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

COMMISSION MEETING

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

333 South Grand Avenue, Lansing, Michigan

Wednesday, December 7, 2016, 9:30 a.m.

COMMITTEE MEMBERS:	SURESH MUKHERJI, M.D., VICE CHAIRPERSON
	DENISE BROOKS-WILLIAMS
	GAIL CLARKSON
	CATHLEEN COWLING, D.O.
	JAMES FALAHEE
	DEBRA GUIDO-ALLEN, R.N.
	ROBERT HUGHES
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	JOSEPH POTCHEN
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Wednesday, December 7, 2016 - 9:40 a.m.

DR. KESHISHIAN: Good morning. We're going to have the meeting start. First item of the agenda is call to order. I do have an announcement. Commissioner Kochin had a baby girl about four months ago, so we'd like to congratulate her.

MS. KOCHIN: Thank you.

DR. KESHISHIAN: Mother and child are doing well. Thank you for returning and coming back to the CON Commission.

MS. KOCHIN: Thank you.

DR. KESHISHIAN: Next item is review of the agenda. Is there any comments or changes to the agenda? Okay. Next is declaration of conflicts of interest.

UNIDENTIFIED SPEAKER: Excuse me. We need a motion to accept the agenda.

DR. KESHISHIAN: We need a motion to accept the agenda. Do I hear a motion?

MS. BROOKS-WILLIAMS: Commission Brooks-Williams. I move to accept the agenda.

MS. COWLING: Cowling second.

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

(All in favor)

DR. KESHISHIAN: Opposed? Declaration of conflicts of interest. At any time during the meeting if people believe they have a conflict of interest, please state so, or at this point you can also state that you have a conflict of interest. Review of minutes of September 21st, 2016. Do I hear a motion for approval?

MR. MITTELBRUN: Commissioner Mittelbrun. Motion to approve as submitted the minutes of September 21st, 2016.

DR. KESHISHIAN: Thank you. Do I hear a second?

MS. CLARKSON: Commissioner Clarkson. Second.

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

(All in favor)

DR. KESHISHIAN: Opposed? Next item is lithotripsy. As just a review for everybody in the January meeting we had decided to have a SAC. We were unable to sit a SAC. We tried multiple times under state law there are people that have -- certain groups that have to be represented. There was not people who were willing to represent these groups.

At the September meeting we made a decision to turn it over to the department to make recommendations for the changes in the lithotripsy standards and to report back to this commission at this meeting. So I'll turn it over to Brenda at this point.

MS. ROGERS: Good morning. This is Brenda. You should have the draft -- some draft language in your packet. And as Marc stated, what we -- what the department asked the commission to do since the -- in lieu of a SAC is make any more technical-type changes and/or administrative feasibility changes to the standard. So that's what you have in that draft language today. And just kind of -- you should -- the informational sendout last week.

I will just quickly go through it and mention every single edit. Hopefully you've had a chance to take -- look at the language. And if you have questions, feel free to ask. One of the first things that we did, and this did come up through the public comment a year ago when we put it out seeking any changes on the language, and that was whether or not we could have a contractual agreement with a facility versus requiring the on-site having to supply some materials for infusions, medications, et cetera, under section 3(1)(c)(iii) and (vii) of the standards.

So not only for the supplies and material, but also the 23-hour holding unit. And in going back and looking at that -- for that possibility, years ago that actually was a part of the standards. It was removed in 1998. It just seems to make sense to allow that in the -- and so we have inserted that language back in here. The other changes that we made were similar to what we just

recently did with CT and MRI and in doing the -- oh, I'm losing my train of though there -- the 36-month operation requirements, making it easier if -- for the common ownership, if or something comes up in that time frame that's unforeseeable to the applicant after their application has been approved under relocation to be able to make a move out from their original point that they had applied for.

So those changes have been added to the lithotripsy standards. And then -- excuse me -- appendix A, the factor calculation and using in the methodology has been updated. Paul Delamater ran that for us. So that edit has also been included and that was just a slight change in the factor. And other than that there were some technical edits, like updating the department name and some of those types of things throughout the document.

So having said that, the department does support the language as we're proposing today for proposed action. However, if the commission deems that other changes need to be made, then you certainly can suggest that as well and not take proposed action today. But if you take proposed action, then we will schedule public hearing and then we will bring it back for final action at your March meeting. Thank you.

DR. KESHISHIAN: Are there any questions for

Brenda?

MR. FALAHEE: Yeah. This is Commissioner Falahee.

DR. KESHISHIAN: Commissioner Falahee.

MR. FALAHEE: Brenda, just a wording question on section (iii). I'm just making sure that I understand the new language that is shaded in yellow. And I'm looking at (iii) and (vii). Both of them say "that has," and I'm not sure if the phrase "that has" makes sense, because I think the poin that is -- look at number (iii) -- that you want IV supplies and materials for infusions and medications either on site or through a contractual agreement. And I just think using "that has" -- and Mr. Potchen I'm looking at you as well.

MR. POTCHEN: Right.

MR. FALAHEE: Using "that has" sort of throws it off and it doesn't make sense to me. I've read it a few times. I've tried to make it work and it didn't.

MS. NAGEL: Would you suggest the word "with"?

MR. FALAHEE: Well, or just delete "that has." "Either on-site, or through a contractual agreement with another healthcare facility, IV supplies" -- da da da da da. Because the point is you want IV supplies and materials, either on-site or through a contractual agreement.

UNIDENTIFIED SPEAKER: You need a comma there.

UNIDENTIFIED SPEAKER: Uh-huh (affirmative). And

delete "that has"?

UNIDENTIFIED SPEAKER: Yeah.

MR. FALAHEE: And I think the same thing would work in (vii) as well, where it says "either on-site or through a contractual agreement that has a 24-hour holding unit." I don't think you need the "that has" in (vii) either, unless I'm all wrong.

MR. POTCHEN: No. I just think putting a comma there clears it up between those two phrases.

MR. FALAHEE: Yeah. Okay.

MS. ROGERS: Yup. Thank you.

DR. KESHISHIAN: Any other questions, comments? Okay. Public comments, we have three cards. In alphabetical order, Melissa Cupp, represent United Medical Systems, Great Lakes Lithotripsy.

MS. CUPP: Sorry. There's two mics up here and I just -- good morning. My name is Melissa Cupp. I'm with RWC Advocacy here before you this morning representing United Medical Systems and Great Lakes Lithotripsy. We simply just wanted to state our support for the department's recommended language and thank them for the effort in putting that together.

DR. KESHISHIAN: Are there any questions? Thank you. Carrie Linderoth from Kelley Cawthorne.

MS. LINDEROTH: Good morning. My name is Carrie

Linderoth and I'm with Kelley Cawthorne and I'm here today representing Sparrow Hospital. We did submit some written testimony for your review and consideration and we really do appreciate all the work the department put into the proposed language. And we've been actively trying to work through a situation where we could convert a mobile host site into a fixed unit. Sparrow has particularly high volume and would benefit greatly from having a fixed unit.

At the current time the lease costs are rather high with the amount of volume that Sparrow has and it would be more cost-effective and efficient for them to be able to utilize a fixed unit at their site. I'm happy to answer any questions and I'm happy to work with the department or the commission to work through that. We had submitted a number of folks interested in serving on the SAC, but as Dr. Kershishian mentioned the SAC wasn't able to be formed. So we're hopeful we can work with everybody here to get to some type of change.

DR. KESHISHIAN: Are there any questions? Thank you. And Bob Meeker, Greater Michigan Lithotripsy.

MR. MEEKER: Good morning and happy holidays to everyone. I see some familiar faces. I would just echo Melissa's comments representing Greater Michigan Lithotripsy, the other major lithotripsy provider in the state, and say that we would support the changes and ask

them to go forward for public comment.

DR. KESHISHIAN: Are there any questions for Mr. Meeker? Okay. Thank you. Commission discussion. Any discussion?

MR. HUGHES: I would just say it's good to see Mr. Meeker's holiday tie again --

MR. MEEKER: I wore this for you, Bob.

DR. KESHISHIAN: We heard some comments from Carrie regarding moving a mobile to a fixed unit. Does the department have any thoughts on this? And Sparrow has brought these comments up in the document that's included in our package.

MS. NAGEL: Yes. We did receive the langauge that was included in the packets yesterday and so we understand that this is a change that has been brought up before. We would need more time to vet that particular language internally. However, this, also, I think, language would -- potentially others may want to comment on it as well. So I think that it's a substantial change to these standards.

