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

COMMISSION MEETING

BEFORE SURESH MUKHERJI, M.D., CHAIRPERSON

333 South Grand Avenue, Lansing, Michigan

Thursday, February 8, 2018, 9:30 a.m.

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Thursday, February 8, 2018 - 9:30 a.m.

DR. MUKHERJI: Good morning, everyone. We are going to go ahead and begin the Certificate of Need Commission meeting. We have obviously a very busy agenda, a lot of interest in today's meeting, so thanks, everyone, for coming. Just review the agenda. I'll need a motion for that.

DR. GARDNER: Motion.

DR. MUKHERJI: So we have a motion to approve.

MS. GUIDO-ALLEN: Second.

DR. MUKHERJI: We have a second. We have a motion and a second. Any discussion?

REPORTER: Who was the first?

MS. GARDNER: Gardner.

DR. MUKHERJI: Gardner.

REPORTER: Okay.

MS. ROGERS: Yeah. This is Brenda. Just a reminder to identify yourself. Thank you.

DR. MUKHERJI: So I think Gardner was motion to accept and I think --

MS. GUIDO-ALLEN: Guido-Allen.

DR. MUKHERJI: -- Guido-Allen was the second. Any discussion? There's no discussion. All in favor?

(All in favor)

DR. MUKHERJI: Okay. The motion passes. The next is declaration of conflicts of interest. Does anybody have any relevant conflicts of interest? All right. No relevant conflicts of interest. We'll go next to the review of minutes from the last meeting.

MR. MITTELBRUN: Mittelbrun, motion to approve the minutes as presented.

DR. MUKHERJI: We have a motion on the table.

MS. CLARKSON: Commissioner Clarkson, second.

DR. MUKHERJI: Motion and a second. Any discussion? Okay. All in favor?

(All in favor)

DR. MUKHERJI: All right. That passes. All right. The next item on the agenda is bone marrow transplant services. We have a public comment period and summary. Brenda or Elizabeth, you want to tee us up for us?

MS. ROGERS: This is Brenda. So first, to preface for all four sets of standards; for BMT, Heart/Lung/Liver, MRI and Psych Beds; a public comment period was held October 6 through the 20th of 2017 to determine what, if any, changes need to be made for each of the standards and on the need for continued regulation or deregulation of each standard scheduled for review this year in 2018. So starting with BMT, we received testimony from six entities, the majority in support of continued regulation. Two

entities suggested a change to the definition of BMT service to address the new therapy Kymriah that is now FDA-approved for the treatment of acute lymphoblastic leukemia in children and young adults. Their proposed change would limit this new therapy exclusively to only BMT programs. And then there was one entity that supported deregulation. As the department looked at this, the department continues to urge the Commission to either look at deregulation or developing a needs based methodology for this service.

If you looked at the recommendation that was provided, we did provide a brief history of what has happened with this service each time that it's been looked at over the last several years. So based on that, if the Commission chooses to open the standard to look at either deregulation or any other changes to the standards, we would urge the Commission to look at this as a body of the Commission as a whole since this has been reviewed by SAC's, work groups and department in the past. And the department would be happy to answer any questions.

DR. MUKHERJI: Thank you, Brenda. Any questions for Brenda or Elizabeth? Okay. Hearing none, we'll then move on to agenda item V(A), which is public comment. We have several public comment cards. I would ask that everyone must limit their comments to three minutes, otherwise we're going to be here 'til dinnertime. All

right. The first one is Malcolm Henoch from Beaumont Health.

MALCOLM HENOCH, M.D.

DR. HENOCH: Good morning, Dr. Mukherji and respected commissioners. I speak here on behalf of Beaumont Health where I am the associate chief medical officer and also lead the cancer programs at Beaumont Health. Thanks to the Commission for accepting and including our letter that provides written testimony on this subject.

The Commission is already familiar with Beaumont's and others' perspectives that the regulation and cap on bone marrow transplantation services represents an excessive barrier to the responsible provision of these services which is already subject to strict quality and safety control for all of the citizens of the state of Michigan. My remarks now will be really confined to a new form of therapies which are referred to as CAR-T.

CAR-T, which stands for chimeric antigen receptor T-cell therapy, is a new modality of treatment of cancer. It is different fundamentally from bone marrow transplantation. CAR-T is one type of what's called immune effector cell therapy where a patient's own immune system can become effective in treating and eradicating a cancer. It is based on more than two decades of scientific research culminating in the approval by the FDA in 2017 of two new

therapies. It represents a breakthrough in cancer therapies and would likely find a substantial place for treatment of many different cancers. This new modality of cancer care requires strict adherence to quality and safety in each phase in the process of evaluating and treating patients. The foundation of accreditation of cellular therapy known as FACT, is an independent, not for profit accrediting body which has published standards for immune effector cell therapies in January of 2017.

