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

COMMISSION MEETING

BEFORE MARC D. KESHISHIAN, M.D., CHAIRPERSON

333 South Grand Avenue, Lansing, Michigan

Thursday, March 16, 2017, 9:30 a.m.

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	JAMES FALAHEE
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DR. KESHISHIAN: Call the meeting to order. I don't think there are any introductions this morning. Next item is Review of Agenda. Is there any questions about the agenda? Do I hear a motion to approve the agenda?

MR. FALAHEE: Falahee, motion to approve.

MR. MITTELBRUN: Second, Mittelbrun.

DR. KESHISHIAN: Thank you. Any discussion? All in favor say "aye."

(All in favor)

DR. KESHISHIAN: Opposed? Declaration of Conflicts of Interest? People can make any declarations now or at any time during the meeting if they feel they have a conflict of interest. Next item is Review of Minutes of January 26, 2017. Do I hear a motion to approve the minutes?

MR. FALAHEE: Falahee, motion to approve.

DR. KESHISHIAN: Do I hear a second?

DR. TOMATIS: Tomatis, second.

DR. KESHISHIAN: Any discussion? All in favor say "aye."

(All in favor)

DR. KESHISHIAN: Opposed? Next item is Urinary Extracorporeal Shock Wave Lithotripsy Services Draft

Language and Public Hearing Report. I'll turn it over to Beth.

MS. NAGEL: Good morning. The Commission too proposed action on the draft language of the December 2016 meeting. A public hearing was held on February 2nd, 2017. Written testimony was received by two organizations and those pieces of testimony are in your packet. The Department supports the language as written and presented at the December 7th, 2016 meeting. Department also supports a review of the testimony urging for a conversion from mobile to a fixed unit either for this update of the standards or a future iteration. If the Commission takes final action on the language for the standard as presented, the draft would move forward to the JLC and the Governor for the 45-day review period. If the Commission makes a substantial change to the language for the standards as presented and proposed action is taken, then a public hearing will be scheduled and the proposed language will be moved to the Joint Legislative Committee for review.

DR. KESHISHIAN: Thank you. Public comments. Mr. Meeker?

ROBERT MEEKER

MR. ROBERT MEEKER: Good morning. I'm Bob Meeker and I'm representing Greater Michigan Lithotripsy this morning and it's nice to be speaking before you again.

I'd like to just spend a few minutes talking to you about the history of the regulation of lithotripsy and how we got to where we are now. You know, originally some -- I don't know -- dozen or more years ago, probably more like 20, there were four fixed lithotripsy machines in the state all located at large teaching hospitals. Those first generation machines were huge, they were cumbersome, took up a whole room. They required the patient to be immersed in a water bath through which the shock waves were transmitted in order to treat their kidney stones. The CON requirement at that time for each machine was to perform at least 1,000 procedures per year, which was attainable at these larger centers. Over time a couple of things happened. The first alternative kidney stone treatments were developed that didn't require lithotripsy, and secondly the technology evolved becoming more effective and portable. And that's the key that how we got today. Because today the mobile lithotripsies that are serving the people of the state of Michigan are the state of the art machines that would be at major centers if they were fixed in major centers. They're wheeled right into the operating rooms of the host hospitals, and the practicing urologist at each host site have access to the best technology available.

Now, the evolution of lithotripsy is very different from the evolution of other services that are

regulated under CON that have a mobile component. And for all mobile services, of course, the units provide access to hospitals without fixed equipment. However, the other modalities like MRI or PIT, they serve primarily rural hospitals without the volume to justify a full-time machine and, when those rural hospitals make sufficient volume for an MRI, for example, they can then evolve to a fixed MRI. The mobile machines are constrained by the boundaries of the trailers that they're hauled in. They have to be sort of butted up against the side of the hospital, they're cramped, but they work and they work fine. But when there's a fixed MRI in the hospital. It can be integrated into the hospital, there's more room, better patient flow and that sort of thing.

In the case of lithotripsy as I just described, that has reversed that the mobile machines go into the hospital itself, and so they're integrated into the operating room of a hospital. Incidentally, the CON minimum for mobile lithotripters is the same 1,000 procedures per year as was previously the case for fixed units. This is in contrast to other CON requirements where mobile requirements are actually less than fixed.

DR. KESHISHIAN: If you could wrap up your comments?

MR. ROBERT MEEKER: I can certainly do that.

DR. KESHISHIAN: Thank you.

MR. ROBERT MEEKER: You know, there are several large volume hospitals in the state having, you know, over 300 procedures per year. Sparrow making the request to convert to mobile, from mobile, is one of them, but they kind of serve as the anchor unit for like the anchor store in a mall. If you take that anchor away from the route, the route -- I won't say it collapses, but the volumes would be lower and they would have trouble serving the smaller hospitals and the cost for the smaller hospitals would be less. So I think that, for the terms of both access, cost and quality, converting to mobile -- from mobile to fixed doesn't make a whole lot of sense and, as other people will talk about, it's more complicated than just saying, "Oh, now you can have a fixed."

DR. KESHISHIAN: Thank you.

MR. ROBERT MEEKER: And I'll take questions.

DR. KESHISHIAN: Are there any questions?

MR. ROBERT MEEKER: Thank you.

DR. KESHISHIAN: Okay. Thank you. John Shaski, Sparrow Health System?

JOHN SHASKI

MR. JOHN SHASKI: Hi. Good morning. My name is John Shaski, and I'm the government relations officer from Sparrow Health System. Sparrow appreciates the opportunity

to speak this morning on the subject of lithotripsy.

As we noted in our testimony during the public comment period and over the past year, the lithotripsy standards do not contain a provision to allow high volume sites to convert from a mobile to a fixed. Sparrow compiled patient data in lithotripsy volume over the past five years has never fallen below 500 procedures annually, and this is given a very limited schedule of six to seven days per month or about 84 days per year. However, the six to seven days per month equate to hundreds of thousands of dollars in lease fees every year. Specifically Sparrow pays nearly $800,000 in annual fees where a new fixed lithotriptor would cost approximately $600,000 one time. At the rate we are paying, we could have purchased over ten lithotriptors and had 365 days of access for our patients.

Lithotripsy is not a service that can wait to be received as the acute pain and discomfort that lead up to the need for procedures cannot be scheduled into six to seven days per month.

We ask for a consideration, support and a motion of the methodology being distributed this morning that would allow for high volume facilities to apply for a fixed lithotriptor after demonstrating consistent patient volume. This language would make lithotripsy standards consistent with mobile imaging modalities such as MRI, CT and PET

scanners. We appreciate your time and we welcome any questions.

DR. KESHISHIAN: Are there any questions?

DR. TOMATIS: I --

MR. MITTELBRUN: I -- go ahead. No; no. You first.

DR. TOMATIS: I have two questions. First, when you replace to a fixed unit, you don't keep the mobile unit, too?

MR. JOHN SHASKI: No, it would be a fixed unit would be the end.

DR. TOMATIS: And the second question is, how does this affect the people who use now the mobile unit?

MR. JOHN SHASKI: I can't -- I don't feel it's appropriate that I speak on behalf of the mobile provider. But I would say that looking at our volume over the past five and ten years that I would imagine that there is demand from other providers on our mobile route, and I would imagine that any opportunity that we left by achieving a fixed unit would provide a new opportunity for those providers on that mobile route more access for their patients as well.

DR. KESHISHIAN: Any other questions?

MR. MITTELBRUN: Tom Mittelbrun. You mentioned the $800,000 in annual fees.

MR. JOHN SHASKI: Yes.

MR. MITTELBRUN: And it would be a $600,000 one-time cost. But I'm assuming there's ongoing costs per year to maintain and operate that unit. So what would be in addition to the $600,000 or what would be your annual costs going forward?

MR. JOHN SHASKI: I'm unaware of any additional costs associated with the annual operation of the lithotriptor.

MR. MITTELBRUN: Okay. I'm just trying to compare apples to apples since you threw the numbers out there.

DR. KESHISHIAN: Commissioner Falahee?

MR. FALAHEE: This isn't a question for John so much as it is for the Department. We've received just now proposed language. We all know how at least this Commissioner thinks about language being thrown at us at the last minute because, it's strike one and strike two already and the fastball is coming in from Verlander as we speak. But a question for the Department: If the Commission approved this language, how does that work? Let's assume -- and not saying it's a given but, if we approved it, how does that work going forward?

MS. NAGEL: It's a good question. If you wanted to add any language to the standard today, you could do so. It would then go back to a public hearing -- it would

essentially start the process over. You would need to take proposed action, go to a public hearing, and then it would come back to you for final action at the next meeting which is June.

MR. FALAHEE: The other alternative would be not proceeding with this language which would then keep us on the same time track we're on now?

MS. NAGEL: Yes. You could -- you have the option today to take final action, because we have met the public hearing requirement and the proposed action requirement.

DR. KESHISHIAN: Commissioner Mukherji?

DR. MUKHERJI: So in the lexicon of a CON rule, is this considered a substantial change?

DR. KESHISHIAN: I won't even refer to the lawyer. Yes.

MR. POTCHEN: Yes.

DR. MUKHERJI: In the lexicon of CON language, is this a substantial change?

MR. POTCHEN: Oh, yes. The answer is yes.

DR. KESHISHIAN: Any other questions?

MR. JOHN SHASKI: If I may add one more comment?

DR. KESHISHIAN: Sure.

MR. JOHN SHASKI: Over the course of a number of years, we submitted testimony in October of 2015 aligning our situation, we submitted a number of nominations for the

SAC that was ultimately not set because of the lack of consumer interest in this, and we've provided testimony and comments during the public comment period as well.

DR. KESHISHIAN: Okay. Thank you. Doug Stairs, United Medical Systems?

DOUG STAIRS

MR. DOUG STAIRS: Good morning. My name is Doug Stairs. I'm with United Medical Systems. I'm the vice president of sales. I thank the Commission for allowing me to speak today. I'm speaking on behalf of Jorgen Madsen who has been to a number of meetings before, our CEO, who could not be here today, so I'd like to read a statement from him.

"I apologize for not being able to attend today's Certificate of Need Commission meeting but had previous commitments. However, I did not want to miss this opportunity to thank you for your continued support of the Certificate of Need Standards for Urinary Extracorporeal Shock Wave Lithotripsy Services and to reiterate our support for the language you passed at the December meeting.

It is my understanding that Sparrow Health System has requested a last minute change to the standards to allow for a mobile host site to convert to a fixed lithotripsy unit. I am not aware of any specific language they have suggested, but wanted to share my

concerns with this concept and approach. The system we have for lithotripsy in Michigan is one of the best examples of how CON helps to ensure broad access to high quality healthcare services while keeping costs down and changes need to be made in a very thoughtful manner.

CON has encouraged lithotripsy to become a mobile service in Michigan by requiring multiple inpatient facilities to collaborate and commit MIDB data to the initiation of a new service. Because lithotripsy is not a high volume procedure at any one individual location, it is ideally suited for mobile service which has led to a more efficient and effective means of providing this service to Michigan patients. Rather than each hospital purchasing this expensive piece of equipment and only utilizing it a few days a month, they can instead obtain the services from a mobile service provider and share the costs with all of the other facilities receiving service on that route. This has resulted in an expansion from 4 fixed lithotripsy units originally to 81 host sites in 2015. These sites range from large tertiary hospitals to small rural critical access hospitals, to freestanding surgery centers. The small rural facilities would never have enough volume to justify a fixed lithotripter, but

because of the CON system here in Michigan, now can provide this service to their communities as needed. In addition, the CON standards make it very easy for new host sites to be added to existing routes, encouraging broad geographic access to this service.

Allowing large volume host sites to convert to a fixed service would have a significant impact on existing mobile routes, likely jeopardizing at least some of them. By pulling significant volume off of a route it would likely fall below minimum volume, making them non-compliant with their CON approvals. This would also impact their ability to replace equipment as it ages and becomes outdated. All of this puts access to the smaller and more rural sites at risk and we ask that you take this into consideration as you deliberate Sparrow's request.

The system that is in place now not only provides for tremendous geographic access to this service, it also ensures high quality. By concentrating lithotripsy procedures across the State on mobile providers who provide their own technician to operate the equipment, these technicians have developed a proficiency that just could not be obtained if they were stationary at one facility performing lithotripsy procedures just a couple of days per week or just a

couple of procedures per day. In addition, the efficiencies created by this system has also resulted in much lower costs for the host sites by ensuring that utilization of each lithotripter is maximized and being able to spread those fixed costs over a higher number of procedures. In addition, if a facility needs more access, there are days available on the existing routes.

We believe that the modifications to the Standards that were already passed in December best meet the needs of the providers, patients, and payers in the State of Michigan as well as uphold the tenants of CON to ensure access to high quality healthcare at lower costs. However, if the Commission is interested in exploring Sparrow's request, we hope that you understand what a significant change this would be to the entire lithotripsy system across the state and ask that you proceed with caution. There are a lot of factors that would need to be considered and addressed in the process. We would be happy to participate in that process in whatever way you decide to proceed. This is most definitely not a simple change.

We hope that you will take final action on the proposed standards as written. I appreciate your time in considering these comments and the issue at hand.

Jorgen Madsen, CEO."

DR. KESHISHIAN: Thank you. Are there any questions?

MR. FALAHEE: Falahee. Does United Medical Systems provide the service to Sparrow?

MR. DOUG STAIRS: Yes.

MR. FALAHEE: And what's the impact if Sparrow went to fixed on the mobile routes?

MR. DOUG STAIRS: Well, the impact would be significant to us in the sense that we would lose, you know, obviously a large account with revenue that helps us pay our bills. So, you know, whether it would affect our volumes as they relate to the CON, I can't answer that question specifically today.

MR. FALAHEE: Thank you.

DR. KESHISHIAN: Any other questions? Okay. Thank you.

MR. DOUG STAIRS: You're welcome.

DR. KESHISHIAN: Commission discussion.