It's a significant policy change in lithotripsy and that, you know, we're -- we will certainly at your direction take it back and look at it and fit it into language, if that's your -- what the commission would like.

DR. KESHISHIAN: Any other questions or comments

from any of the commissioners? Okay. Then proposed action?

MR. FALAHEE: This is Falahee. I'll move that we approve the proposed language and schedule a public hearing at which the language can be discussed and that the proposed language also be moved to the Joint Legislative Committee for its review as well.

MR. HUGHES: Second.

MS. KOCHIN: This is Commissioner Kochin. That would incluide your suggestion on the revision?

MR. FALAHEE: Yeah; correct. Thank you very much. Right. Those revisions that are up on our screen right now in section 3 that we discussed earlier, which I'm assuming, Mr. Potchen, are technical.

MR. POTCHEN: The ones you just made?

MR. FALAHEE: Yeah; yeah.

MR. POTCHEN: Yes.

MS. NAGEL: Can I clarify that this doesn't include the language -- or does include the language that is brought up by Ms. Linderoth?

MR. FALAHEE: Well, no, because the language -- this language does not include that.

MS. NAGEL: Yes. I was just clarifying.

MR. FALAHEE: So no, I'm just talking about this language that we have in our packet. That's what I'm moving go to proposed heawring.

MS. NAGEL: Okay. And the amendment you reference is the --

MS. KOCHIN: The "that has."

MR. FALAHEE: The section 3.

MS. NAGEL: Okay. Thank you.

MR. FALAHEE: Yes.

DR. KESHISHIAN: Was there a second?

MR. HUGHES: Yes.

DR. KESHISHIAN: Thank you. Any discussion on the motion? Okay. All in favor, say "aye."

(All in favor)

DR. KESHISHIAN: Opposed? Thank you. Next item is Bone Marrow Transplant Services Report. Dr. Delamater will be providing testimony.

DR. DELAMATER: Hi, everyone. I'm Paul Delamater. I'm a professor at George Mason University. I've met many of you before, but you haven't seen me around very much. However, behind the scenes I have actually been running all the numbers and you get reports all the time from me. So I did my Ph.D. at Michigan State University. I have worked very closely with the department on CON-related matters.

So today I'm going to talk about the work I've done with bone marrow transplant. And I do want to apologize for you guys getting it so late, my presentation. That is not on the department. That is on me. It's the end

of my semester, so there's lots going on right now for me. Though today I'm going to try to keep it short. I haven't prepared a written -- a full written report and I would like to do that, if you would -- if you want me to, where I can put in more of the details about what I actually did in my analysis. But today I'm just going to talk a little bit about BMT in Michigan because we've never really dove into BMT's themselves, like I did for this report or this presentation.

I seem to remember about three years ago this came up and I did a report back then, but it was much more about access and travel time and things like that. So this one's a little different. I also -- I'm going to discuss the survey that I sent out and the results, and finally a little bit about moving forward. So the data that I used for this came from the annual survey, the MIDB, any bone marrow transplant procedure code and the US Census Bureau for the population that I used.

So everything you see in here, all the BMT numbers, are from the MIDB. I just used the annual survey to make sure that the numbers were close. It's interesting, though, how there are some little discrepancies between what I find in the MIDB and what's in the survey, but just by a couple of procedures a year or so, so it's not a ridiculous difference. But -- yeah. So the first thing I did was just

looked at the -- who's getting bone marrow transplants in our state and where they're getting them, and also who are facilities in our state are transplanting. And you can see in this first table we have all of the Michigan residents that received transplants for the last six years, and you can see 682 of them in state, so they went to an in-state facility, 42 went out of state for 724. But our facilities also transplanted 23 patients that were out of state.

So you can see we actually have more people leaving than we have coming in, but those numbers vary over time. It doesn't seem to be very consistent. When we look at the percents you can see it roughly works out to about 95 percent; 94 and some change; over the last six years. Michigan residents actually received their bone marrow transplants from facilities that are located in state. And our facilities, in-state facilities, just over 96 percent of their patients or their transplats are in-state residents.

And we can actually map this to see where residents from each county are going, if they're going in state or out of state to get their transplants. And you can see very high dark green, so that means 95 percent or more of the transplants that were done for residents of that location were done at a in-state facility. And as a geographer I love this because it shows a very traditional distance decay, where people further out here away go out of

state a little more, and then moving towards our facilities actually. So these are percentages, and you can see some of these are quite low. We have some between zero and 50 percent of the people who received transplants actually get them in state. So the map, the area distorts it a little bit. These aren't counts. These are rates. If we go back and look, we still see that roughly for a state we're between 94 and 95 percent residents receive their transplants in state.

So again, I'm not going to go through every single one of these tables, every one of these numbers. A lot of this was -- I included because I haven't prepared a actual report yet, just so you could see. But this is actually the first time we, meaning Michigan State and George Mason and the department, have kind of dove into the numbers like this. You can see that bone marrow transplants -- about 60 percent of transplant recipients are male and only about 40 percent are female.

And I can calculate per 100,000 people rates for the state. You can see they're quite different between male and female. We can also break this down by age group. What I'm getting to here is I'm working towards the fact that I can actually calculate age and gender stratified rates for these. So I started breaking this down just to look at -- so this is percents of all BMT's performed; right? And we

can see most of them are for patients between ages of 50 and 69 years old. And then we can also calculate the rates -- associated per 100,000 in our state population. And what was interesting about this -- and I'll -- I can get into this a little bit later -- is you can actually see some movement here. Some of the age groups are quite stable through the years, but you can see that older patients, actually from 2009 to 2014, are getting more transplants, are actually having higher -- or a higher incidence rates for bone marrows per 100,000 people.

And you can see a lot of the other ones are quite stable. But that was one thing that I noticed that, after reading the literature as well, that I -- you can actually see it happening in the state. So you also break this down by gender and age group. Now, because there's not a lot of BMT's in the state; we're dealing with, like, 600, 700 a year; I can't make really detailed age and gender categories.

As you can see, these are counts for our whole state number of BMT's. But I can start using this to start -- if we want to, start working towards a way to predict in the future what the state's going to use. Again, here are just the incidence rates. Rather than just counts we can look at incidence rates per 100,000 people for the state. So I also tried to use race and ethnicity to see if

that would affect, but unfortunately in the MIDB there's a lot of missing data and there's a lot of places reporting just "other" and there's no corresponding census category for "other," so I couldn't actually use the information from the MIDB for this. So moving on, now, this is the first time we had ever mapped this out and looked at how places around the state compare to each other as far as how they use bone marrow transplant or how many people received bone marrow transplants.

So this first map is age and gender adjusted utilization for the state. And what I've done is just basically account for differences in how the populations are structured. Now, you can see I used the HSA's here. We do have bone marrow service areas. We have two for the whole -- two service areas for the state. To be honest, as a geographer who works on these things, those things don't really make sense to me at all, so I didn't use them.

I just used our HSA's. We all know these. But what you can see generally here is that you -- even after accounting for differences in age composition of the population, use is highest in southeast Michigan in HSA 1, also a little bit high in HSA 5 and HSA 4 use is just under the overall state rate. So everywhere else you can see is quite low compared to the state rate. We can also just calculate a ratio, which is the observed amount of bone

marrow transplants from this location's -- expected given their -- how people use them in the state. And again, this is like a percentage. So this would be, in south -- in HSA 1, 108.6 percent of what the -- what we would expect given the state rates of bone marrow transplant usage. You can see again HSA 5, just over 1 and HSA 4 is just under 1. In places like the UP we have .816. So that's for every -- for all the population between zero and 80 or 79.

I also calculated it just for the adult population, because I know that pediatric BMT is a little different, so I only included people between the ages of 20 and 79 in the next map. But what we see is whereas Michigan as a state had 8.4 BMT's per 100,000, you can see again HSA 1 was quite high, followed by 5 and 4 and then the rest were quite low. And I have another similar map that shows in this case everyone's quite low compared to the state rate other than southeast Michigan. So that's just about BMT.