They represent and recognize institutional, not individual, practitioners in their accreditation process. FACT has emphasized that all of these immune effector cell standards as well as the bone marrow standards have independent criteria. Bone marrow transplantation in their view is neither a prerequisite nor defacto evidence of competence for CAR-T cell therapy. The pharmaceutical manufacturers have also established standards for whom they will distribute these new agents.

CAR-T and immune effector cell therapies will treat and quite possibly cure cancer for many Michiganders. Every health care organization that seeks to offer these therapies should demonstrate necessary competence through the FACT accreditation process. The Commission will best serve the needs of all the citizens and communities in Michigan by encouraging health care organization to pursue a

FACT accreditation, not by regulating or restricting the development of safe and high quality cancer services that hold such great promise. Thank you very much.

DR. MUKHERJI: Thank you very much. Do we have any questions for the -- just one second, Doctor. Do we have questions? All right. Thank you very much.

DR. HENOCH: Thank you.

DR. MUKHERJI: The next card that I have is Barbara Bressack from Henry Ford Health System.

BARBARA BRESSACK

MS. BRESSACK: Good morning. I'm Barbara Bressack with Henry Ford Health System. As many of us can recall, the Commission spent almost two years debating the BMT CON standards which finished less than a year ago with the conclusion that the state of Michigan did not need another BMT program. Clearly this is distinguished from the request demonstrating a strong want for an additional program.

The actions leading up to the March 2017 CON Commission vote on this were thorough involving an external expert and a Standard Advisory Committee all pointing to the complexity of revising the BMT standards and that, in the end, the existing standards are effectively working to control cost, quality and access throughout the state. From a cost perspective, adding a new BMT program is expensive and puts existing programs at risk. From a quality, each

program currently offers high quality care based on all current programs meeting or exceeding the expected outcomes. Spreading a low volume service with volumes that have been relatively stable for many years over more programs would just compromise quality. From an access perspective, the existing BMT programs throughout Michigan all have capacity to see more patients, and their programs both on the east side and the west side of the state providing that geographical access, and studies have proven that Michigan has good or better access than most states.

We believe this demonstrates there's no need for an additional program at this time. Of note, the Detroit MSA has the highest health care provider concentration than any other metropolitan area of comparable size in the nation. And this is according to the Herfindahl-Hirschman Index, which is commonly used to measure market consolidation and concentration often used by the Department of Justice as they evaluate merger issues.

So with this high level of consolidation in the Detroit MSA, this demonstrates how difficult it is to compete in this market. All the health systems are competing to keep patients aligned to them for all of their care from birth to death. This reinforces why individual health systems may want a BMT program in order to stay competitive. That doesn't translate into the market needing

another program. Reopening the standards on the number of programs within the state will utilize a lot of resources without any reason to believe the outcome will be any different. Henry Ford supports the continued regulation of these standards with no changes. We would ask that the Commission consider taking action on a modification to the definition of the BMT service in order to accommodate the change in technology.

So there's a current definition of BMT that does not incorporate the use of the T-cells or CAR-T cells. We recommend updating the CON standards to delete the word "stem" in the definition which would then accommodate the inclusion of "CAR-T" into the standards. There are additional BMT experts here that I know are in line to speak from Karmanos and Michigan Medicine, so I will defer to them on the details of this new therapy.

So we would ask that the Commission take action on the modifications and the language required to best accommodate the inclusion of CAR-T into the standards.

DR. MUKHERJI: Thank you very much. Any questions? Okay. Thank you. The next is Joseph Uberti from Karmanos.

JOSEPH UBERTI, M.D.

DR. UBERTI: Thank you very much. My name is Joe Uberti. I run the BMT and leukemia program at Karmanos

Cancer Center. I'd like to thank the Commission for allowing me to make some public comment here. So since our last meeting, which just seems like yesterday, there's been one significant change and that is the approval of CAR-T cells as you've heard, and it's been approved now for the treatment of two different diseases, Non-Hodgkin's lymphoma and acute lymphoblastic leukemia. These diseases are diseases we normally do transplants for, and this therapy over time may be used in place of transplantation, so we don't know exactly where this therapy is going to fit in.

Now, these cells are genetically modified cells which contain a virus particle inserted with the patient's own cells which then go on to target the tumor cells. These modified cells are infused into the patients and target the tumor cells after they're infused into the patients. This is a brand-new technology only approved by the Food & Drug Administration in October of last year.