MS. BROOKS-WILLIAMS: Commissioner Brooks-Williams. So I don't know -- I ask this to the Department; right? When we collect data, I'm struck by the comment from Sparrow that they have an ongoing expense of $800,000 of the mobile. If they were to acquire the fixed, I don't know the full cost, but they said, you know,

$600,000 was the unit and then, you know, they'd have some ongoing costs. But if we're -- how do we create the value proposition around what is it costing us to have mobile versus fixed units? I mean, I'm slightly confused, because I know on the mobile unit there's fixed numbers of days. What Sparrow also introduced was, you know, that patient flow isn't necessarily always able to be managed on those fixed days when the volume gets to a certain level and what the cost is is concerning to me as well. Because obviously -- I'm not a mathematical genius, but I know what it means to pay $800,000 recurring versus documenting getting a fixed unit, but I don't know what it means to increase the cost to those that remain mobile. Right? So that part I don't -- because no one's giving us numbers on that. Is there any thought that you all have or anything that we are collecting now around costs this way versus what costs would be to convert in a different way?

MS. NAGEL: It's a great question. And unfortunately, I don't think we have what you're looking for to answer that. We don't collect cost data at this point. When we do our annual survey, we collect what is in the project delivery requirements of each standard. And so if the Commission were to put something in the project delivery requirements, we could then collect cost data. But at this point, we don't have that.

MS. BROOKS-WILLIAMS: Okay. Thank you.

DR. KESHISHIAN: Commissioner Mittelbrun?

MR. MITTELBRUN: Tom Mittelbrun. Just to comment on Commissioner Brooks-Williams' comment. The way I viewed the $800,000 annual fees included the people, the experts to do the work. So the 600,000 for a one-time fee I'm assuming is the equipment, but there's still going to be the cost for the people. And it's kind of the argument or the thought process you go through if you want to outsource something or keep it in house. If you outsource it, the people you're outsourcing it to are keeping the equipment up-to-date, the software up-to-date, their personnel license or whatever qualifications are required. If you do that in house, you then absorb all that cost of upgrading the equipment, keeping the people trained, if there's software or hardware, all those things. So, you know, the cost numbers we got, I think, are incomplete. I wish the gentleman from United Medical Systems had a little more detail of what the impact would have been to their mobile facility, because certainly we don't want to harm access to the rest of the community -- surrounding communities.

DR. KESHISHIAN: Thank you. Any other comments? Commissioner Falahee?

MR. FALAHEE: We've been given language by the folks from Sparrow, and I'm familiar with litho and mobile

litho. I also sit on the board of a company that delivers mobile MRI across the state of Michigan, and I'm familiar with mobile MRI versus fixed MRI and the differences between each. And I personally see the argument that Sparrow is making here. So for the sake of moving us forward, what I'll do is make a motion, if that's okay, with the chairman to approve the language we have in front of us as submitted by the Department but add to it the language that we have been given to us this morning from Sparrow that apparently amends Section 3.2 of those standards. I'm taking as given what Sparrow says for numbers and all that. But my motion would be to approve the language that was submitted to us with the addition of this language we've received from Sparrow.

DR. KESHISHIAN: Do I hear a -- and I would move -- I would assume your motion would also include moving into public hearing?

MR. FALAHEE: All of that.

DR. KESHISHIAN: Okay. Commissioner Tomatis?

DR. TOMATIS: I think we aren't very clear the argument is about a company losing revenue or access.

DR. KESHISHIAN: Is there a second to Chip's motion, first of all?

DR. MUKHERJI: I'll second. Mukherji, second.

DR. KESHISHIAN: Okay. Thank you. Yeah. That is

something the speakers talked about, but that's the information they provided us. I don't have any additional information to how to evaluate access that small hospitals versus the cost to Sparrow. We have the information that we have right now unless -- I don't -- I think the Department doesn't have any additional for us.

MS. BROOKS-WILLIAMS: Commissioner Brooks-Williams. I would agree with Commissioner Tomatis to say it's hard -- and I don't know the path that we're setting this on -- right? -- if we approve the motion, so I'm just going to ask. I would not feel comfortable -- I do understand Sparrow's request. I do understand mobile and fixed MRI and we figured out a way to live with both, so I don't think we can't figure out how to, you know, have fixed lithotripters. But I do think we need to know the answer to what is the impact of those that remain on the mobile route before we can say we're going to allow anyone to have fixed, not just Sparrow. And I think the economics make a difference, because I could hear what the company is saying about the loss of $800,000 but not my motivation because, if you're going to have whatever the operating costs, equipment, maintenance, so on and so forth, I'm sure when Sparrow does the P&L, the costs are going to be less to have a fixed unit. And so how will that be absorbed and are those other providers I don't want to compromise the access

for critical access facilities. So I do think somehow we have to know that or we're not staying true that what our responsibility is to keep the access and the cost and the quality consistent.

DR. KESHISHIAN: Commissioner Falahee?

MR. FALAHEE: Never let two lawyers talk to each other behind the scenes and whatnot. Mr. Potchen has made a good recommendation. And to get to what Commissioners Brooks-Williams and Tomatis just said, what I'd also like to do is add to my motion that the parties, whatever side of the coin you're on, are requested to come to the public hearing with information, data, testimony to support either side of the argument as to what would happen to that mobile route, positive or negative. And I think that would be a request to the parties at the public hearing, and I would like to add to my motion that amendment.

DR. KESHISHIAN: Commissioner Falahee -- Mukherji, do you accept as second?

DR. MUKHERJI: I accept the friendly amendment.

DR. KESHISHIAN: Thank you. Mr. Meeker would like to say something. Having said that, typ- -- I did it once and I sort of regretted it. Do we want to have people come back up to answer questions if have from the audience --

MR. ROBERT MEEKER: I just have a suggestion for procedure.

DR. KESHISHIAN: Okay. Do we want to allow -- I think -- okay. Go ahead. Just not -- not a rebuttal, please.

ROBERT MEEKER

MR. ROBERT MEEKER: This is not a rebuttal. You know, none of us have seen this language and, you know, there are a lot of issues that need to be taken care of. I don't know if this language addresses it or not. I wonder if it might be prudent to convene a work group to meet once or twice between now and the next meeting to look at the language, tweak it perhaps, and then come back with language that has a broader constituency than just one party making the recommendation. That's a suggestion.

DR. KESHISHIAN: Thank you. Realize that if we turn down the motion on the table and we approve the motion, the language that the Department provided us, it moves on and becomes a law or regulations until such time that we review it again, and that would be potentially in two-and-a-half years or so. If we accept the motion, we do have a public hearing. And, in fact, public hearings are, in fact, supposed to be where people give us input. And at these meetings, we're supposed to take that input from the public hearing before we make our final decision. So having said that, if we adopt a motion, we do have another bite at the apple before we finalize our decision with the friendly

amendment that if we requested everyone provides data and I believe that the data will be conflicting and we'll have to try to make a decision based on conflicting data of what we believe. But I tend to support the motion, because it does give us another bite at the apple. I did have to say one of the critiques of CON in the past has been it takes too long to make a decision. But on this one, maybe we just take a little bit longer to make the right decision. Because if we do adopt the standards, we could always open them up at any time we want. That's our right as a Commission. So with that, any other comments?

MS. BROOKS-WILLIAMS: Commissioner Brooks-Williams. So just to be clear, if we adopt the -- or vote the motion that was just -- that's on the floor now in the affirmative -- right? -- then we're sending this to public comment and then through the -- back to us or --

DR. KESHISHIAN: Yes, back to us in June.

MS. BROOKS-WILLIAMS: Back to us in June.

DR. KESHISHIAN: And then in June -- you know, let's be hypothetical -- we decide the public comment we want to go back to the original language.

MS. BROOKS-WILLIAMS: To the original language. Okay.

DR. KESHISHIAN: Then between June and September there will be another public comment and then in -- no?

MS. BROOKS-WILLIAMS: They're shaking their head "no."

MR. POTCHEN: Yeah, you wouldn't have to go. You've already had a public comment on it.

DR. KESHISHIAN: Okay. So you can do both at the June meeting?

MR. POTCHEN: Yeah, you could go either --

MS. NAGEL: Final act- -- you could -- please correct me if I'm wrong, Joe.

MR. POTCHEN: Yeah; yeah.

MS. NAGEL: But how I understand the question is that you could do final action on the language as presented today in June.

MR. POTCHEN: You've had a public hearing.

MS. NAGEL: You've had a public hearing.

MR. POTCHEN: Yeah.

DR. KESHISHIAN: Okay.

MS. NAGEL: If you do proposed action on language with an amendment today, we'll hold a public hearing and you could do final action on that language as well. Now, if you make a change to either of those, it would go back to public hearing.

DR. KESHISHIAN: If there are no other comments, I'll call for a vote. All in favor of the motion, raise your right hand.

(All in favor)

DR. KESHISHIAN: Ten affirmative. All opposed? Zero. The motion passes.

DR. KESHISHIAN: Nursing Home and Hospital Long-Term-Care Unit Final Report & Draft Language. Marianne Conner?

MARIANNE CONNER

MS. MARIANNE CONNER: Good morning. I'm Marianne Conner. I served as the work group chairperson for the Nursing Home Hospital Long-Term-Care group. The work group met a total of seven times, and we had a total of eight charges to review. I'll just go through briefly each of the charges, what our recommendations were and kind of a little bit of background with it.

The first charge was to review the criteria for Nursing Home Hospital Long-Term-Care replacements and relocations of beds. The work group basically thought that it is spelled out well. We just wanted to clarify some language in Section 14 of the standards to clarify that replacements and relocations within the replacement zone or under Section 7.3, which is the new design standards are not subject to comparative review. There was some confusion on this, and it affected the date when those applications could be filed.

Charge two was to review the criteria concerning

lease renewals. The work group spent a lot of time and discussion on this matter based on the desire of providers to find a way to relieve some of the financial burden of the CON application process for the lease renewals and tempered with the Department's desires to review the standards and make sure that we were adhering to them. Unfortunately the group was unable to come up with a recommended change, and so at this point in time we recommend no changes to that area, which is Section 9(3) of the standards.

Charge three was to review the threshold for high occupancy provisions. A subgroup of the work group spent quite a bit of time on this and reviewing what the current occupancy standards are in the industry and coming up with what they thought were fair recommendations. So the work group agreed to a recommendation of an average occupancy rate at 92 percent for the most recent 12 months and minimum of 90 percent or above for the prior 12 months as a high occupancy, which would then allow a facility to request and up to a maximum of 20 additional beds. Those beds would have to be duly certified for Medicare and Medicaid. The facility would have to eliminate any wards that were in the existing building, and the beds could not be relocated for two years after licensure. We felt this better reflects occupancy standards. For 2015, occupancy in the state of Michigan was 84 percent. So 92 percent is a high occupancy

facility under today's standards.

Charge four was to review the special population groups in the addendum. Because of some changes in hospice, hospice had 60 beds, they no longer wanted those special pool beds. So the work group had a sub work group who basically came up with a proposal for bariatric -- a special population for bariatric. The state ombudsman was very supportive of this saying that those are very difficult patients to place and offering this as a special population may create an incentive to providers to have those beds. So a section -- a population group for that 60 beds with a maximum of a ten-bed bariatric population is being proposed by the workgroup.

Our charge five was to review the bed need formula and the data sources. Basically a lot of the issues that have been a problem in the bed need methodology have improved as the data collection through the CON annual survey has improved also with provider participation and better data collection. So the work group felt that had been addressed. Currently there are two categories for ADC, and the adjustment factor for ADC was included, one at .9 percent and one at .95 percent. And because of -- the work group felt that really it should be one standard for everybody, so the recommendation is the ADC factor be a consistent .9 percent for all areas. Overall it's not a

significant change in the bed need, but we felt it was worthwhile.

Charge six was to review quality metrics to determine if they're up-to-date with national Nursing Home Hospital Long-Term-Care trends. The Department had asked us to review Section 9(1)(5) to determine if there were specific quality standards that needed -- and quality programs that needed to be addressed. We did look at it, and there was no consensus that there is any one particular program. And we basically would leave it to the discretion of the Department to continue to make their recommendations as they see fit at the time. So no changes are proposed in that area.

Charge seven revises the acquisition requirements to reflect a situation where the Nursing Home Hospital Long-Term-Care is being acquired by a new entity that is not currently operating a Nursing Home Hospital Long-Term-Care group. This was a request from the Department to address the fact, if providers who are inexperienced in the state -- if they were buying troubled facilities, that there was some way to create a quality measure for them. The work group agreed on wording that was provided by the Department to create a quality review and survey process for the first five years of ownership.

And charge eight were just technical changes from

the Department, and most of those were the name change but there are some others that address web site references versus paper to try and make it a little less necessary to make changes on an ongoing basis. And that's it.

DR. KESHISHIAN: Thank you very much. Are there any questions? Commissioner Falahee?

MR. FALAHEE: This is Falahee. First, thank you to you and everybody in the work group, number one, for plowing through all these charges and, number two, for a very good report.

MS. MARIANNE CONNER: Thank you.

MR. FALAHEE: I liked it. The one, -- the only question I had was on the lease renewal, charge two. Can you explain what that's about so the layperson can understand it?

MS. MARIANNE CONNER: Sure; sure. So when you file Certificate of Need and you are leasing a property, you file it for a certain term, whatever your lease term is. So I lease my nursing home, and I have a ten-year lease on it. At the end of that ten years, I have to file a new Certificate of Need application for my renewal. So the application is based on the total cost of the lease for the entire term. So the providers were looking for some relief from the fact of it would be the same nursing home, the same lessor and paying basically, you know, a lot of fee just

because of the fact of the cost of a ten-year lease. So that's what they were looking for. And because of the capital thresholds that are in place, we weren't able to find wording that would get us to where everyone was happy.

MR. FALAHEE: Thank you.

DR. KESHISHIAN: Any other questions? I also want to thank you for leading this work group, and you did a great job. And I know it takes time out of everybody's day to do this, so thank you very much on behalf of the residents and citizens of the state.

MS. MARIANNE CONNER: Thank you.

DR. KESHISHIAN: Any Commission discussion? Do I hear a motion?

MS. CLARKSON: I make a motion to accept the Committee's report.

DR. KESHISHIAN: And move on to the Joint Legislative Committee and a public hearing?

MS. CLARKSON: Yes.

DR. KESHISHIAN: A second?

MS. BROOKS-WILLIAMS: Second, Commissioner Brooks-Williams.

DR. KESHISHIAN: Thank you. Any discussion? All in favor, raise your right hand.

(All in favor)

DR. KESHISHIAN: Ten affirmative. Opposed? Zero.