I want to talk a little bit about need and about where I can fit into CON or where I have fit in through the years to CON. We talked about our aims being cost and quality and access. Generally I don't get involved in the first two. I'm usually only looking at access. And when I think about this, I'm thinking about methodologies and how can we actually evaluate BMT and try to identify if there's some unmet need. I mean, that's what I do, that's what my

training was in, that's -- those are the things I've been working on with the CON for six or seven years. So the -- really the fundamental question is does the supply meet the needs of the population. I mean, when I do all my work, that really is what it breaks down to. Interestingly enough, and I'll talk about this, bone marrow is -- it's just difficult to answer this question. For acute care hospitals it's easy; right?

We have utilization and we have beds, and we can compare the supply that we have and the future demand. We can literally look at those two numbers and see if -- which one's higher basically. If projected demand is higher than supply that we have, we say there is going to be an unmet need; right? It's pretty simple in the end when you break it down. For BMT, not so simple. So let's talk about my survey. It wasn't really a traditional survey.

I was just trying to get information. But because I'm an academic and I would maybe want to publish research based on the results of the survey, I thought I should call it a survey and be a little more traditional about it. I sent to 20 people that are recent BMT SAC members and BMT experts that I had identified from the literature, and I received a grand total of 3 responses to my survey. I think it was -- this is -- again, this is on me. I've never actually -- this wasn't a Likert scale survey. This was a

12-page document, I think, that had a lot of my text in there explaining what I was trying to get at and I think the survey was just too hard. I think it was too long and too -- there was too much in there and people just didn't have time for it. But I will talk about what people brought up. The first thing I asked about was how do we measure supply. That was the big thing that I kept thinking about, is we can talk about use, use, use all day, but how do we know what our supply is, what the state can actually handle.

So the respondents brought up beds, but there's not a BMT-specific limit on acute care beds. Respondents brought up physicians and I thought this had some potential; the number of physicians that were in a program. Our other respondents survey also brought up support staff, talking about the specialized training that both the physicians and the support staff need. I did find some research from Dr. Majhail.

I think -- did he come and talk one time or -- I don't know if he came and talked here once. But he did a survey and found the median number of transplants that a physician performs at these different-sized facilities. So if we eventually are going to go down that route, we do have a little information about how we could possibly get to this idea of supply, of potential supply, because we could probably identify how many physicians are working at each of

our BMT facilities. So I was able to find a little information about that. I asked some questions about this idea of unmet need. The first was are there outcomes that signal unmet need, like some health outcomes in the state, and I got a big resounding "no." That would signal a opportunity for bone marrow transplant. I asked about proxy procedures or treatments that signal unmet need.

This is how we actually approach lithotripsy, is a hospitalization for kidney stone, it works as a missed opportunity for lithotripsy. Again, a big resounding "no" from the respondents. And one of the respondents talked about new advancements in cancer treatment. They actually make some of these ideas hard to even wrap your head around because BMT's changing so much and cancer treatment is changing so much that things we could maybe decide today may change in the near future.

So number 4 I asked about barriers for patients to access or to get BMT's or transplant. And everyone had a lot to say about this because there are a lot of barriers to accessing this service. There's the financial and social cost. One of the respondents brought up sometimes this means a new care team to get a BMT. Also, physician knowledge, this came up in the SAC again about just physician knowledge of what BMT is and who it should be made available -- or would kind of qualify for it. Everyone

talked about geography and age and comoribidities and then other things like donor availability and physician availability. So we found that everyone says there's a lot of barriers to bone marrow. So I asked about is it fair to compare Michigan to other states. Everyone said yes, but with caution or we should be cautious. So what I did was actually I went out and looked at a couple of states, how they regulate bone marrow transplant or transplants in general.

I actually found use data or utilization data from Maryland and North Carolina. And I dove into other states' regulation documents, like our review standards. And if you guys think reading our standards are fun, which we're used to, everyone, you should, you know -- going and looking at another state's is -- it's quite an experience. But I did dive in and look at Alabama, Florida, Maryland and North Carolina, who all regulate transplants and bone marrow transplants.

So first the state comparison about how many bone marrow transplants the state facilities do and the population. The number's a little different here because I tried to make our numbers comparable to how the other states were reported. You can see in North Carolina 750 bone marrow transplants for about the same population number we have here in Michigan. The rate's just a little bit higher

than ours, 705 for our 10 million. Maryland was a little bit lower, 320 BMT's performed for a population just under 6 million. You can see the BMT per 100,000 a little lower. So Maryland's lower than us, North Carolina's a little bit higher. We're in between. And again, this was just -- this is information I found while looking for the regulation documents. I didn't actually go searching for this, so this is kind of like bonus information for you guys. All right.

So let's talk about other states. Alabama regulates BMT through their CON. For a need to open a new facility in Alabama the other facilities have to be operating at 80 percent or greater of their capacity, which is not defined in their standards. I looked everywhere for it. But this was interesting "or unwilling to take new patients." I don't know how they measure that, to be honest.

And then they have some language in there about qualified personnel available in state and existing programs will not be detrimentally affected. This was in their standards language. I don't know how they make the decision, to be honest. That's about as far as I could understand it right there. So Florida, they have a 10 transplant limit for -- or minimum for pediatric and adult allogeneic programs, but they have language in their standards that says BMT is limited to teaching and research

hospitals only for these two services. For autologous 10 transplants was the minimum, but again, they had this limitation language in their standards document. Here they've relaxed it a little bit, teaching and research hospitals or community hospitals that are attached to a research program. So again, interesting language around BMT. Maryland actually uses past utilization to predict future BMT's.

Their method to do this is actually just like or very similar to our bed need methodology. So that actually made me happy because I was behind that bed need methodology. But they actually use a time series analysis and then put minimum threshold volumes, utilization -- or if there's need you have to find either 10 autologous or 40 allogeneic. This was interesting, though. They have more language in there.

"All other programs must be operating above the thresholds." And this was interesting as well. Right in their standards language they have a preference for less programs operating at higher volumes. So that's part of their policy. Their CON language talks about this. Finally, North Carolina, need is demonstrated when all the existing services are providing 20 or more transplants. This is limited to facilities already having solid organ transplants. And again, this language, I found it in

multiple states, it's limited to academic medical center teaching hospitals. So when I was looking at North Carolina's state health plan, it said no -- there was no need for bone marrow transplants. I e-mailed a person from North Carolina's CON and they said, "Well, basically there's no more academic medical center teaching hospitals, so there's no more need for BMT because we have put this language in there and there are none left."

They all have programs already. So I guess I wanted to put this in there because I know that our BMT language is a little -- we don't like it. We don't like the idea of having caps. I didn't find any amazing approach out there. I find that this is a specialized service and so you get this specialized-type language around it. So survey question number 6, I believe, I asked about minimum BMT volumes.

And we have FACT that provides these minimums for being able to be accredited. Currently in our review standards we have minimums. I asked a question about are there quality metrics. Everyone said, "Yes. There's a ton. We don't have to really worry about that." I asked about if we should try to do a regional approach, like I showed you with the maps of the HSA's, or if we should just try to do it at a state -- the respondents said maybe regional. Some of them mentioned we should try to understand the existing

supply or the capacity of the system. And then they also brought up this idea of 60-minute travel time. Because for BMT, if a patient lives further than 60 minutes from the facility, the facility recommends or -- I don't know if the terminology is correct here to say "makes them" move closer or be closer to the facility. So if they live further than an hour away, they have to relocate closer to the facility to get the transplant. So -- yeah.

Survey question number 9 was asked about if we identified some unmet need in the state how should we actually site a facility. I used a poor example and I said, "What if we identify unmet need in the UP? How should we -- given the UP's a massive area, and a facility is a point in space, how should we site that facility in the UP?" And everyone couldn't get past the fact that I said "identified unmet need in the UP."

They're, like, "You're crazy. That would never happen." So I didn't get any clear information on this one. This is a bad question. It was my fault again. Finally I found this paper that Besse et al. had developed this methodology to try to determine if there were unmet need throughout the US for BMT. They used BMT-related disease incidence rates in places. They also estimated the proportion of disease cases receiving BMT and then they had population characteristics. I asked the respondents about

that. They basically said it was somewhat too simplistic in that it didn't incorporate kind of the complexity of the pathway that people take when -- to get to BMT; that it's not so simple that we can just throw these numbers on disease cases, and that there was -- I guess I would say there was some unease about using this kind of approach for -- to predict need in the state. Someone also brought up the idea of spatial scale, which actually made me really happy because I think about that all day long.

So then I asked more questions about Besse because they did this very -- they had all these disease groupings right here and they had to come up with BMT rates per each of these. And so I said, "Are there more aggregated groupings than what Besse had used?" Some of the respondents said no. Some pointed out the groupings that Dr. Akhtar had provided in the SAC, and so that we do have these six groupings of diseases that often, I guess, can be attached to bone marrow transplant.