I want to point out this is the first and only commercially available genetically modified cells that are infused into patients approved by the FDA and genetically modified by a virus particle that puts into the cells. The companies that are producing these products require that these cells be administered through a FACT-accredited stem cell transplantation program. They do not allow any exceptions to that. The reason for this is that these cells

require all the infrastructure, the quality management, the tissue handling protocols, and personnel training that is normally part of all stem cell transplantation programs. The preparation with the aphaeresis, the chemotherapy administered with these cells, the infusion of the cells, and the post infusion complications which are fairly severe really are very similar to the procedure a patient goes through with an autologous stem cell transplant, only actually more difficult with more toxicity, more chance of ICU care.

No other services in hospitals provide all the safeguards of quality and patient safety that you need to administer these cells. This is the appropriate precautionary use of these cells and we believe they should fall under the CON BMT guidelines and included for the time as being only administered through BMT programs approved through our CON. There is no access issue to these cells.

There's really been -- the only access issue has been the inability to get Medicare and Medicaid to pay for these cells. These are very expensive procedures, probably in the 6- to $700,000 range. So this is for one infusion of these cells, and that's what the cost is. The cost of the infrastructure is already built up in the stem cell transplantation programs, so there's no extra cost in the programs that already have transplantation programs. When

we met last, one year ago, we voted to maintain the current CON standards for bone marrow transplant programs. The concepts and the methodology allowed us a flexible policy in CON standards based on quality, utilization and access, while limiting needless costs and expanding to more programs. We believe those standards should remain with the addition of CAR-T cells being placed under the same regulatory guidelines embedded in the existing stem cell transplantation program.

I was on recently a -- I'm part of the board of directors at MSHO, the Michigan Society of Hematology Oncology, and we had a vote on the issue of where CAR-T cells -- and the Michigan Society of Hematology and Oncology, which represents approximately 90 percent of all the practices in the state of Michigan, voted to keep CAR-T cells and stem cell transplantation programs. And with that, I'd like to answer any questions.

DR. MUKHERJI: Any questions from the Commission?

MR. MITTELBRUN: Mittelbrun. You talked about the dangers of this therapy and it's very new. Do you have any statistics you could share as to the success rates or the results?

DR. UBERTI: So the success rates are probably a 30 to 40 to maybe 50 percent response rate in the patients who receive these cells, and these patients have already

been followed about three or four years now. Some patients do go into complete remission, some patients have stayed in complete remission for three to four years, but we don't have any long-term outcomes beyond that. The toxicity of these cells -- about a third of the patients go into intensive care units. There have been several deaths reported on some of the CAR-T cell programs.

So it is a very intense therapy; very unusual toxicities that occur with these cells that are only known to transplant physicians and people who give CAR-T cells. So it's complications we've never seen before other than the infusion of these cells. So it is a very difficult procedure to go through, and probably more difficult than our autologous stem cell transplants which we've been doing for years now.

MR. MITTELBRUN: Thank you.

DR. UBERTI: Now, realize these are genetically modified cells, too, and this is the first time this has been done in any -- by FDA-approved process.

DR. MUKHERJI: Did you say that the FACT recommendations currently are to only perform the CAR-T cells in transplant centers?

DR. UBERTI: Those pretty much are their recommendations. The companies have also made that recommendation, that these cells only be given to

FACT-accredited stem cell transplantation programs.

DR. MUKHERJI: So what do you mean by "pretty much" for FACT?

DR. UBERTI: Well, the FACT has said that they should be done by a transplantation program.

DR. MUKHERJI: They should be, but it's not mandated? It's just --

DR. UBERTI: It's not mandated.

DR. MUKHERJI: And does ASCO have a recommendation on this?

DR. UBERTI: I haven't seen the ASCO recommendations on that. They may, but I haven't seen them. You know, again, it's mandated by the companies that stem cell transplantation programs are the ones delivering the cellular therapy.

MS. BROOKS-WILLIAMS: Commissioner Brooks-Williams. So the Michigan Society of Pain -- we have a letter from them. And so it looks like it was a very close vote as it related to their recommendations here with the transplant program. Can you enlighten us to -- they talk about the quality and belief, I guess, because it's so new and it's a highly toxic concern --

DR. UBERTI: It's pretty much the same discussion that we have here. You know, the cells are administered -- the companies require the cells to be administered in

transplantation programs, so there's no other way the cells could be administered at present. You know, it's a newer therapy. It seems like it's the -- to maintain patient quality, maintain patient safety, this is the important way to maintain that those standards are in place. These are the things we do routinely. We have the infrastructure in place to give these cells, assess all the complications of the cells, and all the quality is already built into the programs that do stem cell transplantation.