Motion passes. Next item, Bone Marrow Transplant. Okay. We're going to take a break, ten minutes. Be back in ten minutes.

(Off the record)

DR. KESHISHIAN: The meeting starts again. Bone Marrow Transplant Services, draft language. Beth?

MS. NAGEL: One moment. At the December 2016 meeting that the Commission asked the Department to come back to this meeting with some draft language that incorporated some of the qualities that were seen in the other states that regulate Bone Marrow Transplant through Certificate of Need and that removed the cap on services that had been there previously.

So with that, the Department submits this draft to you. This draft has a couple of things. First, this draft has not been through public hearing, and so changes can be made to it. We submit this with the understanding that there are things in it that need to be discussed and potentially refined. So with that, I can walk you through the changes that were made and some of the implications of those.

First, there's some technical changes. You'll note that the Department's name has been updated throughout, and so that's really what you see on the first page of changes with the exception of a definition was removed. The

definition for comparative group was removed, and that's because, with removing the cap, there's no more need for comparative review. And so mentions of comparative review have been taken out of the standard, and you'll see that as I move through the standards.

On page 2, the "planning areas" were updated. Now, this doesn't seem significant, but it is. In the previous version of the standard, the planning areas were two sides of the state. There was a line drawn down the middle, and this was one planning area and this was the other planning area. And the point here is that each program for initiation can only pull cases from their planning area. So when we took out the cap of just two planning areas in the state, we updated this planning area or the definition of planning area to be consistent with other CON standards. So these are the typical health service areas. So what that means -- it becomes relevant later in the draft -- that, as you plan for cases to initiate as you show those for initiation, it could only come from your planning area, which now is a group of counties as opposed to half of the state.

All right. Moving on. There were no significant changes to page 3. Page 4, these are the initiation requirements. So this is Section 3. These are all the things that a potential application would need to do, would

need to show to initiate a service. And so what we did is we added just a couple letters: P, Q, R and S, come from the comparative review standards that had been deleted, and we brought these forward because they were quality measures that seem to make sense that we would want from an initiation of a new program. Again these are for your consideration and certainly debatable. I will note there are a couple of misspelled words throughout, specifically the word "suppressed."

Moving on now to what is the bottom of page 4 which is subsection (5) of the initiation requirements. This is something that was in the charge to the Department and was something mentioned by Dr. Delamater when he came and presented in December, was that in other states that regulate Bone Marrow Transplant through Certificate of Need, there is a requirement for a connection to some sort of academic pursuit, so having a heavy training or research component. We looked for the definition of academic medical center. Some of the normal sources that we go to for -- to copy definitions would be the Centers for Medicare and Medicaid. They did not have a definition that seemed to mean what the Department was led to believe you wanted from the December meeting. We couldn't find one in Federal Statute. One was pointed out to me in State Statute, but it is very vague, and this was the most detailed definition

that we could find. It's from a source that we wouldn't normally use, the Joint Commission International. Certainly the Joint Commission we would, but this is not a definition that would mean much to many of the hospitals today. However, we did find it to be detailed and a good starting place to have this discussion on what an academic medical center is.

Moving on to page 5, on page 5 of subsection 7, 7(a) is a holdover from the previous standard. In the previous standard you had to have megavoltage radiation therapy services in order to apply for a Bone Marrow Transplant program. What we wanted to do in 7 was to make it clear that, not only do you have to have an MRT service, but you must be in Certificate of Need compliance. Unfortunately our intent with subsection (b) and subsection (c) is not clear in this standard -- or in the language that we've given to you. What we wanted to do in subsection (b) and subsection (c) was to reflect what some other states have done. And the language doesn't line up, so I'll tell you our intent knowing that, if you like this intent, we will have to change the way that this reads.

So some of the other states that we looked at regulate organ transplant in one standard. They don't separate like we do. In Michigan, we separate out heart, lung and liver in one standard. We used to separate

pancreas, but it has been deregulated as has kidney and, in other states, those are together with Bone Marrow Transplant. So we tried to just make a connection based on the direction we were given by the Commission, the connection of organ transplant services. Now, certainly that can be debated, and many of our friends and colleagues in the audience have called me to debate that this week, so that argument can and will be made. And then we had thought to do the same thing with Surgical Services. Really this was just a way that we were -- the intent was to measure services or providers that were doing a lot work or had a high volume. Again that is certainly up for debate and again not listed correctly in this language.

Moving on to page 6, again we deleted reference to the cap in Section 4, which is for acquisition. You'll see this again. We did this throughout the document. Section -- on page -- I believe this is page 7, Section 6, remains the same. Section -- there was a previous section that was the comparative review requirements, and we have deleted that. And then number 7 is the project delivery requirements for all applicants, and those have remained the same. You'll see that no changes were made to that section, again on page 8, page 9. Page 10 there are some references that would potentially need to be updated. And then on page 11, the final page, some references to the dates were

changed as a technical edit by the Department and then again on sub (2) of 10 used to reference areas that were subject to comparative review. And we changed it to be clear that an applicant under this standard would not be subject to comparative review. Appendix A again lists those planning areas and, in the past, those were different and these planning areas along with other standards again for your review, which may or may not be appropriate. Any questions on --

DR. KESHISHIAN: Commissioner Mukherji?

DR. MUKHERJI: I just want to make a comment of again this is important. First of all, Beth, I want to thank you and the Department for putting this together. Putting this together is -- I guess it's like in my household being married and having two kids. No matter what you do, you're going to piss someone off. So I'm sure there's going to be robust discussion even about the language before we even delve into this, but I just want to appreciate the fact that we can work with highly trained professionals like yourself. So thank you.

MS. NAGEL: Thank you.

DR. KESHISHIAN: Any other comments? I think everybody on the Commission seconds Dr. Mukherji's comments. Okay. Any discussion? Okay. Public comment. I'm going on this issue -- as all issues, I'm going to try to have a

three-minute time limit. At three minutes I will be notified. I will say wrap it up and at three-and-a-half minutes I'm going to say stop. So people who are going to be doing testimony, please realize that at three minutes you have 30 seconds to wrap it up. I have many cards and, if somebody has said the same information previously, consider whether you really need to provide the information again. Muneer Abidi from Spectrum Health?

MUNEER ABIDI, M.D.

DR. MUNEER ABIDI: Good morning, ladies and gentlemen. First of all, I would like to thank you for giving me this opportunity to public comment on the Bone Marrow Transplant service draft language. My name is Muneer Abidi, and I was -- I'm representing Spectrum Health Bone Marrow Transplant Program. I'm working as a medical director since September 2014.

The Spectrum Adult Bone Marrow Transplant Program was established in November of 2012 and is the only BMT program on the west side of the state and is the most recent addition. I was also a part of the SAC group, though I have never used the word SAC in a sentence before that.

Our first adult stem cell transplant was performed in February of 2013 followed by the first unrelated donor transplant in April of 2014. Since then, you know, we have performed 300 transplant in the last four years' duration.

It's important to pause here, despite it makes us sounds like McDonald's franchise, but, you know, for a program of this size to do -- achieve this much achievement is pretty remarkable.

The comment that I want to make specifically is related to quality. I know it sounds like that we're trying to avoid competition, but the quality, despite we are not a surgical speciality, is inherent in the number of transplants. If you focus on a program of our size, 80 to 100 transplant, you would average count six to seven transplant per month. Our speciality heavily relies on other specialists like gastroenterology, pulmonary critical care. And not only it is important for the training of the staff but also to make -- you know, to keep the competency of other specialists as well.

As part of our quality program, we obtain our initial Foundation for the Accreditation of Cellular Therapy accreditation in October of 2013. That gives you some idea about the time that is required. And then we were re-accredited as it is required every three years in July of 2016. We are the most recent addition of BMT program in the state and in the position to provide insight into challenges that we have faced in setting up and maintaining this BMT program. Spectrum Health thanks the Department for its hard work in drafting the language for a very complex service.

We do support the Department's language released on March 9th, but we have a few recommendations to strengthen the standard. Based on our experience, I would like to recommend adding a geographical component to the draft language. The essence, the -- of the transplant, you know, patients is highly dependent on the incidence of the disease which can be diluted as you're getting away from the metropolitan area as well as the -- by us which is directly, you know, related to the available non-transplant treatment options creating a new --

DR. KESHISHIAN: 30 seconds, please.

DR. MUNEER ABIDI: So I would basically say that we request the Commission consider that all the required existing programs maintain or exceed the survival performance, and they also create a 60 miles radius before they consider adding a transplant program and increase the limit from 30 to 50 transplants per year. And I would like to thank, and I'm available to answer any questions.

DR. KESHISHIAN: Thank you. Are there any questions? Commissioner Mukherji?

DR. MUKHERJI: So I have two questions for you. In your opinion, if Bone Marrow Transplant were deregulated, what would that do -- how would that affect, you think, the total number of transplants done in the state?

DR. MUNEER ABIDI: You know, there is a

possibility that, for some duration of time for the new centers, the number of trans- -- the statistics are that it might slowly -- you know, the number of transplants are going up. But over a period of time, you know, they have -- they potentially can be steady or they have a potential of going down depending on the indications. To give you an example, we had the -- you know, a indication of breast cancer in the past. When the breast cancer was removed, the number of autologous transplants went down. Multiple myeloma is our first and most, you know, common indication for autologous transplant. If things change for autologous stem cell transplant tomorrow for multiple myeloma, the numbers can potentially go down. So it's hard to predict that. Right now the numbers are slowly going up but not like to 300, 400 transplants.

DR. MUKHERJI: Okay. So from your -- it's hard to say, but you don't see a huge bump up there?

DR. MUNEER ABIDI: Correct.

DR. MUKHERJI: The second question I want to ask is, at Spectrum -- and I use this term with all due respect -- was a bit of a carve out in the sense that we realized that there was a geographic need in the western part of the state. So you started with a brand new transplant program, and you had to gain experience. Can you comment on the quality and safety challenges that you met

when you initially started your program? One of the concerns that's been brought to my attention is that, if a new program is started in the state as yours were, there are concerns about providing quality and potentially redirecting patients that normally wouldn't go for a transplant to a transplant. Can you comment on your experiences at Spectrum?

DR. MUNEER ABIDI: So as I mentioned that it's not a surgical skill, but we, you know, strictly hone in and depend on training the new staff. There is a significant dearth of Bone Marrow Transplant physicians, so I can give you the example. Right now the transplant physicians that are in the state have been, you know, at and moved around, you know, different centers. I was at Karmanos and moved to, you know, Spectrum Health when the new program started. We have significant challenge in terms of hiring the new staff, training the advanced practitioner. They have a huge shortage, and they are -- it's very competitive. We have hired new candidates and spent, you know, time in training them, and then they become more marketable and then move. It was very difficult to hire new faculty. We have started a fellowship program. We are advertising for a very long duration of time and we are now being able to hire, you know, in the fellowship position. So basically it's the, you know, competing the staff amongst the transplant center

and, as the new transplant center will open up, it will further dilute. And in addition to that, we are heavily dependent on the other ancillary services; radiologists, pathologists, need to be aware of the complications that are associated with bone marrow transplant. And if you have -- you know, that's non-existent or you have to training required, then you basically are impacting the quality.

MS. GUIDO-ALLEN: So this is -- just a question for you. Guido-Allen. So would you say that, when your program started, that your quality was less, your outcomes were poorer than established centers?

DR. MUNEER ABIDI: So to answer, you are required to, you know, start slow so we were, you know, methodical about it. We started with autologous stem cell transplant. So the institution committed their resources. Within the time frame, we obtained our FACT accreditation. The FACT is a peer reviewed board that looks at the survival, and that's a public knowledge. And we demonstrated that we are maintaining quality. And then further accreditation, we are required to maintain a survival, you know, within that range. If we don't maintain that, the FACT basically can take away our accreditation, which will basically impact directly on our -- you know, the -- and the insurance approvals. So we'd have to continue to demonstrate. But if our numbers go down, you know, and if, like, you know, a

program is open across the street and we are competing against each other for the patients, that indirectly over a period in -- which you have demonstrated before. We had to open up a transplant program that shut down over a period of three to four years' duration and that, you know, created a situation. So we have a history, you know, in the past.

DR. KESHISHIAN: Any questions?

MR. FALAHEE: This is Falahee. Your 60 mile geographic circle, if you will, what's the justification for that?

DR. MUNEER ABIDI: And again I would say that I'm not, you know, specialized. We need somebody who's, you know, experienced in the methodology, and that's basically, you know, extend us to talk about, you know, working group. Again that can be challenged whether it should be 60 miles, how fast you drive and all that. But I think there are many factors that should be taken into consideration besides just the mile radius. What's the incidence of the disease? What has been the (inaudible)? How many transplants has been performed in that area? And then, you know, I think the Commission in the past have taken into consideration, they have considered that, you know, it should be 75 miles for existing programs. So I don't know what was the reason that they considered 75 miles at that time. But I think there should be many factors that should be taken into

consideration for which you need a specialized group that has the expertise in this area to answer all those questions.

MR. FALAHEE: And then one other question. In terms of demand, is there a -- I'll say, a waiting list -- that might be the wrong phrase -- for patients that need services, BMT services?

DR. MUNEER ABIDI: No, right now there isn't. And again, you know, as I said, our, you know, field is changing so rapidly. We have to compete against the immunology, the new science of, you know, antibodies. And the new treatments virtually has exploded for multiple myeloma. There are like ten new drugs. So still, you know, it takes time to see if we can maintain the indication. We competed against a pill for CML where transplant was the, you know, most important curative indications. But now ever since we have those pills available and they are demonstrating long-term response, you know, we are not seeing that many CML patients.

DR. KESHISHIAN: And Commissioner Hughes?

MR. HUGHES: Based on your previous point if another facility was to open up within a area that already has some, based on the lack of qualified physicians to serve, there's no way that costs would start going up to get those physicians. It'd just be because another one would

open up and starting hiring them away and start -- I mean, costs are already too low; right?

