| 1   |  | STATE OF MICHIGAN                        |  |
|-----|--|--|--|
| 2   | MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES |  |  |
| 3   | CERTIFICATE OF NEED COMMISSION                   |  |  |
| 4   |  |  |  |
|     |  | COMMISSION MEETING                       |  |
| 5   |  |  |  |
|     | BEFORE SURES                                     | H MUKHERJI, M.D., CHAIRPERSON            |  |
| 6   |  |  |  |
|     | 333 South Gr                                     | and Avenue, Lansing, Michigan            |  |
| 7   |  |  |  |
|     | Thursday,  | December 7, 2017, 9:30 a.m.              |  |
| 8   |  |  |  |
| 9   | COMMITTEE MEMBERS:                               | THOMAS MITTELBRUN, III, VICE CHAIRPERSON |  |
|     |  | DENISE BROOKS-WILLIAMS                   |  |
| 10  |  | JAMES FALAHEE                            |  |
|     |  | TRESSA GARDNER, D.O.                     |  |
| 11  |  | DEBRA GUIDO-ALLEN, R.N.                  |  |
|     |  | ROBERT HUGHES                            |  |
| 12  |  | MARC D. KESHISHIAN, M.D.                 |  |
|     |  | MELANIE LALONDE                          |  |
| 13  |  | LUIS A. TOMATIS, M.D.                    |  |
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| 19  |  | MATTHEW LORI                             |  |
|     |  | BETH NAGEL                               |  |
| 20  |  | TANIA RODRIGUEZ                          |  |
|     |  | BRENDA ROGERS                            |  |
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| 1  | Lansing, Michigan  |
|----|--|
| 2  | Thursday, December 7, 2017 - 9:32 a.m.                     |
| 3  | DR. MUKHERJI: Good morning, everyone. Welcome on           |
| 4  | this snowy December morning. Just want to thank everyone   |
| 5  | for coming to the CON Commission. So I'm going to call the |
| 6  | meeting to order. The next is the review of the agenda.    |
| 7  | Does anybody have any comments on the agenda? If not, I'll |
| 8  | take a motion to approve the agenda.                       |
| 9  | DR. GARDNER: Motion.                                       |
| 10 | DR. MUKHERJI: Okay. We have a motion to approve.           |
| 11 | Second?  |
| 12 | MS. BROOKS-WILLIAMS: Support.                              |
| 13 | DR. MUKHERJI: We have a second. We have a motion           |
| 14 | and a second. Any point of discussion? Oh. Sorry.          |
| 15 | MS. ROGERS: This is Brenda. Just as a friendly             |
| 16 | reminder, would you please identify yourself each time     |
| 17 | before you speak? So the maker of the motion was?          |
| 18 | DR. GARDNER: Tressa Gardner.                               |
| 19 | MS. ROGERS: Thank you. And the second one?                 |
| 20 | MS. BROOKS-WILLIAMS: Denise Brooks-Williams.               |
| 21 | MS. ROGERS: Thank you.                                     |
| 22 | DR. MUKHERJI: You're slowing me down. Okay. So             |
| 23 | we have a motion and a second. Any further discussion? All |
| 24 | in favor?  |
| 25 | (All in favor)   |

| 1  | DR. MUKHERJI: Any against? The agenda is                     |
|----|--|
| 2  | approved. The next is declaration of conflict of interest.   |
| 3  | Anybody have any relevant conflict of interest? Hearing      |
| 4  | none, I'll go to the review of the minutes. So the minutes   |
| 5  | are included in the package, so we'll give people a couple   |
| 6  | minutes to review the minutes. Once they've been reviewed,   |
| 7  | I'll be happy to take a motion to accept the minutes.        |
| 8  | MR. FALAHEE: This is Falahee. Make a motion to               |
| 9  | approve.   |
| 10 | DR. MUKHERJI: So we have a motion to approve.                |
| 11 | Any second?  |
| 12 | MR. MITTELBRUN: Mittelbrun, second.                          |
| 13 | DR. MUKHERJI: Mittelbrun, second. We have a                  |
| 14 | motion and a second. Any further discussion? Hearing no      |
| 15 | discussion, all in favor?                                    |
| 16 | (All in favor)   |
| 17 | DR. MUKHERJI: Any against? Okay. The minutes                 |
| 18 | are approved. The next agenda item is Urinary                |
| 19 | Extracorporeal Shock Wave Lithotripsy draft language. I      |
| 20 | have one blue card for public comment. Brenda, do you want   |
| 21 | to just tee this up for us before we get public comment?     |
| 22 | MS. ROGERS: This is Brenda. Good morning. In                 |
| 23 | your packet of material you have the draft language. As      |
| 24 | you'll recall at your September Commission meeting you asked |
| 25 | the Department to go back and possibly make some             |

modifications, taking a further look at the MRI conversion language, which includes looking at it for a tax-exempt not-for-profit hospital, operating a 24/7 ER, et cetera. So the Department has done that. We've kind of done that in conjunction with the requester of this addition to the language. So you have that in front of you. So the major changes from what you had in September -- okay? -- are we have changed it from -- originally we were suggesting 1,000 procedures be done.

That's been changed to 500 procedures annually for the past three years. But along with that, we have looked at the ER visits, similar to what MRI does. In MRI, they used 20,000 visits, but obviously that's a different modality. In taking a look at the data for the -- I think it was the 2016 data that we looked at, 80,000 visits kind of seemed to be the mid point and seemed to be a reasonable suggestion.

So that is an addition as well. I think the other things we've done -- we've looked at removing the volume requirement for replacement, same as what we've done in the other CON review standards. And we've also -- under Section 4(3) there's language in there for a conversion from fixed to mobile units. That was put in there years ago when there were only fixed units in the state, and it was to be able to allow them to convert to mobile. So we are leaving that in

there, but with a modification that if you want to convert -- let's say as time goes by, if more facilities convert their mobile units to fixed and at some point they feel that they want to convert back, they may be allowed to do that. However, you will have to be meeting the volume requirement which isn't there right now. So we've left the language in there for possibilities down the road, but you do have to meet the volume requirement in order to do that.

I'm trying to think. The other major change, you'll see some language in Section 7(4) of the draft language which has been completely stricken. That is being removed as to give mobile routes more flexibility to change, to accommodate if there's changes caused by larger facilities converting from mobile to fixed units. So it's -- again, so trying to find a balancing act in all of this. So that's really what that's doing.

So I believe those are the major changes in the draft language. And if you have any questions, we will try to answer those. Otherwise, we submit this language and do support it for proposed action if the Commission chooses today. Thank you.

DR. MUKHERJI: Any questions for Brenda?

DR. GARDNER: Tressa Gardner. Brenda, why was ER even considered as this is not an emergent procedure, and why was there an 80,000 visit?

MS. ROGERS: There was a discussion, as you'll recall, at the last meeting to kind of take a look at that and to add some additional parameters if we are going to allow this in the state. So even though these seem to be done in an outpatient setting, it still is done -- it's kind of a demonstration of a facility that they are operating not necessarily just lithotripsy, but they are a high-volume facility that wants to do this.

So that was proposed and the Commission asked the department to take a look at that. We looked at it and, you know, we can support that if that's what the Commission chooses. And I believe it was Commissioner Falahee that made that suggestion, so I'll let him chime in if he's got any additional comments.

MR. FALAHEE: No. I don't have any additional comments. You're correct. When I mentioned that in September, I said look at what we do for MRI as an example, not to be zealously followed. But I think the department did a good job of trying to thread the needle and I'm comfortable with that language.

DR. GARDNER: Tressa Gardner. How many hospitals would that include and is this a disadvantage to the hospitals that do not have -- once again, ER volume is not related to this procedure -- that do not have 80,000 ED visits?

| 1  | MS. ROGERS: I don't have the data with me, but I             |
|----|--|
| 2  | believe it was the top ten percent of the hospitals in the   |
| 3  | state.   |
| 4  | DR. GARDNER: And does it cover a service area?               |
| 5  | Appropriate coverage for the state?                          |
| 6  | MS. ROGERS: I personally did not look at where               |
| 7  | the individual hospitals are, so that I can't answer the     |
| 8  | question on that, but it was the top ten percent of the      |
| 9  | hospitals in the state.                                      |
| 10 | DR. GARDNER: I think those would be very                     |
| 11 | concentrated and my concern would be if you had 50,000-visit |
| 12 | ED's that could do the same procedure, it should be related  |
| 13 | to the volume that they have if they're doing it from a      |
| 14 | mobile unit as opposed to the ER volume overall.             |
| 15 | DR. MUKHERJI: Any other questions?                           |
| 16 | MR. MITTELBRUN: I have one. Tom Mittelbrun.                  |
| 17 | Brenda, when you mentioned the change from the 1,000 to 500, |
| 18 | was that 500 annually or average?                            |
| 19 | MS. ROGERS: It's an average over the three years.            |
| 20 | So let's say so it's the previous three years. And I had     |
| 21 | to do this for myself because I keep getting those confused. |
| 22 | But it's so if you had 500 one year, 700 another, 600        |
| 23 | over the other, a third year, and divide that by three, that |
| 24 | comes out to 600 so you meet the requirement.                |
| 25 | MR. MITTELBRUN: Okay. Thank you.                             |

DR. MUKHERJI: Other questions? Okay. Hearing none, we have two cards. The first is from John Shaski at Sparrow Health System. And just to remind all the speakers, we're going to hold them to strict three minutes presentation period. Right, Tania?

## JOHN SHASKI

MR. JOHN SHASKI: Thank you. Good morning. I'm

John Shaski and I'm the government relations officer at

Sparrow Health System. Sparrow appreciates the Commission's

time and deliberation on the issue of UESWL standards,

specifically the conversion of a mobile to a fixed unit.

We've read the department's proposed standards and we

believe they provide for a good compromise to those who have

weighed in on this issue. The language allows hospital

providers with a demonstrated, consistent, high volume to

convert to a fixed unit at one location.

We believe the language is consistent with other sets of standards and reflects the direction given by the Commission to the department at the September meeting. As you are aware, over the past several years Sparrow Hospital has raised concerns about the cost of providing high-quality high-volume lithotripsy services in a mobile environment. Sparrow is very committed to our patients. In the past six years our volume has maintained high levels. However, the cost of the annual lease and service contract exceeds the

cost of a new machine, which creates a significant barrier.

We appreciate the work that is done by the department and the Commission, and we look forward to working together to advance this proposal.

DR. MUKHERJI: Thank you very much. Any questions for Mr. Shaski? Thank you. The next card I have is from Melissa Cupp from RWC Advocacy.

## MELISSA CUPP

MS. MELISSA CUPP: Good morning. My name is
Melissa Cupp and I'm with RWC Advocacy. I am here this
morning representing Jorgen Madsen at Great Lakes
Lithotripsy. He actually did fly in for this meeting this
morning, stayed by the airport in Detroit and unfortunately
we didn't give him the warmest welcome. Someone broke into
his vehicle -- his rental vehicle -- and he is stuck dealing
with the police and the insurance and the rental company
this morning. So he did send me his comments and asked that
I deliver them on his behalf. So not quite the introduction
he was planning to make.

"Thank you for this opportunity to provide additional comments regarding the CON standards for lithotripsy services. We appreciate the additional time and effort the department has put into finding a compromised proposal to cautiously allow for the conversion of higher volume lithotripsy host sites to

1 convert to fixed service and obtain their own units.

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Although we continue to have concerns about the overall impact these conversions will have on access to lower volume sites throughout the state, we do support the Department's proposal with just one exception. The Department's proposal looks at a three-year average of lithotripsy volumes at the host site proposing to convert to fixed service. We do not feel this is the most accurate way of projecting need for a service. a host site has had really high volume three years ago, but since then experienced a decrease in volume, the most recent 12 months would show a much more accurate picture of what the facility should expect for volume going forward. We do not believe a three-year average is used in this way in any other standards and would request this be changed to require 500 in the previous 12 months to qualify for this provision.

We do appreciate the inclusion of a couple of provisions that will help remaining mobile routes to adjust to significant changes in volume and schedules which will hopefully allow them to maintain as much geographic access as possible including assurance that they will be allowed to replace aged equipment when needed."

This was not in Jorgen's comments, but I'll add it

just regarding the 80,000 ED visits. Although we do recognize that this is not an emergent procedure, as Sparrow actually had pointed out in their comments last time, many patients do arrive at the facility via the ED. And then in looking at -- I did just a real quick review of the data that I had on my laptop and there are facilities with 80,000 or higher ED visits that seem to be spread out pretty well.

I saw Grand Rapids, Jackson, Lansing, some in Detroit. So I can't speak to everything, but there did seem to be a reasonable distribution. "We hope that we found a balance here that will allow the mobile routes to continue to provide excellent access across the state and we support the concept." Thank you.

DR. MUKHERJI: Thank you very much. Questions for Ms. Cupp?

MS. BROOKS-WILLIAMS: Commissioner

Brooks-Williams. So talk a little bit more about the most recent 12 months of the data versus the average of 3 years.