MS. BROOKS-WILLIAMS: Thank you.

DR. MUKHERJI: Any other questions? Okay. Thank you very much.

DR. UBERTI: Thank you.

DR. MUKHERJI: Next is David Walker from Spectrum Health.

DAVID WALKER

MR. WALKER: Good morning. My name is David Walker and I'm here on behalf of Spectrum Health. Thank you very much for the opportunity to provide comment on the Bone Marrow Transplantation CON review standards. Just a mere 11 months ago, after more than a year of deliberations, this Commission voted to keep the current BM standards in place. At that time, commissioners felt there was no need for additional BMT program in the state. Spectrum Health does not believe anything has changed within the last 11 months

that would require reopening the standards at this time. We agree that reopening the standards broadly will utilize a lot of resources and, again, no reason to believe the outcome will be any different. The last time this issue was discussed there was a lot of debate on the program cap, and some suggested that this was not a methodology. Spectrum Health respectfully disagrees. The Commission decided years ago that the appropriate number of programs in the state was three based on the need at the time.

The Commission concluded just a few years ago that changes in need warranted a fourth program on the west side of the state and modified the standards accordingly. If the Commission decides in the future that there is a need for an additional program, the standards can be changed at the time to accommodate it. This is a methodology. It is a methodology that puts more control in the hands of the CON Commission than any other standards, but it is a methodology nonetheless.

And given the nature of BMT, it seems to be an appropriate one that balances cost, access, and quality. Spectrum Health recognizes that changes in medical treatment are evolving and new technologies and treatments occasionally require minor updates to CON standards. A recent therapy approved by the FDA warrants such a minor update now. This therapy, known as CAR-T, modifies a

patient's own T-cells to transfuse them back into the patient's body and attack cancer cells. While this therapy is more effective for some patients, it is very expensive. The cost of the product alone is over $300,000. When other medical costs are considered, the therapy could cost close to one million dollars per patient compared to the traditional BMT that costs between 300- and $500,000.

Given the cost and challenging nature of this therapy, it is best left to already established BMT programs. To be clear, this update requires an extremely minor modification, merely deleting one word, "stem," from the definition. Spectrum Health would ask that the Commission direct the department to bring back proposed language at the March meeting or merely direct that this change be made and not open the rest of the standards for debate.

Again, thank you for the opportunity to provide feedback on the CON review standards for bone marrow transplant services. Spectrum Health appreciates the opportunity and I'd be happy to answer any questions that you may have.

DR. MUKHERJI: Thank you very much. Any questions for Mr. Walker? Okay. Thank you very much.

MR. WALKER: Thank you.

DR. MUKHERJI: The next is Greg Yanik from the

University of Michigan.

GREGORY YANIK, M.D.

DR. YANIK: Thank you, Dr. Mukherji. It is good to be back here. So one week ago today, on February 1st, the New England Journal of Medicine published a landmark study on the role of CAR-T cells in the treatment of childhood leukemia. This was the largest gene therapy trial ever reported to date, involving 20 bone marrow transplant centers worldwide. What can we learn from this report?

Simply put, the complexity of CAR-T therapy is enormous. I can speak from personal experience. I was one of the co-authors on this article. These were the sickest patients that I have ever treated in my 30-plus years as a transplant physician. There are a number of important issues that CAR-T therapy presents to an institution. Number one, the field has a history of high profile, serious adverse events including deaths.

Two, dedicated facilities are required to handle cellular and gene therapy products like this. The cost to build this infrastructure can be enormous. Three, a team of experts is required. The high tech nature of CAR-T therapy requires 24/7/365 coverage by providers with cell therapy expertise. Complexity of this therapy cannot be overstated. For the 12 patients treated at the University of Michigan with CAR-T therapy, hospitalizations were not 1 to 2 weeks,

7 to 10 days, they were 3 to 12 weeks, shorter in those patients that died quickly. In the New England Journal article, cytokine release syndrome, an immunologic storm, was reported in 77 percent of patients, and neurologic toxicity including seizures, strokes, were reported in 40 percent of patients. At our center in the 12 patients we treated for childhood leukemia, half of them ended up on ventilators or on dialysis within a week of therapy.