DR. MUNEER ABIDI: So again -- well, I'm not again privy to those exact numbers to be able to debate, you know. But I think the cost eventually when the transplant program has clinical component, it has a laboratory component, the processing facility and a collection facility. So when you add that all together, you can even hire these services, but it's prohibitively expensive. And when your transplant program shuts down, there is a, you know, significant negative impact in terms of where would you direct those patients. There are stem cell product (inaudible) for which there are not many, you know, the cords available to continue to build that. So transplant program is investing the resources of where would you take those products, who's going to take them, and what are you going to do in the long-term of these product. Eventually closing a transplant program is going to cause a, you know, significant negative impact financially.

MR. HUGHES: Thank you.

DR. MUNEER ABIDI: Thank you very much.

DR. KESHISHIaN: Thank you. Dennis McCafferty, EAM.

DENNIS McCAFFERTY

MR. DENNIS MCCAFFERTY: Good morning. Dennis

McCafferty, Economic Alliance for Michigan. We're the statewide business labor coalition. We represent consumers and purchasers across the state. We don't provide these services, but our members are consumers of these services.

While we support the idea of eliminating the cap, we feel that there still needs to be some geographic component in the standards. The concern is access should be defined as geographical access. It'd be great if there could be one in the Upper Peninsula or Traverse City or Saginaw Bay area, but another one in southeastern Michigan causes us some concern. We feel that adding an additional BMT program in close geographic proximity of existing programs will only result in reshuffling existing patient load and not really improve access to more patients.

We're suggesting an amendment to similar to what was said before. This is really a matter of emphasis, but under Section 3(2):

> "An applicant shall specify a license site at which BMT services will be provided and demonstrate that the site is at least 60 minutes from an existing BMT service."

Sixty miles, 60 minutes, depends on the time of the day and the particular area of the state you're in and the traffic, but that's our comment.

DR. KESHISHIAN: Thank you. Are there any

questions? Thank you.

MR. DENNIS MCCAFFERTY: Thank you.

DR. KESHISHIAN: I have two cards from Karmanos. Both people can speak, but I would hope that they will have different comments. If not, if you want to huddle and decide who's going to speak if it would be appropriate, I'll let you huddle. Next would be Edward Peres from Henry Ford Health System.

EDWARD PERES, M.D.

DR. EDWARD PERES: Good morning. My name is Edward Peres. I'm one of the transplant physicians at Henry Ford Hospital. I want to thank the Commission for allowing me to have public comment. And I concur with Dr. Abidi in regards to the geographical recommendation to be added to the language. And again that really kind of stems from the ability for a patient to have to relocate to undergo a transplant, and that kind of is something we use for allogenic transplant, 60 to 75 miles in regards to that patient having to relocate, get their transplant and stay close to the facility. And there was a recent publication a couple years ago in regards to better outcome the closer they are to a transplant facility.

So again I want to focus on a couple things in regards to access. I think the current centers have excellent access for the patients that we serve.

Southeastern Michigan again in regards to the numbers of transplants that we perform has really not significantly changed. There's been multiple studies that continue to compete in regards to transplantation versus medical oncology therapy. And again I think in regards to the comments that Dr. Abidi mentioned about multiple myeloma as well as immunotherapy are currently on the horizon.

In regards to the capacity for transplantation, our center again is under capacity. We can still serve another 30 to 40 percent of patient population in Southeastern Michigan, so we have excellent capacity. We have well trained physicians that are adequately trained to perform these transplants. Again Karmanos is under capacity and the University of Michigan as an existing center is currently under capacity in regards to the patient population they serve.

If another center opens within a very close geographical location, my concern would be that again the clinical trials that we offer in regards to our patient population as well as the ability for those patients to undergo and continued research for that patient population will be affected. So if another center opens and again we decrease the population of patients that we transplant, the facilities in regards to clinical trials research that we currently conduct will be at risk. And again -- I think I

again agree with Dr. Abidi in regards to closing a center in regards to the resources would not be in the best interest of the state in regards to the expertise that we deliver to our patient population and that we care for. And I'm happy to take questions in that regard.

DR. KESHISHIAN: Are there any questions? Thank you. Justin Klamerus from Karmanos.

JUSTIN KLAMERUS, M.D.

DR. JUSTIN KLAMERUS: Good morning, Mr. Chairman and members, distinguished members of the Commission and staff of MDHHS. My name is Justin Klamerus. I'm the president of the Karmanos Cancer Center and Cancer Network. I'm also a medical oncologist. I thank you for the opportunity to address the Commission today.

I come before the Commission frankly as a practicing medical oncologist who practiced community oncology in Northern Michigan. As you may know, Karmanos is a network now of 14 cancer centers located throughout the state. We have a distributed network that provides services all the way to Petoskey and into the Upper Peninsula. I myself was born in the Upper Peninsula. Traveling for health care services is something that we are used to in Northern Michigan.

I assert and concur with the comments that have been made by my physician colleagues and Dr. Uberti from

Karmanos, our distinguished program leader will be following me. What I wish to emphasize today to the Commission is that, without a doubt, the quality of our transplant programs are going to be diluted if we allow further programs to open in the state of Michigan. The indications for transplant are decreasing, the population of the state is not increasing. And what is most important when you're providing a life sustaining, life saving service is the excellence of that service, the quality of that service. The Commission should be confident in the quality of care that we have in the state of Michigan for this service. Opening further centers, I contend, will dilute the quality, because we simply, in today's day, reference a joke I believe was made about the growing costs of health care. We simply -- if we dilute the number of patients to more centers in the state and don't impose a geographic restriction, we are going to dilute the investment that institutions can make in preserving their programs, advancing cutting edge science and research. And so I hope the Commission will bear this in mind as it considers its very important work today.

I had the privilege of training at Johns Hopkins University. This is a place that performed the second successful transplant in the United States. The first was at the Seattle Program, the Fred Hutchinson program. And I

saw very acutely the talent and skills that are necessary to deliver a high quality program. This is something that takes years, decades to build. Certainly the colleagues at Spectrum had the experience of their pediatric program to grow upon. I would implore the Commission to consider the right care for patients, the quality of the service and the excellence that is provided when we can put these treasured, cherished and limited resources into limited programs. Thank you very much.

DR. KESHISHIAN: Thank you. Any questions? Commissioner Tomatis?

DR. TOMATIS: Commissioner Tomatis. Is there any -- is he merely discussing to take out the cap? And anybody else in talking that we have a very highly sophisticated system that covers all the need of the patient, that likely maybe go down, and the only way to keep the quality is maintaining a larger number of patients. Then you really are telling us that we should keep the cap.

DR. JUSTIN KLAMERUS: I am.

DR. TOMATIS: Okay.

DR. KESHISHIAN: Are there any other questions? Okay. Thank you.

DR. JUSTIN KLAMERUS: Thank you.

DR. KESHISHIAN: Joseph Uberti from Karmanos. And, please, if the testimony is the same, we've heard it.

JOSEPH UBERTI, M.D.

DR. JOSEPH UBERTI: Thank you very much and thank you for inviting me to talk. I'll be sure to keep my comments different from what Dr. Klamerus said. What I really want to talk about is what the unmet need is for transplantation.

We've heard a lot that there's an unmet need for transplantation, that patients can't get to transplant and need a transplant and should be transplanted, but there's really no way to actually quantitate that number. You know, how do you document this? We have no really formal methodology. All we have is unlimited subjective opinions on projected volumes with no foundation on how many actual cases are out there who aren't transplanted for one reason or another. And none of the projected volumes take into account the many issues that very often prevent patients from going to transplant. These include co-morbidities the patients have, these may include the lack of donors the patient have, these may include social problems the patient has with the lack of ability to provide help after the transplant, and these may provide -- these may include economic factors. So there are a lot of reasons patients don't go to transplant, and these factors sometimes will never be overcome by building more transplant centers. So it's not an issue of numbers of beds; it's really a number

of issues with the patient coming to transplant that prevents patients from going to transplant.

And there's a constant need to examine what -- the roles of transplant in various diseases. Many of you don't understand this, but we're really on the cusp of an explosion of new transplant, cellular therapy, and new therapies that may change the role of transplant for many of the diseases we need to do transplants for now. So the need for transplant has to take how many patients are out there that need a transplant, plus it has to take into account the current availability of transplant centers.

I don't think you can afford a duplication of services, because there's a duplication of costs. It's a threat to quality and really does nothing to provide better geographic access. We've already done studies that have shown the geographic access in Michigan is on par with the geographic access in every other state in the country and every other state we have and better than most. So we've really positioned the transplant centers to be as close as possible to patient population centers. I mean, there is certainly patients have to go home after they get a transplant. It's important for them to be close to transplant centers, and I think we've done that very well.

You know, one of the things I think we must look at is that there's not an unmet need to do more transplants.

Really the unmet need is to do better quality transplants. We have a mortality right now with transplants that can be as high as 50 percent. When we have that high of a mortality in a very subspecialized field that really doesn't have many volume, you know, we have to be careful about how you're going to proceed forward. It's not so much to do more transplants. Really we have to improve the quality and improve our outcome of the transplant.

We have submitted some recommendations that we'd like to put into the proposal, and what I'd like to talk about is perhaps forming a work group to really decide and figure out how many patients really do need a transplant in the state looking at all the various factors. I think a work group can sort that out a little bit easier. I know we just went through a SAC that didn't have time to go through this, but I think a work group can tell us if there really is a large need of patients out there --

DR. KESHISHIAN: Thirty seconds.

DR. JOSEPH UBERTI: -- who do go to transplant. This is based on the volume of the patients a center sees and based on all the factors that go into allowing patients to go to transplant. I'd just like to stop here and thank you for allowing me to come up and talk about these issues. I'd be happy to answer any questions.

DR. KESHISHIAN: Thank you. Are there any

questions?

MR. FALAHEE: One question.

DR. KESHISHIAN: Commissioner Falahee?

MR. FALAHEE: One comment, I loved your phrase "limited, subjective opinions." So thank you. In your knowledge base, is there anything out there that's a solid population based metric for number of BMT procedures per X hundred thousand people?

DR. JOSEPH UBERTI: So what they have done is they've given the number of BMTs per disease. Let's just say it's AML. You know, let's just give you a figure. They say 20 percent of patients with AML are potential for bone marrow transplant. What that doesn't take into account, however, is what's happened to those patients. Do they have co-morbid conditions that they can't go to transplant with? Do they have social issues that prevent them from going to transplant? Do they have donors? Do they have some economic problems that prevent them from going to transplant? So there's been some attempts to define what percentage of patients with a certain disease may need a transplant. But again they don't take into account those downstream issues that affect patients going to transplant. So it's a pretty hard figure to come up with, and that's what makes it difficult to decide is there really an unmet need. You know, you would think that, if patients need a

life saving procedure, they're going to drive an hour to get one, and most patients in the state of Michigan can drive within an hour to get a life sustaining procedure. So why aren't these patients coming to us if they're out there? You know, we're not preventing them from coming to us. There's no waiting list in any of the transplant centers right now. So we should be seeing these patients if there is really patients out there who can't get to a transplant.

MR. FALAHEE: Thank you.

DR. KESHISHIAN: Any other questions? Thank you.

DR. JOSEPH UBERTI: Thank you.

DR. KESHISHIAN: Greg Yanik, from the University of Michigan.

GREG YANIK, M.D.

DR. GREG YANIK: Thanks, Mark, and to the Commission. Just for your reference, I actually gave my oral presentation to everybody ahead of time.

So I'd just like to start by saying that existing transplant programs currently provide cost efficient, high quality service with outcomes that exceed CIBMTR standards. Eighty-four percent of patients in the state are currently within 60 minutes, 60 miles, of a transplant facility. Increasing the number of transplant centers will create duplicity in resources, shifting patients and those resources from one center to another. Over the past three

years, the Spectrum program has grown by approximately 40 patients per year at the exact time our program at U of M has decreased by 40 patients per year. Where have our patients gone? They've all shifted to the west side of the state. We lost that. This same shift would now happen on a larger scale under the current MDCH proposal.

Should BMT services be deregulated entirely? No. As Joe said, now more than ever, strict regulation is required. Over the next 10 years, BMT will become a platform for cellular immunotherapy, tumor vaccine strategies and tissue regeneration. Deregulating transplant services will create an unregulated environment for our patients at a time when these regulations will be needed more than ever.

Are there other factors to consider? In the past month, a request was actually made to the Health Economics Group of the CIBMTR -- that's our transplant database -- to study the impact of CON regulations in transplantation regarding outcomes and costs in CON-regulated versus non-regulated states. The state of Michigan should not deregulate the service now if data could ultimately come forth from a definitive CIBMTR study.

In terms of the MDCH proposal -- we actually appreciate Beth's work, and it's actually tremendous. We just have a few thoughts. To ensure quality, the proposal

should incorporate strict FACT and CIBMTR metrics.

FACT accreditation and CIBMTR performance are the primary metrics used to judge a program's performance. Neither metric are actually required in the current MDCH proposal. To ensure that new applicants provide quality service, we recommend that FACT accreditation be required within a defined time period (36 months) and that new applicants meet CIBMTR outcome standards over this same time period. New applicants that cannot meet these two metrics should not continue provided the service. Section 3.10 should be modified.

Section 7.4 of the proposal should actually be modified as a recommendation. To limit a proliferation of transplant services within the state, the metric for minimum transplant volume should be increased to, as others have said, at least 50 adult transplants per year and 15 pediatric transplants per year. New applicants that cannot attain this requisite transplant volume within that defined time period of three years should not continue providing the service.

So in summary, I just want to bring to your attention something a patient last night told me. It's one of our --

DR. KESHISHIAN: Thirty seconds.

DR. GREG YANIK: -- transplant patients from an

hour away and she just had a nice line. She said, "Dr. Yanik" -- when I informed her of this meeting today, she said, "I don't want convenient care. I want quality care." And I'd leave you with that. Thank you.

DR. KESHISHIAN: Thank you. Any questions? Commissioner Mukherji?

DR. MUKHERJI: Sure. Thank you very much. Two questions. And I'm not going to ask you questions, because I already knew the answers for the other speakers. In your opinion, if the cap was removed and everything was deregulated, what would FACT do to the total number of transplants --

DR. GREG YANIK: It wouldn't change.

DR. MUKHERJI: Okay. Good.

DR. GREG YANIK: In fact, it may go down. We're finding more and more reasons not to do transplant right now in terms of transplants just being limited to high risk populations, these high risk populations typically defined by molecular markers and stratification. Transplants would go down.