MS. MELISSA CUPP: The average 3 years? Yeah. So I think the idea of being -- and I'll throw this out just as a really absurd example. But I think sometimes the absurd kind of demonstrates the concern that we have. So let's say -- so we're looking at a 3-year average of 500. So if a facility performed 1500 three years ago and nothing in the most recent 12 months, their average would still be 500.

And so historically, at least from what I can remember -- and I admittedly did not look through every set of standards, so if somebody knows otherwise, please jump in and correct me -- but I don't believe we used a 3-year average in this way in any other standards. So we used, I think, like an average per year for, like, 3 consecutive years out of high occupancy for hospital beds, and I think we maybe used, like, a 2-year every, you know -- every two years of high occupancy on psych. But for projecting, like, a specific volume needed to do something in this area, we've always just used the most recent 12 months.

MS. BROOKS-WILLIAMS: Okay. Thank you.

DR. MUKHERJI: Other questions?

MR. FALAHEE: This is Falahee. I can see the other flip, though. You don't want to have a spike up or down meaning that that's what you're going to have going forward. So I understand why we do the average as we talked about earlier. I'd like to know what the department's position is on that. That will inform us.

MS. NAGEL: Sure. This is Beth. The average was meant to recognize that today on the mobile routes, the provider, the host site, is -- actually has less control over their volume than in our other modalities. So if a host site gets added to the route, the volume at that facility will drop. And so the average was meant not to

| 1  | capture the absurd, but to capture the very real thing      |
|----|---|
| 2  | that's going on. The phenomenon we're seeing is that these  |
| 3  | sites, unlike our other standards, have very little control |
| 4  | over the volume.  |
| 5  | DR. MUKHERJI: I kind of agree with that, too.               |
| 6  | I'm not a statistician I did stay in the Holiday Inn last   |
| 7  | night.  |
| 8  | MR. MITTELBRUN: You didn't have your car broken             |
| 9  | into.   |
| 10 | DR. MUKHERJI: Yeah. I didn't have my car broken             |
| 11 | into. Sorry about that. But in general if you have the      |
| 12 | flip side, if someone did have 1500 and they qualified and  |
| 13 | the next year they have zero, this actually suffices for    |
| 14 | that. So I think it does indicate a consistent need and     |
| 15 | volume over time. Any other questions for Melissa? Okay.    |
| 16 | Thanks.   |
| 17 | MS. MELISSA CUPP: Thank you.                                |
| 18 | DR. MUKHERJI: So those are the only two blue                |
| 19 | cards I have for lithotripsy. Would anybody else like to    |
| 20 | comment? Okay. We'll move on to commission discussion. So   |
| 21 | commission discussion on this proposed language?            |
| 22 | MR. FALAHEE: Hearing none, I know there's some              |

MR. FALAHEE: Hearing none, I know there's some questions about the 80,000 and where hospitals are located that have 80,000 and whether if you draw a line north of Grand Rapids no hospital is over 80,000. Given that, at

| 1  | this stage of the game, because this now would go out to     |
|----|--|
| 2  | public hearing if assuming we would approve it, what I       |
| 3  | would do is make a motion to approve the revised standards   |
| 4  | as we have in front of us right now; that's number one.      |
| 5  | Number two, that they be sent to the JLC. Number three,      |
| 6  | they be sent out for public hearing, and I would encourage   |
| 7  | those at the public hearing or submitting written comments   |
| 8  | if they so choose, to specifically comment on the 80,000     |
| 9  | visits issue and the other items that were identified during |
| 10 | our discussion.  |
| 11 | DR. MUKHERJI: And your name?                                 |
| 12 | MR. FALAHEE: Mukherji. Falahee.                              |
| 13 | DR. MUKHERJI: That was Falahee before I get                  |
| 14 | reprimanded. So we do have a motion by Mr. Falahee to        |
| 15 | approve and move this forward.                               |
| 16 | DR. KESHISHIAN: Commissioner Keshishian, second.             |
| 17 | DR. MUKHERJI: We have a second. We have a motion             |
| 18 | and a second. Further Commission discussion? Hearing none,   |
| 19 | all in favor?  |
| 20 | (All in favor)   |
| 21 | DR. MUKHERJI: Any against? Motion carries                    |
| 22 | unanimously. The next is Surgical Services, Vascular Access  |
| 23 | draft language. Brenda?                                      |
| 24 | MS. ROGERS: Again, this is Brenda. You have                  |

language in front of you. At the September Commission

meeting you did move forward surgical standards that just became effective on November 17th. So the draft that you have in front of you today -- which you asked us to take a look at the vascular access issue, and in working with Fresenius; we worked with them. And so the proposal we have for you today is actually in the new set of surgical standards, so that worked out good so we didn't have to mess around with two different standards.

So what is being added, there are new definitions being added to accommodate, we're defining CMS, we are defining dedicated vascular access operating room, and ESRD facility, vascular access surgical cases. So those are new definitions to support this type of OR. And then we're adding language under "Initiation" to allow for surgical service of one or more operating rooms to be used exclusively for vascular access surgery cases.

This will allow for sites to meet the CMS regulations for ESRD facilities performing these types of surgical cases, which I believe is the basis the Commission asked the department to take a look at this. So in addition to meeting the existing requirements in the surgical standards, there are additional requirements that will have to be met and they are outlined in the draft language. I may miss one or two, but hopefully you've had a chance to take a look at the language. They still have to meet the

same volume requirements as a regular OR, the 1128 in this case. They will have to demonstrate that they currently offer an ERSD facility. However, we've added language -- and if Tania pulls it up -- Tania, if we can, go to Section 4(1) -- or excuse me -- 4(4)(a) of the standards. It wasn't in your packet yesterday, but it's on the -- you'll see it up on the board here. We've added language in here to accommodate for common control, common parent or consulting agreement to -- because there could be different situations as we put this language together.

We received some feedback earlier this week and so we were just trying to cover all bases. And this is similar language that we use in our other standards. All right. So that's actually the only change that -- in this language from what we sent out to you a week ago. Surgical cases service shall be used only for vascular access surgical cases.

"The applicant shall obtain accreditation from the Joint Commission, the Accreditation for Ambulatory

Health Care or another accrediting body approved by CMS for purposes of Medicare Certification," et cetera.

They have a certain time period that they have to do this within. They shall participate in the Medicare program and be certified as an ambulatory surgical center, again, within a certain period of time. "The applicant

shall have a policy and procedure for assuring prompt access for any ESRD patient in need of a vascular access surgical case." And also, with one or more operating rooms being used, they shall employ or contract with an interventional radiologist, nephrologist, vascular surgeon, or other physician trained to provide vascular access procedures for clinical oversight of the surgical services. Additional project delivery requirements have also been added for anybody seeking approval under these standards.

And again, still meeting all the other project requirements as applicable. So they will have to maintain compliance with the accreditation. They will have to, again, maintain the Medicare. They will have to -- the rooms are only used for vascular access. So again, they're agreeing to that up front, but they're also continuing to agree with that project delivery requirements.

And again, policy and procedure for assuring access. Again, something they agreed to up front, but again reinforcing that in the project delivery requirements and the same thing with the individual providing oversight; agreeing to it up front, but again maintaining that compliance and the project delivery requirements. And then we also updated the "Documentation of Projection" section to again accommodate for the vascular access surgical cases. And then one carryover from the last approval of the

standards in September, where we made the revision regarding the physician commitments, it was suggested that there was a couple of other subsections that should also be exempt under Section 11(2)(d) and so we've made those exclusions in this draft per the Commission's request. And again, today, if the Commission chooses to take proposed action, the department can support the language that's being presented. Thank you.

DR. MUKHERJI: So just to frame things from my standpoint, my understanding is that we're not creating a separate carve-out for this type of procedure, but what we're doing is we're integrating this type of procedure into a standard that's currently in place. It just doesn't count for this type of procedure?

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

MS. BROOKS-WILLIAMS: Commissioner

Brooks-Williams. So to add to that clarification, as this is stated, so if it's a renal dialysis facility that has a room where they're doing vascular access, as long as they have the volume threshold of an OR and get it certified by an accrediting body and have a licensed appropriate physician to deliver the care, they're then able to operate under the ambulatory surgery standard. Are there no other requirements beyond just a dedicated room that has the volume and the certification and the physician?

| 1  | MS. ROGERS: It can't just be for any OR                      |
|----|--|
| 2  | procedure. It's vascular access                              |
| 3  | MS. BROOKS-WILLIAMS: So restricted to vascular               |
| 4  | only. Okay.  |
| 5  | MS. ROGERS: Yes; correct.                                    |
| 6  | MS. BROOKS-WILLIAMS: It just seems broader                   |
| 7  | that it that word. I apologize. Yeah. Brooks-Williams.       |
| 8  | But Falahee can say it.                                      |
| 9  | MR. FALAHEE: No. Go ahead.                                   |
| 10 | DR. TOMATIS: Commissioner Tomatis. For my own                |
| 11 | education, how many procedures did the BCS service a year on |
| 12 | new access or revised access? Just to understand, what are   |
| 13 | we regulating?   |
| 14 | MS. NAGEL: Was your question how many of these               |
| 15 | procedures are done now?                                     |
| 16 | DR. TOMATIS: Just take the BCS service. How many             |
| 17 | cases they do a year, new or revised accesses? Just I        |
| 18 | want to know, what are we regulating?                        |
| 19 | MS. NAGEL: So we don't currently regulate these,             |
| 20 | so we wouldn't have that data available.                     |
| 21 | DR. MUKHERJI: This is Mukherji. We will be                   |
| 22 | having public comment coming up by content experts, so maybe |
| 23 | that could be a question to ask in public testimony.         |
| 24 | Commissioner Falahee?  |
| 25 | MR. FALAHEE: Falahee. Following up on                        |

MR. FALAHEE: Falahee. Following up on

Commissioner Brooks-Williams, I had some questions about the language and maybe the commenters can comment. But when I look at the definition of "vascular access surgical case," I get worried when I see at the end, "Or any combination of the foregoing or directly related procedures." I mean, can you drive a truck through that or not? I'm not sure. Then when -- I see in Section 10(5)(c),

"The surgical service shall be used only for vascular access surgical cases unless the applicant has obtained CON approval for any operating rooms that are not dedicated exclusively to vascular access surgical cases."

So again, this to me is potential OR creep and this is a Certificate of Need, not a certificate of want, as I've said many times before. So this commissioner at least has several questions about the language, what it means, or how it could be applied.

MS. NAGEL: I can comment on at least 10(5)(c). That was meant to actually be a protection. So it's interesting to hear your take on it because it was really meant to be that they can only do these vascular access cases unless they have a Certificate of Need to do other services as well. How do you --

MR. FALAHEE: I'll take that argument any day of the week. The way I read it is the exact opposite.

| 1  | MS. NAGEL: That they can do what can you tell               |
|----|---|
| 2  | me how you read it?   |
| 3  | MR. FALAHEE: It said "only for vascular cases."             |
| 4  | Okay? Now I've got one of those. Now it says "unless I've   |
| 5  | obtained CON approval," so now I apply for CON approval for |
| 6  | another OR to do the volume that I'm generating for         |
| 7  | combinations of the "foregoing or directly related          |
| 8  | procedures." I think it creates some uncertainty as to what |
| 9  | can happen next.  |
| 10 | MS. NAGEL: I'll tell you that was very meant                |
| 11 | not the intent. So I appreciate                             |
| 12 | MR. FALAHEE: Oh. I'm sure. I'm sure. Right.                 |
| 13 | MS. NAGEL: So I certainly appreciate you bringing           |
| 14 | that up. And you know, I think, would it satisfy your       |
| 15 | concern if we put a period after "cases" and struck         |
| 16 | "unless"?   |
| 17 | MR. FALAHEE: It would satisfy this commissioner's           |
| 18 | concerns.   |
| 19 | DR. MUKHERJI: Which line number is that?                    |
| 20 | MR. FALAHEE: I don't know what line. I'm looking            |
| 21 | at draft  |
| 22 | MS. NAGEL: It's 10(5)(c), but it's line 573.                |
| 23 | MS. ROGERS: It's yeah up on the screen.                     |
| 24 | 574 and -3.   |
| 25 | MS. NAGEL: So this was meant how this thing                 |

| you think of the words. The intent was that it would or be used for vascular access cases, but if these this wasn't meant to limit the if at some point of another kind of FSOF or another kind of surgical service wanted add this, they could. So it wasn't meant to be  MR. POTCHEN: So if I'm understanding the | î     |
|---|-------|
| wasn't meant to limit the if at some point of another kind of FSOF or another kind of surgical service wanted add this, they could. So it wasn't meant to be  |       |
| kind of FSOF or another kind of surgical service wanted add this, they could. So it wasn't meant to be  |       |
| 6 add this, they could. So it wasn't meant to be  | to    |
|   |       |
| 7 MR. POTCHEN: So if I'm understanding the  |       |
|   |       |
| 8 problem/desire, if you put the word "previously obtained  | l CON |
| 9 approval" see, but what's unclear here is what comes  |       |
| 10 first.   |       |
| MR. FALAHEE: Right.   |       |
| MR. POTCHEN: And if that's the department's   |       |
| intent, I could suggest that addition there if that's wh  | nat   |
| 14 you're trying to do.   |       |
| MS. GUIDO-ALLEN: Unless the applicant has   |       |
| 16 previously obtained CON approval   |       |
| MR. POTCHEN: Or "prior," or putting a period  | like  |
| 18 you suggested.   |       |
| 19 MS. NAGEL: Thank you. That's very helpful to   | )     |
| 20 know.  |       |
| DR. MUKHERJI: Chip?   |       |
|   |       |
| MR. FALAHEE: I prefer just putting a period a   | ıfter |
| MR. FALAHEE: I prefer just putting a period at that and just leaving the rest of it out. That to me   | after |

