does a lot for -- a lot of the rooms in psych units, especially the older units, are double rooms. So a high acuity patient can't really share a room so a lot of health systems are having to have single occupancy so that really cuts down a lot. Then the new joint commission requirements around ligature risk are really affecting a lot of health systems and they're demanding a level of renovation that is out of scope for many health systems. So that was part of it, recognizing those two. I don't know if there was --

MS. NAGEL: I just wanted to clarify. The number didn't change from 60 to 40. It has historically been 60 to 40. What we did is add that for clarity.

MS. BROOKS-WILLIAMS: This reads like it says lowering it.

MS. NAGEL: You're right. You're definitely right that it does, so I just wanted to clarify that we didn't, but we just added it to Section 6, 7 and 10 for clarity.

DR. HIRSHBEIN: So was that my error in transcribing it or -- okay.

MS. BROOKS-WILLIAMS: This may be a question to the Department and I hope I'm framing this right. What I'm trying to have us think about is what may be within in our control. We want facilities to be able to be contemporary to serve the population, so what I don't want is for us to have a threshold that makes that difficult to do so maybe it's just a question to help us understand. I don't know what the occupancy rates are so let's begin with that, but because there's a number there, is that a restriction maybe is the way to ask it.

So would there have been consideration to not an occupancy standard as it relates to being able to build or modernize a unit, if that makes sense. So the units are needed. The units probably have occupancy rates that are low. I don't know what they are. They may fit this threshold. They may not. But before we would impose a number, just making sure we're not going to create an unintended consequence so that people can't create a modern facility because they don't meet the occupancy standards. Because you're trying to modernize to be able to accommodate more people or to be within standards for admission.

MS. NAGEL: Yes.

MS. BROOKS-WILLIAMS: And I don't know if that was

discussed in the work group at all as a concern.

DR. HIRSHBEIN: We didn't really have concerns. I think the question that continued to come up is how much the CON standards are actually a restriction because -- it wasn't clear that they necessarily were. Because the places that are really struggling are the places where there's a lot of demand anyway so they would be able to proposed increased beds based on high occupancy, but I don't -- we expressed concerns about modernization in the joint commission.

MS. BROOKS-WILLIAMS: So that's -- so if an organization came forward and they did not meet those occupancy requirements but they had to be if they wanted to update the facility, are there exceptions to that occupancy standard? I know you're puzzled. I apologize.

MS. NAGEL: That's okay. So you're saying if there's a facility that's not meeting the 60 percent?

MS. BROOKS-WILLIAMS: Right, in a hypothetical.

MS. NAGEL: But there is demand.

MS. BROOKS-WILLIAMS: Remember, if you're a facility let's say where you've got, you know, large development total delayed population and you're not -- and I worked in an environment. I just don't know the numbers, so that's why I feel a little hesitant right. At the facility I just most recently ran, we could have 55 percent. I'm

making it up; right? Because if you just look back over a year and you came to the door, we would still say we have high demand. We still have the requirement to have the literature requirements for fill, to want to renovate. So I'm saying I don't know if you guys can tell us, you know, who falls within and outside of those occupancy rates.

Because I think you might find facilities that describe themselves as having high demand, but they don't walk around knowing exactly what their occupancy rate is, not meeting that threshold.

MS. BHATTACHARYA: Excellent question. I don't know if Brenda is going to walk through the changes in the standards, but if you look at the replacement section, for example. So the requirement is 60 percent for adult or 40 percent for child. It goes on to say if a facility does not meet that occupancy requirement, then they would agree to reduce the appropriate number of beds to achieve that occupancy. It's not a denial, that you cannot do the project, but you have to right size your unit to meet that occupancy to get that approval.

In the future due to those replacement, relocation, acquisition number, new management, you know, you build up your occupancy. Then you can get more beds through the high occupancy language or if the new methodology produces more beds and you can request from the

pool.

MR. FALAHEE: Other questions? I've got a couple. On Paul's work -- and you've attached a chart here. I think it's part of your report. I don't think it was from the state. I'm not sure. But it shows the psychiatric proposed bed need, new methodology and it says Results. It looks like to me under the -- and you can blame this on Paul. Under Paul's calculations, almost all areas now will, under the new numbers, show a need for beds.