Now, if anyone claims that CAR-T therapy will become the standard of care in the upcoming decade, I can only reply, "I simply don't know." Cell and gene therapy protocols are in their infancy. Long-term survival was not reported in the New England Journal article. They looked at of a day 30 response, 6- and 12-month survival. We do not know the long-term consequences of administering CAR-T cells, including the risks of secondary cancers, autoimmune disorders, organ complications.

We simply cannot state yet that this will become the standard of care over the next decade. And simply put, I ask the CON to think quality first. Access for CAR-T therapy should be limited until the quality for the service has been proven. This topic is even more complex when you take into account the fact that this doesn't include CAR-T cells. It includes dendritic cells and K cells, natural killer cells, and tumor vaccines. All must be considered.

A January 23rd memo to the Institute for Clinical and Economic Review from the American Society of Bone Marrow Transplantation -- I'm just going to read it to you. It just came out on January 23rd. "Due to their unique clinical expertise and training, ASBMT member clinicians and cell therapy programs will be the primary individuals providing CAR-T therapy."

In conclusion, access to CAR-T therapy should be limited to transplant centers until quality is ensured and costs are considered. Therapy should be handled by centers with expertise in administering these products. Transplant physicians have this expertise. The existing CON standards should be amended as noted by other speakers. If I could just say one last thing? We treated a patient yesterday at noon with CAR-T cells.

At 10:00 o'clock at night I was still at the bedside. By midnight I was talking to our ICU face to face. I rounded on that patient this morning before driving up here from Ann Arbor to Lansing. That's the type of quality that these patients require, 24/7/365. One of my colleagues is at that patient's bedside right now. So for anybody to think that this is simply a transplant, this is gene therapy at its finest.

DR. MUKHERJI: All right. Thank you very much. Any questions for Dr. Yanik? So I'm going to ask the same

question I asked before. Does ASCO have a recommendation on this?

DR. YANIK: Not to my knowledge. ASBMT does from Krishna Komanduri, but I don't know if ASCO has a recommendation.

DR. MUKHERJI: What about ASH, American Society of Hematology?

DR. YANIK: ASH has come out and stated also, again, that transplant physicians should be the primary physicians. They're not stating permanently, but at least to start.

DR. MUKHERJI: So how would you -- CAR-T is new, obviously, and it's possible it could have widespread use once the safety is determined. But in the current state or in the upcoming years, if it does evolve where it's more safer and the recommendations change, whether ASCO comes out with a recommendation or ASH comes out with a recommendation or FACT comes out with a recommendation, do you feel that once efficacy is determined, then it should become more widely available?

DR. UBERTI: I think so. I think at this point -- in fact, I think people are looking at us, the CON, to see how are we going to respond; are we going to set the standards for other states, in fact other CON's, because everybody isn't sure what to do. In terms of how long is it

going to take to get that long-term quality data, even the indications -- we don't even know the best timing of the CAR-T therapy, the proper indications. Certainly long-term consequences and survival aren't even known. It's only been looked at really in childhood leukemia, large cell lymphomas, starting to be looked at in multiple myeloma. I think we're actually ten years away from that. And the issue is not just -- the issues isn't CAR-T.

The issue is the other cells I mentioned. Now, by regulating cell and gene therapy, we're also then looking at tumor-pulsed dendritic cells, natural killer cells, NK CAR cells. All this stuff is being looked at in gene therapy programs around the country. So by modif- -- making the modification as was amended to deleting the word "stem" to just proliferating hematopoietic cells; proliferating hematopoietic cells are any of these immunosurveillance cells, T cells, NK cells, dendritic cells.

Then we're actually stating until, you know, over the next five, ten years, this technology is better vetted, then at least we're putting some brakes on the system. The CON can always come back and look at it in five to ten years. But at least for right now -- I just can't imagine. As one investigator told me the other day, they said, you know, this is like car companies -- not CAR-T, but car companies -- in the 1900's when they had 300 or 500 of them

until it got eventually whittled down to who could do it best. We just can't have a wild west do gene therapy programs out there right now.

DR. MUKHERJI: Any questions for Dr. Yanik? All right. Thank you. The last card that I have is from Eric Fischer from DMC Children's Hospital of Michigan.

ERIC FISCHER

MR. FISCHER: Good morning. I'm Eric Fischer from the DMC and this morning I'm representing Children's Hospital of Michigan. And basically I'll be brief. We just support. We want to continue the support of the current BMT standards. We don't think that we need a new standard advisory committee or another work group, and we would welcome any new changes in technology that would help our pediatric patients and it seems like this CAR-T may be a possible solution. Thank you for letting me speak. And if you have any questions, please let me know.

DR. MUKHERJI: Thank you. Any questions for Mr. Fischer? Thank you very much.