DR. MUKHERJI: You resemble that comment.

| 1  | MR. FALAHEE: Thank you.                                     |
|----|---|
| 2  | DR. MUKHERJI: So how would you propose it read              |
| 3  | then?   |
| 4  | MR. FALAHEE: Falahee. When I'm looking at line              |
| 5  | 573, that line would not be touched. But on line 574 where  |
| 6  | the word "cases" is right now, put a period after the word  |
| 7  | "cases" and strike the remainder of that sentence that goes |
| 8  | to the end of line 575. And I'll look to Mr. Potchen to see |
| 9  | if that's one of the options you were looking at.           |
| 10 | MR. POTCHEN: I think that is one of the options             |
| 11 | and I think that does make it very clear.                   |
| 12 | DR. MUKHERJI: Is the department okay with that?             |
| 13 | MS. NAGEL: Yes.   |
| 14 | MR. FALAHEE: And then the only other just a                 |
| 15 | general comment and maybe the witnesses can talk about it   |
| 16 | is what's the need for this? What happens now? Why the      |
| 17 | request that we got in September and what's driving all     |
| 18 | this? I understand we got a letter this morning, but,       |
| 19 | again, I haven't had time to read that letter.              |
| 20 | DR. MUKHERJI: Other comments by the Commission?             |
| 21 | DR. KESHISHIAN: This is Commissioner Keshishian.            |
| 22 | I second Commissioner Falahee's comments. I'd like the      |
| 23 | witnesses to discuss why we need this policy change at all. |
| 24 | I know we discussed it in September, but I'd like a review  |
| 25 | of the issues.  |

| 1          | DR. MUK | HERJI:   | Other comm  | nents b | y the cor | mmission?  |
|------------|---------|----------|-------------|---------|-----------|------------|
| We'll move | on to   | the next | sub item    | and I   | have two  | blue cards |
| for this.  | One is  | from Da  | ıvid Walker | from    | Spectrum  | Health.    |

## DAVID WALKER

MR. DAVID WALKER: Good morning. Please excuse my voice. My name is David Walker. I'm from Spectrum Health. Thank you very much for the opportunity to provide comment on the Surgical Services CON Review Standards. Spectrum Health would like to thank the department for the hard work on the draft Surgical Services Review Standards before the Commission today.

Spectrum Health is specifically pleased to see that the current draft addresses earlier concerns with the physician volume exemption that was previously approved. By exempting applicants from having to identify specific physicians and cases to commit to a new facility, it relaxes the administrative burden imposed on healthcare systems. Spectrum Health supports the current draft and is glad a solution could be found for our earlier concerns.

Again, thank you for the opportunity to provide feedback on the proposed changes to the CON Review Standards for surgical services. Spectrum Health appreciates the department's and the Commission's work. I would be happy to answer any questions the commissioners have.

DR. MUKHERJI: Thank you very much. Any questions

for David? All right. Thank you very much.

MR. DAVID WALKER: Thank you.

DR. MUKHERJI: The next blue card I have is from Greg Miller from Fresenius. And just a reminder, anything you say is three minutes.

GREG MILLER, M.D.

DR. GREG MILLER: And, yes, it is pronounced Fresenius (pronouncing). So thank you to the Commission for allowing me to come and give comment. My name is Dr. Greg Miller. I've been focused on performing vascular access procedures for the past 15 years. This is essentially all I do these days. I'm a licensed physician in the state of Michigan and I've actually personally cared for some ESRD patients who require vascular access procedures here in the Lansing area.

As I stated in the September meeting, this ESRD population has very high co-morbidities. If they wind up with a hemodialysis catheter as their main source of getting their hemodialysis source of treatment, that has a very significant risk of infection which really drives a very significant increase of cost. Medicare has looked at these patients and stratified them and understood that simply by pushing patients from catheters to fistulas is a very significant cost savings associated with doing that and a significant improvement in morbidity and mortality. By

allowing these freestanding outpatient vascular access centers to participate in CMS fistula first initiative and ESCO and ESRD seamless care organizations, we anticipate that there will be a significant cost savings. All of these renal focused ASC's, as I like to call them, they exist for the betterment of ESRD patients. They participate in Medicare and Medicaid services. They're dedicated to vascular access on advanced CKD, chronic kidney disease, stage IV, V and ESRD patients.

They essentially maintain affiliation with pathologists and local hemodialysis clinics. And these types of centers focus on QAPI, quality assessment process improvement programs, focused on catheter reduction services. I have a letter of support here from

Lawrence Spergel. Lawrence Spergel is the educational architect from the Fistula First Initiative. That may be the letter that one of the commissioners referenced.

He wrote it from -- to the Commission on behalf of what we're attempting to do with these renal focused ASC's. The language in front of you today does not change your current requirements for initiating or maintaining surgical services. However, it allows physicians performing these outpatient office-based surgical procedures to commit these cases toward initiation of OR's dedicated to vascular access and ESRD patients. I'll stop there.

| 1 |    | DR.     | MUKHERJI: | Thank you | very much | n. Questions | for |
|---|----|---------|-----------|-----------|-----------|--------------|-----|
| 2 | Dr | Miller? |           |           |           |              |     |

DR. KESHISHIAN: This is Commissioner Keshishian. I think you discussed this in September, but can you review for us what has changed? There was something about CMS, they had changed their regulations which precipitated you coming to make a request to change the state of Michigan CON. So what did CMS change and any ideas why they changed it?

DR. GREG MILLER: Right. So what they did was they actually shifted a very significant amount of reimbursement from the office-based surgical services. I mean, they cut the office-based surgical reimbursement by 30 percent and increased the ASC, ambulatory surgery center, reimbursement by about 30 percent, so it was a 60 percent delta.

Our centers are currently no longer viable and we're actually going through Certificate of Need processes across 15 different states to convert our centers. So, I mean, we are clearly driven by a change in reimbursement. But what they have done is they've basically said, "Well, you guys have fragmented care, and we need to bring together the fragmentation by combining the surgical access creation as well as the interventions, angioplasties, thoracotomies, catheter insertions/removals, all so that we can control

| T  | costs because this chronic disease patient population is   |
|----|--|
| 2  | costing Medicare a tremendous amount of money."            |
| 3  | DR. KESHISHIAN: This is Commissioner Keshishian.           |
| 4  | To make sure I understand, so there still the sites        |
| 5  | you're doing them now are considered office?               |
| 6  | DR. GREG MILLER: Correct.                                  |
| 7  | DR. KESHISHIAN: It'll be the same sites if we              |
| 8  | pass this, they'll just be called ambulatory surgical      |
| 9  | centers?   |
| 10 | DR. GREG MILLER: Well, actually in order for us            |
| 11 | to meet Medicare-deemed status, we will have to do some    |
| 12 | retrofitting and some other facility modifications because |
| 13 | they weren't necessarily built to those specifications at  |
| 14 | the time. However, they might certainly be in the same     |
| 15 | location or they could be relocations. But certainly       |
| 16 | without these types of facilities, you know, the patients  |
| 17 | will definitely, you know, have access-to-care issues.     |
| 18 | DR. KESHISHIAN: This is Commissioner Keshishian            |
| 19 | again. I want to understand the access to care. You're     |
| 20 | doing them right now in these facilities?                  |
| 21 | DR. GREG MILLER: Right.                                    |
| 22 | DR. KESHISHIAN: You could still do these in these          |
| 23 | facilities, it's just the reimbursement from the CMS would |
| 24 | be office versus a ambulatory surgical center?             |
| 25 | DR. GREG MILLER: I mean, that is correct to the            |

| Т  | extent that the center that we have here in Lansing will be |
|----|---|
| 2  | forced to close given the current state of reimbursement.   |
| 3  | MS. BROOKS-WILLIAMS: Commissioner                           |
| 4  | Brooks-Williams. So to just piggyback on that, currently it |
| 5  | can be done in an ambulatory surgery center setting; right? |
| 6  | DR. GREG MILLER: Yes.                                       |
| 7  | MS. BROOKS-WILLIAMS: Can you describe I think               |
| 8  | the question was asked earlier just volume and impact. I    |
| 9  | know you've spoken about the center here in Lansing. More   |
| 10 | globally how much of the care right now would have been     |
| 11 | delivered on what we're calling an outpatient basis, an     |
| 12 | office-based versus an ASC or just other settings? Do you   |
| 13 | have insight on that number?                                |
| 14 | DR. GREG MILLER: So nationally about 70 percent             |
| 15 | of all vascular access interventions are performed          |
| 16 | outpatient. I apologize. Your other question?               |
| 17 | MS. BROOKS-WILLIAMS: No, that's fine. That was              |
| 18 | the gist of it.   |
| 19 | DR. KESHISHIAN: This is Commissioner Keshishian.            |
| 20 | Follow-up on that question, 70 percent are done outpatient; |
| 21 | office outpatient or ambulatory surgical outpatient?        |
| 22 | DR. GREG MILLER: Correct. Office-based surgery              |
| 23 | outpatient is where the overwhelming majority of cases are  |
| 24 | performed today.  |
| 25 | DR. KESHISHIAN: Commissioner Keshishian. Can you            |

DR. KESHISHIAN: Commissioner Keshishian. Can you

help me understand? If we improve this and you start
billing CMS ambulatory surgical units, costs for society
will go up because we've moved it from office-based over to
ambulatory surgical. So there will be a net increase cost
to society. Is that a correct understanding?

DR. GREG MILLER: So I would actually argue that that is not a correct assertion.

DR. KESHISHIAN: Okay.

DR. GREG MILLER: The correct assertion is that by decreasing fragmentation of care between both inpatient and outpatient services we will actually significantly reduce costs because we will now be able to combine both the vascular surgical access creation piece with the interventional radiology management piece. And by coordinating that care, as we've demonstrated in other Medicare programs specific to this population including the ESCO's, we've actually been able to decrease the total cost of care for these patients.

MS. BROOKS-WILLIAMS: Commissioner

Brooks-Williams. So what you're describing is that you're

really not suggesting that you will limit what you currently

do today in the outpatient setting. You're saying that this

allows you to have more comprehensive care by moving to the

ASC model. So we're not talking apples to apples. You're

not saying this allows you to continue to do what you're

doing, it actually allows you to change what you're doing?

DR. GREG MILLER: Yeah. It allows us to combine the full spectrum of care that the patients need. So at the moment these patients require a three-time-a-week hemodialysis treatment. Okay? In order for them to get the total spectrum of their services, the first event that occurs is the surgical access creation by a vascular surgeon. Okay? That happens.

Then they'll, you know, come for a follow-up visit. Then maybe the fistula is not maturing. Then they'll get an intervention. And if they're, you know -- so they're bouncing back and forth between the dialysis unit, the vascular surgeon's office, the interventional radiology suite, however that's all occurring, and it's actually quite complex.

And when you're already obligated to three-time-a-week hemodialysis, what then happens is it pushes out your entire length of time from the time the access is created until your hemodialysis catheter can get removed. So by us coordinating that care and having surgeons and interventional radiologists and nephrologists sort of all participating in the care of those patients, it dramatically shortens those times. We have had pilot studies within the Fresenius system. We know that currently across the global United States it takes us 120 days to

remove a hemodialysis catheter. When I came in September I presented that in several cases we've been able to shorten that to either 90 days or even 45 days in the best case scenario. And every day that you're able to decrease a patient's catheter exposure, it's less bloodstream infection, less sepsis, less ICU admission, and that's really where the cost savings comes in.

DR. MUKHERJI: So I'm just going to ask a question. So I think we all understand and say -- my mother had end stage renal disease, so I get it. But this interdisciplinary approach, what prevents that from being done now in a facility that is not currently classified as an ASC that's already serving the populace?

DR. GREG MILLER: So in the office-based surgery you would not perform the actual surgical creation. There's no reimbursement for it. There is a professional fee that physicians can obtain, but there's no facility fee such that the patient can come in, have an access created, facility gets reimbursed for services, and then whatever follow-up care they would need would essentially happen under the same roof in a very timely fashion.

DR. MUKHERJI: So where are those procedures now currently being done, the actual access of the fistula -- creation of the fistula, I should say?

DR. GREG MILLER: Those cases are at the moment

primarily performed in the hospital, but those cases are a one-time event. And so the patient may have one surgical creation today and not require another surgical creation for many years until the access becomes dysfunctional or there are some other issues with it.