DR. HIRSHBEIN: That's my understanding. Yeah, it definitely projected the number upward. It wasn't huge, but it was significant.

MR. FALAHEE: Then there's a discussion here about mental health professional, how it's defined and whether you need to add certain people. Could you explain what was going on there, please?

DR. HIRSHBEIN: Certainly. So we were asked whether advanced practice providers, specifically nurse practitioners and physician assistants should be defined in the standard under mental health professional. While there was widespread agreement that middle providers would be helpful in the state as mental health professionals and pretty much everybody was enthusiastic by the idea, it turns out that the language in the CON standards doesn't help that at all. Because there were -- this is an arcane thing that

Brenda explained most clearly so maybe she can do it again.

It's basically we have the definitions up front, but the only place in the standard where the definitions are relevant defines mandatory requirements for child units. We don't want to mandate a unit to have an advanced practice provider if they don't want one. That doesn't make any sense. Other than that, it doesn't seem to matter. We couldn't override other parts of the state to call advanced practice providers physicians because other parts of the state have said they're not. We sort of felt that we were caught in the different somewhat conflicting standards around what an advanced practice provider in the state can do.

There's mental health code, there's something else and then there's CON. At this point we just sort of said, okay, it doesn't seem relevant to what we're doing right now. It's not going to help anybody. The best it could do is to hurt systems that want to build a child psych unit and we're not going to -- we certainly don't want to create any more barriers for that.

MR. FALAHEE: Going along with don't create barriers. So however it's defined, wherever, if entity says we need advanced practice providers, go ahead and get them?

DR. HIRSHBEIN: Yeah, absolutely. There's noting in the standards that says they can't.

MR. FALAHEE: Thank you. That's what I thought. Thank you very much. Other questions? Again, thank you very much. If you, too, could stick around. I have one card. Tracey from Henry Ford. I don't have any other cards so if anybody does want to comment, please submit those cards to Tonia.

MS. DIETZ: Good morning. Again, I'm Tracey Dietz with Henry Ford Health System. Thank you for the opportunity to share Henry Ford's position on the proposed changes to the psych beds and service standards before you this morning. Hospitals are experiencing more high acuity psych patients requiring one-on-one or private room type of arrangements. Many of the hospitals don't necessarily have infrastructure currently or private, semi private type rooms to accommodate these types of patients and are forced -- we're often forced to close beds to accommodate these patients.

These bed closures are significantly impacting the occupancy. CON should be encouraging providers to invest in their facilities to create private and semi private rooms and find other creative solutions to providing this care while maintaining the ability to keep all beds available. The recommendations includes modifications to the comparative reduced standards or criteria to in fact encourage some of these investments. However, the workgroup

recommendation also adds minimum occupancy requirements at the time of acquisition, replacement and relocation. This will strongly discourage facilities from making these improvements.

In order to build a new wing of a private -- with private and semi private rooms for example, a facility could be forced under these minimum occupancy provisions to de-license the very beds they're trying to replace with the new or -- the new construction or the renovations. As you know, the psych workgroup was initially proposed to be a standard advisory committee. Due to lack of nominations it became a workgroup. In the workgroup setting there's no vote when recommended changes are shared. While the discussion occurs, ultimately it's up to the leader of that workgroup to adopt the recommendations.

This particular recommendation we don't feel received enough discussion and we do not feel there's consensus to add it. The proposed requirements to have minimum occupancy of 60 for adult or 40 for pediatric beds in order to acquire, replace or relocate beds or be put in a position of reducing de-license beds or license beds. To achieve the new occupancy threshold at a time hospitals are trying to come up with solutions to accommodate increasing demand is counterproductive and limiting.

Henry Ford Health System does not support these

proposed occupancy requirements and request that the proposed language be removed from the proposed standards being shared and possibly voted on today. Thank you. Any questions?