MR. FISCHER: Thank you.

DR. MUKHERJI: These are all the cards that I have so far. Is there anybody -- would like to give public testimony? All right. That will be the close of the public comment session. We now have Commission discussion. So Beth or -- Brenda and Beth, just to clarify, to change, to

take out the "stem," is that a major revision?

MS. ROGERS: This is Brenda. And I'm looking at Joe and I would say, yeah, that -- because it's a major change to the definition, even though it's only removing one word. So the Commission could ask the department to do that. We'd bring it back at a future meeting. And assuming the Commission would take proposed action on it at the time, then it'd have to go out for public comment and then back for final action. So it has to go through the whole process just to make that change.

DR. MUKHERJI: And just one other clarification for those of us that have short memories. This was just -- the standards were just approved a year ago; is that correct?

MS. ROGERS: Correct. The standards were -- it took -- as some of them stated, it went through a SAC as well as a department and third party outside review. If you'll recall, Dr. Delamater looked at this issue as well. And the Commission did take action back in March to take no action; to make no change to the standards. But the standard is back up for review this year as part of the three-year review cycle.

DR. MUKHERJI: All right. Thank you. Commission discussion?

MS. BROOKS-WILLIAMS: Commissioner

Brooks-Williams. So our options would be to continue no review, no action related to the standard, but request language to include CAR-T; maybe that's removing the "stem," maybe that's something else. So that is an option; is that --

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

MS. BROOKS-WILLIAMS: We don't have Chip here to make a, you know, motion.

MS. ROGERS: Right. No, that is -- that is -- this is Brenda. Yes, that is one of your options.

MS. BROOKS-WILLIAMS: That is an option? Okay. So not to be presumptuous, but if someone helps me to make that a motion -- so I would move that we take no action on the BMT standards, but request the Department bring back language to the Commission that would allow inclusion of CAR-T and other related changes. That is taking action?

MS. ROGERS: Yes, it's taking action.

MS. BROOKS-WILLIAMS: I asked.

MR. POTCHEN: I guess you could open it up for the limited purpose of what you want to do rather than, you know, opening up the standards. You want to just open it up for that limited purpose, that would be --

MS. ROGERS: Yes.

MR. POTCHEN: As I understand what you're trying to do.

MS. BROOKS-WILLIAMS: There we go. So Commissioner Brooks-Williams again. I would recommend that we open up the standards to allow the inclusion of the CAR-T language, but to that limited purpose.

DR. MUKHERJI: Okay. We have a motion on the table.

MR. MITTELBRUN: Mittelbrun. Second.

DR. MUKHERJI: So we have a motion and a second. We have a motion and a second. Further discussion?

MS. GUIDO-ALLEN: Further discussion. So this is Guido-Allen. Back in March, the CON, we did not conclude that the standards didn't need to be changed or revisited, but needed to be revisited this year and we needed to come up with something better than the arbitrary cap. I asked Brenda or Beth -- Beth, you had testimony back in March when you said that, you know -- that the department did not support regulation and didn't continue to support a cap because, as you said, "There's no ability for anyone ever to get this service again with this arbitrary cap in place" and the department supported deregulation of bone marrow transplant.

Right now we know that FACT does not restrict CAR-T cell to a BMT specialized center. I just think that we have to have a lot more discussion on this because I just don't think it's right from being the nursing voice on this

Commission. Patients and families, I still -- as I did in December of '16 and March of '17, I still feel that we have to have more discussion about the current cap, arbitrary cap that's in place, and the department's continued support for deregulation of BMT in the state of Michigan. I -- yeah, period.

DR. MUKHERJI: Thank you. Other comments?

MR. MITTELBRUN: I guess I just want -- since I seconded Commissioner Brooks-Williams' motion, I just wanted to -- because this CAR-T is obviously very complicated. It's dangerous. Based on all of the improvements and a wide variety of technologies, we're going to have more complicated, dangerous procedures coming forward and hopefully they're all improvements.

So my only other thought is I, you know -- the motion was regarding, you know, removing of possibly the term "stem" and including "CAR-T," but should we consider even making it more general because there's going to be other therapies and procedures down the road that we may want to keep under the umbrella to make sure of the quality first before, you know, we even think about deregulating?

I mean, I think the role of a Commission like this is going to get more important over time with all these changes that are coming because the industry I deal with is going through that in a very different way and we're facing

those same challenges and I think the medical community is going to face even bigger challenges with all these improvements that are coming in the near future and I don't think we can really just let it go without supervision, I guess, or "oversight" would probably be the better term.