DR. MUKHERJI: And the reason they're performed in the hospital is because the physician offices don't have enough oversight or what is going to change? If these procedures are currently being performed in the hospital due to quality and safety concerns, and what is going to change by our reclassification to now provide the same quality and safety guardrails to provide these in a different setting?

DR. GREG MILLER: It's an interesting journey through history, and the history here is that up until 2015 there was zero reimbursement for access intervention, surgical creation or any of these vascular-related procedures for the ESRD patients, and only after 2015 or 2015 forward did they start to increase the reimbursement as they came up with these initiatives.

So where there was essentially zero outpatient access creation going on prior to 2015, we're now beginning to essentially coordinate the care and, you know, attempt to improve the timeline from which a patient can get a surgical creation to a catheter removal.

MR. FALAHEE: So this is Falahee. I am not

following this. I'm trying to follow the money and I think that's what I'm -- follow. Right now there's nothing to preclude better care from happening but for the fact that the reimbursement isn't there; right?

DR. GREG MILLER: So it suggests fragmentation; right? The care is fragmented; right? So if 70 percent is already being performed outside the walls of the hospital for the access interventions, 100 percent is being performed in the hospital. And so the patients wind up in this ping pong between dialysis, outpatient centers, the hospital for surgical creation, the vascular surgeon's office. It's actually --

MR. FALAHEE: But I thought you said it could be done in one location except that there isn't reimbursement for it.

DR. GREG MILLER: Well, I mean, the office-based surgical facilities today aren't really set up for it; right? They don't have the same requirements for oxygen and anesthesia and all those things, so they weren't built to those standards and so it wouldn't make sense to do them in that environment today. But by becoming a licensed ASC, obtaining deem status, following, you know, Joint Commission guidelines, you know, as we do in all of our centers, I mean, I think that the opportunity is really there to get those, you know -- to combine all of the surgical and

- 1 interventional procedures.
- 2 MR. FALAHEE: Let me ask Brenda. I'm sorry I
- didn't go through all the PDR's here. Does Fresenius take
- 4 Medicaid patients?
- 5 DR. GREG MILLER: Absolutely.
- 6 MR. FALAHEE: Does Fresenius turn away any
- 7 patients for ability to pay?
- B DR. GREG MILLER: Absolutely not. So the one
- 9 point that I actually made in September was that if I were
- 10 to take my business model and go to a outpatient ambulatory
- 11 surgery center, that's not so easy because this patient
- 12 population is 70 percent Medicare, 15 percent Medicaid, you
- 13 know, 7 -- whatever the rest of the math is -- on
- commercially insured, and that is not the model that the
- 15 overall majority of ambulatory surgery centers function.
- So these centers do not cherry pick. By the
- 17 nature of our business we have to take care of
- 18 Medicare/Medicaid patients. It's the majority of our
- 19 business. And I feel very comfortable telling you that you
- 20 would not look back on this and say, "Oh, that wasn't a good
- 21 idea. These people aren't serving the patients that they
- 22 said that they would take care of."
- MR. FALAHEE: One last and this is on a
- 24 definitional issue. The definition for "vascular access
- 25 surgical cases" -- still Falahee. I'm quizzical at the very

| least when I see at the very end, "Combination of the      |
|--|
| foregoing or directly related procedures." And that's line |
| 123. Especially where it says "or directly related         |
| procedures," my concern is what size truck can you drive   |
| through that?  |

DR. GREG MILLER: I respectfully didn't draft the language, so I don't know that I -- that I'd necessarily know how to modify it. But, you know, if we look at the language and we say that this is really limited to CKD, chronic kidney disease stage IV, stage V, and ESRD patients, that's our niche.

That's our sweet spot for patient care. I think that, you know, when -- that there are some affiliated procedures that they might need, they could need a drainage procedure or something similar to that for one reason or another; aneurism reduction of the hemodialysis access itself. I mean, there's a lot of things. So I think when I looked at the language it seemed appropriately broad to me, but not overly so.

DR. MUKHERJI: Commissioner Mittelbrun?

MR. MITTELBRUN: Yes. Tom Mittelbrun. I hope I can articulate this, but I'm listening to everything you're saying and I'm trying to understand. CMS had a reason for making their change in reimbursement. Everything you're describing is going to affect other organizations besides

you. All right? And was it CMS' desire to have these changes take place to what's being described today; to what's being talked about so it's not so fragmented, so it's more consolidated? So you believe it's overall cost savings; right? So I'm trying to get my arms around the whole change in your industry. Is it being driven by CMS to try to get you to this spot or, you know, organizations like yourself and organizations like this Commission to that spot?

DR. GREG MILLER: So I will not pretend nor will I be arrogant to say that I know exactly what's on Medicare's mind, but they certainly have put their stake in the ground. So for ten years we functioned in the office-based surgical environment. And, you know, following the Affordable Care Act -- right? -- there were a couple of changes; right?

These things went through CMMI at the highest

Medicare levels and they came up with models by which they
thought would control costs, one of which is the ESCO or the

ESRD seamless care organization. And in every market where
Fresenius has an ESCO -- and they're participating in 26

ESCO's across the United States -- we are scrambling to put
in a good vascular access center because these centers

can't -- these ESCO's can't control costs adequately without
being affiliated with a good vascular access center. So I
hope that sort of answers your question. Look, was it

related to straight-up utilization of CPT codes? Yeah; sure. Right? It probably was related to straight-up utilization. Was, you know -- you know, overuse of angioplasty. Okay? At the same time I think that they've made it very clear that they need to control costs within this patient population, and coordination of care is the way to go, and there's article after article that comes out in the late press about coordination of care is the way to go for patients with chronic disease.

MR. MITTELBRUN: Thank you.

DR. MUKHERJI: This is Commissioner Mukherji. Do you perform purely regular routine dialysis in these procedures, too? Because this was specifically for -- what we discussed, it was specifically for vascular access.

DR. GREG MILLER: Correct.

DR. MUKHERJI: But, well, dialysis is now being performed in various outpatient dialysis units. Will this center now be -- performed routine dialysis and then receive the additional payment for it?

DR. GREG MILLER: All right. One statement that I'll comment on. Somebody had stated something to the effect that, you know, dialysis will have a room and that's where the vascular access center would be. So these are completely separate entities. So dialysis centers only perform the hemodialysis treatment, which is the cleansing

| of the blood. The vascular access center is a totally       |
|---|
| standalone, freestanding ambulatory surgical facility which |
| purely performs vascular access interventions and surgical  |
| creations.  |

DR. MUKHERJI: And how does that facilitate coordination of care?

DR. GREG MILLER: So, you know, one of the points that we put in the language is that the facilities will either have a consulting agreement with a nephrologist or --staffed by nephrologists and radiologists. And so the nephrologists are integral to the vascular access surveillance, monitoring, and ultimately the interventions. In the facility that we have here in Lansing it's a --Dr. Edin Basic is an interventional nephrologist.

So he sees the patients. He rounds on them. He takes care of them. He sees them in the office as needed. And he also performs the actual interventions for the hemodialysis accesses.

DR. KESHISHIAN: This is Commissioner Keshishian.

I'm a little confused. He could go to an ambulatory

surgical site there under CON regulations right now and do

any procedures that he needs to do right now. Has he had

any trouble getting a surgical time in order to do the

procedures? I mean, if we have a problem with access for

ambulatory surgical units, we probably should deal with that

versus separating it off. So does he have any problems that you're aware of? Wait times, lead times? I mean, it's easier if you -- I understand it's easier if you own the center and you can -- it's next door or it's down the street and you get to schedule it whenever you want to schedule it, but that's the purpose of CON. So I'm just curious. Any problems?

DR. GREG MILLER: So at the moment he has his own, you know -- we have our center. He functions 100 percent there exclusively. You know, we have been maintaining it as best as possible. I don't have an answer for what it would look like if he then needed to start finding ambulatory surgery centers to take these patients to.

DR. KESHISHIAN: Thank you.

DR. MUKHERJI: Any other questions? All right.

Thank you very much. There's a bar across the street if you want to go -- thank you very much. Are there any other public comments for this topic? Okay. Let me go on. We'll now have Commission discussion. Commissioner

Brooks-Williams?

MS. BROOKS-WILLIAMS: You can see my face.

Commissioner Brooks-Williams. I guess my question to the department would be -- so it's proposed now as a language change based on some of our discussion. And I'm going to say to some degree my -- I don't want to say it's confusion.

I think I understand, but I'm not 100 percent sure I'm ready to move forward with the language because I would like to have a little bit more information about the setting, which is kind of where I started with my questions. Are we saying that this is within the four walls of the existing site? It doesn't sound like that's necessarily always going to even be possible to be done. So what are our options based on what's in front of us?

MS. NAGEL: So this is proposed action. At this point the Commission can -- you could take proposed action on it and it would go to public hearing and it would go to the JLC and then we come back at the March meeting for final action, or you could take no action on it and defer it to another meeting. You could, you know, request another presentation. Really, at this point there's -- you have a lot of flexibility is what I'm trying to say. There are a lot of options. You're not tied to any timelines with this language right now.

MS. BROOKS-WILLIAMS: Thank you.

DR. MUKHERJI: This is Commissioner Mukherji. So,
Beth, my understanding is that this was -- this language was
added to the surgical services. The surgical services
outside this has been -- it seems like it was approved or -by the Commission. So this was an add-on plugged into this?

MS. NAGEL: Yeah. Brenda, when did they become

effective? The Commission made changes to surgical services that became effective just recently.

3 MS. ROGERS: Right. November 17th.

DR. MUKHERJI: Okay. So they are effective.

Okay. Thank you.

MS. GUIDO-ALLEN: So this is Commissioner

Guido-Allen. Lines 120 and 121 were -- after "fistulagrams, angioplasty, stent placement, percutaneous thrombectomy, transluminal balloon angioplasty of extremities," that category to me, if indeed we keep the language, is way too broad because that opens it up to cardiac, peripheral -- just way too broad. I would rather have that language to be very specific to the venous access that is particular to dialysis.

But based on the comments that we just heard -where I was very confused just like everybody else -- I just
don't feel that we as a group should proceed with something
that is really based on reimbursement from office-based
reimbursement to an ambulatory surgery center reimbursement
without seeing a true patient quality and safety advances or
improvements. That's just my opinion.

DR. MUKHERJI: Commissioner Mukherji. I wanted to ask something, too, Beth. My understanding was -- when we first discussed this my understanding was that these types of procedures were not identified by CON to be credited

towards creating a ambulatory surgical center. That was my understanding. Are we creating a specific ASC geared towards vascular access for end stage renal disease or are we creating credits that can be applied to creating a general ambulatory surgery center?

MS. NAGEL: You are creating specific vascular access surgery centers that only can be established by demonstrating vascular access cases and then can only do vascular access cases. So I'm not sure if that was one of your choices.

DR. MUKHERJI: You answered my question.

MS. NAGEL: Okay.

MR. FALAHEE: This is Falahee. I share the same concerns about the lines 120 and 121. I've still got concerns about the need. There's a lot of open questions in my mind. I think that assuming there's a need.

DR. MUKHERJI: Commissioner Keshishian?

DR. KESHISHIAN: I'd like to try to move this forward and so I'm going to make a motion. We asked the department to come up with this language based on the testimony last week and so I want to -- and as part of my motion I want to thank the department for doing an excellent job in developing the language. And the second part of the motion is we don't want to adopt this language. We don't want to move it forward to any public hearing. We thank the

| 1  | department. We understand the issue. And the next time    |
|----|---|
| 2  | surgical ambulatory surgical centers come up, we can      |
| 3  | discuss it again at that point. So it's a three-part      |
| 4  | motion: Thank the department, no further action, and next |
| 5  | time there is an ambulatory surgical center they can be   |
| 6  | discussed at that time.                                   |
| 7  | DR. MUKHERJI: So the "no further action" means            |
| 8  | that we're not going to include this language into the    |
| 9  | current standard that's currently implemented?            |
| 10 | DR. KESHISHIAN: That is correct.                          |
| 11 | DR. MUKHERJI: So we have a motion on the table.           |
| 12 | MS. BROOKS-WILLIAMS: Support. Commissioner                |
| 13 | Brooks-Williams.  |
| 14 | DR. MUKHERJI: So we have a motion and we have a           |
| 15 | second. Further Commission discussion?                    |
| 16 | MS. NAGEL: I'm sorry. Could you say who                   |
| 17 | seconded? I'm sorry.                                      |
| 18 | DR. MUKHERJI: It was Brooks-Williams.                     |
| 19 | MS. NAGEL: Thank you.                                     |
| 20 | DR. MUKHERJI: So all in favor of Commissioner             |
| 21 | Keshishian's motion say "aye."                            |
| 22 | (All in favor)  |
| 23 | DR. MUKHERJI: Any against? Okay. Commissioner             |
| 24 | Keshishian's motion passes. The next is Nursing Home and  |
| 25 | Long-Term-Acute Care. This was recalculating the bed need |

numbers. There is a written report by Mr. Delamater that's in our package. We have two blue cards. So Brenda, do you want to take this?