MR. FALAHEE: Any questions? I guess I'm confused. I'm always confused. I don't understand the issue. If you're at X occupancy and let's say it's -- Commissioner Brooks-Williams used 55 so I'll use that. Okay. You want to build a new unit. As I take it, you don't -- and Tulika, correct me if I'm wrong. You're not at the requisite standard, occupancy standard. So you can always reduce the number of beds to be built in that new unit and then, if that new unit hits high occupancy, you can add new beds at that point. So what's the issue?

MS. DIETZ: True, there is that opportunity to do that, but by doing it in two steps, it potentially adds to additional cost in order to accommodate that increased bed number. In that type of situation, we would then be building out or remodeling an area to accommodate a larger number of beds so you're talking about -- and then having to go through the process of then moving -- I should say not even moving at that point but reestablishing those beds that we lost in this space. So what we're trying to do -- specifically at Henry Ford.

I can talk on behalf of Henry Ford. We often have

a high -- when I say high acuity, more volatile, difficult to work with patients that require us to have to close beds and that's a reality for us. While we still have the demand, though, too, and we're having to sometimes not accept patients into the floors. So we have the demand, but due to that complexity with the patient mix that we serve, it's creating that challenge or that difficulty for us to then place. There is interested in trying to accommodate and that accommodation will then require us to either remodel, renovate, build, but unfortunately, given these standards, it will limit us and we'll end up having to do that in a multiple step process.

MR. FALAHEE: Falahee again. As one who's gone through multiple step process multiple times, it can be done.

MS. DIETZ: It can be done. It's just difficult; time consuming. It takes a long time. And in the interim, it could potentially cause us to not be able to continually -- we'll end up with the same challenges we have now, not being able to meet the demand that we have.

MR. FALAHEE: Other questions? Thank you very much. Appreciate it. I don't have any cards. Dr. Hirshbein, do you want to make any comments in response to any of that?

DR. HIRSHBEIN: Sorry about the walking time.

That issue didn't come up at all in the workgroups. Absolutely the workgroup definitely is a different -- we do things more by consensus rather than the specific vote, but the specific issue of objecting to those numbers did not come up so I was kind of surprised to hear that as well. I don't have any particular attachment one way or another. The standard has to be adjusted in some way. You know, there has to be some kind of guidance. I don't know that any of the group was particularly attached to a number. As Beth and Brenda pointed out, this isn't really a change.

It's a clarification to carry standards forward into multiple areas of the standard as a whole. I did think that particular issue around high acuity patients and accommodating high acuity patients was the reason we wanted to create the special pool for high acuity patients. Because with that, then you can apply -- that's a very substantial number. Anybody who is anticipating a high acuity population, even if their existing unit is 50 percent, even if every bed in that particular health service area is open, they could still quality for high acuity area. I mean, we did try to address some of that.

Again, I don't really care about the numbers particularly. We wanted to make sure we did as much as possible to make it possible to take care of higher acuity patients.

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

MS. BROOKS-WILLIAMS: It's continuing to be confusing. This is a department question; right? I know in some other standards there's language about -- and this is specifically saying like going from an existing facility to a more modern facility with the intent of really just accommodating the demand that you have today, that maybe you aren't accommodating effectively, to have a one time relief from the occupancy standard? Is that -- I know it is other standards, but is that in something that would be able to be considered here? Would there be objection to that?

DR. HIRSHBEIN: I think administratively you guys have to --

MS. BROOKS-WILLIAMS: I think there might be --

MS. NAGEL: That was my thinking face, just to be clear. You know, I think that's a question for the Commission, if you wanted to add language.

MS. BROOKS-WILLIAMS: If we could have that --

MS. NAGEL: Yeah. There's nothing further to be met.

DR. WANG: Commissioner Wang. I just wanted to kind of get a little bit of a reset. My understanding is the pie for the total number of beds, using the new methodology around the state will go up substantially; correct?

DR. HIRSHBEIN: Uh-huh (affirmative)

DR. WANG: And then on top of that, despite these recommendations or requirements for minimal occupancy, the high acuity beds issue is a special pool bed that institutions, such as Henry Ford, could apply for?

DR. HIRSHBEIN: That's correct. And that's an extra pie. We have an extra pie. More pie for everyone.