Then I asked about potential data sources, where if we were going to try to create a need methodology, where can I get data. That's always my question, as the guy who works with data, is, "Where can I get data?" Respondents talked about the Cancer Surveillance Program in the state, but I don't know if I can get that data in a resolution, like a county level or a HSA level, that would be helpful

for me. I know that there are facility tumor registries, I just have no idea how to get those or where they would be or if the state is even interested in getting those to use in a methodology. So -- all right. Moving forward. As far as a BMT methodology goes, there was the proposed facility-based methodology that came out of the -- that was something proposed in the SAC. I really -- I have concerns over that because mostly it's just about transferring services.

I know we have facility-based methodologies in some of the standards right now. That's not by my design. Everything I've done with the department has been actually trying to move away from those. Every time something new comes up, we at MSU and myself at GMU always attempt towards moving towards population-based methods rather than facilities. So I do have concerns over the methodology that was presented.

I do think now that I've looked at the numbers for the first time in such detail that we could maybe do some kind of time series analysis, like we do in a bed need where we look at changeover time. We could use five or six years, where I was able to use six years worth of BMT data for a lot of the maps I'm showing you here today. So that could be a promising approach, but really in the end I can't do anything at all. I don't think I should do anything until we can figure out how to measure supply or capacity of the

system. Because I could spit out numbers all day, all day, all day, but what do we compare those numbers to to see if we have a need? Until we can get an idea of what our capacity of our system is, then whatever methodology I come up with to predict future use, it won't be usable because we would say, "How -- what do we compare it against? Can our system" -- we won't be able to say, "Can our current system handle that amount of utilization as it's currently configured?"

So before I could do anything or move forward, this would be the biggest question, is, "Can we measure supply or capacity of our current system?" So that's it. Thanks for listening. Questions or comments?

DR. KESHISHIAN: Commissioner Falahee?

MR. FALAHEE: Paul, first of all, number one, good to see you. Number two, thank you for taking time out of a very busy time. It is end of semester. You probably have a few exams to grade or whatever like that, so thanks for taking the time to --

DR. DELAMATER: I was going over papers this morning before the meeting.

MR. FALAHEE: So the bottom line for you is -- and if you can flip back to that prior slide, just to make sure I understand it -- you make things very easy to understand, so thank you for that. As I look at it, we've got these

other states and what they -- the interesting wording they use.

DR. DELAMATER: Uh-huh (affirmative).

MR. FALAHEE: The bottom line is until we get an idea of what the supply is or the capacity is in the state of Michigan, everything else just sort of rings hollow because we don't know -- okay -- how many can you get through the pipeline and how many are trying to get through the pipeline.

DR. DELAMATER: Right.

MR. FALAHEE: Until we get that, we're at a loss to determine whether there's a true need, in quotes; is that right?

DR. DELAMATER: That's true. And when I saw some of the other states, and especially when I saw Maryland and how they had approached this, and for the first time actually diving into the data, I got pretty excited about being able to develop a methodology that I could present to a SAC or to you guys and explain how this method works. But then my excitement was tempered by the fact -- I'm, like, "Oh, yeah, I don't have anything to compare my output to in the end." So --

DR. KESHISHIAN: Commissioner Mukherji?

DR. MUKHERJI: Well, great presentation.

DR. DELAMATER: Thank you.

DR. MUKHERJI: I'm delighted you have the green in the background so that's --

UNIDENTIFIED SPEAKER: Some of us are not delighted --

DR. DELAMATER: Sorry.

DR. MUKHERJI: Just two real quick questions. Do you know how many states currently regulate bone marrow transplant?

DR. DELAMATER: You know, I think it's 7.

DR. MUKHERJI: So 7 out of 43?

DR. DELAMATER: Yeah. It's --

MS. GUIDO-ALLEN: -- 7 out of 50.

DR. DELAMATER: Is it 7?

MS. GUIDO-ALLEN: 7 out of 50.

DR. MUKHERJI: Oh. 7 -- yes -- 43. That's --

DR. KESHISHIAN: That's why you like the green.

DR. MUKHERJI: -- my geography wrong.

DR. KESHISHIAN: That's why the green there.

DR. MUKHERJI: I just assume -- exit by the way. That's where I -- so then the second question is, if there's 7 yes, 43 no -- that's what I meant obviously. Okay. Is there any data suggesting utilization in those states that have BMT regulation versus those that don't?

DR. DELAMATER: So I believe -- I don't know if that exists, to be honest. A couple of years ago when I

prepared the presentation on access I looked at differences in access to BMT between states that had CON and states that don't have CON. And from what I remember from that report there wasn't a big difference between access to care. But utilization I don't know. I kind of serendipitously found those use numbers from the other state. I wasn't really looking for them, but I was able to find them when I was diving through the reports.

You know, one of the things I did find, though, with BMT and the regulation you brought up when these 7 do it, is it's -- a lot of times it's buried under organ transplant, where there's a lot of language about heart and liver and other organs transplants, and then BMT is kind of at the bottom. And it's often like -- I asked -- I remember back in Maryland -- but Maryland produces need projections for transplants every year and I went and downloaded it.

And even though the standards say they project bone marrow transplant, it's not in the state report. And I -- they haven't gotten back to me. I sent an e-mail Monday morning, like, "Hey, where are these? Your standards say that they should be here." So -- yeah. So I don't know if there's any more board data. I don't know where I can find it, to be honest. I think that there are some databases, but --

MR. MUKHERJI: I had another one but I'll let

somebody else ask a question.

DR. KESHISHIAN: Commissioner Falahee?

MR. FALAHEE: Yeah. One thing I forgot to ask, Paul, a few years ago Michigan State put out this survey -- and you may have been one of the authors. Basically if you build it, they will come for healthcare facilities.

DR. DELAMATER: Yes.

MR. FALAHEE: So could this be an example, if -- forget the last -- the real important question at the bottom. But is this one of those -- and you may not have any opinion on it. If we said, "Okay. Go ahead and build another one," is it just a matter of, "Okay. Now we'll get more in the 108th percentile HSA anyway. We're just going to move those 108 from one place to another"? Is there some of that that could potentially happen?

DR. DELAMATER: So that was actually my dissertation. You were correct in that. That was my article. You know, it's hard to say for this, to be honest, because that was acute care hospitalizations. It's a lot different. This is much more specialized. There's much fewer of them. I would struggle to make the connection between the two. And I don't know, to be honest. So you know, I would say that for some things we can kind of -- we can compare hospital bed utilization to other services, but I would feel like that was a bit of a stretch here for

saying that. But I don't know, to be honest. The answer is "I don't know."

MR. FALAHEE: Okay. Thank you.

DR. KESHISHIAN: Commissioner Mukherji?

DR. MUKHERJI: I think the original meth- -- I mean, part of the challenge that we have here is to try to figure out whether -- how to adjust the methodology moving forward so it's more -- spaced, if you will. And this isn't a question necessarily to you, but to anyone else. Could someone sort of explain to me how the original methodology was initially created and put into state statute?

And this is a follow-up question, is that we're taking a very thoughtful approach right now to determine supply, demand and determine what capacity is. Were those initial questions asked at the outset and does that factor into the way the initial methodology was currently created?

DR. DELAMATER: Now, anyone feel free to correct me, but there isn't -- there is no methodology; right?

MS. ROGERS: This is Brenda. Yeah, there's no methodology. And of course, I know these go way back before my time, but I'm trying to remember -- and I don't know if it's BMT or if it's some -- another service I'm thinking about, but a lot of these started with -- I think they were the planning -- state planning policies or something like that. And those laid out what should be part of the

standards when standards were going to be developed. And it may have just started out with, you know, we're going to have three -- two regions in the state or whatever it was. I don't have a good answer for you. I mean, like I said, that goes way back.

DR. MUKHERJI: I mean, that was my understanding. My understanding is that there was -- the number was created, I think three was the initial number, and then in order to make access more equitable then a fourth was added on the western side of the side. But was the number three based on any type of thought or analysis that was done here?

DR. DELAMATER: No. I wasn't part of it. This was all before my time as well.

DR. MUKHERJI: And do you know how long ago that initial methodology was created? Any idea? Was it 20 years, 30 years, 1 year?

MR. FALAHEE: Falahee. I'm going to say late 70's, early 80's.