MS. ROGERS: Yes. This is Brenda. Just a quick update on this. It is that time to update the bed need methodology according to the schedule of every two years. We delayed it this summer knowing that standards were moving through the process. And so in September -- I can't remember the exact date of the standards becoming effective, but at the September Commission meeting the Commission asked the department to go ahead and run the bed need calculation based on the new set of standards, which we've done -- or Mr. Delamater has done. You have that report in front of you. And so what the Commission needs to do is set the effective date of the new bed need. Thank you.

DR. MUKHERJI: Any questions for Brenda or the department? Commissioner Guido-Allen?

MS. GUIDO-ALLEN: Guido-Allen. What if we question the increase? What if we question the number that is being proposed as -- it just seems really high to me. Sorry.

MS. ROGERS: Yeah. This is Brenda. The only thing -- and I'll let Joe chime in if he's got additional information. The only thing I can tell you, under the standards we are required to run the bed need every two

| 1  | years. We did postpone it based on that there were new       |
|----|--|
| 2  | standards becoming effective with some changes that affected |
| 3  | the methodology, so it was held off. The standards for the   |
| 4  | bed need has been re-run with the updated methodology and    |
| 5  | numbers, and it's up to the Commission to set the effective  |
| 6  | date. Whether or not you want to postpone that, I'm going    |
| 7  | to let Joe respond to that. Thank you.                       |
| 8  | MR. POTCHEN: So this is Joe. The numbers being               |
| 9  | high, based on what we have in Paul Delamater's report,      |
| 10 | appear to be accurate. So just as a fact to the extent the   |
| 11 | Commission disagrees or wants to change it at the            |
| 12 | appropriate time, it'd be the next time these standards come |
| 13 | up. We have no evidence before us that we're aware of that   |
| 14 | these numbers are wrong, it's just high.                     |
| 15 | DR. MUKHERJI: Other questions before we take                 |
| 16 | public comment?  |
| 17 | MS. GUIDO-ALLEN: In Dr. Delamater's or in                    |
| 18 | yeah. Table 4 is referenced under bed need, but I don't      |
| 19 | have table 4. Does anybody have table 4?                     |
| 20 | MR. FALAHEE: Page 46 of our packet.                          |
| 21 | MS. NAGEL: It's the fourth page.                             |
| 22 | MS. GUIDO-ALLEN: Okay. Sorry. Got it.                        |
| 23 | MS. NAGEL: I will note these are the just so                 |
| 24 | you're aware, this is the first time we've run these numbers |
| 25 | with the standards and the changes to the methodology that   |

| 1  | the Commission approved last. So yes, they are different.    |
|----|--|
| 2  | The standards that you approved last did have changes to the |
| 3  | methodology and so now we're seeing the effect of those      |
| 4  | changes.   |
| 5  | MR. HUGHES: Commissioner Hughes. I remember a                |
| 6  | few years ago when this came up a long time ago when and     |
| 7  | I'm a little bit confused, but there was some census data    |
| 8  | that was being used in this calculation and it appeared to   |
| 9  | be older. Is the census data here? Because I know it         |
| 10 | changes every once in awhile. I remember we were using old   |
| 11 | census data and new census data was just about to come out.  |
| 12 | MS. NAGEL: I remember the issue being about the              |
| 13 | survey data. Do you think that that might be                 |
| 14 | MR. HUGHES: No.  |
| 15 | MS. NAGEL: Okay. So I'm just trying to look.                 |
| 16 | Paul usually says what year he uses the survey or the census |
| 17 | data for. I will say if I could address not your             |
| 18 | question, but the survey data, that was something that we    |
| 19 | worked on with the nursing home community. And we do have    |
| 20 | higher confidence now in that survey data that we used to    |
| 21 | calculate this. Did either of you see the census data that   |
| 22 | Paul used?   |
| 23 | MS. ROGERS: It says 2016.                                    |
| 24 | MS. NAGEL: The 2016 census data. Oh. Yeah.                   |

It's in the second line. The updates to the -- used the

2016 CON annual survey data and the 2016 U.S. Census population data.

MS. ROGERS: And this is Brenda. Typically we've always kind of project -- the standards say you can project out I believe it's three to seven years, and so typically we've always used five years. We did not use five years this time. Based on Paul's suggestion we projected out three years because that's what the data was available for. Anything beyond the three years was simply an estimate, so we did not want to use estimated projections. So this time the projections are three years out versus five years out, but based on actual data.

DR. MUKHERJI: Any other questions for the department before we go to public comment? Okay. We'll move forward with public comment. The first blue card I have is from Pat Anderson from HCAM.

## PAT ANDERSON

MS. PAT ANDERSON: Good morning. Thank you. I am Pat Anderson from the Health Care Association of Michigan. And you did receive our testimony I think late yesterday afternoon. But I wanted to express on behalf of HCAM, we represent about 320 nursing facilities across the state. And I do agree with the Commissioner, that the bed need as is recalculated seems extremely high. If you ask a number of our members, we're not sure why. I've read

Mr. Delamater's report and he's claiming that the change in the ADC factor is about 2300 of the beds, yet when you compare the beds based on the bed need from the DHHS web site, it's almost 7,000 beds more. There's 4,000 beds more than that factor alone changing the item when the overall occupancy across the state is currently only 82 percent. So our members are concerned that this will make a flood.

We're not sure. Mr. Potchen is saying the numbers are right. I haven't really seen the detail on that to see -- to know that. And this does seem extreme high. From the testimony I picked out five counties to see where they landed. They were all getting quite a few beds. For example, Oakland County was going to 400 more beds. They only have 80 percent occupancy right now. That just doesn't have a common sense logic to it. I don't know.

They could be fully right as Mr. Potchen said, but it appears that this is way higher than it should be. So we have concerns. What we would like the Commission to do is to delay any action on setting the date until the March meeting for the Commission and have a group of interested parties sit down and look at the report and the data and then act on it from that, and we would be interested in doing it. Thank you for listening.

DR. MUKHERJI: Thank you. Questions?

Commissioner Falahee?

| Τ  | MR. FALAHEE: Yean. This is Falanee. Okay.                    |
|----|--|
| 2  | Let's assume you're right or there's questions. To the       |
| 3  | department or to Mr. Potchen, does it have to wait 'til      |
| 4  | March? Couldn't we try to do something, if we have           |
| 5  | questions, at the January meeting? Couldn't we try to        |
| 6  | resolve those there? I know it's a, quote, "special          |
| 7  | meeting," closed quote. But couldn't we do it there if we    |
| 8  | had the time to get together between now and then?           |
| 9  | MS. ROGERS: Yeah. This is Brenda. Yeah, if you               |
| 10 | put it in a motion as part of, you know, the next meeting    |
| 11 | agenda, that's truly up to the Commission to decide on that. |
| 12 | MR. FALAHEE: Okay. Thank you.                                |
| 13 | DR. MUKHERJI: Any other questions? Thank you                 |
| 14 | very much.   |
| 15 | MR. POTCHEN: I just want to clarify. I'm stating             |
| 16 | that the numbers that we have before us are based on Paul    |
| 17 | Delamater's who has done it for the department for years.    |
| 18 | So it's not that it's right or wrong. It's based on the      |
| 19 | application of the standards as we have seen before us and   |
| 20 | we haven't seen any evidence to the contrary that there's a  |
| 21 | mistake here.  |
| 22 | DR. MUKHERJI: Commissioner?                                  |
| 23 | DR. KESHISHIAN: This is Commissioner Keshishian.             |
| 24 | Could we ask him to take another look at these numbers and   |
| 25 | to come back to make sure they are correct? Because if       |

| 1  | there is they're so much different than they have been in   |
|----|---|
| 2  | the past. A second look seems reasonable. Because I think   |
| 3  | what you're saying is what are we going to know in January  |
| 4  | that we don't know today? And the question is, "Please take |
| 5  | a second look. We're shocked at we're surprised at these    |
| 6  | numbers."   |
| 7  | MR. POTCHEN: And I think the Commission has the             |
| 8  | authority to make such a request in a motion and can do     |
| 9  | that.   |
| 10 | DR. KESHISHIAN: Okay.                                       |
| 11 | DR. MUKHERJI: Any other questions before we go on           |
| 12 | to the next? It's Melissa Cupp from RWC Advocacy.           |
| 13 | MELISSA CUPP  |
| 14 | MS. MELISSA CUPP: Good morning. Again,                      |
| 15 | Melissa Cupp with RWC Advocacy. This time I am before you   |
| 16 | representing Sienna Health Care. I just wanted to indicate  |
| 17 | on their behalf that we support the comments that Pat       |
| 18 | Anderson just made from HCAM. Thank you.                    |
| 19 | DR. MUKHERJI: Any questions for Melissa? Get                |
| 20 | back there. Any questions? Okay. Now you can leave.         |
| 21 | MS. MELISSA CUPP: Thank you.                                |
| 22 | DR. MUKHERJI: Any other blue cards, public                  |
| 23 | comments for this? Okay. You know, this really wasn't       |
| 24 | Commission discussion, but I'll take prerogative of the     |
|    |   |

chair to have more discussion on this specific topic.

MR. MITTELBRUN: Commissioner Mittelbrun. I was just curious. I think we all got an e-mail from fellow commissioner Clarkson and I just was wondering your thoughts on her opinion as she is an expert in that field.

DR. MUKHERJI: And I'll make a comment here. I, you know -- I've listened to what everybody says and I'll just revert to my previous life as a scientist. And we've had the same methodology for years. And sometimes in science we do experiments, we look at data, and we use a scientific formula as statistical analysis, and so on and so forth, and sometimes we like the results and sometimes we don't like the results.

And if we like the results, we publish them and we accept them. But if we don't like the results, we can go back and make sure we did the right analysis. But if we don't like the results and we've accepted a certain methodology or analysis, I think we just have to accept it. And I completely agree with Commissioner Keshishian that because these are not what we expected, we should ensure that the methodology and the analysis is correct.

But if it is correct, my own feeling is that we should accept this and move forward because that's what we've done in the past and that's probably what we're going to do in the future to make our policy for the state.

MR. MITTELBRUN: Commissioner Mittelbrun. Is the

methodology exactly the same? It was my understanding the methodology changed.

MS. NAGEL: Yes, there were major changes to the methodology.

MR. MITTELBRUN: So if the methodology changed, I mean, maybe, you know, to the scientific community, sometimes you make changes in your analytical formula and you say, "Well, maybe that wasn't the right mix or right variable to use in the calculation." So I'm just curious if there's -- I mean, it seems like there may be negative effects to the changes in the methodology.

MR. HUGHES: Commissioner Hughes. This kind of gets down to me what the core mission of CON is in terms of quality, cost, and access. And you know, we've seen plenty of data over the years; if you build it, they will come and fill things. When I'm looking at the occupancy test, yeah, we can have the methodology and we have computers do things, but that's why we have humans here to look at things.

And when I'm seeing these occupancy rates and then seeing these large increases in beds, it just doesn't add up. And I don't know of anybody out there waiting and I think that's -- we have to dig deeper into this because if we just go ahead with things just because it says that's what the procedure was, that's how we get too many facilities out there and that's what costs more.

| 1  | DR. MUKHERJI: This is Commissioner Mukherji. Are             |
|----|--|
| 2  | we saying that we should have a target rate for occupancy    |
| 3  | then?  |
| 4  | MR. HUGHES: I'm saying that a 80 percent                     |
| 5  | occupancy rate in places where they're putting up massive    |
| 6  | increases in the number of beds and I don't hear a problem   |
| 7  | from other people, it just doesn't add up. It just doesn't   |
| 8  | pass the eye test. Has there been massive population         |
| 9  | growth?  |
| 10 | DR. TOMATIS: Commissioner Tomatis. I don't think             |
| 11 | that we are going to solve the problem limiting the number   |
| 12 | of beds. The idea is just to find out exactly what are we    |
| 13 | talking. And really, I don't trust the data that we got.     |
| 14 | DR. MUKHERJI: Let me ask the department. Can                 |
| 15 | they re-run the bed needs using the old methodology and the  |
| 16 | new methodology to see what the difference is?               |
| 17 | MS. NAGEL: We certainly can, but I will say the              |
| 18 | new methodology is the one that is in the statute currently  |
| 19 | that the Commission passed and became effective in           |
| 20 | September. So if you like the old standard, you're going to  |
| 21 | have to change it.   |
| 22 | DR. MUKHERJI: I think from an evidence-based                 |
| 23 | approach we can at least look at the delta, and then if we   |
| 24 | did something that we probably shouldn't have done, we could |

have the opportunity to change. That's part of the

- iterative process of public policy.
- DR. TOMATIS: Commissioner Tomatis. The idea is
- not which methodology, it's which one is right. We are
- 4 making a decision of -- not using one methodology or the
- 5 other. Which are the fact?
- 6 DR. MUKHERJI: Other comments? So this really
- 7 wasn't -- I guess this is an action item; right?
- 8 MS. ROGERS: Yes.
- 9 DR. MUKHERJI: Okay. So we're open for an action
- or a detail action.
- 11 MR. FALAHEE: All right.
- 12 DR. MUKHERJI: I can't make one because I'm the
- 13 chair.
- 14 MR. FALAHEE: Well, what he said five minutes ago.
- This is Falahee. Motion would be, number one, that we ask
- 16 Mr. Professor Delamater to go back and relook at his numbers
- using the current methodology. Number two, look at the
- change in numbers using the old methodology to see what the
- 19 delta has been and, as Commissioner Keshishian said,
- 20 basically just relook, recheck, recalculate and bring us
- 21 those numbers back for the January meeting.
- 22 And then the last part of my motion would be to
- work with HCAM and the others to see if there's any
- difference in numbers and calculations. There may not be,
- 25 but at least to work with those that are raising the

questions. 1 DR. MUKHERJI: Okay. We have a motion on the 3 table. MR. HUGHES: Could I just add? Could we also ask 5 for some feedback and interpretation of what's driving the big increase that's changed? 6 7 MR. FALAHEE: I would approve. MS. NAGEL: Could I ask for a clarification? Who 8 9 did you want that --MR. HUGHES: I was just piling on to what --10 11 MS. NAGEL: Just for clarification, did you want that from the industry or from the department? 12 13 MR. HUGHES: The professor. 14 MS. NAGEL: For Dr. Delamater? 15 MR. HUGHES: Yes. 16 DR. MUKHERJI: Okay. So we have a very nice motion on the table. Any second? 17 18 MR. MITTELBRUN: Mittelbrun. Second. 19 DR. MUKHERJI: Mittelbrun second. We have a motion and a second. Any further discussion? Okay. All in 20 favor? 21 (All in favor) 22 DR. MUKHERJI: Any against? The motion passes. 23 The next is item number VIII, which is Cardiac 24