MR. FALAHEE: Commissioner Brooks-Williams, did you have anything else?

MS. BROOKS-WILLIAMS: I'll wait.

MR. FALAHEE: Thank you very much. Let me turn it over -- let me ask Beth or Brenda. In terms of looking at that additional let's call it exception language I'll call it for shorthand, do you have an opinion one way or another? I mean, we just heard about the extra pie that's out there if someone needs it. So how does the ability to get the extra pie positively or negatively impact maybe an out clause in the standards?

MS. NAGEL: I think it's a great point that there are two pies essentially. And so someone could apply for those special pool beds. However, I think that the sentiment of the workgroup, not speaking on behalf of the workgroup but the sentiment was certainly not to hold back anyone from investing in psych units. And so with that, I don't think that there would be anything negative from

adding an exception.

MR. FALAHEE: This is Falahee. So hypothetically if the Commission approved this language and voted to send it out to public comment, hypothetically we could also instruct the department before it went out to public comment to add that language to see what the public comment was in response to it; correct?

MS. ROGERS: This is Brenda. That is correct, but we would want to make sure you're specific in the language that you want added.

MR. FALAHEE: Which hypothetically may require your help on making sure of that.

MS. ROGERS: Yes, all of us will get together.

MR. FALAHEE: Thank you. Takes many people to make two pies. Great. Any questions amongst the Commission members? If not, I'd entertain -- yeah.

MS. ROGERS: This is Brenda. Also just a reminder, especially for some of maybe the newer commissioners. Keeping in ming whether it's psych bed standards, ICE, ECT, et cetera, any changes in a standard are only proactive. They're not retroactive so they're only going to be applicable to somebody under those standards once they become effective. So just a reminder about that for everyone. Thank you.

MR. FALAHEE: Thank you for that reminder. It's a

good reminder. Commission questions, discussions/motion, carefully worded with the help of the Department?

MR. DOOD: Sorry, a little bit of a question, but we had asked the workgroup to add minimum occupancy requirements. That was part of the charge that were heard; is that true?

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

MR. DOOD: And now we're saying that maybe that wasn't a very good idea so let's add an exception? I'm just a little confused about why when we established the workgroup, we thought it was a good idea and now we're saying let's put in an exception. I'm sure there -- many of you are here to discuss. I just don't know the background.

MR. FALAHEE: This is Falahee. Any comments first from Brenda or Beth on that?

MS. ROGERS: This is Brenda. If I recall correctly on the minimum occupancy requirements, we do this in our other standards like hospital beds and I believe nursing home beds as well. So it was more for bringing everything into alignment and to clarify in the standards. It was already a requirement in the project delivery requirements, but it was carrying it through to acquisition, replacement and relocation. And I want to turn to Tulika in case I missed something in that regard.

MS. BHATTACHARYA: This is Tulika. Sorry, Brenda.

Am I explaining what?

MS. ROGERS: I just basically said that this came from the department. We do this in other standards and we were trying to make that clarity in these standards that minimum occupancy requirement should be met if you're going to be going through acquisition, replacement and relocation. It certainly wasn't to stop anybody from doing any of those things, but basically right sizing a facility which was a term that was used earlier. So I just turned to you to make sure that that was accurate or if I was missing something.

MS. BHATTACHARYA: No, you are absolutely correct. If you look at the current hospital bed standards which have been in place I think since 2012, has the similar type of occupancy minimum occupancy requirement. Before you invest in modernizing, replacing or acquiring, what is that bare minimum occupancy that you should be meeting before you invest. So that was one of the factors or the thinking behind proposing this or at least ask the workgroup to revisit these provisions.

The other factor that we have observed in the state that is happening more often now, there are zero occupancy beds, nonoperational beds with a valid license and without any minimum occupancy requirements, the department would have to allow acquisition, replacement, relocation of those beds because there are no requirements in the current

psychiatric standards. So when you think about exemption, please also think about that so if you are concerned about 60 percent and 40 percent, maybe you want to lower that.

I'm not quoting any number of maybe 30 and 20, but is it really okay for the state to allow somebody with zero occupancy or 5 percent occupancy to really allow to build a replacement facility or something like that because we are talking about investing capital and substantial amounts.