MS. ROGERS: And this is Brenda. That would be my guess.

DR. MUKHERJI: So I'm terrible at math.

MR. FALAHEE: Is Mr. Meeker still here? I mean, Bob may know because of what --

MR. PATRICK O'DONOVAN: I have it. It was 1988.

MR. FALAHEE: '88? Okay.

DR. MUKHERJI: So that was 30 --

MR. FALAHEE: Thank you, Patrick.

DR. MUKHERJI: -- 30 --

DR. KESHISHIAN: Bob, I think we -- the question's been answered.

DR. MUKHERJI: It's been answered?

MR. FALAHEE: Yup.

DR. MUKHERJI: Okay. 30 -- I think 30 years ago. So that's really when we had individual hospitals versus integrated health systems then.

DR. DELAMATER: Right.

DR. KESHISHIAN: Any other questions, comments? I want to thank you on behalf of the CON Commission for participating today. Thank you very much for being here in person. It means a lot that you're able to explain the data that you evaluated. Thank you.

DR. DELAMATER: Thank you.

DR. KESHISHIAN: Next item is public comment. I have one blue card, Patrick O'Donovan from Beaumont.

MR. PATRICK O'DONOVAN: Thank you. My name is Patrick O'Donovan, representing Beaumont. Just to answer the last question on the original number of three, that was part of the state medical facilities plan. It was approved in 1988. It says, "During phase 1 the following policies will apply. No more than three bone marrow transplant

centers will be approved statewide." So hopefully we're moving toward phase 2. Well, I really appreciate Dr. Delamater's presentation. There were a lot of good information, a lot of good numbers in there. As you can see, there was nothing really in there that would support movement toward a specific methodology. The only thing I'll mention about the two methodologies, sort of the regional- or the population-based and the facility-based, he did make a comment that a facility-based would only result in transfer from one place to the other.

I think during the SAC process we showed data that when a program was added to the west side of the state, more people who lived there got transplants. So the actual numbers in the state did go up. But our main point here is that this has really gone on for too long. We were just talking about 1988. Just this last round it's been almost 2 years. The decision to establish the SAC was January 2015, it was seated later that year, provided the final report in June of 2016.

The commission asked for a methodology for September, if possible. So there was no methodology in September and no methodology yet today and no real momentum in terms of what direction to go. So I just want to make the point that, you know, I think it might be time to deregulate. You could take proposed action to deregulate

and over the next three months if a methodology magically pops up that is defensible and that the commission wants to adopt, they could -- you know, you could certainly substitute that. But I think it's time to move it toward closure and we hope that there's a good discussion toward closure. Thank you.

DR. KESHISHIAN: Thank you, Patrick. Any questions? Okay. Thank you, Patrick. Okay. Commission discussion. Commissioner Guido-Allen?

MS. GUIDO-ALLEN: Hi. Just I want to thank Dr. Delamater for his presentation. Is this working?

DR. KESHISHIAN: I can hear you.

UNIDENTIFIED SPEAKER: Yeah.

MS. GUIDO-ALLEN: So it was really quite informative. I want to just make a couple of points. 43 states do not regulate BMT and there has to be some rationale for that. It would be interesting if there was some utilization data for it, but I can't see that it's that significant. Based on the data in the report it shows that BMT -- the need is growing in our state, especially with older adults and -- sorry, guys -- males, older males.

We have to have a way forward and it's up to us as a commission to make that way forward. And then one request would be to have the department weigh in on their stance on this issue. Thank you.

DR. KESHISHIAN: The department, could you weigh in on your stance?

MS. NAGEL: Sure. For the last, I think, three maybe even four times that this standard has come up the department has recommended deregulation for several reasons. One, as was discussed, the access. You know, when we look at deregulating we look at access, quality and cost. And we've found that the access is comparable between the states that do regulate and don't regulate. So we've found no reason to continue regulation based on access.

As far as quality goes, BMT is highly regulated by many other bodies; not only accreditation bodies, but the federal government as well. We find no benefit to quality for the department to continue certificate of need regulation. We feel it's highly specialized, that there's no risk for undue proliferation in the state. We have long held this argument going back more than a decade that bone marrow transplant services should be deregulated.

This past go-round we asked you, the commission, to either deregulate or develop a methodology because it's the department's stance that a cap can no longer stand, that it's our only standard with a cap, that the cap is not based on anything other than the 1988 regulation and we'd like to see some change in the standard.

DR. KESHISHIAN: Any questions for Beth?

MS. BROOKS-WILLIAMS: Commissioner Brooks-Williams. It doesn't sound like they're on this morning.

UNIDENTIFIED SPEAKER: I know. It doesn't.

MS. BROOKS-WILLIAMS: Can you just tell me what the -- so I hear the recommendation. What is before us today in terms of the action that we would be taking? Is it deregulation and a methodology? Is it completely open?

MS. ROGERS: Excuse me. This is Brenda. Actually at that this point it is open because you -- there is -- you have not -- there is no methodology at this point other than -- I mean, as you'll recall, the SAC did put a methodology in front of you back in June, so that one is still sitting out there. But yes, short of that you could, you know -- you can continue this out and have the department and/or whomever continue to work on the methodology.

But again, as Paul stated, there are some other areas that really need to be addressed before a methodology can even be developed. And again, you can also discuss deregulation. And as Beth stated, the department does support that. If you were to go that route, then it would go out for public comment. We would hold a public hearing. And then it would come back to you at your March meeting for final action on whether or not to deregulate BMT from the

CON review standards. So I mean, you really -- you really have a full scale of what you can do today.

MS. BROOKS-WILLIAMS: Commissioner Brooks-Williams. So my next question would be -- and maybe this is to the department or to the fellow commissioners. So as we talk about what the options are that are in front of us -- and I know we saw data. And I'm not that good.

I don't remember all the data that we saw last time, but -- which is why I'm asking what it is that we think would be the course that we're trying to discuss because if I look at the presentation that we had, I think the question is still just -- well, I don't necessarily agree that we should hold to what we did in '88. And I think I do want to figure out how to move forward. I'm not sure what new data we have other than the interest for others to enter into delivering the service, which may very well be a good cause for discussion, but how do we add more to it when we don't fully understand, it sounds like, how we're assessing what we currently have.

So don't we at least have to try to figure out the methodology that we had before wasn't satisfactory or not understandable as a logical next step at least to have a methodology, so that if you were to do anything else; keep it like it is, do something different; you at least have something -- upon which to confirm that the cost-quality

equation is being maintained?

DR. MUKHERJI: You keep looking at me. This --

MS. BROOKS-WILLIAMS: I'm looking that (indicating) way.

DR. MUKHERJI: Well, this -- I mean, I'll go and stick my neck in the noose. This is just the way one commissioner looks at it. The initial three of -- which was initially created, which was obviously created when I was in diapers, because I know -- there's only 43 states obviously. But the initial three that were created were from my understanding, a very parochial opinion, is that when there were lots other individual large hospitals that were acting independently.

And because bone marrow transplant was an evolving treatment option that had tremendous promise and would have major impact on surviving, I think the concern was that because you had a lot of independent hospitals everybody would try to create their own service just based on the promise. And at that time, because this was more of a regulated state planning at the state level, the number three was generated.

And how that number was generated I'm not quite sure, but it was generated. And then the western part of the state was disadvantaged because obviously people from Grand Rapids would have to drive all the way over to the

southeastern portion of the state, so a facility was created in the western part of the state. So that provided more geographic equity. Since that time there's been a tremendous amount of consolidation in our system as we all know. So I think part of the challenge is, is that the currently facilities that currently have it do an outstanding job. That's unequivocal.

And two of those four centers, I think, are NCI-designated cancer centers, and I think that's Karmanos and U of M. So their quality is unassailable. And having said that, over the last 30 years there has been tremendous consolidation. And a lot of the health systems that have evolved are some of the best in the country as acknowledged by typical quality indicators that we all agree to, whether it's hospitals -- hospitals.gov, the CMS website or US News & World Report, so on and so forth.

So I think part of the challenge is, is that the fundamental market has changed. It's difficult to come off with a thoughtful methodology add-on and adjust the current thresholds that allowed more people to provide the service because there were none initially. So we don't really have a good benchmark. So I think part of this discussion is to figure out, given the fundamental change in healthcare providing, it's more health-system-based as opposed to hospital-based, how do we allow quality providers to now

enter this field when, if we look across the country, 43 out of 50 states don't even regulate the service. That's just my assessment of this.