DR. MUKHERJI: So the changes that you're recommending, the FACT accreditation and the threshold numbers, it seems this was -- this would be different than what Spectrum had to achieve in order to start their transplant program; is that correct?

DR. GREG YANIK: No. And actually -- what I'm actually recommending is that, once a program is given -- once an applicant is given okay to proceed, that that applicant should actually attain FACT accreditation within 36 months of that -- you know, that opening or that approval. If they can't attain --

DR. MUKHERJI: Is that what Spectrum had to do? Was that part of their criteria?

DR. GREG YANIK: I would have to ask Muneer on that one. By the way, you should also appreciate that Spectrum was building their program not from scratch unlike other programs in the state would. Spectrum was building their program from already an existing pediatric program. So they already had in-house experience for their pediatric patients, for their young adults, for all their subspecialties, for their bone marrow processing facility, for the laboratory facilities needed. They were not starting from scratch.

DR. KESHISHIAN: Commissioner Falahee?

MR. FALAHEE: I don't see anything in here about a geographic, minutes, miles?

DR. GREG YANIK: I actually support my colleagues from Spectrum and my colleagues from Karmanos on this, that we should have a geographic distance. I figured just for the sake of time, I just didn't incorporate it. But, yes, I

think that -- I do think that a 60 mile -- I mean, we could argue 45 miles, 65, 60 miles, it's reasonable. I think the take-home point is, as Dennis McCafferty said, having more centers in Southeast Michigan is not the answer. Having centers in outstate areas, maybe. But not building. Building another center in Southeast Michigan is not going to improve access for patients outstate.

MR. FALAHEE: Thank you.

DR. KESHISHIAN: Are there any other questions? Commissioner Hughes?

MR. HUGHES: If -- from your perspective if it was deregulated, what do you think would be the effect of the cost of a procedure? You would do more of them, but --

DR. GREG YANIK: It's a good question. Right now there's only approximately 800 to 1,000 transplant physicians in the US. Over the last ten years we've actually only trained three transplant physicians at our center. There's about to be a dire shortage of transplant physicians by the year 2020. We're all older, we're all about to retire. The only way the centers will be able to acquire this service is by overpaying existing personnel, not only transplant physicians, but our cell therapy personnel. We'll probably have to overpay them. Meaning a center would actually buy out our personnel thereby literally creating a duplicity of resources by overpaying

existing personnel. Costs will go up. You will have duplicity of resources at multiple levels not only for fixed equipment, not only for laboratory needs, but you will have to then overpay personnel.

DR. KESHISHIAN: Any other questions? Okay. Patrick O'Donovan, Beaumont Health.

PATRICK O'DONOVAN

MR. PATRICK O'DONOVAN: Good morning. My name is Patrick O'Donovan. I'm director for strategy and business development for Beaumont Health. I appreciate the comments we heard from Doctors Abidi, Peres, Dr. Uberti, Dr. Yanik. I'm also very familiar with these comments as I think many of you are, because these are all issues that were addressed and brought up and worked through as part of the SAC. And for that, we didn't bring our clinicians today. And I'm kind of glad that we didn't, because these issues that are brought up are not new. They were brought up in this past SAC. They were all brought up in the two previous SACs as well. So I didn't really hear anything new.

What is new is that we had a very good, long discussion -- you did -- in December about the potential for deregulation, and the Department supported deregulation. And we think that deregulation makes sense for a lot of the reasons that Dr. Delamater put through and the ones that the Department made.

But the Department has done exactly what the Commission asked, and that was to bring back language that eliminated the cap and also put in some guardrails about what could be included in the standards in order to initiate. We think the Department did a good job with that, and we would look forward to hopefully moving forward with those standards. I think we need to always keep in front of us that there are only seven states that regulate bone marrow transplant at all, and all those have low barriers to entry. So I think we need to consider that as we deliberate the language that the Department provided.

On the geographic restriction, if you're going to -- a geographic restriction, other than an arbitrary mile limit, requires a methodology to project need, and the Department hired an expert to try to develop a methodology. And he came and told everybody that that's very difficult to do, and that's why the motion that asked the Department to go back and develop language was to expressly exclude a cap and that's what the Department has done. There's comments, you know, earlier today about, oh, the volume's going to go down, there's going to be, you know, changes to medical practice. That's all true, but the fact is the number of transplants in the state has been going up every single year.

So I guess we support the standards. We hope that

you'll move forward with that based on and building out the discussion that you had in December versus debating the comments that were -- should have been made and were made in the SAC. Thank you for the opportunity to comment.

DR. KESHISHIAN: Thank you. Any questions?

MR. FALAHEE: Yeah.

DR. KESHISHIAN: Commissioner Falahee?

MR. FALAHEE: Patrick, you just said the numbers have gone up year after year. Do you have that data? And we probably have had it six times, but I've forgotten it.

MR. PATRICK O'DONOVAN: I do have it. I didn't bring it up here. But it's through the MDCH annual survey publishes that.

MR. FALAHEE: Okay. So the numbers are going up, but I hear at the same time that the prior folks commented that there isn't any unmet need. So --

MR. PATRICK O'DONOVAN: Well, that's the point I was trying to make is that discussion of unmet need was probably three-quarters of the SAC deliberation. And there are a lot of -- so most of our discussion at the SAC -- the previous SACs was on access. Access has a lot of dimensions besides geography. So there's really -- we really need to be couched in the -- I think the whole issue needs to be couched in the discussion that was had initially. Unmet need has a lot of components, and those were all discussed.

The question was asked is there -- would there be any change in volume if a new program were added? Well, we provided data in the SAC that showed that, yes, when Spectrum added a new program, the number of people who lived in that area experienced an increase in transplants, so that was not simply a shift. And even Dr. Delamater, I think he was pressed on that. If there were more programs, would there simply be a shift? And he said, "I'm really not prepared to say that." So I don't think that we know, but I think we need to look at this really across the country is not a service that's regulated. And if it is going to be regulated -- I mean, we abdicated for deregulation, and we still think that makes sense. But the Commission opted to go with the language and gave the Department specific direction on what they would like to see in that language, and they've done that. So I think that that -- that's the road that the Commission should take.

DR. KESHISHIAN: Any other questions?

MS. BROOKS-WILLIAMS: I do.

DR. KESHISHIAN: Commissioner Brooks-Williams?

MS. BROOKS-WILLIAMS: Commissioner Brooks-Williams. Can you comment on your thoughts about what happens to the quality in terms of there's been the previous folks that spoke talk about if, in fact, we assume that it's a slight increase every year or fixed and we had

new entrants into it, what would be the quality consideration if you then diluted that number across more facilities? Take the geographical piece out and deregulate --

MR. PATRICK O'DONOVAN: Yeah. Well, there are accrediting agencies like FACT that assure quality. I think even the question was asked, Spectrum, they started a new program. I did not hear any suggestion that there were quality issues or problems with that. You know, the language that the Department put in with regard to assuring quality are reasonable, and so we have a process in this state and the accreditation agencies have a process to assure quality. I mean, if there was an issue, you know, be it volume or mortality or other things, we would be or any applicant would be subject to them. I don't see a diminution in quality as a result of -- I also -- you know, I think -- I don't think we're going to see a whole lot of new programs, you know. We've obviously been the biggest proponents. Others have come in and out. But I don't think we're looking at five new programs. I mean, the Department when they -- when they made their conclusion, they said, "Well, we're not recommending deregulation because we can't come up with standards. It's because we just don't see any benefit. It doesn't improve cost, quality or access to continue it to be regulated." And if Bone Marrow Transplant

were not regulated today, the Commission, it would not be on their radar, I'm quite sure, to regulate that.

DR. MUKHERJI: Patrick, is there any -- I mean, certainly one of the key discussion points is quality. And the statement was made earlier that the number of transplants does appear to be going up in the state at least based on (inaudible) stage. I'd love to see that at some point if you have it or make it available. But the point was made also that only seven states continue to regulate Bone Marrow Transplant; is that correct?

MR. PATRICK O'DONOVAN: That's what Dr. Delamater found, yes, and that's what we found.

DR. MUKHERJI: And maybe -- and I'm just thinking out loud. Is there any suggestion that the presence or absence of regulation somehow affects the quality of Bone Marrow Transplant based on FACT data? Is there a linkage?

MR. PATRICK O'DONOVAN: No. I mean, not that I'm aware of. I think, if that was available, that would have been uncovered either through the SAC or subsequent research or through Dr. Delamater's presentation.

DR. KESHISHIAN: Commissioner Mittelbrun?

MR. MITTELBRUN: Yeah, Tom Mittelbrun. So when you were answering Commissioner Brooks-Williams' questions, I couldn't help but think, if a new program -- or if you establish a new program, where are you going to get the

specialized staff and people to do the work? Where are they going to come from based on, you know, some of the other facts we've heard today and before and about it being so specialized and there being, you know, not too many people who do this work? Where are they going to come from?

MR. PATRICK O'DONOVAN: Well, we are a full-fledged cancer program. We have almost all modalities of cancer treatment except for Bone Marrow Transplant, so we already have a lot of specialized personnel. There are specific requirements and proposed standards that we would need to meet. We would go through like, you know, Spectrum did when they started a new program or anyone who starts a program. They would have to recruit, and, you know, sometimes you track people from outside the local area that could add to the expertise in the state. So you might end up with a very positive situation. And I guess the other thing is, if we didn't think that we could attract the right people or if we couldn't attract them, well, we wouldn't be able to start a program. We're just looking for a state regulation program that doesn't prevent it.

MR. MITTELBRUN: Well, that wasn't really the answer I was looking for, but I understand.

MR. PATRICK O'DONOVAN: Okay. I'm sorry.

MR. MITTELBRUN: The second part is, when it comes to the seven states, I'm not really too concerned what other

states do unless we can steal a good idea. We have to do what's right for us. If we got to be a leader in one area or another, that's just fine.

MR. PATRICK O'DONOVAN: And I respect that was the Commission's decision last time in December that they wanted to keep it regulated and gave the Department instructions on what they wanted to see. And I think the Department's done that.

MR. MITTELBRUN: Thank you.

DR. KESHISHIAN: Commissioner Hughes?

MR. HUGHES: Given that the biggest charge of this whole deal here is cost, access and quality, your previous Oakwood that you purchased closed down because of not enough volume to support. You're potentially putting up a place in a location where there is lots of coverage nearby. On the cost aspect, can you please address to me how deregulating and adding another one in this area, fighting over a limited talent pool is not going to increase costs?

MR. PATRICK O'DONOVAN: Well, there's always some element of, you know, when there's new programs, there are -- you know, competitive issues that could come up that could have an impact on cost. You know, the capital costs are not extreme. I think that the -- you know, a service like Bone Marrow Transplant, there's no potential for overutilization. No one's going to get a bone marrow

transplant who doesn't need one. We've already made the point numerous times that we're not going to see a large increase. So we're not talking five or six programs. No one's really talking about this. We're talking about a couple. Speaking about Beaumont Health, I mean, we're the largest health system in the state by a large margin and, you know, we're looking to -- you know, we have managed care contracts and clinical integration networks that are all linked together. And we would like to be able to provide as many of those services within our network as possible. And there's really no reason that we should be prevented from, you know, one aspect of a cancer program when we have all the other components.

MR. HUGHES: Well, I would go to Cleveland Clinic for my heart, but I would not go there for orthopedics, so I'm not quite sure I agree with that. But you're saying that the pressure to hire for other physicians is not going to boost costs for everybody; is that -- I want to make sure I understand that.

MR. PATRICK O'DONOVAN: Well, I don't know exactly, but I think hospitals and clinics start new services all the time. And there are -- you know, Bone Marrow Transplant is not the only shortage of health care personnel. There's a shortage of specialized personnel in a lot of different specialties. So this is really not -- it's

really not unique. I don't know why we would single out Bone Marrow Transplant.

DR. KESHISHIAN: Are there other questions? Thank you.

MR. PATRICK O'DONOVAN: Thank you.

DR. KESHISHIAN: Okay. Thank you. Commission discussion?

MR. MITTELBRUN: Well, I guess I'll start.

DR. KESHISHIAN: Go ahead. Commissioner Mittelbrun?

MR. MITTELBRUN: I went back and looked at my notes. And throughout my youth I was always told there's no such thing as a dumb question, so I hope I don't screw that up. But for the life of me, you know, I can't -- you know, based on everything we've heard, the fact that the existing facilities are under capacity, they're servicing, you know, our residents, I can't figure out what's the matter with the existing language. What is the problem? Why is there a change necessary? And I don't -- you know, like I completely understand somebody wanting to do something. I, like, would like to do a lot of things. Unfortunately I get told "no" quite a bit, too, but that's just the way it is. We have to do what's right. And I'm trying to figure out what -- what's the matter with the existing regulations? And I can't -- I went back and looked at all my notes and,

if somebody can help me, I'd appreciate it.

DR. KESHISHIAN: I'm not sure if you're addressing that to the Department or --

MR. MITTELBRUN: Anybody who can help me.

DR. KESHISHIAN: Commissioner Tomatis has a comment but, if he doesn't answer your question, I'll --

DR. TOMATIS: I am not answering that question. I support what he just said. If everyone who has testified, except the last gentleman, says there is a need, the number possibly going down and even disappearing (inaudible) we emphasize quality. The access is guaranteed, they have it now. Then why are we going to leave the cap? And if we leave the cap, the (inaudible) such a way that we (inaudible) the cap.

DR. KESHISHIAN: Does anybody in the Department like to answer Commission Mittelbrun's question?

MS. NAGEL: Sure. So to specifically answer your question, the Department recommendations come from a place of wanting to get rid of an arbitrary cap. The purpose of Certificate of Need is that -- one of the purposes of Certificate of Need is that, as need increases, there needs to be a way for the state to meet that need. And with a cap on BMT services, there's no ability for anyone to ever get that service again. It's static at that point. That goes against all of our other standards, it goes against the

purpose of the program. And so from the Department's perspective, we've put forward several recommendations. And lastly this language to remove that cap that was set in place and allow for some provisions for this service to expand to meet need if, in fact, it does need to expand to meet need. So we are against maintaining the version of the standard that has been in place up until now because it contains this arbitrary cap.

DR. KESHISHIAN: Tomatis?