MR. DOOD: Commissioner Dood. Just a follow up question to that. So if we weren't meeting the occupancy requirements, let's say we're coming in at 40 percent but there was overall need, we could file for a CON for the same number of beds you have now. It would just be a different type of CON. It wouldn't be an acquisition or a replacement facility. It would just be a new facility; right?

MS. BHATTACHARYA: You mean requesting new beds from the departments inventory?

MR. DOOD: Yeah.

MS. BHATTACHARYA: Yeah.

MR. DOOD: You could get that even if your occupancy was low if there was a need?

MS. ROGERS: Uh-huh (affirmative)

MR. DOOD: So this just requires there to be overall need before you can follow these procedures for requiring or replacing something; correct?

MS. BHATTACHARYA: Yes.

MR. DOOD: And if there's need, you can get as many beds as needed.

MR. FALAHEE: This is Falahee. One thing that as a health care -- working for a health care provider, what you see going on and the worker excel at, mental health and the bed need for that as we've discussed at this commission for four years, we've seen that going up and up. In patient stays, down, down, down. So they're going in opposite directions, so that's why when I meet with legislatures as you'll hear the report later, their first question is what are you doing about psych beds. We need more. I say I get that. It's not the beds. It's the people to staff the beds.

MS. BROOKS-WILLIAMS: This is Commissioner Brooks-Williams. I think -- I don't know if it's the perfect answer as to why we should have an exception. One, I think I started right with asking the question. I don't know this -- right? -- but what does the 60 and 40 really look like against, you know, the performance of the facilities that are currently in operation? I think Commission Falahee's point earlier, we've all figured out ways -- right? -- to tier the replacement when we were not maybe there, you know, from an occupancy perspective but from a cost to the institution and a service -- a worker of over 90 people

talked about fully understanding the need in the end.

So it's one thing to do the right thing, not having to do it at an accelerated cost so it's not an exception to say have zero occupancy. I wish I had a number so I made up 55, 58, 59, something that's just short of 60; right? So the exception would not depend on how it was written imply to have no occupancy. It would simply be occupancy below the required. So I agree you would have an occupancy rate. Just simply saying you don't want to put a penalty there in a replacement scenario.

What you're doing with replacement configurations to try to get to, or maybe exceed the occupancy level because you'll have the beds assembled appropriately by being able to have a single room in order to meet the requirement. So that really is the logic model. It's just not to create the artificial barrier through the occupancy rate, but I would agree with you, Tulika. It's not to suggest you want no occupancy rate. It's just saying if there's not some specific science behind that number, not letting that number to be a trigger to say then you're thrust into either having to do an additional CON or whatever it is.

Not that that's an excessive loss or whatever, but you're trying to do it in two phases. So you can write the exception that will make sense that still has an occupancy

requirement. You could simply say if in a replacement scenario you're below the occupancy threshold, you're allowed to move forward and you meet it within some period of time when the beds come in compliance. It would be written in a way that still absolutely makes sense and doesn't put it into a case where it's a zero occupancy scenario.

MS. BHATTACHARYA: I see what you're saying. Okay. I now understand. Okay. So the 60-40, if you look at the project delivery requirements, that's the maintenance requirement for all adult and child programs in the state. And in the delivery requirements, even if you don't have this new language, it says if you don't meet that 60 and 40 percent requirement, you may -- I don't know if it says shall require to be licensed enough beds to maintain that 60 or 40 percent requirement for the psychiatric programs. So that's where it came from. We are asking to add that language in these other sections. That's where the 60 and 40 came from because those are the maintenance requirements.

MR. FALAHEE: Other commissioner discussion?

MR. DOOD: I'm just still under the impression that there is an exception if we were to -- there's already an exception if there's bed need. You just file a second CON to get those beds if they're available. Is that true?

MS. NAGEL: That is true. We publish all of our

data from our annual surveys on our website. Right now the most recent one is up and the vast majority of facilities are running higher than 60 and 40 percent. Certainly there are some that aren't, but --

MR. DOOD: Especially if we do this, the bed needs go way out so there's plenty of room for that, at least in the short runs. I'd like to make a motion, if I could.