MS. BROOKS-WILLIAMS: And this is Commissioner Brooks-Williams. I am very open to amendment if that makes sense to the department. I tried to limit it to what was before us with the knowledge that we had -- hoping that if in fact there are additional therapies that become available, that the community would make us aware by making that request. If there is a way to do the language broader that makes sense, then I'm happy to -- yeah, you know, I don't know how to -- yeah.

If there's a way that you might recommend, Joe, that I amend it to support what Commissioner Mittelbrun said -- it's not my intent to limit it, but I was just trying to be focused on --

MS. GUIDO-ALLEN: So Guido-Allen. I continue to have reservation around limiting access as access, quality, and cost are what we are to be focused on. By continuing to limit BMT to an arbitrary cap, we are limiting access to this therapy to the people of Michigan and I think that the department should weigh in again.

DR. MUKHERJI: We do have a motion on the table

and a second. Further discussion with the motion on the table? So do you wish -- can she amend the motion once the motion is -- if she's the author?

MS. ROGERS: If she's the author, she can.

DR. MUKHERJI: Can she amend the motion?

MS. BROOKS-WILLIAMS: If I can ask a question in seeking to do so? So I don't want to make it so broad that I say, you know, we can add anything so I'll talk to -- but Brenda, just to say beyond CAR-T and other therapies that are known, is there, you know -- the department can bring back broader language, but I'm comfortable with it being the way I made it unless somebody can give me guidance on how it would help you guys if I just said -- I don't want to say just add anything.

I don't want to say just open it up. There's got to be some parameters around it. So I just went with what was presented to us currently as the gap. So with that, I'll leave it as is. I think I'm just looking at the department to say for now that might be the best way to go.

DR. MUKHERJI: You're not amending your motion?

MS. BROOKS-WILLIAMS: I'm not. I'm just confirming --

MR. MITTELBRUN: I guess my point was I realize bone marrow transplants and CAR-T are different, but there's certainly obviously a lot of similarities in the

infrastructure and the expertise of the people, so on and so on. So really my point when you look at these types of services, to use the proper phrasing that is other services that fall under that umbrella should be included as the FDA or any other entity approves these procedures so that we have the capability to make sure that we do the job we're supposed to do.

MR. POTCHEN: So where we are today, it seems the department can seek to address your motion, and then when the language comes back you can seek to amend it and discuss it at that time, should further information become available between the language being offered and it being presented at the meeting.

MS. BROOKS-WILLIAMS: Okay.

MR. MITTELBRUN: That's fine.

MS. BROOKS-WILLIAMS: That's fine. So we'll let it stand as it is.

MR. HUGHES: So just to clarify, the motion is to keep BMT the way it is except to slide whatchamacallit in there with it? You'll be amazed what a broken finger does to your brain.

DR. MUKHERJI: So I think it's -- you're going to remove "stem" from -- is that --

MS. ROGERS: Yeah. This is Brenda. Yes. So my understanding of the motion is basically the one change we

will make in that standard is removing "stem" from the definition of BMT service. That's what was suggested to take care of this CAR-T cell therapy.

MR. POTCHEN: Yeah. Then as the language --

MS. ROGERS: And then we will bring this back to the Commission to take a look at it for proposed action, and then from there, at that time, the Commission can take proposed action or it can make additional changes as needed.

DR. MUKHERJI: Other discussion? Okay. So we have a motion on the table. We have a second. We've had discussion.

MR. MITTELBRUN: Call for question.

DR. MUKHERJI: So we have call to question. All right. All in favor of the motion on the table say "aye."

(All in favor)

DR. MUKHERJI: All against?

(Ms. Guido-Allen opposes)

DR. MUKHERJI: Motion passes. Thank you very much for everyone's public comment. The next is heart/lung and liver transplantation services. Brenda?

MS. ROGERS: This is Brenda. There was testimony received from four entities regarding heart/lung/liver all in support of continued regulation and no changes. Again, the department does continue to urge the Commission to either consider deregulation or developing a needs-based

methodology for this service. If there's any questions, we'd be happy to answer. And again, a history has been provided in the packet for you.

DR. MUKHERJI: Any questions for Brenda or Elizabeth? We'll begin the public comment session. The first one is from Barbara Bressack from Henry Ford Health System.

BARBARA BRESSACK

MS. BRESSACK: Good morning. I'm Barbara Bressack with Henry Ford Health System. Henry Ford supports the continued regulation of heart/lung and liver transplant services and we do not believe there are any necessary changes to the standards. The existing standards are effectively working to control costs, quality and access throughout the state.