DR. TOMATIS: We are talking about eliminating these relations in order to allow expansion and everybody came and told us that it's reducing, then why are we going to create something that is not necessary and what has testified that doesn't exist?

MR. MITTELBRUN: Tom Mittelbrun again. You called it an arbitrary cap, but I'm assuming in the past -- and I wasn't here for that history -- that there was a rationale for the cap.

MS. NAGEL: Unfortunately the history is that there wasn't a rationale.

MR. MITTELBRUN: Okay. So based on your comments, I understand everybody's recommendation for, you know, the geographic disbursement of the centers where there would be a 60 mile, 70 mile, 60 minute, 70, whatever we, you know, would be agreed upon.

DR. KESHISHIAN: Commissioner Guido-Allen?

MS. GUIDO-ALLEN: So there was discussion back in December that revolved around Dr. Delamater's presentation, but there was also discussion about access and whether or not the need for Bone Marrow Transplant is unmet or met. Nothing really could be solidified or finalized or even agreed upon. However, there is some discussion -- there was discussion around the fact that there are patients who opt out of BMT because they cannot be treated within their region, their area, their -- with their physician, so hence the -- there is -- we don't know what's going to happen with the volume with BMT. If it is offered in other settings, whether it be in Northern Michigan or whether it be somewhere -- anywhere else in the state, will that allow more patients to have access, which is one of our charges as this Committee?

DR. KESHISHIAN: Commissioner Brooks-Williams?

MS. BROOKS-WILLIAMS: So my comment originally was going to be to the question around having a cap, but I'm going to also, if I can, say something about Commissioner Guido-Allen's most recent comment. But how did Spectrum -- this is a question. How did Spectrum put their program in place? So I'm assuming that even if we left for the fact that we can't perhaps figure out how to quantify unmet need, if we left the language as is and we found that there was

unmet need by whatever definition -- so I would concur if you decided in Northern Michigan or some other part of the state that we weren't adequately meeting need, I would hope that people would flood us as they're doing now and come and tell us that there's a sudden need for patients that can't be serviced, and I'm assuming we open up the standard. So is that not an option? That when we have need, then, because I'm assuming that's what had to happen with Spectrum? I'll pause and you can answer. Because we have expanded with the language as is.

MS. NAGEL: No. The expansion came because of a language change. So there was a cap that was statewide, and then --

MS. BROOKS-WILLIAMS: And again not to make you rehash the specifics. I think I'm saying, when there was a defined need or discussion around how to get to before -- I think I'm saying, if we had unmet need and you need to grow beyond what the language allows today, could we not look at the language at that point?

MS. NAGEL: Yes; absolutely. However, the problem that we have had with this language is that there is no mechanism to assess need. It was really -- at one point it was that the whole state can only have X number of programs, and then the Commission changed it so that the -- this half of the state can have X number of programs and this half of

the state should have X number of programs. The problem that happened with the staff, the problem that happened with Dr. Delamater, the problem that we face today is that there is no way to quantify Bone Marrow Transplant need in a way that makes sense for these standards.

MS. BROOKS-WILLIAMS: And so here's the Groundhog's Day. So at our last meeting we had this conversation, and I don't think that I'm hearing a reluctance amongst the Commissioners to say, if we knew how to define the unmet need, that we might have more comfort with saying -- okay -- create a way for access. But when you can assume -- and I'm only assuming by the testimony of those today -- that Southeast Michigan does not appear to have geographic constraints, doesn't appear to have need and whatever language we would create wouldn't have any prohibition, let's just say, around how that would get interpreted. So to not repeat what happened before to say, well, half the state could do this and the other half to do that, I just -- I go back to at least just wanting to be on the record to say I don't want, because of the frustration of an artificial cap, to then open it up so wide that we are back to how do we ensure the balance of the cost, quality, access equation if we can just buy the testimony of those that are practicing now here that they are not feeling there's a compelling need based on where we are today.

MS. NAGEL: And if I could just respond for the record? The Department isn't against adding additional criteria that wasn't included in the draft. We just included what we were asked to include by the Commission.

MS. BROOKS-WILLIAMS: Thank you.

DR. KESHISHIAN: Commissioner Kochin?

MS. KOCHIN: Yeah, this is Commissioner Kochin. I just have a quick statement for us as we think about this complex problem. Us as the Certificate of Need Commission, we're charged with considering cost, quality and access. I outside of this Commission am a numbers person by trade. I love numbers. I wish we could use numbers for every single decision. The problem comes with the definition of quality and access. It's not a simple thing to define, and we have been struggling with that for some time. In addition, we are faced with the regulations as they stand today which includes a cap that is completely, from what everybody knows, arbitrary in nature and inconsistent with the other regulations as they exist. So I think a lot of the discussion where we landed as a Committee was to continue to regulate but figure out a way to remove the cap so that we can think about in the future, if need arises, how we can consider that. I believe what I'm hearing today from our distinguished speakers and everyone who's presented is there's not a good way to predict the future. We're not

sure if there's unmet need. There might be and there might not be. But I am hearing some reluctance by my fellow Commissioners of thinking about two issues separately. One is can we remove the cap or not and can we also make sure the regulations are tight enough to ensure that we're not going to have unexpected consequences from removing that cap. I think we should have more of a discussion about what some of those regulations should be to ensure we're not losing the quality and the access that we already have in the state of Michigan. So just more of a comment and less of a question.

DR. KESHISHIAN: Thank you. Any other comments?

MR. FALAHEE: Yeah, Falahee.

DR. KESHISHIAN: Commissioner Falahee?

MR. FALAHEE: Somebody a long time ago said it's a Certificate of Need not a Certificate of Want. And we always at this Commission -- in the nine years I've been on the Commission and the 28 years I've been sitting at Commission meetings, it's always tough to grapple with that. And we sometimes couch it as quality, access and cost, and it's tough to figure out which is where and where we end up on that. It's a tough decision.

We've heard really years and years of unlimited subjective opinions on this matter, and it's a tough call. I for one am not a fan of a hard number. But when I hear

repeated arguments about unmet need, yes or no, quality, access and cost, it still comes down to the same point that, in my opinion, we've got the need met in this state by what's out there now. And we've heard hours of testimony and the SAC met for dozens of hours and presented. So though there is an arbitrary cap -- and I hesitate to use the word "arbitrary" there -- I think that I at least could be comfortable leaving that. But I agree with Commissioner Kochin that, if we ever remove the cap, I agree we should put parameters, controls, language in place to make sure that we don't have unnecessary, unneeded proliferation of costly programs. I like some of the language that Dr. Yanik presented about mandatory requirements. I'm not necessarily sold on the geographic miles, minutes, whatever. But I think we've heard so much testimony that, to me, what it boils down to is what we've got now works and provides quality, cost and access.

DR. KESHISHIAN: Any other comments? Commissioner Mukherji?

DR. MUKHERJI: And I agree. I'll try to be short and brief, but -- summarize my thoughts. I think this is a tough one, because it really gets down to the modern day definition of Certificate of Need. We as a group are trying to make public policy not for the people we know but the people we don't know. And all of us around the table, I

would say, are given some level of marching orders, especially the people that came and gave their testimony.

The challenge that I have is that CON is a very -- this is a clear example of a buried entry which presentation of franchises and these franchises as we all know are very profitable franchises. Bone Marrow Transplant is a very profitable contribution to. Otherwise we wouldn't have lots of high powered people here and lots of people from other high powered places.

When I look at the data, a need is always hard to quantify. But at least the data that Elizabeth gave me, if we look at the total number of adult transplants -- and I realize that people say the transplants are stable, they're reduced. Maybe they're looking at allogenic, maybe they're looking autologous, maybe they're looking at adult, maybe they're looking at pediatrics. We really didn't get to that level of -- but what we can look at for specific numbers of transplant in the state that we can all point to and agree that the data is the data -- is the data that's provided by the Michigan Department of Health and Human Services and that demonstrates a 4 to 5 growth in total transplant, autologous and allogenic since 2012. So it's '12, '13, '14, '15 it's grown between 4 to 5 percent. So obviously the number of transplants is going to go up. So I kind of scratch my head when people say if we remove the cap, the

number of transplants is going to go down. It doesn't make sense to me.

I also haven't seen any linkage between quality, FACT and other states that don't have Certificate of Need. So, yes, we could be leaders, but we could be behind the curve as well. I don't know. If someone came to me and said, yes, the state of Michigan, if you look at our three transplant services are higher than any other state that has transplant services, then we can point to Certificate of Need and say, yes, it is working. But I'm just for -- part of it, too, is the fairness issue. I don't want to use the word "arbitrary." Someone else used it, not me, but somehow a cap was placed and a carve out was made for the rest of the state. So I think part of our modern day definition of CON is, as we evolve, do we try to maintain a level of fairness for all institutions throughout the state? This was created when there were three hospitals. Now they're very large healthcare institutions, so how do we grapple with that?

And the final area is, I probably feel that in the Southeast Michigan there's probably enough transplant services there with two large systems. But one of the main things from the CON Commission is how do we provide access for those people we don't know in other parts of the state? Because I know, if I lived in -- I mean, let me get it right

here. If I lived in the thumb, or the mitt, or the Upper Peninsula, I probably wouldn't want to go for a transplant if I had to drive two-and-a-half hours somewhere, then come back. So how do we provide access for people that we don't know?

So I just ask the Department, I know we have HSAs for -- that we implement in other Certificate of Need standards. Is it possible that could be integrated into Bone Marrow Transplant and come up with some way where we lift the cap but we actually provide guardrails so that we actually meet the needs of people that we don't know who are citizens of the state?

MS. GUIDO-ALLEN: HSA?

MS. NAGEL: Health Service Area. And those are the groups of counties that are in Appendix A of your draft.

DR. KESHISHIAN: Commissioner Guido-Allen, did you have any comment?

MS. GUIDO-ALLEN: (Shaking head negatively)

DR. KESHISHIAN: Any other comments?

MS. KOCHIN: This is Commissioner Kochin. May I ask a procedural question? Can somebody outline the options we have on the table? I know that we can take the language that we were presented today and accept it as is although we heard a lot of testimony that there's some opportunities for improvement in that language including from the Department

itself. I -- or we could choose to do nothing. I understand that, too, and just keep the existing language. Where -- is there an in between between those two options?

DR. KESHISHIAN: This is Commissioner Keshishian. I will try to answer, and the Department can state if I get anything in error. Essentially we can do essentially anything we want to do in this area. We can take another motion to deregulate and, if we do that, it would go to public hearing and it would be back here in June for final action. We could maintain standards as we have today, go for public hearing in June -- a public hearing before June and final action in June. We could adopt this language that we have here today, then public hearing with final action in June. We could ask for another work group to develop language and to have them report back in June, and then we could look to see what that language would be. And there's probably other options that I'm not thinking about but --

MS. KOCHIN: May I throw out one question --

DR. KESHISHIAN: Yeah.

MS. KOCHIN: -- as an option? Would it be possible for -- just thinking out loud here -- for a motion that asks the Department to go back with considering their recommendation that's on the table today and with the specific charge of including some of the recommendations that we have heard from the people who have testified? Is

that one of the options that's on the table?

MS. NAGEL: Yes.

DR. KESHISHIAN: Yes. And just -- the Department developed this (indicating) language in response to our request at the December meeting, so we would have to give them further guidelines on how we would want them to change the language so that, when they come back in June, we would be comfortable with the language at that time. I think the Department's stance still is this should be deregulated. And so I don't want "this is the Department's language," this is the Department's language at our request.

MS. KOCHIN: Thank you.

MR. POTCHEN: This is Joe. One of the options that you have is to table this matter. I mean, you have been -- you heard testimony, and this is a complex issue. It may take some time for all of you Commissioners to review this language and kind of take it all in. So you could table this and bring it up at the next meeting. At that point you could propose changes that, you know, more focused on the changes you want to make, if any, or again make a decision.

DR. KESHISHIAN: Yeah. I do want to just remind the Commissioners we started this in 2015, the SAC was sat at the end of 2015, we had language in June -- heated debate in June about where we should end up. We asked for a

specialist to come in and evaluate the criteria, make recommendations. He came in December, and we in December then asked for language for the Department to develop. Officially these standards actually are up again for discussion again in 2018. I don't know, if we take action now, whether it delays it for three years or what happens at that point. But, you know, in theory everything happens every three years. In a lot of ways I think whatever happens we're going to be faced with the same questions again. We're going to hear Bone Marrow Transplants are going to go down, they're going to up. We're going to hear it won't affect cost, it will affect cost. You know, the state legislature passed a law back in 2002, if I remember correctly, that said we don't want to make these decisions. We want experts. And we said we have experts across the board from physicians, people representing physicians and hospitals and medical school faculty and insurance company and nurses and let them make the decision. We'll review those decisions. And this Joint Legislative Committee reviews all of our decisions. And -- but we're not going to get -- in my eyes, we're not going to get perfect data under any circumstances. We're just going to have to listen to the testimony and try to make a decision what we think is best in the interest of the residents of the state.

MR. MITTELBRUN: So after listening to all that,

and I did get a couple answers to my first question. But I can't get past the limit on the number of people that do this work. And I can't help but think -- we talked about the fairness to the institutions, which is a valid point, but I'm trying to think of fairness to the patients. And if we disrupt -- if we have new entrants into this marketplace and we disrupt people who are providing these services and we disrupt the centers that are already in existence, how are we hurting the patients? And you brought up a good point. There's a lot of unknowns. But I'm pretty certain there's going to be disruption to the people receiving the services as these professionals move around from place to place because -- well -- and I'm assuming they're going to be incentivized (sic) to move from one place to another place. So I'm having a hard time getting around that, trying to have the perspective of the patient or the residents.

MS. KOCHIN: May I make a quick comment to one of your comments? This is Commissioner Kochin. As I'm thinking through this and there's so many difficult aspects to grapple with, but doesn't that risk of losing talent in terms of doctors who perform this service already exist, because there's a risk that these individuals could move out of state to other programs? I'm not sure on that point alone that that's something super high from a priority list

in the state of Michigan. I'm just going to throw that out there.

DR. KESHISHIAN: Commissioner Brooks-Williams?