MR. FALAHEE: Proceed.

MR. DOOD: That we adopt the workgroups' recommendation and send them on for public comment.

DR. WANG: Wang; second.

MR. FALAHEE: So we have a motion on the floor. Any discussion/questions? Hearing none, all in favor of the motion say aye.

ALL: Aye.

MR. FALAHEE: Opposed same side?

MS. BROOKS-WILLIAMS: I abstain.

MR. FALAHEE: Okay. Motion carries with Commissioner Brooks-Williams abstaining.

(Motion carries at 11:05 a.m.)

MR. FALAHEE: Thank you, Doctor, for all your help on this. Thanks so much and for herding cats and for herding 90 very helpful people, so appreciate all the work you've done. Thank you. Let's head now to the proverbial every agenda topic; Lithotripsy. Brenda will describe the

latest iteration of our eternal agenda item.

MS. ROGERS: This is Brenda. Maybe this will be it for awhile, but we don't want to limit ourselves. All right. So you do have some draft language in front of you. Minimal changes but basically what these changes are going to do is for fixed lithotripsy units, we're correcting the standards and reducing the volume requirement from 1000 down to 500 procedures which we did, if you'll recall, the last go-around of these standards for initiation for fixed lithotriptors. It just never got carried through the rest of the document. So instead of 1000, the minimum volume for fixed is going to be 500.

Then there was a clarity in Section 4 or 5. There were some words missing which was just an oversight so we added that back in to a new site. Under Section 7, 1C, again clarity for the language. We added some wording. A separate CON application has been submitted by the CSC in each proposed O site. Then also under Section 7, 7(3), again for clarity purposes, we added the language regarding the normal route schedule, et cetera. I think there's a couple other maybe miscellaneous type corrections in there, but overall these are the proposed changes to these standards.

So what you would be doing today is taking proposed action. These then would be sent out for public

hearing and then would be brought back to you again at your September commission meeting for potential final action. Thank you.

MR. FALAHEE: Falahee. Brenda, thank you very much. Any questions of Brenda? I do not have any public comment cards so if anyone would like to speak on it, let us know right away, please. Seeing no one and seeing no questions, any commission discussion? Otherwise I'll entertain a motion, please.

MR. MITTELBRUN: Mittelbrun. Motion to accept the language as proposed and move forward to public hearing.

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

MR. FALAHEE: Motion on the floor. Any discussion? All in favor of the motion please say aye.

ALL: Aye

MR. FALAHEE: Opposed? That motion carries. Thank you very much.

(Motion carries at 11:09 a.m.)

MR. FALAHEE: We'll continue with the rest of the agenda. The next item is Legislative Update. My name is next to that. There's been some changes within the department. I want to let you know that as chair of the commission, for years and as a member of the commission as well I will speak with legislatures and either proactively or in response to a request. As I said in March, I

testified in front of the Senate health committee at their request in January or February, I forget, and I testified not about CON but about hospital care, what's going on in the health care field. I said on here not to talk about CON, but I am the chair of the commission.

Then it got to question time. The first nine questions were on CON. So it's a keen interest on the Senate health policy committee. Since then the chairman of that health committee, Senator VanderWal has asked me to his office twice, once for half an hour and -- I don't know why because I inflicted enough pain on him and he wanted to invite me back for an hour. So I met with him now twice, him and his staff and some other people as well. Then two days ago I got another email from his chief of staff. Hi, Chip, how are you? What's going on at the commission? What are you going to do this week? What are you gong to do on CAR-T? Please call me.

So there's continuing discussions going on. As we talked about at the commission before and within the department, they know this, there is keen interest in the legislatures on the CON. Is it good, bad or indifferent? Should we keep it? Should we modify it? The question I get are the size of the commission, should we make it bigger? Smaller? What do we do about air ambulance? What about psych beds? That's the most common question I get. What

are we doing to increase the number of psych beds in the state? That's where I said, as before, it's not increasing psych beds.