Catheterization Standard Advisory Committee, interim written

| 1  | report only. It's in your agenda. I believe it's on page    |
|----|---|
| 2  | number 47. Brenda, is that informational or an action item? |
| 3  | MS. ROGERS: This is Brenda. It's just                       |
| 4  | informational.  |
| 5  | DR. MUKHERJI: Does anybody have any comments on             |
| 6  | the report? All right. Hearing none, should we move on to   |
| 7  | the next topic then? The next topic is Hospital Beds        |
| 8  | Standard Advisory Committee. There's another interim report |
| 9  | that's in your packet and that is on page number 48. Again, |
| 10 | informational; correct?                                     |
| 11 | MS. ROGERS: This is Brenda. That is correct.                |
| 12 | DR. MUKHERJI: Any comments on the report? Let me            |
| 13 | just also, we're going to get through now to the            |
| 14 | legislative reports and our legal reports, so on and so     |
| 15 | forth, but there is a public comment regarding proton beam  |
| 16 | based on the agenda. And Brenda, tell me if this is         |
| 17 | appropriate. That still is going to be under agenda item    |
| 18 | XV; is that correct?  |
| 19 | MS. ROGERS: This is Brenda. That is correct.                |
| 20 | DR. MUKHERJI: Okay. So the next one is the                  |
| 21 | legislative report. Mr. Lori?                               |
| 22 | MR. LORI: I do not have anything to report from             |
| 23 | the legislative side.                                       |
| 24 | DR. MUKHERJI: Thank you. I appreciate that.                 |

MR. FALAHEE: We all do.

| 1  | DR. MUKHERJI: The next is the administrative               |
|----|--|
| 2  | update, planning and access and care section update. Beth? |
| 3  | MS. NAGEL: This is Beth. I'd just update that we           |
| 4  | are continuing our work with the two standard advisory     |
| 5  | committees that are in play at the moment and are looking  |
| 6  | forward to wrapping those up and reporting back to you in  |
| 7  | March.   |
| 8  | DR. MUKHERJI: Thank you. Any questions for Beth?           |
| 9  | Next, the CON evaluation section update. Tulika?           |
| 10 | MS. BHATTACHARYA: This is Tulika. So there are             |
| 11 | the three regular reports for CON activity and compliance  |
| 12 | monitoring in your packet, but you also have two special   |
| 13 | reports on the statewide compliance review of Cardiac Cath |
| 14 | Services and Megavoltage Radiation Therapy Services. I'll  |
| 15 | be happy to answer any questions.                          |
| 16 | DR. MUKHERJI: Questions? Tulika, the quarterly             |
| 17 | performance measure? Or did you cover that as well?        |
| 18 | MS. BHATTACHARYA: Yeah, so                                 |
| 19 | DR. MUKHERJI: All right. That was covered?                 |
| 20 | MS. BHATTACHARYA: Yes.                                     |
| 21 | DR. MUKHERJI: I can only think of one thing at a           |
| 22 | time. Legal activity report, Joe?                          |
| 23 | MR. POTCHEN: This is Joe. There is no current              |
| 24 | active litigation and we continue to assist the department |
| 25 | in drafting of the rules and various other issues.         |

| 1  | DR. MUKHERJI: I really appreciate that. Any                 |
|----|---|
| 2  | questions for Joe? The next is for the January meeting. We  |
| 3  | always have a it was a special meeting in January that      |
| 4  | got morphed into a regular meeting essentially. And it      |
| 5  | turns out in January I'm not here, Tom's not here, Chip's   |
| 6  | not here. So we have to figure out, number one, do we have  |
| 7  | a quorum? And number two, if we have a quorum, is anybody   |
| 8  | willing to run the meeting? So how many people, I guess,    |
| 9  | are planning to be here for the January meeting on that     |
| 10 | specific date, which is January 25th?                       |
| 11 | MS. GUIDO-ALLEN: Will be here?                              |
| 12 | DR. MUKHERJI: Yeah. Who will be here for that?              |
| 13 | Otherwise, we'll have we may have to reschedule the         |
| 14 | meeting. So how many people raise your right hand if you    |
| 15 | plan on being here for that meeting. One, two, three, four, |
| 16 | five possibly. That's not a quorum. So what we probably     |
| 17 | will have to do is reschedule that. So I don't know if      |
| 18 | we're available the week before and the week after, so I    |
| 19 | think just work offline. How much time do we need to give   |
| 20 | for public notice if we change the meeting?                 |
| 21 | MS. ROGERS: I'm trying to remember what the                 |
| 22 | MR. POTCHEN: I think it's 30 days.                          |
| 23 | MS. ROGERS: I'm thinking 30 days as well. We                |
| 24 | might have to go into February. We'll try early February.   |
|    |   |

We just have to see what days we have available. That's

1 part of it. MR. POTCHEN: I think it's 30 days, but we'll 3 verify that. But to be safe --DR. MUKHERJI: So the bottom line is that we won't 5 have the January 25th meeting. I'll work with the department to pick an alternate date. And we apologize for 6 7 any unintended convenience to the department. 8 MR. POTCHEN: And I'm just going to go back on the 9 record. We had an earlier motion to postpone it to the January date. I'm believing that that motion would be to 10 11 the next --MR. FALAHEE: To whenever we next meet. 12 13 MR. POTCHEN: -- next scheduled Commission 14 meeting. DR. MUKHERJI: So we have a motion on the table. 15 16 MR. POTCHEN: I'm not motion. MR. FALAHEE: This is Falahee. The motion that I 17 18 prior made to have this data come to the January meeting, 19 I'll amend it to be the next regularly scheduled meeting of 20 the Commission. 21 DR. KESHISHIAN: Commissioner Keshishian, 22 seconded. 23 MR. FALAHEE: "Scheduled." Take out "regularly." DR. MUKHERJI: We have a motion and a second. All 24

25

in favor?

(All in favor)

DR. MUKHERJI: Thank you. So is everyone clear about that? We'll change the date of the January meeting and then we'll just iterate and figure out what works best. The future meeting dates then, we won't have one on January 25th, but the meeting dates after that are in the package. The next is public comment. We have one public comment card from Dr. Theodore Lawrence from the University of Michigan regarding CON for HMRT Proton Beam. Dr. Lawrence? And please note three minutes.

THEODORE LAWRENCE, M.D.

DR. THEODORE LAWRENCE: Three minutes? Right. So I'm Ted Lawrence. I'm chair of radiation oncology at the University of Michigan. Thank you for taking the time to listen to our request to reopen the regulations for Proton Beam Therapy or HMRT. You have a handout in front of you. I hope all the commissioners have that handout, so I'll stick closely to the handout.

The original CON written years ago proposed a collaboration to mitigate the cost of proton beam therapy. So back then the cost of the facilities were -- the regulations were written in a era of \$150-million-plus multi-room facilities that were going to treat 1200 or more people per year. So this drove a logical argument that there should be collaboration among multiple groups.

Collaboration was much easier 10 years ago compared to today. Radiation therapy was provided by many more and smaller facilities. So back then the regulation was that there were only 5 providers who have more than 30,000 ETV's, which is a unit of activity for radiation therapy, and at that point only 2 of 5 were required, that is 40 percent, to form a collaborative. So that was then and this is now.

So now the cost has decreased and consolidation of health services in the state impedes collaboration. So now the cost of a single-room proton beam facility -- is now -- it's not cheap, but it's down in the range of 25 to \$30 million; very different from \$150-million-plus. These can treat up to 250 patients a year. And this then suggests to us that a new normal now exists so we can return to an appropriate standard CON metric based on activity and not number of facilities, which is a unique thing as far as I can tell in CON.

And then the collaboration requirement has become much more difficult because, due to consolidation, there are now 6 providers who deliver more than 30,000 ETV's. So the impact of this is that to achieve the 40 percent rate we need 3 partners. 2 of these 6 groups already have facilities, one of which is functioning. So the 40 percent rule we feel is an unreasonable barrier to providing access to required cancer services. So CON, as you Commissioners

all very well know, are typically based on activity and not on the number of facilities. Activity has always been a reasonable basis for determining qualifications for covered services under CON standards. For instance, the University of Michigan Health System now has over 60,000 ETV's at our own facility, so our facility alone would meet the activity requirement that was originally described in the CON. The 40 percent rule prohibits advancement despite meeting an activity requirement.

I'd like to make a couple notes about the potential role of proton beam therapy. Children with cancer are prime candidates for PBT. Children who are treated for cure are the most likely to benefit from proton beam therapy and the University of Michigan has the largest pediatric program in the state. "The care of our children now is being fragmented under the current standards by not being able to provide timely and appropriate access."

And in particular, many treatments for children require chemotherapy and radiation therapy and it's not optimal, and in some cases it's even not safe to give chemotherapy in one facility and then send the child to another facility to receive radiation. Proton beam therapy is likely to be effective in other diseases. Emerging data suggests brain, head/neck cancer, liver cancers. In addition, a new indication is that many -- some cancers, not

many, but some recur after treatment and proton beam therapy is looking to be effective in this segment as well.

Thousands of people in the state of Michigan could potentially benefit from proton beam therapy. So in conclusion we feel it's time to review the CON regulations and thresholds. The need for PBT cannot be met by one or even two facilities, assuming the second one can become functional in the state.

However, there have been no applicants for proton centers since the current language was written, so this to me is a sign that the current regulations are too restrictive. It takes two or three years to build and implement a proton facility. Given the decrease in cost and the limitations in access, we propose that the Commission charges a review of the existing HMRT standards to determine reasonableness of the 40 percent rule and the collaboration requirement.

DR. MUKHERJI: Thank you very much. Any questions for Dr. Lawrence?

MR. FALAHEE: This is Falahee. I've been around long enough that I remember all too well the initial discussions and governor's actions and all that fun stuff with proton beam. Help me understand what happens now if there's a child at U of M that needs proton beam? What happens now?

DR. THEODORE LAWRENCE: So that child will be sent to a different facility. We're now referring patients out on a regular basis. It depends on the expertise that the — the problem that the child has and the expertise of the institution. So we'll try to send that child to an institution that's expert in giving that treatment, but the rest of that child's care before and after that proton beam will typically still occur at the University of Michigan.

MR. FALAHEE: So again, I'm trying to understand what's going -- how many children do you send out on a yearly basis?

DR. THEODORE LAWRENCE: So as more data develops, it's becoming more and more. Right now it's in the range of between, say, 60 and 80 children right now will ultimately be sent out for other treatment.

MR. FALAHEE: So then a devil's advocate question would be for 60 to 80 children we're looking at a request to potentially to allow a proton beam unit to be built by the University of Michigan or anybody else for millions of dollars? That's the devil's advocate question.

DR. THEODORE LAWRENCE: Absolutely. And if that were -- the only reason to use proton beam therapy were treating children, I would agree with that. I think children are the best example of who could benefit, but there's a lot of emerging data now that there are other

diseases; head and neck cancer, potentially lung cancer, brain cancers. So for instance, in the case of brain cancer, we know that mild doses of radiation can affect neurocognitive function. So even in an adult, a modest dose of radiation can affect neurocognitive function. We've done this research. We've published this. And so the difference between proton beam therapy and x-ray therapy is that proton beam therapy will not give those moderate doses to the rest of the brain.

Now, proton beam therapy is -- I would say it's early in its development. It's sort of moderate in its development. So all these data are coming out now and being developed now. But the data now are suggesting that there are other diseases other than in kids where this is going to be -- the kids are the best example, but there are other diseases.

MR. FALAHEE: Okay.