MS. BROOKS-WILLIAMS: So at the risk of looking like a copycat from our last meeting and having had the conversations with tremendous respect for the Department, I'm going to venture to say I'll make a motion to see if it moves us forward; right? So based on the options I think that I heard, I would move that we do not adopt the language as presented and leave the standard as is and revisit it in 2018 when it comes back up and take the time in between to come with something better perhaps than what we have today.

DR. KESHISHIAN: Okay. And with that, I will add move to public comment and Joint Legislative Committee.

MS. BROOKS-WILLIAMS: Yes. It doesn't have to, I think. I'm saying --

MR. POTCHEN: No action is what you're saying?

MS. BROOKS-WILLIAMS: Right.

DR. KESHISHIAN: Okay. We have a motion. Is there a second?

MR. FALAHEE: Falahee supports.

DR. KESHISHIAN: Okay.

MR. FALAHEE: With a question for Mr. Potchen.

MS. GUIDO-ALLEN: We can have still discussion.

DR. KESHISHIAN: I thought whatever we pass had to

go through public comment. I was informed by legal that, if we keep everything the same, no change in language at all, and you're -- you know, this is technical. You said we will review this in 2018. I'm not sure -- that's part of your motion -- whether that then --

MS. BROOKS-WILLIAMS: And I can strike it if that's not, but I thought that's what I heard.

DR. KESHISHIAN: Okay. So then keep everything the same is the language, and we have a second. Any -- Commissioner Mukherji?

DR. MUKHERJI: I just have a question. I mean, obviously this is being driven by one major health system in the state. Are there any other health systems that have lobbied any of us to also express a similar desire to open up a transplant center?

DR. KESHISHIAN: I can say that, in my time on the CON Commission, various people have expressed a comment about CON. But nobody's lobbied me, no one's pushed it or anything of that sort.

MR. FALAHEE: This is Falahee. Can I ask Mr. Potchen a question? So with a motion on the floor that basically says leave it as is, if that passed, does that go for public --

MS. NAGEL: No.

MR. POTCHEN: You're required to review the

standards particularly like every three years or whatever the time period is. Now, I think you could incorporate the date that you want to review it again and because of the delay, just to clarify, in case it comes up again.

DR. KESHISHIAN: Would that need to then go for public comment if we make that change?

MS. NAGEL: No.

MR. POTCHEN: No.

DR. KESHISHIAN: Okay.

MS. NAGEL: It's only a change to the standard.

MS. GUIDO-ALLEN: Guido-Allen. There was discussion at the December meeting. We broached this topic for many hours, and we came up with the conclusion that we wanted the Department to go back and take out the arbitrary cap and ensure that the citizens in this state had access to quality Bone Marrow Transplant programs. Right? They did that. I don't understand why we would entertain a motion to go back to where we were effectively 2015.

DR. KESHISHIAN: I don't know if Commissioner Brooks-Williams or Falahee, since they made the motion and seconded it, can respond?

MS. BROOKS-WILLIAMS: Yes; absolutely. And as I said as a preamble to it, it clearly is not what I would suggest my best motion. But I would say that from now hearing all of the information that's been presented, I'm

not compelled that the language that we have moves us any further along than where we are. I agree that we don't want the arbitrary number, but I'm not convinced we have anything that's better to replace it with. And I go back to my point that, if there is a compelling reason -- and I guess I'll just be honest. I don't know that what's been presented so far is compelling, because in Southeast Michigan I do not feel that there's unmet need. So if something compelling were to come forward, then I think we as Commissioners would do the right thing and hear that. And we can open it up at any time that there's a need to address that.

MS. GUIDO-ALLEN: Guido-Allen. Again it's a perception. There is no data. There is no methodology to support that perception of unmet need. From a patient, family standpoint, we do know that there are patients and families who opt out of life saving treatment because of lack of access.

MS. BROOKS-WILLIAMS: In Southeast Michigan?

MS. GUIDO-ALLEN: In southeast Michigan, yes.

MR. HUGHES: There's people that smoke, and it says it kills you.

MS. GUIDO-ALLEN: Pardon?

MR. HUGHES: Never mind.

MR. FALAHEE: This is Falahee. The reason I supported and seconded the motion as much along what

Commissioner Brooks-Williams said. There is a number in this current standards. I will not say that it's arbitrary. It's a number. We as the Commission, based on testimony we hear and the votes we take, can, in effect, do away with the number when we hear that there are issues of cost, quality, access, need not being met. I'm not there yet. So that's why I seconded that motion.

DR. KESHISHIAN: Commissioner Tomatis?

DR. TOMATIS: And I'm with you. Just for argument, it could be a met need, though we don't have any document. That would change it to something. Let's postpone until we are aware of that need.

DR. KESHISHIAN: Commissioner Mukherji?

DR. MUKHERJI: I just want to -- just a clarifying statement. What the data does show from the MDCH is there's growth in this market. Does that translate to unmet need? I don't know.

DR. KESHISHIAN: Commissioner Falahee? Any more discussion? I'll call the question. All in favor, raise your right hand.

(Commissioners Keshishian, Mukherji, Brooks-Williams, Falahee, Hughes, Mittelbrun, Tomatis in favor)

DR. KESHISHIAN: Seven in favor. All opposed, raise your right hand.

(Commissioners Guido-Allen, Clarkson, Kochin opposed)

DR. KESHISHIAN: Three opposed. Motion carries. I want to thank everybody for all the time and effort that they've put into this work. It is a very controversial issue. Thank you. Hospital Beds Standard Advisory Committee. Public comment?

MS. NAGEL: This issue is up for your review. It was tabled from the January meeting. In the January meeting as part of our special meeting, the Department recommended review of the Hospital Bed Standards for a number of different issues. That same issue briefing is in your packet today. There was some discussion on the Commission's ability to regulate observation beds, and that tied up the discussion or any movement of forming a SAC to review all of the issues and the SACs charge. So this issue comes back to you. You asked the Department specifically to work with the Attorney General's Office to determine if this body had any authority over observation beds, and we have done that. And Mr. Potchen is here to provide that update.

MR. POTCHEN: So we have -- this is Joe. We have researched this issue, and what I can say is that there is a viable legal argument that the Commission has authority to regulate in this area. However, it's something that we do not address and something that you probably should consider

is whether you do want to start by getting into this area. That's all I'll say.

DR. KESHISHIAN: Thank you. Commissioner McCaffer- -- not Commissioner. Dennis McCafferty -- I'm sorry. Any questions for the Department or for Joe? Okay. Public comments, first Dennis McCafferty.

DENNIS MCCAFFERTY

MR. DENNIS MCCAFFERTY: While I appreciate the impromptu promotion to Commissioner, I believe legally I'm not -- as a lobbyist, I'm not eligible to serve, so I have to respectfully decline. I want to clarify what our members ask is on this. We are asking if the charge could merely include the question should hospital beds be included in the CON regulated services and ask that the SAC if they consider requiring a reporting of the number of patients for each institution annually that are classified or -- I don't want to say admitted but provided services that were observational -- in observational beds and how many observational beds services did they provide. If this should be regulated or how it should be regulated, we first need to know how big is this thing? And we're hearing from our members that it is a problem that is growing. And they are concerned. And by having included in the regulation a requirement that we at least know how big it is, we then would know whether this is something that needs to be

regulated or not and whether -- and how that might have to be done.

DR. KESHISHIAN: Thank you. Any questions?

MR. FALAHEE: Just a comment.

DR. KESHISHIAN: Commissioner Falahee?

MR. FALAHEE: This is Falahee. Much of this, maybe all of this, is out of the hands of the hospitals in the state. Even if we could tell the Department we had X number of observation days per year, we as the hospital don't control what's an observation day. That's subject to physicians, it's subject to requirements imposed by Medicare and other payers. So even if we had the number, whatever the number is -- I don't care -- so what? And maybe that's part of what Mr. Potchen was saying. I don't think we're going to have the ability, regardless of what we might want to do, to tell CMS we don't care what you say. I'd like to say that, but I don't think we have that ability.

MR. DENNIS MCCAFFERTY: In my first iteration of comments on this, I tried to reflect that concern to suggest -- and this is from our members' perspective -- the business and labor community in the state -- that they're more keenly concerned about the non-Medicare patient observation bed usage recognizing that the Medicare patient observation beds are, like you said, beyond your concern and often retroactively determined. So if we were to ask the

SAC to consider this, we might clarify that point to say that, if hospitals are reporting on the number of observational beds, are we talking about just Medicare patients or are we talking about something else in addition to that?

MR. FALAHEE: This is Falahee again. I'll look to my other hospital representatives at the table or in the room. As far as I know, observation beds are Medicare. That's it. There aren't non-Medicare observation beds.

MS. GUIDO-ALLEN: They're just observation.

MR. FALAHEE: They're just observation.

MS. GUIDO-ALLEN: It doesn't matter what coverage they have.

MS. BROOKS-WILLIAMS: Other payers will categorize care as observation --

MS. GUIDO-ALLEN: Correct.

MS. BROOKS-WILLIAMS: -- care, but there's no distinction in terms of how we treat them as a result of them, you know, being with a private payer or with CMS.

MR. DENNIS MCCAFFERTY: Oh, it's not whether you treat them or not. Our members -- again I'm --

MS. BROOKS-WILLIAMS: I understand.

MR. DENNIS MCCAFFERTY: -- getting this third hand.

MS. BROOKS-WILLIAMS: I get what you're trying

to --

MS. GUIDO-ALLEN: I have a question for you. This is Guido-Allen. Are your members concerned about the co-pays that folks are getting because they're in observation status versus inpatient, which are generally much higher than if they were an inpatient? Is that the concern that they're hearing?

MR. DENNIS MCCAFFERTY: That's part of the concern, yes, and -- that's part of the concern. But the concern also relates to the fact that here is a whole new category of people using hospital services. They're in a bed. We're not calling them, quote, unquote, inpatient. But for every layman's perspective, they seem like inpatients.

MS. GUIDO-ALLEN: They are a pa- -- they're as sick as our inpatients are, too; right?

MS. BROOKS-WILLIAMS: Right.

MR. DENNIS MCCAFFERTY: True; sure.

MS. GUIDO-ALLEN: So after October, (inaudible) data, (inaudible) criteria is updated and you may have qualified for an inpatient stay on September 30th and on October 1st, the criteria changed and now you're observation. We don't have as hospitals -- we don't have control over that. It's third party payers that dictate what status the patients are in.

MR. DENNIS MCCAFFERTY: Okay. The CON regulations for beds require that hospitals show how many admissions they have and how many lengths of stays they have. And we have certain things regarding capacity, excess capacity, and a lower -- low capacity hospitals that affects how many beds they're licensed to have. All of a sudden observation beds come along, and now there's a whole bunch of beds being used that are not included in that number. So you may have a hospital that is full, 90 percent or more of their beds are filled with patients, and they might qualify for excess beds under the standards but, in fact, they can't get them because they're not inpatient beds. They're not counting them as that. Or you might have a hospital that is looking at very low occupancy. Their CON counted admissions and bed stays are 39, 40 percent and they might lose some of their licensed beds but, in fact, they are actually experiencing 75 or 80 percent capacity because those other patients are the observational patients. So we're merely asking that they be included in the charge and that the number be reported so we know how big this thing is, how big is the apple, how big is the balloon. We don't know.

DR. KESHISHIAN: Any other questions?

MS. BROOKS-WILLIAMS: This is Commissioner Brooks-Williams. I do have a question. So what you just described very different than what I would assume could be

your members' experience, but I don't know. So just if you can re-frame for me again, what is the concern? The issue that you're describing I fully understand, because we live it every day in terms of figuring out who's who and not having any control of the regulations. Is the concern that we're using too many beds for obsvs patients? We don't have enough beds for obsvs patients? Because I don't think you have anyone from the operating side coming forward and saying we need a definition for obsvs or we need more beds for obsvs or we need regulation around it. So I'm just trying to understand what the issue is from your members' perspective? Not arguing to quantify or count it, and it does get counted. It's an outpatient. I mean, it's not an inpatient. So we're not changing anything in our inpatient reporting as a result of observation other than the number going down.

MR. DENNIS MCCAFFERTY: Okay. Again I'm reporting what our members are telling me. They're seeing a dramatic growth in the number of claims that they're paying related to observational beds.

MS. BROOKS-WILLIAMS: Okay.

MR. DENNIS MCCAFFERTY: It's not controlled by CON. They would like to know more about how big is this problem and is this something that needs to be addressed in future regulations or not. We don't know. We think the CON

process is a way of collecting that data and we'd like the SAC to consider doing that.

MS. BROOKS-WILLIAMS: Okay. Thank you.

DR. KESHISHIAN: Any other questions?

MS. NAGEL: If I could just clarify one thing with the Commission. The observation beds is a topic that the Department has looked at as well but not in the context of a hospital setting. What we're seeing is a growth of observations beds in freestanding surgical centers where there's surgical procedures going on and the -- these aren't licensed hospital beds. These are just beds where the patient has no -- the clinician has no feeling that this person's going to need inpatient care but will then be observed, and that's where we're seeing a rise in this service. Now, we've never taken a stance that that's an inappropriate or an appropriate use of observations beds. But as far as -- that would be something that we would consider to be interesting to collect to know whether or not it's worthy of regulation. We've never had any indication of collecting information on observation beds in a hospital setting where there are other licensed beds. We're concerned about settings where there are no licensed beds today.

MR. DENNIS MCCAFFERTY: I can amend my comment. I thank you, Beth, for bringing that up, because that's part

of the issue our members see is the use of observational beds in facilities that do not have licensed beds and how big of a problem is this and is this, in fact, facilities around the state who are circumventing the CON rules of having licensed beds by using observational beds in lieu of licensed beds.

DR. KESHISHIAN: Thank you.

MS. CLARKSON: This is Commissioner Clarkson. I had a question in regard to quality. Do the stats in the observational beds count in the quality stats that we keep on hospitals, whether they're outpatient or inpatient?

MS. BROOKS-WILLIAMS: When you say stats?

MS. CLARKSON: Whatever your statistics are. For instance, if I died.

MS. NAGEL: Yeah; yes.