DR. KESHISHIAN: Commissioner Mittelbrun?

MR. MITTELBRUN: It just seems to me listening to discussion, and I'm looking at this PowerPoint, it seems to me it needs to get to the point where we have public comment to try to figure out the pros and cons from the people involved in the industry. So whatever that step is -- because there seems to be, you know, no decision in sight, I guess, from listening to the comments. So just, you know, from my point of view since I'm not an expert in this field, like some of you are, it just seems to me that there's more information needed from the people that are participating.

DR. KESHISHIAN: This is Commissioner Keshishian. I think that the SAC tried very hard to come up with -- to answer that question and I think there was disagreement among members of the SAC on those issues of quality and cost. And so, you know, to go back I think we have a couple options. We can deregulate. We can maintain three.

And the SAC actually had a majority and minority report where there were different methodologies that would be -- that we could consider to do but -- and to implement. At this point, though, I think -- and the point was made that it's been going on for a couple years now and we need

to try to make a decision on what we're going to do, because I don't think there's going to be any methodology that is going to -- that's going to pop up and that the have -- the people that have and the people that don't have it are going to agree to the methodology that we have.

DR. KESHISHIAN: Commissioner Guido-Allen?

MS. GUIDO-ALLEN: Guido-Allen. May I make a motion?

DR. KESHISHIAN: Absolutely.

MS. GUIDO-ALLEN: Very good. So based on the department's recommendations, based on the report we received and the data we reviewed, I would like to recommend that we move to deregulation of BMT.

DR. KESHISHIAN: Okay. Thank you. Is there a second?

MS. COWLING: Cowling seconds that.

DR. KESHISHIAN: Okay. Any discussion on the motion? I think we do. Commissioner Falahee?

MR. FALAHEE: To Commissioner Mittelbrun, that's how you call the question in terms of getting it, because if we approve the motion that's in front of us -- Brenda will tell me if I get it wrong -- this will go out for, I guarantee you, public comment, which, in March, plan on a long meeting. But that's how --

MR. MITTELBRUN: I'll be here.

MR. FALAHEE: -- that's how we'll get it.

MR. MITTELBRUN: I wasn't sure which motion to make, so that was kind of --

MR. FALAHEE: That'll do it.

DR. KESHISHIAN: Thank you. Commissioner --

MS. BROOKS-WILLIAMS: Brooks-Williams. That's okay. I have this long girl names. I think -- I applaud you for saying, "Okay. We're going to move in a direction." I still challenge us to say, though, deregulating -- I just -- I'm not clear -- right? -- how it ultimately answers what it is that we're suggesting is the dilemma around how much more of the service do you need, how do you confirm that what you're having outside of obviously the regulation that exists beyond the CON Commission.

And so I just would say I don't know that I agree with the default strategy that just says, "Okay. We don't know what to do, so deregulate it," if I'm not dismissing the motion. I don't believe that's entirely the motive there. But I question what have we resolved and what will we garner through public comment if we didn't get any clarity through the SAC.

DR. KESHISHIAN: Mr. Falahee?

DR. MUKHERJI: I think you asked the --

UNIDENTIFIED SPEAKER: Mukherji.

DR. KESHISHIAN: Mukherji. Yeah. I get one

name --

MR. FALAHEE: Sorry.

DR. MUKHERJI: This is Mukherji. I think you ask the pivotal question, is what really are we trying to achieve. And as I mentioned earlier, I think what we're trying to achieve is equanimity and transparency for all healthcare systems within our state to participate on a level playing field. And currently that is not necessarily in place based on the initial meth- -- or I don't want to say "methodology," but provisos that were created 30 years ago.

And I mean -- what I'm not saying -- I don't want this to offend any healthcare services because I fall into this. Because of imaging and the sense that you can look at CT, MOR and ped as almost commodity-based services. And when you have commodity-based services, a lot of these things are regulated. So in a way general hospital beds are regulated. General standard of care are regualted.

But when you have something as specific as was mentioned before that is regulated both -- highly regulated both at the state level -- excuse me -- at the federal level and through other medical bodies, such as bone marrow transplant, it's hard to figure out what additional value a state regulation of a service that is so highly specialized and so highly trained will add in addition to what's already

in place besides just preventing other large systems from being able to provide the service. So at the very least what this discussion will do, whether -- if the commission votes not to deregulate then my understanding is it stays in this -- it's over. But if we vote to deregulate, then it goes to public discussion. Is that correct, Marc?

DR. KESHISHIAN: My understanding is if this motion failed we would do another motion and we could take either the majority report from the SAC or the minority report from the SAC and present that to public comment and come back, or we could in fact continue as we are now and that would go to public comment. No matter what we do it's going to public comment and we will have another bite at the apple in March on -- based on the public comment hearing.

MS. ROGERS: This is Brenda. Just one correction in that if you decide to leave the standard status quo, that would not allow for public hearing. So only if you are going to suggest changes to the standards and/or deregulation, those items would go out for public hearing and to the Joint Legislative Committee.

DR. KESHISHIAN: Thank you for that clarification.

MR. HUGHES: And that would include taking either the minority or majority report from the SAC?

MS. ROGERS: Yeah. If you were to take one of those and, you know, have the department, you know, draft

language, then -- you still haven't seen actual language yet either. So that would be the other thing. Would you be -- I think personally -- and again, I just -- it's going to be your call, but I would suggest if you're going to go that route you would want to have the department draft the language, bring it to you in March where you can actually do proposed action and then at that point in time then it goes out for public hearing if you take proposed action in March. Today I think it'd be hard to take proposed action on language that hasn't been drafted yet.

MR. HUGHES: Thank you.

DR. KESHISHIAN: Any other comments, questions? Commissioner Falahee?

MR. FALAHEE: Brenda, a question on that. So we've got a motion in front of us now. Help me understand. Another potential option is if that motion failed and I'm -- whatever. I'm just trying to lay out the options here. If that motion failed, another one could be, "Department, please draft language based on the majority report of the SAC and bring that language to us as the commission in March"?

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

MS. NAGEL: Can I just add -- could I just add one thing? I just would like to remind you that the reason the department expressed great concern about the majority

report, and it wasn't from a deregulate or not perspective, it was just that there were some data points included in there that don't exist. And so we have some big concern about that majority report. So if you were to go down that route, we would need much more discussion. And that's wny we contracted with Dr. Delamater, was to help us answer some of those unknowns. And unfortunately, you know, some of those unknowns it appears we just --

MR. FALAHEE: Still unknown?

MS. NAGEL: Yeah.

MR. FALAHEE: So -- Falahee again -- following from that, if there are issues with the majority report and even with the professor's report there's not -- arguably there's no substantiation for some of the data points in the majority report?

MS. NAGEL: That is correct.

MR. FALAHEE: Okay.

DR. KESHISHIAN: Commissioner Brooks-Williams?

MS. BROOKS-WILLIAMS: Commissioner Brooks-Williams. So I'm going to ask again. And maybe this is -- so one option is we obviously vote and if what we have on the floor is approved, it's approved. The other option, I think, that -- so what are -- all I want to make sure we do is not have a vote because it's the only vote we can make -- I don't know -- to deregulate and then let everybody

else figure it out. Am I hearing you correctly that the department is feeling there is nothing else that you can weigh in on, or are you not able to work from where we are today with the data and information that we've received to give us better clarity on what we could do, you know, beyond -- so if you throw out the SAC work and you say you're starting from where you are today, there are other, I'm assuming, ways that we have tried to still contain the cost and the quality while allowing the access of other facilities that might have the capability to deliver service.

I mean, you've done it with NICU and beds. I mean, and I don't know that BMT relates to that. It's not just -- bed-oriented-type service or whatever. But is there not some way to put some parameters around it that take away the restriction perhaps on who participates, but does allow you to still have some cost-quality containment or structure?

And I'm not seeking to design it because obviously we've had people way smarter than me try to do that. I don't know that I have the answer. But I'm not comfortable with just saying we're not going to have any regulation either. And I'm trying to identify what are other options that allow you to maybe get at what is more about access of other facilities, but that we will do more than that if we

just say, "Okay. Anybody can do it." You're not going to be able to make sure that it's the high-quality academic facility that does it if you just say deregulate it.

MS. NAGEL: Yeah.

MS. GUIDO-ALLEN: Go ahead.