DR. THEODORE LAWRENCE: Head and neck cancer, brain cancers, liver cancer are an area that I publish in extensively. There's a group at Massachusett (sic) General Hospital that's now generating data that liver cancer outcomes are better with proton beam therapy than x-ray therapy. So our estimate is that there are about 25,000 people who will receive radiation therapy in state of Michigan, at least 2015 data, the most recent data I have.

Somewhere between 10 and 20 percent of those patients would likely benefit from proton beam therapy.

MR. FALAHEE: Thank you.

DR. THEODORE LAWRENCE: If it were just kids, I agree with you.

DR. MUKHERJI: So Ted, you know, I remember very well that we used to refer patients out to Mass General for patients with skull-based tumors, especially adenoid cystic carcinomas, because of the very focused beam. And when proton beam did come out initially, it was really targeted towards skull-based tumors with perineural spread or very -- adjacent to very sensitive structures. I think kids now -- it seems there is a potential dissemination of a very potentially expensive technology that actually has excellent curates by other commonly accepted treatment modalities.

So can you help us understand how CON cannot prevent dissemination of this technology in the state, but by the same times ensure that appropriate guardrails are in place so that other tumors that have been treated by other techniques -- and I'll specifically say prostate cancer -- all of a sudden are not sent to a proton beam therapy?

DR. THEODORE LAWRENCE: Right. So I think that's very important. First of all, I think we all agree that an activity requirement which -- still makes sense. You wouldn't want to put a proton beam facility in, I guess,

Marquette. I don't know if anyone's here from Marquette.

But there may not be enough people in Marquette to generate to justify that. So you still want an activity limitation. I think that there are certain diseases where there really isn't any evidence that proton beam therapy is better and I would list prostate cancer as one of those. So I could imagine regulations that would require generating radiation plans that would show that you really get a benefit from proton therapy as opposed to x-ray therapy -- proton beam

therapy.

And so one could have similar requirements. For instance, in some situations we've -- modulated x-ray therapy. We need to generate plans to show that we would get benefit from that compared to standard 3D formal radiation. So I think one could -- and I'd be delighted to help. One could develop regulations that would only permit treatment for patients who have a reasonable chance to benefit.

DR. MUKHERJI: Other questions for Dr. Lawrence?

MR. HUGHES: I'm nervous to ask this question

because I might be wrong. But old school, like Commissioner

Microphone over here (indicating), I remember this

discussion a long time ago, and the impressions that I have

in my head were that we were going to have two in the state,

which was very unusual. It's unusual just to have one. And

| 1  | if there was seven in North America and then an expert       |
|----|--|
| 2  | had made the comment, "How many do we need from a volume     |
| 3  | and being able to service people?" We needed one in North    |
| 4  | America and we had seven and potentially two in the state.   |
| 5  | If I'm talking about the right thing, then I'm really        |
| 6  | confused by this because, yeah, the price has come down from |
| 7  | 160- to 25- or 50-, but I don't see the volume and am I      |
| 8  | missing something here on we're not able to service the      |
| 9  | people that we have with existing facilities and why we      |
| 10 | would need more? Help. Is that a dumb question?              |
| 11 | DR. THEODORE LAWRENCE: Can I answer that?                    |
| 12 | MR. FALAHEE: This is Falahee. First, you're                  |
| 13 | recalling exactly correctly the discussion we had around     |
| 14 | this table and in the audience as well. I think what we're   |
| 15 | hearing, and I think the doctor is going to expand, it's     |
| 16 | now not only is it cheaper, but there are more potential     |
| 17 | beneficiaries of that same therapy than there were when we   |
| 18 | discussed this ten years ago, whenever it was, 2009.         |
| 19 | MR. HUGHES: When our hair cells were different.              |
|    |  |

DR. THEODORE LAWRENCE: I think he answered your question quite well. I mean, that's really it and you were very succinct in your answer. I agree.

MR. HUGHES: But I guess the question I would have is the existing facilities that we have, what kind of utilization are they having?

| 1  | DR. THEODORE LAWRENCE: Well, sir, the only                   |
|----|--|
| 2  | facility in the state that's functioning is at Beaumont and  |
| 3  | it's coming up to speed. But again, if we go back to about   |
| 4  | 25,000 people in the state of Michigan are going to get      |
| 5  | radiation therapy and we think that at a minimum 10 percent  |
| 6  | based on the data we have now will benefit, we don't have    |
| 7  | the facilities to treat patients who are likely to benefit   |
| 8  | from treatment.  |
| 9  | We're well below. Just to reiterate, in the past             |
| 10 | they were \$150 million facilities plus that were going to   |
| 11 | treat 1200 to 1500 patients a year, and that was a           |
| 12 | different, you know a different day back then. You know,     |
| 13 | one other thing I didn't mention that is worth mentioning is |
| 14 | that the technology has improved proton beam therapy at the  |
| 15 | same time during these last 10 years which has helped to     |
| 16 | open up new applications.                                    |
| 17 | MR. HUGHES: What is the status of the one that               |
| 18 | got the governor exception for the second facility?          |
| 19 | UNIDENTIFIED SPEAKER: It's Beaumont.                         |
| 20 | MR. HUGHES: So there's two?                                  |
| 21 | DR. THEODORE LAWRENCE: Well, there's one at                  |
| 22 | McLaren which is not producing beam as best I know right     |
| 23 | now.   |
| 24 | MR. HUGHES: That's what I'm confused I thought               |

there was two approved.

DR. MUKHERJI: Yeah. So I think the challenge is -- and I agree with everything that you said. Back when I was -- when I had black hair instead of gray hair or whatever, there was two centers in the country that we would send patients to. It was the Mass General and University of Washington; right, Ted? This was probably fifteen years ago when I was a pup. And now the technology has gotten better, but the elephant in the room regarding this is that eventually when you make a multi-million dollar investment you have to somehow justify that investment.

And the challenge is -- is there are specific areas in which proton beam has been historically used and clearly it's beneficial specifically in children and small-based cancers and so on and so forth. But when you make an investment like that, how do get that return? And I think the challenge that we will face moving forward, especially with insurance and payers and everyone around the table, is to ensure that it's used appropriately, and when you look at your pro forma and your P&L statement for this that you're not doing other cancers -- treating other cancers on that inappropriately just to get a return on the investment. That's the challenge moving forward on it.

DR. THEODORE LAWRENCE: You know, the truth is with the pro forma, we don't really -- I mean, the truth is we don't expect -- this will not be a particularly

money-making venture for us. We just feel like we need to deliver the top quality care to our kids and to the patients where it's becoming clear that this is a better technology.

We don't anticipate this is going to be a money maker.

That's not the goal in this.

MS. GUIDO-ALLEN: This is Guido-Allen. According to our docket it's up for review in 2020. Maybe we'll have more data prior to that so that when it comes up for us to review again we'll have more evidence to support what proton delivers, more patient populations, that it may be beneficial for survival rates, recurrent rates. I don't know.

DR. MUKHERJI: Any other questions for Dr.

Lawrence?

DR. THEODORE LAWRENCE: May I just say, the problem with waiting 'til 2020 is that means there won't be another facility in the state before 2023 or 2024, which is quite awhile from now, and the data are here already that could benefit for other groups of patients. So we'll be depriving our patients, people in the state of Michigan, for at least another seven years if we wait 'til 2020 to look at this again.

DR. MUKHERJI: Any other questions for Dr.

Lawrence? Thank you. We have about two more, both from the University of Michigan. Don Tomford?

| 1  | DON TOMFORD  |
|----|--|
| 2  | MR. DON TOMFORD: Hi. I'm Don Tomford. I'm the              |
| 3  | administrator for the Department of Radiation Oncology. I  |
| 4  | would just like to address the one comment about that      |
| 5  | there were 7 centers nationally. There are now 26 centers  |
| 6  | nationally and 16 currently being planned. So within the   |
| 7  | next couple years there will probably be 42 centers        |
| 8  | operationally within the country. Florida has 5 or 6. So   |
| 9  | there are more companies.                                  |
| 10 | There are 2 or 3 companies now actually doing              |
| 11 | proton centers. So there are a big push across the country |
| 12 | for proton centers. So I just wanted to address the change |
| 13 | in technology and in treating more cancers.                |
| 14 | DR. MUKHERJI: Any questions for Mr. Tomford?               |
| 15 | MR. HUGHES: Are people having an issue getting             |
| 16 | into Beaumont currently?                                   |
| 17 | MR. DON TOMFORD: Pardon me?                                |
| 18 | MR. HUGHES: Are people having an issue getting             |
| 19 | into Beaumont currently?                                   |
| 20 | MR. DON TOMFORD: I didn't hear you.                        |
| 21 | MR. HUGHES: Are people here in Michigan waiting            |
| 22 | to use the existing facility?                              |
| 23 | MR. DON TOMFORD: I'm not sure if people are                |
| 24 | waiting to use the existing facility. I don't really I     |
| 25 | haven't talked with Beaumont, but we do send some kids to  |

Cincinnati Childrens. We have sent many kids out of state.

We will send kids to Beaumont if that's our choice, but we have sent, just in the last -- Dr. Lawrence mentioned 60 to 80 in the last six months. We've sent 28 kids -- many of those have been out of state because Beaumont was not operational.

DR. MUKHERJI: Any other questions? Thank you.

MR. DON TOMFORD: Thank you.

## TONY DENTON

MR. TONY DENTON: Thank you and good morning. I'm the senior vice president operating officer for the University of Michigan Health System. I just wanted to make a couple of additional points of emphasis on Dr. Lawrence's comments. The letter that I think is in your packet, both he and I signed the communication. And actually my thought about it was fairly narrow. We talked about what the situation was ten years ago and how things have transpired and there's not been any application.

But as we were preparing to try and meet the Certificate of Need Standards, we actually do or thought we did until there was a nuance. So the activity -- as Dr. Lawrence mentioned, we actually doubled the activity requirement in terms of the ETV's. In terms of the collaboration we actually found a partner that would meet the current standards the way that they are written. The

challenge came when we discovered this 40 percent rule, which we did not understand, and I pursued clarification with Certificate of Need staff, eventually the Attorney General's office. And maybe Chip Falahee has good recall being here 10 years ago, but no one seemed to understand why 40 percent.

For the last 10 years or so it's been 5 providers that have exceeded 30,000 ETV's and so we thought we were all set with the current standards, but then found out that there was a sixth, which meant that we really had to meet 50 percent. And so it varies with the number even though we meet the activity as has been prescribed to be the important goal. So we demonstrated on volume that we are provider of choice.

We're a comprehensive cancer center without the ability to be as comprehensive as we would need to be, which is why we're now sending patients away. So we're trying to get to the intent with regard to Certificate of Need because we thought we met the criteria only to find that there was one nuance that could not be ignored called 40 percent. And not having any explanation coming back to us, we would ask the Commission to try to help clarify why that 40 percent rule is actually in place since we meet all these other criteria that will allow us for any other covered service to go forward and be approved to put that capacity in place to

- 1 support the needs of our patient mission.
- DR. MUKHERJI: Thank you. Questions for Mr.
- 3 Denton?
- MR. FALAHEE: Not so much a question but others

  may disagree. Let's just say I don't think there was a lot

  of scientific analysis that went into coming up with 40

  percent. One could stick one's finger in the air and see

  what number came out. I don't recall any discussion, "Is it

  35? Is it 45?" I don't recall specifically why we ended up

  with 40.
- DR. MUKHERJI: So just to clarify, are you saying
  that you've met all the other requirements except for the 40
  percent?
- MR. TONY DENTON: Yes, based on the most recent data available.
- DR. MUKHERJI: Other questions for Mr. Denton?