We as a commission have done that every time we've been asked. It's getting the people to staff those beds. That's the issue. Then other questions come up about open heart and who knows what the next set of questions will be. So bottom line is keen interest in our House and Senate friends. I continue to believe there will be continued interest. I know in speaking with Governor Whitmer she is a strong proponent of CON and believes we need a strong CON program in this state. So that's my legislative update. I'd be glad to -- if the folks to my right have anything to add or if any of you have any questions, happy to talk about it. Okay. Move on. Next the Administrative Update. Beth, you're first, please.

MS. NAGEL: All right. So we are working to form a nursing home standard advisory committee. This is our third round of nominations. It started earlier this week I believe, and we'll close next week. We are very close, but we need additional experts and purchasers which are typically employers in order to round out the statutory requirements of that standard advisory committee. We are also working to kind of connect the last couple of dots on the CT workgroup as well, so that should be starting in the

near future.

MR. FALAHEE: This is Falahee. Let me add for the nursing home, we're trying to create as Beth said a SAC, three strikes and you're out. So if anybody is here from the nursing home community and you haven't responded to the now third invitation, please do so. Otherwise we'll create a workgroup. Any commission questions for Beth? Okay. Move on to the report from Tulika on the CON section update, please.

MS. BHATTACHARYA: This is Tulika. The written reports are in your packet. If you have any questions, I'll be happy to answer and update on the statewide compliance reviews. Our compliance analysts, Jack and Katie sent out the compliance questionnaire to the MRI facilities. We are getting responses, getting back responses. The questionnaire for the PET services will soon be sent out within a week or so.

MR. FALAHEE: Thank you, Tulika. I'll tell you, when you're on the receiving end of those emails from Jack or Katie and you see CON Evaluation Section Compliance Review or whatever, you're almost afraid to open the email. So they do come out. They're doing a very good job on the compliance piece of it. For those of you that don't know, many, many years ago the auditor general criticized the CON department for being lax in compliance and enforcement.

That is not true today. Carl, I'll turn it over to you for Legal Activity Report, please.

MR. HAMMAKER: This is Carl Hammaker. I have enclosed a Legal Activity Report in the binder you all received. There is currently one administrative appeal ongoing for disapproval of a CON occupation. I'll answer any questions that you have.

MR. FALAHEE: Commissioner Dood.

MR. DOOD: Any update from your status conference yesterday?

MR. HAMMAKER: Yes. The status conference yesterday, opposing counsel requested a 30 day adjournment, which was granted.

MR. FALAHEE: Maybe it will be resolved by the time we get together in September. Okay. Next item, future meeting dates. Just so everybody has it, these are not new. They have not been changed, but September 19 and December 5 for this year. So 19th of September and the 5th of December. Any other public comment? I do not have any cards. Any public comment? Okay. Brenda, turn it over to you for Commission Work Plan.

MS. ROGERS: This is Brenda. You do have the draft work plan in your packet. The only change that I'm going to state that I would see making according to what I gave you today, we do show a nursing home SAC meeting

starting in July. Given that we've had to send it back out, that meeting will not happen. They will most likely start in August. That would be the only change to what I presented to you today.

MR. FALAHEE: Thank you. Given that, I don't think we need commission approval of that kind of a change.

MS. ROGERS: No. It's just an approval of the work plan overall.

MR. FALAHEE: Great. Thank you. Any other commissioner -- yeah.

MS. ROGERS: This is Brenda. We need a motion to accept the work plan.

MR. FALAHEE: Motion to accept the work plan? Entertain that?

MS. BROOKS-WILLIAMS: Brooks-Williams. I'll move.

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

MR. FALAHEE: All in favor say aye.

ALL: Aye.

MR. FALAHEE: Opposed? Great.

(Motion carries at 11:16 a.m.)

MR. FALAHEE: We're at adjournment. A motion to adjourn, please.

MS. BROOKS-WILLIAMS: I move.

MR. FALAHEE: All in favor?

ALL: Aye.

(Motion carries at 11:16 a.m.)

MR. FALAHEE: Thank you everyone. Enjoy your summer.

(Proceedings concluded at 11:16 a.m.)

-0-0-0-