MS. NAGEL: That's a great question. And to answer your -- what I believe was your first question --

MS. BROOKS-WILLIAMS: Multiple. I apologize.

MS. NAGEL: No, we don't have the -- we don't have what we need to develop a needs-based methodology. That said, you've brought up a great point that there are other things we could add into the standards to achieve some of those other goals. So for instance, some of the other states, as you saw in Dr. Delamater's presentation, have some regulation that say it has to be a academic facility.

We could certainly insert something like that. We could take away the language in the standard that has a cap on it now and add in some of those other qualifiers. There's different ways -- there's certainly different ways that we could do this. I think from the department's perspective we wanted a needs-based methodology, and so my answer to that is no, we don't have what we need to do that. But to answer your second question, yes, there are many other options, things we could do, that could potentially address need. It wouldn't be done in a way that we normally

do our other standards. It's very evidence-based and based on population statistics and other data that we collect, but that's, you know, the purview of the commission to decide between those options.

MR. FALAHEE: Falahee. But it's still something other than just, "We don't know what to do. Deregulate"?

MS. NAGEL: Yes.

MS. BROOKS-WILLIAMS: And again -- I'm sorry. Commissioner Brooks-Williams. With all respect to my fellow commissioners, I get it. I mean, it's, like, we -- I think we're at an impasse to say we want to stop circling the conversation. I think I'm just saying from a accountability perspective, given how well we have performed and how well we've served our citizens, I would hate to say we go to the other extreme and somebody looks back and says, "What did they do in 2016 and those 43 state or 7 places or whatever?" And I think we could do better than that. So I don't know that I have the answer, but I also don't want us to create an unintended consequence if we really are just talking about creating greater access for high-quality institutions, you know, that may be more than capable to do this and the cap doesn't allow that. You still want to have some parameters of entry, I hope, in some ways to confirm that you keep the level of quality that you've had all this time.

MS. NAGEL: If I could just add onto that, if you

don't mind.

MS. BROOKS-WILLIAMS: Yes.

MS. NAGEL: I do want to make clear one thing. The department's recommendation is not deregulation because we don't think there's anything else we can do. The department's recommendation is deregulation based on rationale. Based on the rationale that we see very little difference from other states with quality and access. We believe that the regulations are in place to protect patient safety.

We believe that the regulations are in place from the largest payer to -- from the federal government to highly regulate this service. It isn't for us -- the question, I just want to make clear, isn't deregulate because I can't come up with a great methodology. It's deregulate based on what's been a decades worth of research on this particular topic.

MS. BROOKS-WILLIAMS: Can I just -- oh. I'm sorry.

MS. GUIDO-ALLEN: No. Go ahead

MS. BROOKS-WILLIAMS: Just in direct follow-up to that. So my only other question, and it's not a challenge whatsoever, would be that if the -- if that is the perspective of the department based on that research, is there not any guidance -- right? So it's more asking --

right? -- to say if we want to move in a different direction, because that's where our conversation started, and have an alternative to deregulation that, I guess, recognize what you're suggesting occurs and deregulate environment, does the department have enough knowledge to frame that in some context that is still allowing the commission perhaps as we transition -- maybe you're moving towards deregulation, but the interim step is that you're putting some parameters around it.

Is there enough knowledge within the department to feel comfortable doing that? Not on a need base, I understand, but just in general putting some guardrails around it?

MS. NAGEL: I'm so sorry. I'm not sure exactly the question.

MS. BROOKS-WILLIAMS: So when I made my great hypothesis that maybe we could do something like NICU --

MS. NAGEL: Oh.

MS. BROOKS-WILLIAMS: -- and you said, "Oh, that's a good idea."

MS. NAGEL: Oh.

MS. BROOKS-WILLIAMS: And then I think you were framing that it wasn't just about deregulation because we didn't have anything else to do. I'm saying so based on that, if there's research and a basis that you, you know,

support deregulation, does it also lend itself, though, to a transition step? So before you would get to deregulation is there something else you could do?

MS. NAGEL: So then, no, I don't think that we particularly have the expertise, but we could certainly find it.

MS. BROOKS-WILLIAMS: Okay. Thank you.

MS. GUIDO-ALLEN: I have a --

DR. KESHISHIAN: Commissioner Guido-Allen.

MS. GUIDO-ALLEN: Guido-Allen. I have a question for Beth. Beth, at the current time with the programs that are existing for BMT, does the state review quality measures, quality outcomes, cost, efficiency, number of cases, deaths, you know, as part of -- does the state review that and have they done anything with any of them that don't meet or do you even have standards for any of those? Or is it based on CMS and what they have to report accordingly? I don't know, so I --

MS. NAGEL: Good question. We do collect data on cases, the --

MS. GUIDO-ALLEN: Number?

MS. NAGEL: -- number of cases. We do -- I'm looking to Tulika. We do collect some limited outcome, but not to the level that you're describing.

MS. BHATTACHARYA: Excuse me. This is Tulika.

Exactly right. The most important thing we collect are the number of cases. And if my memory serves me right, all of the programs are meeting the volume requirement. But if you compare BMT to the recently revised open heart surgery standards, there are no specific measurable quality metrics in the BMT standards that we can collect data on or kind of collaborate with quality consortium like BMC2 to review them.

For us they are FACT accredited as long as that accreditation is valid as monitored by CMS and the feds. That's all we do. There are no additional quality metrics in the standards for us to monitor.

MS. GUIDO-ALLEN: So -- Guideo-Allen -- by deregulating, the quality oversight would still be in place by CMS and the -- if any institutions opt to create a BMT program, they would still be held to the same standards our current practices are? Deregulation would not change that?

MS. BHATTACHARYA: Exactly. Because if you look at transplant hospitals and if you discuss or ask LARA, you would find it out, for every transplant hospital there is a separate facility that they create as a transplant hospital because CMS requires that in-depth formal review of the program before they will accredit and give them FACT accreditation. And that's a very in-depth review of any program. I mean, I don't think you can start every MD

service based on --

MS. GUIDO-ALLEN: No.

MS. BATTACHARYA: -- right of care expectations. And if you want CMS to approve the program, that's who you have to go through and LARA has complete oversight over that.

MS. GUIDO-ALLEN: Thank you.

DR. KESHISHIAN: Any other comments? Commissioner Mittelbrun?

MR. MITTELBRUN: I guess my question would be the staff has spent a lot of time with Dr. Delamater, but there's stuff missing. There's information missing. Is it better for us as all this time has already been spent to help him get the rest of the information he needs, such as supply, and try to finish his work? I'm just curious. That's just my thought.

DR. KESHISHIAN: I mean, is that a question to me, to the department?

MR. MITTELBRUN: Well, I guess it's just a thought. I mean, you know, the staff and the doctor have spent a lot of time doing this. But from what I can tell, it's not complete because he doesn't have all the information he needs. And I don't know how to get him the information he needs. So I guess it's a question. Can we get him the information he needs to complete his work?

DR. KESHISHIAN: This is Comissioner Keshishian. I'll try and attempt -- I don't know if we're ever going to get that information because when you go to the SAC, there is various viewpoints at the SAC on does more cases improve quality or not. There's differences. What is the cost of these procedures. We've heard testimony it's a minimal additional cost. We've heard testimony it's significant.

We can't even get -- we just have to take the information that we have at this point. As it's been pointed out, it's been a couple years in the making now. I think we do have a motion on the floor. And we don't pass that -- and if we do, it moves on to public comments and we have another bite at the apple in March when the comments will be made. And as Commissioner Falahee said, I'm sure we will have public comments.

And if we don't, then we're back at -- if we do something else, other than just maintenance of three, we'll be at that point with other comments at this point.

MS. ROGERS: This is Brenda. And just for clarification, before you do take a vote on this motion, I just want to clarify that Ms. Guido-Allen's motion wasn't simply to deregulate. She did give her -- some very specifics. I just want to clear -- make sure that we're clear on that. Correct? Thank you.

DR. DELAMATER: I'm sorry. Can you repeat the

motion then? Because I heard deregulate.

MS. ROGERS: Yeah. I'm going to ask her to repeat it for us.

MS. GUIDO-ALLEN: This is Guido-Allen. Motion was based on -- let's see if I can remember -- based on the report of Dr. Delamater, based on --

MR. POTCHEN: It was really well said before. If you want to be specific, we have a court reporter here. She can read that back.

REPORTER: I have to find it. It'll take me a couple of minutes.