  Thank you.
- 18 MR. TONY DENTON: I would add one comment, 19 Commissioner. It's not in our interest to have to open up the standards again, but if there's no real basis for the 40 20 percent, I don't know what the jurisdiction is for the 21 22 Commission to interpret the facts the way they are based for the primary criteria, which would be the activity. Short of 23 that, we're asking that there be a review clarification to 24 25 make the 40 percent rule more valid or, as you say,

| 1  | scientific. Thank you.  |
|----|---|
| 2  | DR. MUKHERJI: Thank you.  |
| 3  | DENNIS MCCAFFERTY   |
| 4  | MR. DENNIS MCCAFFERTY: Dennis McCafferty,                       |
| 5  | Economic Alliance for Michigan. 10 years ago, when I was 28     |
| 6  | years younger, I went through that process in the entire        |
| 7  | year of 2009. And my recollection the 40 percent rule was       |
| 8  | fundamentally to make sure that there were no more than two     |
| 9  | in Michigan and it was as simple as that, $40/40$ , and there's |
| 10 | not enough for a third one. That was the thought process        |
| 11 | back then. We didn't really think we needed one, but for        |
| 12 | sure we didn't think we needed more than two.                   |
| 13 | DR. MUKHERJI: Any questions for Dennis? Thank                   |
| 14 | you. This was an add-on item. So where should we begin?         |
| 15 | Brenda and Elizabeth, can you provide any historical            |
| 16 | perspective for the Commission regarding alternatives?          |
| 17 | MS. ROGERS: This is Brenda. I'm not sure what                   |
| 18 | you're asking, I guess, when you say "alternatives."            |
| 19 | DR. MUKHERJI: Well, so are we saying that the                   |
| 20 | IMRT is not going to be reviewed until 2000? So is that set     |
| 21 | in stone and nothing can be done or 2020 so or                  |
| 22 | nothing can be done or are there options for the Commission     |
| 23 | to potentially address this issue?                              |
| 24 | MS. ROGERS: This is Brenda. Yes, it is at                       |
| 25 | this point it is scheduled for the next review in 2020, but     |

| 1  | as has happened in the past, if the Commission deems that   |
|----|---|
| 2  | there is an issue that needs to be looked at in a standard  |
| 3  | out of sequence, that's certainly the Commission's          |
| 4  | prerogative to do that.                                     |
| 5  | DR. MUKHERJI: Thank you. I'm just going to open             |
| 6  | this up for the Commission to just open discussion in       |
| 7  | light of the testimony we just heard.                       |
| 8  | MR. HUGHES: I just still want to understand. I              |
| 9  | understand that potentially there's a growing need here and |
| 10 | there's a lag time to build new facilities, but I also      |
| 11 | understand health systems wanting to do everything for      |
| 12 | everybody. We have an existing one out there. I'm trying    |
| 13 | to understand if there is, from a volume and utilization    |
| 14 | if there's a wait for people that need it and what that     |
| 15 | looks like currently and going forward. I don't hear that   |
| 16 | there's a shortage of providers currently.                  |
| 17 | MR. MITTELBRUN: Commissioner Mittelbrun. Can the            |
| 18 | department provide the data that Commissioner Hughes is     |
| 19 | commenting on?  |
| 20 | MS. NAGEL: Certainly.                                       |
| 21 | DR. MUKHERJI: Commissioner Brooks-Williams?                 |
| 22 | MS. BROOKS-WILLIAMS: Commissioner                           |
| 23 | Brooks-Williams. I was going to ask similarly, did we hear  |
| 24 | correctly that McLaren has the technology but does not      |
| 25 | utilize it and it's only Beaumont that's active in the      |

1 state?

MR. HUGHES: Yeah. That's where it gets confusing because we had one and we were going to get two, which seemed crazy, and then I get confused on what happened with the second one. Somebody here probably is more informed than I am, but --

MS. BROOKS-WILLIAMS: So maybe just if we could get that feedback? And then my second question is if we don't have the science behind the 40 percent rule, would it not be until 2020 that we would look at that or is the request that we're looking at that now? I'm just trying to make sure I understand what we're being asked to do. I don't think it was change the standard, but is it to look at the 40 percent rule?

DR. MUKHERJI: I'll give you my opinion on this.

In general if you look at all of our CON policy issues, they tend to mirror volume and activity. And once we reach a certain activity, then we can trigger something new. I wasn't a member of the Commission back then, but I did hear some of the rumblings and there was a sense of we wanted to limit the number of proton beams, and we almost did it the way we used to do it, was we'll ensure that only X number are in the state. And that, from what I understand, is that's how this was created. And then there was a special option that was created through -- separate from the

Commission that allowed another institution to get a proton beam. So I think the way that I look at it, is that how this was created was not really consistent with the processes and activity requirements of the Commission. I think what we're seeing now is maybe an end result of the initial process that really weren't consistent. So that's where I think -- what I hear University of Michigan saying is that they have done everything.

They actually thought they qualified. The initial 5, now with 6 because of the 40 percent rule -- and that was just because of an increased activity with more cancers that are now felt to be treated appropriately with radiation therapy as opposed to previous they were treated with surgery or some patients that couldn't get any treatment at all. That's how I interpret from a clinical standpoint.

MS. GUIDO-ALLEN: Guido-Allen. Isn't this the same argument we heard with bone marrow and our methodology we used for bone marrow not being, you know -- being arbitrary?

DR. MUKHERJI: I would assume so. It's really up to opinion, but yeah.

MR. FALAHEE: This is Falahee. I think it makes sense as a first step to hear from the department on if there's any history on the 40 percent, and to get some data as Commissioner Hughes talked about, you know, what happens

now; U of M, kids that go to Beaumont, kids that go to Cincinnati, Mass General, wherever. I'd like to know that so we know what's out there. Are the kids suffering? And then I think that information can then help us as a Commission inform whether we want then to look at the standards early, and if so, do we want to have a potential change in the 40 percent rule? I'm not saying we do yet.

I think we need some data first, then we can discuss it, and then we can move forward. I'm not saying wait 'til 2020 yet. I'm just saying, look, let's get the data, figure out what it means to us, and then move forward from there.

DR. MUKHERJI: Any other comments? Commissioner Gardner?

DR. GARDNER: Tressa Gardner. And also include -- and you said the ten percent of the cancers may be treated. If we can look at that and stratify it across the state based on our current information and see how that will be, how it would be serviced by adding another proton beam.

DR. MUKHERJI: Yeah, I think the one clarification commented earlier is that there was -- you're right. It is consistent with the bone marrow transplant, except there was one institution that wouldn't have the special workaround. So it wasn't really created through the initial bone marrow because bone marrow actually, I think, was held to the

| 1  | standards of CON, except for proton beam there was one     |
|----|--|
| 2  | institution that came around. That's the difference.       |
| 3  | MS. GUIDO-ALLEN: I wasn't part of you back then.           |
| 4  | MR. FALAHEE: Right.  |
| 5  | DR. MUKHERJI: So do we have a motion what do               |
| 6  | we do? Do we have a motion on this or do we just ask the   |
| 7  | Commission to come back with more information the next     |
| 8  | meeting? What is the consensus of the group?               |
| 9  | MR. POTCHEN: In January you have or whenever               |
| 10 | that next meeting is going to be we are developing the     |
| 11 | Commission plan to review certain standards. It would seem |
| 12 | appropriate at that time to get that information so you    |
| 13 | can  |
| 14 | DR. MUKHERJI: Do you know the specifics of the             |
| 15 | information that we need?                                  |
| 16 | MS. NAGEL: I can just add one thing. Tulika just           |
| 17 | brought up a great point, that the current proton beam     |
| 18 | service just came online in July of this year. We may not  |
| 19 | have annual the five months of that data until the         |
| 20 | spring.  |
| 21 | DR. MUKHERJI: So what's the information that the           |
| 22 | Commission would ask and what's the information that the   |
| 23 | department can provide? Chip? Denise?                      |
| 24 | MR. FALAHEE: Okay. Thanks.                                 |
| 25 | MS. BROOKS-WILLIAMS: Commissioner                          |

1 Brooks-Williams.

time.

| MR. FALAHEE: Short-term memory is the first to              |
|---|
| go. Number one, let me try to summarize. How many cases     |
| right now are being sent from the University of Michigan to |
| other facilities, whether it's Beaumont, Cincinnati, Mass   |
| General, University of Washington, wherever. Number two, is |
| there a capacity issue or are the kids being is the         |
| treatment being held up because of a lag somewhere else?    |
| Number three, what other cancer modalities are out          |

there that are being or could be treated by proton beam?

How does that extrapolate to the entire state of Michigan?

I'm trying to look at the, quote, "need," closed quote,

here. Number four, what if any history is there on the 40

percent rule? And I don't disagree with what Mr. McCafferty

said, but if there's anything there, that would be helpful

so we as a Commission can get some data. And I may be

leaving something out, but that's where I'm at right now.

MR. HUGHES: Status of that second facility?

DR. GARDNER: McLaren is not functional at this

 $$\operatorname{MR}.$$  HUGHES: But does it have the ability to or what --

MR. FALAHEE: So we can add that to the mix of data we're asking for.

25 MR. HUGHES: And exact utilization of Beaumont.

| 1  | DR. MUKHERJI: Elizabeth and Beth, do you have all           |
|----|---|
| 2  | that info? Are you typing fast enough?                      |
| 3  | MS. ROGERS: I'm trying to, yeah. I think so.                |
| 4  | DR. MUKHERJI: And so we'll get information on               |
| 5  | that at the next whenever that next scheduled meeting is    |
| 6  | in the winter. Is that                                      |
| 7  | MS. NAGEL: So if you were to put it on your                 |
| 8  | agenda for the special meeting, is that what you're asking? |
| 9  | Because at that time you would decide how you               |
| 10 | MR. FALAHEE: As soon as possible.                           |
| 11 | DR. MUKHERJI: What's that, Chip?                            |
| 12 | MR. FALAHEE: This is Falahee again. I'm not sure            |
| 13 | if you're going to be able to gather all of that prior to   |
| 14 | the January or whenever we have that next meeting.          |
| 15 | MS. NAGEL: Correct.   |
| 16 | MR. FALAHEE: I just say as soon as possible.                |
| 17 | MR. THEODORE LAWRENCE: We can get all that                  |
| 18 | information. We're happy to help.                           |
| 19 | MR. FALAHEE: As soon as possible Falahee. If                |
| 20 | you can get it to us as soon as possible, whether it's the  |
| 21 | January-ish meeting or the March meeting, as soon as        |
| 22 | possible.   |
| 23 | MS. NAGEL: Okay.  |
| 24 | DR. MUKHERJI: So if the data is already                     |
| 25 | available, can you work with the individuals that have the  |

| 1  | data, so don't reinvent the wheel? Is that fair? Is that     |
|----|--|
| 2  | okay?  |
| 3  | MS. NAGEL: I was writing it down.                            |
| 4  | DR. MUKHERJI: That was a suggestion, not a                   |
| 5  | directive.   |
| 6  | MS. NAGEL: Yes.  |
| 7  | MS. BROOKS-WILLIAMS: Commissioner                            |
| 8  | Brooks-Williams. I don't know if this is added to the list,  |
| 9  | but I just want to make sure I clarify. Was it the           |
| 10 | University of Michigan's perspective, and does the           |
| 11 | Department agree, that they meet all of the other criteria,  |
| 12 | i.e., the demand criteria with the exception of a 40 percent |
| 13 | rule? I don't fully know what that is.                       |
| 14 | MS. NAGEL: It was just discussions. We didn't                |
| 15 | receive an application. We really couldn't comment on that.  |
| 16 | MS. BROOKS-WILLIAMS: Okay. So can we have a                  |
| 17 | strongman on that, though, when you come back, given that    |
| 18 | the substance of this is that the 40 percent rule is the     |
| 19 | barrier? So I'm not saying they have to complete an          |
| 20 | application, but by whatever way you could objectively help  |
| 21 | us to understand if that really is the                       |
| 22 | MS. NAGEL: I think if I could is that you                    |
| 23 | could request that they come back with that information.     |
| 24 | MS. BROOKS-WILLIAMS: Absolutely. That's my                   |
|    |  |

request.

| DR. MUKHERJI: Other comments? Okay. So we have              |
|---|
| a request and we don't have to have a motion, but that's a  |
| request. Is everybody comfortable with that around the      |
| table moving forward? This kind of popped up over the       |
| last and I just want to make sure that we have a            |
| consensus of all the commissioners before moving forward on |
| this. Okay. Great. All right. I hate to ask this            |
| question: Any more public comment? All right. No more       |
| blue cards then. Next is review of the Commission's work    |
| plan. Brenda?   |

MS. ROGERS: All right. This is Brenda. So you do have the draft work plan in front of you. So a couple of changes based on today's meeting. We will look at rescheduling the January special meeting. And surgical services, you received a report. Draft language was presented, but the Commission decided to take no action and put it out to the next scheduled review.

action, so public hearing will be scheduled with potential of final action in March. And then just based on the current discussion with the proton beam therapy or MRT services, the department will be bringing back some data as requested at a future meeting as soon as available. Thank you.

DR. MUKHERJI: My understanding this is going to

| 1  | be an action item, so thank you, Brenda. Commission        |
|----|--|
| 2  | discussion? Open to a motion to approve the work plan?     |
| 3  | MS. BROOKS-WILLIAMS: Commissioner                          |
| 4  | Brooks-Williams. I move to approve the work plan.          |
| 5  | DR. MUKHERJI: And we have a motion.                        |
| 6  | MS. GUIDO-ALLEN: Guido-Allen. Second.                      |
| 7  | DR. MUKHERJI: Guido-Allen, second. Any                     |
| 8  | discussion? All in favor?                                  |
| 9  | (All in favor)   |
| LO | DR. MUKHERJI: The last one is or I have a                  |
| 11 | separate item. I just want to wish everybody Happy         |
| L2 | Holidays. That's my that's number XVI. Okay. Then the      |
| L3 | next one is adjournment. Motion to adjourn?                |
| L4 | UNIDENTIFIED SPEAKER: Motion to adjourn.                   |
| 15 | DR. MUKHERJI: Second?                                      |
| L6 | UNIDENTIFIED SPEAKER: Support.                             |
| L7 | DR. MUKHERJI: Beth, is there anything else I need          |
| L8 | to do before we adjourn for the holidays? Okay. All right. |
| L9 | All in favor?  |
| 20 | (All in favor)   |
| 21 | DR. MUKHERJI: We're adjourned.                             |
| 22 | (Proceeding concluded at 11:36 a.m.)                       |
| 23 |  |
| 24 | -0-0-0-  |
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