MS. BROOKS-WILLIAMS: This is Commissioner Brooks-Williams. And, yes, the quality of the care -- and I think Commissioner Guido-Allen said it earlier is that, in the hospital settings, there's a limit in every setting, in every setting. I think the scenario that Beth described -- and I'll be honest -- right? -- part of the growth that you're probably seeing is again what Commissioner Guido-Allen said. We aren't what is an in- and an outpatient surgical procedure. And so you have procedure that previously were done as inpatient and we anticipated a

stay; we've decided that now they're outpatient. People come in very different, you know, characteristic, and they are not safe to go home and so they're staying in those environments. And if it's been done in an outpatient freestanding facility, then you kind of don't have a choice. You're either going to transfer them to a hospital, you know, or observe them overnight.

DR. KESHISHIAN: Tony Denton, Michigan Medicine.

TONY DENTON

MR. TONY DENTON: Good morning (sic). I am Tony Denton. I'm senior vice president and chief operating officer. It's kind of hard to make comments that have already been stated already. But for the hospital Commissioners who did comment, I can tell you that, A, we're not circumventing; B, we are impacted by the payers defining level of service and the reimbursement for those levels of service. For hospitals that have capacity and had capacity when the criteria were first changed, they did utilize the capacity that they had to take care of patients just because the stroke of a pen didn't change the type of care that was being provided. It actually created pressures where the hospitals define lower cost environments to take care of patients. At Michigan we had to create observation units, change the level of staffing associated with others' view that the intensity was less in order to continue to cover

the cost if, by definition, give us capacity back in our inpatient beds to take care of inpatients of which there is high demand. There is no way to control what happens day by day when the patient conditions vary day by day.

So while I certainly appreciate the real interpretation that the Commission could review this as under your jurisdiction the question about should, I say the answer is no, because there is no way to define and clarify the scope in a way that it's not going to be reviewed and contested each day and every day.

We sent letters to American Hospital Association, worked with the MHA, to work with Medicare to try to get a better handle on how observation status was going to affect patients. Because like many hospitals, we heard from patients saying, "I thought I was in the hospital." But when it came time to be referred for the skilled nursing facility care and benefit, it wasn't covered and we had a big bill. Those are the questions that we need to understand if there's any issue at all around observation and trying to understand it better. I don't think it should be referred to a SAC. If there's any interest at all, refer it to a work group, do bench marking across the country, see what others might be thinking about. But I don't think it would be appropriate to bundle it into this category of beds standards as you consider other issues for review. Thank

you.

DR. KESHISHIaN: Thank you. Any questions? Thank you.

MR. DENNIS MCCAFFERTY: Thanks.

DR. KESHISHIAN: Discussion?

DR. MUKHERJI: So just want to frame it, because I think I was in that chair last week, so it's my fault. My understanding to put everything in this is that the observation beds issue we're debating is just to determine whether it should be part of the agenda for the SAC; is that right? So we're really debating an agenda item. And even if that agenda item was included, it could not even be supported in the SAC; is that correct? Do I have this framed correctly?

DR. KESHISHIAN: Yes. I need a question, and probably we would need a motion at one point to include a discussion and potential recommendations for observation beds for the SAC or not to include it, because we had that issue on the table in the January meeting.

MS. NAGEL: If I could add, you also did not vote to convene a SAC.

DR. KESHISHIAN: Okay.

MS. NAGEL: So if you want to address the other issues, you'll need to let us know how to do that.

DR. KESHISHIAN: So there are two issues. Do we

sit a SAC for hospital beds and do we put the charge of the observation beds. Usually the charge, the Committee -- the Commission delegates that to the chairperson to develop the charge. Last time it became an issue, so we ask the Department, A, could we do it, put it in the charge, and the answer is, yes, you could. Now, the question we have to decide is, do we?

DR. MUKHERJI: So I'll make a motion. I'll recommend we sit a SAC for the hospital beds, but we do not include observation beds on the agenda.

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

DR. KESHISHIAN: Any discussion? Okay. All in favor of the motion raise their right hand. Eight in affirmative. All opposed? One. Motion carries.

MS. NAGEL: I'm sorry. I apologize. Is the charge delegated to the chair or should it be encompassed the other issues that were identified?

DR. KESHISHIAN: Who made the motion?

DR. MUKHERJI: No, I didn't realize that was part B.

MR. POTCHEN: What we're trying to ensure is that you would leave it to the chair to draft the charge incorporating the other elements that the Department recommended be looked at?

DR. MUKHERJI: In general when I run the SACs is I leave it up to the discretion of the chair in cooperation with the Department. That's the assumption.

MR. POTCHEN: And that's what you meant?

DR. MUKHERJI: Right.

MR. POTCHEN: Yeah. Okay.

DR. KESHISHIAN: And is it accepted?

MS. BROOKS-WILLIAMS: Yes, that's what we meant.

DR. KESHISHIAN: Okay. Does anyone object to that? Thank you. Okay. Legislative report.

MR. LORI: Thank you, Mr. Chairman. Appreciate the opportunity to present this afternoon. Probably the biggest thing that's happened in my life in the last four months is the 298 work group. That is the behavioral health public health integration project. And as most of you may have seen, that report -- the second half of that report came out yesterday. I will say our work is far from done. It's in the legislature's hands right now. We'll let them review that, our final product, and again we still have a lot of work to do.

Next item that has taken a lot of my time is the SIM project or the State Innovation Model. And again we released a boilerplate for that last month in February. If anybody wants a copy, let me know and I'll get that to you. But I think I'm going to be in the instruct staff to do some

sort of -- there seems to be an interest in what the SIM project is doing, where they're headed. I think I'm going to instruct staff to come up with some sort of a reporting system, maybe a quarterly report to our partners out in the community, so that you know what's going on.

The next thing that is begun is the budget process. And at 2:00 o'clock today I begin my first budget work group hearing. And again that's going to occupy my time for about the next three weeks as well as many other staff within the Department. And again this is the start of the legislative process. The legislature's been in a couple of months, but some of the bills are just starting to roll in and we're just starting to get busy, as much as I hate to say that, because I've been extremely busy for the four months I've been in this position.

But with that, Mr. Chairman, I'll conclude my Legislative Report.

DR. KESHISHIAN: Okay. Thank you.

MR. FALAHEE: Question.

DR. KESHISHIAN: Commissioner Falahee?

MR. FALAHEE: Falahee with a question to Mr. Lori. In your visits to offices or across the street, is there anybody out there that has on their plate or front burner Certificate of Need issues?

MR. LORI: Actually I gave my presentation

yesterday to the House Appropriation Subcommittee. But to answer your question, yes.

MR. FALAHEE: Okay.

DR. KESHISHIAN: Any other questions? Okay. Administrative Update, Planning and Access to Care Section Update, Beth?

MS. NAGEL: Yes. We are -- based on the January meeting, we have three main tasks ahead of us that we worked on since that meeting. One is seating a Cardiac Catheterization Standard Advisory Committee. Nominations were due yesterday at 5:00. We are reviewing those nominations, and we'll work with the chair to get them those details. Also we are working on language to bring to you in June for Open Heart Surgery and Surgical Services.

DR. KESHISHIAN: Any questions? CON Evaluation Section Update. Tulika?

MS. BHATTACHARYA: Thank you, Dr. Keshishian. So actually there are four additional report compared to the previous meetings. First off, the program activity reports, if you look at the data, we continue to meet the statutory requirements for processing the application and issuing decisions on time. The second report that I wanted to talk to you about -- or it is in your packet -- are the compliance activity review. If you look, there were two specific compliance action based on information that we

found out during our review process of an application. And so other than that, we had started this year the statewide compliance review for two specific services, which is Cardiac Cath Services and Megavoltage Radiation Therapy.

And I would like to take this opportunity to thank our two newest employees to the CON team, Jack Ho and Katie Timer, our compliance analysts. And they have really done an excellent job in doing all of the research and analysis and historical overview of the facilities.

So a quick look at the Cardiac Cath Service, like, what is the scenario in Michigan? So there are 60 facilities that provide cardiac cath services in the state at different levels like diagnostic only program, diagnostic with primary PCI and/or elective PCI and then therapeutic hospitals with open heart surgery. So that's the number. And the standards that apply to them are there are seven different standards that we'll have to look at in order to decide if they're meeting their project delivery requirements, because the standards are not prospective because we have to judge them under the standards they were reviewed under. So the only standards that are still out there a facility operating under is February of 1997.

So based on the data reported in the annual survey, we found that 30 percent are not meeting their volume requirements, 10 percent are not in compliance with

the 24-hour specialty staffing requirements, 15 percent are not properly registered with the accreditation organizations that they are required to. So what we did is we sent out a detailed survey questionnaire to all 60 facilities. And right now we are in the process of collecting those information, analyzing them. And we will bring back the information at a later date regarding how many are out of compliance and what are the remedies and things like that.

If we look at the MRT services, there are 68 facilities in the state that is currently providing MRT services. Again there are seven different review standards that they're approved under, the oldest going back to June of 1993. When we look at volume, about 44 percent facilities are currently not meeting their volume requirements and then about 13 percent are not in compliance with their accreditation requirements as outlined in the standard like JCAHO or ACR or ASTRO. And we are again currently in the process of following up with them and making sure that their annual survey data is correct and, if they are truly not in compliance, what are the remedies and things like that.

I was also asked to provide an update on the psychiatric special pools that the Commission recently adopted. So there are three different special pool categories that we have added to the Psychiatric Beds and

Services standards; geriatric, developmental disability patients for adult and children and then medical psychiatric patient for adult and children. So in the adult pool, we have 110 beds in each category and, for the child/adolescent pools, we have 20 beds in each category. And February 1 was the first application submission date after the standards went into effect in December of last year. So we have received a total of eight applications in the category of geriatric beds, and they are requesting a total of 140 beds. So they're requesting more beds than are available in the pool, so we cannot approve everybody. So there will be a comparative review and scoring, and we have to decide who has the best project or proposal to get approval for those special pool beds. For developmental disability pool, we have received one application that is requesting 16 beds. For child pool in developmental disability, we have received two applications requesting 20 beds. So if they're approved, there will be no beds available in that pool anymore. In the med side adult category, we have received two applications requesting a total of 45 beds. So even if they're approved, there will be beds available in that pool. And in the med side child category, we have received one application requesting ten beds. So if that application is approved, there will still be ten beds available. With that said, if there are any questions?

DR. KESHISHIAN: Thank you very much. Are there any questions? Thank you. Legal activity report?

MR. POTCHEN: Hi, this is Joe. We continue to assist the Department in drafting standards. I went to (inaudible) District Court, and it looks like we're going to get some activity potentially on the litigation side. And I do want to introduce our newest Assistant Attorney General in our office. His name is Carl Hammacker. He will be assisting on CON matters.

DR. KESHISHIAN: Welcome. Future meeting dates. We are proposing to change the December 7th meeting to December 13th. Commissioner Cowling has a conflict with many of the meetings this year, and this is the one that both Dr. Mukherji and I could actually change and we would both still be there. If there isn't any objections from any of the Commissioners, we would like to switch from December 7th to December 13th. Does any -- and I know everyone has their calendars right readily available to see. But is there any objections that anyone's aware of changing the date?

MS. BROOKS-WILLIAMS: Commissioner Brooks-Williams, I can't do it if it's on that date.

MS. GUIDO-ALLEN: Yeah, conflict.

DR. KESHISHIAN: Two conflicts. Okay. All right. Well, then we'll keep it the same, December 7th. Okay. We

don't need a motion. Public comments? I don't have any cards. Review of Commission Work Plan. Beth?

MS. NAGEL: I will make the necessary changes to the work plan which include seating a SAC for hospital beds and a public hearing for lithotripsy and with that I need a motion to approve the work plan.

DR. KESHISHIAN: Do I hear a motion for approval?

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

DR. KESHISHIAN: Do I hear a second?

MR. HUGHES: Second, Hughes.

DR. KESHISHIAN: Any discussion? All in favor say "aye."

(All in favor)

DR. KESHISHIAN: Opposed? Okay. Thank you. Next item, Election of Officers. Each March we elect officers for the upcoming year. Under CON bylaws, you can serve for three years. I've served for three years as chairperson. I've enjoyed it tremendously. I enjoyed all the support that all the Commissioners have shown me. I believe that CON is one of the major factors that leads to lower costs in the state of Michigan, improved quality, and we keep access available for the residents of the state. So it's been a honor to serve as chairperson of this Commission for the last three years. Having said that, somebody else has to have the fun of this responsibility, so I will open it up

for any nominations at this --

MR. HUGHES: Before you do that, I'd just like to say never do a bad job well. You've done the job very, very well.

DR. KESHISHIAN: Thank you very much.

DR. TOMATIS: And I second that.

DR. KESHISHIAN: Thank you.

MR. POTCHEN: The one thing before you make the nominations, according to your bylaws, the chairperson and vice chairperson cannot be members of the same major political parties.

DR. KESHISHIAN: Okay.

MR. FALAHEE: This is Falahee. Having sat in the chairman role and then the vice chairman role, I'll make -- I assume we should do separate motions. So I'll make a motion that the gentleman sitting to my right be the chairman. I nominate Commissioner Mukherji be nominated as chairman of the Commission.

DR. KESHISHIAN: Do I hear a second?

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

DR. KESHISHIAN: Okay. I don't know if there's any discussion. Any other nominations, I should say, ask that? All in favor say "aye."

(All in favor)

DR. KESHISHIAN: Opposed? Okay. Thank you.

MR. FALAHEE: And then this is --

DR. KESHISHIAN: Motion on Dr. Mukherji, congratulations.

DR. MUKHERJI: Thank you, I think. I'm just reminded of that old story when the outgoing chair is meeting the incoming chair -- and maybe you've heard this parable -- but both are smiling because the outgoing chair knows what he's leaving and the incoming chair has no idea what he's in for.

MR. FALAHEE: Ah, bliss. And then I make a motion that as vice chairman Tom Mittelbrun be the vice chairman of the Commission.

DR. KESHISHIAN: Do I hear a second?

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

DR. KESHISHIAN: Okay. Any other nominations? All in favor raise your right hand.

(All in favor)

DR. KESHISHIAN: Positives are ten, negatives -- any opposed? None. Congratulations, Tom. With that, it is adjournment unless there is other business that needs to be brought forward? I need a motion officially -- I'll get this down. A motion for adjournment?

MR. MITTELBRUN: Motion of adjournment, Tom

Mittelbrun.

DR. KESHISHIAN: Okay. Thank you.

(Proceeding concluded at 12:32 p.m.)

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