MR. POTCHEN: Okay. Because it was really well said.

UNIDENTIFIED SPEAKER: Yes, it was.

DR. KESHISHIAN: Okay. As she's finding that, are there any other comments?

DR. MUKHERJI: Just as I look at Paul's -- and it really was an excellent presentation.

MS. GUIDO-ALLEN: Based on the department's recommendation and based on the report of Dr. Delamater I move to deregulate BMT.

DR. MUKHERJI: So I think just based on Paul's excellent presentation -- really it was excellent. Congratulations on that. If you take -- and I got it right -- 50 states and you take 43 out, that leaves 7.

Correct me with my math because I'll mess it up. The information that he was able to provide, the commonalities that I see with the -- if we want to try to take an evidence-based approach moving forward, for some reason 10 came up in a couple of the states. So all the services have to provide more than 10, which indicates to me -- one's 40; 10 and 40 -- which indicates to me these states have already recognized that this type of service is highly regulated at CMS.

And the point that was made earlier is that we do forget about our sister body, which is LARA. I keep forgetting about them. But they do have all licensing for these areas. And a couple states did have these limited to academic medical centers and teaching hospitals. And to be honest with you, I think most of the large integrated systems in our state either have a hospital now or are participating in the teaching of residents and fellows, either through a direct affiliation or indirect affiliation.

So moving forward to answer Commissioner Brooks-Williams' question, if -- moving forward, if we do move to deregulate and we want to try to have some type of guardrails that are based on the best evidence of the 7 states that currently do regulate, I think there are some lessons and provisos that we could potentially adopt moving forward.

DR. KESHISHIAN: Do you have the language?

REPORTER: I do.

DR. KESHISHIAN: Thank you.

REPORTER: Quoting Ms. Guido-Allen, "So based on the department's recommendations, based on the report we received and the data we reviewed, I would like to recommend that we move to deregulation of BMT."

DR. KESHISHIAN: Thank you.

REPORTER: You're welcome.

DR. KESHISHIAN: Okay. Any other comments? Questions? Call for a question. All in favor of the motion raise your right hand. All opposed raise your right hand. Five to five. Motion fails. We need to have six. So any additional motions at this point in time?

MR. FALAHEE: This is Falahee. I'll move the alternative we discussed earlier, that we request the department, preferably at the March meeting, to present language to us along the lines that Commissioner Mukherji discussed, what can we find from other states or what can you find anywhere that would put some parameters around BMT so that it's not just tied to a number that's 30 years old, whether it's minimum number, whether it's academic medical center, whatever, to request the department to come back with language to us to look at it hopefully in March. And that would be my motion.

DR. KESHISHIAN: Do I hear a second?

DR. MUKHERJI: Second. Mukherji.

DR. KESHISHIAN: Okay. Discussion?

MS. GUIDO-ALLEN: Guido-Allen. Just to be clear, your motion is, is that they provide us with some parameters around BMT services that does not include an arbitrary number?

MR. FALAHEE: That's correct.

DR. KESHISHIAN: Okay. I think that should be part of the motion; that specifically excludes an arbitrary number.

MR. FALAHEE: You read my mind.

DR. KESHISHIAN: Okay. Thank you. And who seconded that?

DR. MUKHERJI: Mukherji.

DR. KESHISHIAN: And you accept that?

DR. MUKHERJI: I accept a friendly amendment.

DR. KESHISHIAN: Any conversation? All in favor, raise your right hand.

(Nine in favor)

DR. KESHISHIAN: Opposed? Okay. Nine votes. All right. Thank you. Was there an abstention?

MS. CLARKSON: Yes.

DR. KESHISHIAN: Okay. One abstained. Nine in favor, one abstained. Nursing home and hospital long-term

care unit. You have a letter from Marianne Conner. Does Brenda or Beth, do you have anything to add as I --

MS. ROGERS: No.

DR. KESHISHIAN: -- the letter there. Okay. Thank you. Next, review draft of CON Commission biennial report to the Joint Legislative Committee. You have a letter that we are sending to the Joint Legislative Committee. Are there any questions? Comments? Do I hear a motion for approval?

MR. FALAHEE: This is Falahee. I know the hard work that goes into this. So number one, thank you. And number two, I would move approval of the report.

MS. COWLING: Commissioner Cowling second.

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

(All in favor)

DR. KESHISHIAN: Opposed? Okay. Legislative report, Beth? Motion passes. Legislative report, Beth?

MS. NAGEL: Yes. I just want to bring to your attention one bill. It's senate bill 1128, which deregulates cone beam CT's for otolaryngologists for the practice of otolaryngology. It is currently on -- it was introduced on October 20th and it was referred to Health Policy Committee at that time. It has taken no further action.

MR. FALAHEE: This is Falahee. Nor will it take any action during this lame duck session in the remaining four days they have left.

DR. KESHISHIAN: I'm glad somebody has a crystal ball. Administrative update, Beth?

MS. NAGEL: Sure. I just have one administrative update and that is that Elizabeth Hertel was formerly the deputy director for the policy office within the Department of Health and Human Services, and currently that is -- now Matt Lori is acting in that position. Elizabeth has left state government service. And that's the only update I have.

DR. KESHISHIAN: Okay. Thank you. CON evaluation section update, Talika?

MS. BHATTACHARYA: Yes. So the annual report for 2016 is in your packet. If you have any questions I'll be more than happy to answer or if you want me to go over some of the payrolls, either way, I'm here to answer. It was -- thanks to staff, especially Abigail Mitchell, to get this done so quickly because until, like, Monday of this week we are still waiting for budget to give us our final numbers. So it was really appreciated that we could pull it through because that report needs to go to JLC report together. So I'll be happy to answer any questions you have.

DR. MUKHERJI: What's an emergency CON? I never

heard that one before.

MR. FALAHEE: You don't want to know.

DR. MUKHERJI: I don't want to know?

MS. BHATTACHARYA: In the packet -- there is a provision that under certain unforeseen circumstances; for example, you are hospital with 24-hour ER and your only CT broke down, so you need service immediately. So the department has some leeway to expedite the review process and issue a decision within 10 to 14 days, but you really have to qualify under the circumstances laid out in the law.

DR. MUKHERJI: Thank you. Thank you.

DR. KESHISHIAN: Any other questions for Tulika?

MS. BHATTACHARYA: I do have one staffing update. As many of you know, Sandy Flanders, our specialist reviewer for many of the services; open heart, cardiac cath, grants plans, MRI, ped, lithotripsy -- I think I got them all -- she is retiring end of this year after 38 years of state service, 33 of those are with CON. So we have an open house for her on December 14, so please stop by and wish her well. She deserves it.

DR. KESHISHIAN: Thank you. Legal activity report?

MR. POTCHEN: This is Joe. We currently have one pending case that has been stayed until March of 2017 and we continue to work with the HHS staff to assist them in

drafting the regulations and rules and answer any other legal questions that they may have.

DR. KESHISHIAN: Any questions for Mr. Potchen? 2016 and '17 meeting date. They're there listed. If you're not going to be able to make them, if you can let us know earlier rather than later. It's always important to have a quorum to ensure that we have a meeting. Thank you. Yeah. I -- just to let you know, I will not be here in January. Suresh will be leading the meeting in January. Any public comments? I do not have any card at the present time. I don't think anybody has any -- rushing up. Okay. Review of the commission work plan. Brenda?

MS. ROGERS: This is Brenda. And you do have the work plan in your packet. And the only change that we will be making on this today is we will be providing a report on BMT and language in the March meeting. Unless there's any other suggestions, then read your report. Thank you.

DR. KESHISHIAN: And we do need to take action on the report, on the work plan. Do I hear a motion for approval?

MR. FALAHEE: Falahee, motion to approve the work plan as presented.

DR. KESHISHIAN: Second?

MR. HUGHES: Second.

DR. KESHISHIAN: Okay. Any questions, comments?

All in favor, say "aye."

(All in favor)

DR. KESHISHIAN: Opposed? And with that, an adjournment. I wish everybody a happy holidays. I will be seeing you in March. Everybody else will be here in January. Thank you very much. We need a motion for adjournment. I wasn't --

MS. BROOKS-WILLIAMS: Commissioner Brooks-Williams. Move to adjourn.

MS. GUIDO-ALLEN: Second.

DR. KESHISHIAN: All in favor?

(All in favor)

DR. KESHISHIAN: Opposed?

(Deposition concluded at 11:17 a.m.)

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