From a cost perspective, adding a new transplant program is expensive and puts existing programs at risk. From a quality perspective, each program offers high quality care based on all current programs meeting or exceeding the expected outcomes and operational measures. Spreading a low volume service over more programs, again, could just compromise quality. From an access perspective, the existing transplant programs throughout Michigan all have capacity to see more patients in their programs on both the east and west side of the state providing geographical

access. The Henry Ford program specifically and some of the others also offer outreach satellite clinics that cover most of the state to increase and maintain that adequate access. We recognize that heart and lung transplants are low volume relative to other types of procedures. However, it is these very specialized services that need Certificate of Need the most.

Allowing new programs to open at the expense of risking existing, well-established high quality programs not only puts Michigan patients at risk, but jeopardizes their continued access to these quality programs with quality being a critical point here. One of the main points of CON is to prevent the expenditure of health care dollars on programs and equipment that are not needed.

Because there are so few of these procedures performed, less than 400 per year total, opening additional centers will likely result in either the closing of an existing one, the failure of new, or even worse, both. Any of these options result in wasting precious health care resource dollars. One of the main points of CON is to maintain high quality services. Because heart/lung/liver services are already low volume, opening additional programs just drives down volume in the existing programs and creates cherry picking, further complicating how to benchmark these quality outcomes of small programs which are in place to

ensure high quality outcomes for our patients. The dilution of lung and heart volumes is very problematic for CMS and the United Network for Organ Sharing to judge quality and metrics. This continues to be the challenge given the regulatory agencies balance volume and access and expect not to compromise those outcomes. Henry Ford supports the continued regulation of this service.

We ask the Commission that if you're considering deregulation, that you postpone any vote until all stakeholders have had the opportunity to provide substantive input either through a formal process such as a work group or standard advisory committee. Thank you.

DR. MUKHERJI: Any questions? Thank you. The next card is from David Walker from Spectrum Health.

DAVID WALKER

MR. WALKER: Good morning. David Walker again from Spectrum Health. What she said. No, I couldn't agree more perfectly myself. Spectrum Health supports continued regulation of heart/lung and liver transplantation services. We believe these standards have served the citizens of Michigan well. I do not see a need to reopen the standards at this time or deregulate the service at this time. Thank you very much for your consideration. Happy to answer any questions.

DR. MUKHERJI: Any questions for the concise Mr.

Walker? All right. Thank you. I only had two cards for the heart/lung and liver transplant services. Would anybody else like to make a public comment? Hearing none, we'll close the public comment period and we'll move on to Commission discussion. So Brenda and Elizabeth, do you guys have anything to add before we begin the discussion?

MS. ROGERS: This is Brenda. Not at this time.

DR. MUKHERJI: Commission discussion? So our options are to --

MS. ROGERS: This is Brenda. Your options are -- is -- one option is to take no action and move it out for the next three-year review period. You can also make a motion to open up the standards for any proposed changes. If the Commission wants to consider deregulation, that can happen in a couple of different ways. One way is to put at this taking -- making a motion today to put it out for public comment for deregulation and then it goes through that process, it comes back to the Commission and -- for final action and you make a final decision then.

As one of the speakers suggested, if the Commission wants to open it up to consider deregulation, you could also form a SAC or a work group and it would go through that process. So Commission has several different options.

DR. MUKHERJI: Okay. Commissioner --

DR. GARDNER: This is Gardner. I make a motion to take no action.

DR. MUKHERJI: Okay. So we have a motion on the table from Commissioner Gardner.

MS. CLARKSON: Commissioner Clarkson. I second the motion.

DR. MUKHERJI: We have a second from Commissioner Clarkson. Discussion? Anybody like to call to question?

MR. MITTELBRUN: Call to question.

DR. MUKHERJI: We have a call to question. So all in favor of the motion on the table say "aye."

(All in favor)

DR. MUKHERJI: Any against? Motion passes. Thank you. The next topic is item number seven and this is MRI services. Brenda?

MS. ROGERS: Again, this is Brenda. You do have the recommendation in your packet. We received testimony from six different entities and two entities did make some suggested changes. After the department reviewed the recommendation, the department basically supports continued regulation of MRI and suggests no changes at this time, and then these standards would be up for review again 2021. And again, those items identified for suggested changes, the department provided its comment as to why the change doesn't need to be there. So if we can answer any questions, we'd

be happy to do that.

DR. MUKHERJI: Thank you very much. I did not receive any blue cards for MR. All right. So we don't have any public comment then. One last chance, forever hold your peace. Okay. We'll close the public comment period. So Commission discussion? So just the regular thing, we can move this forward with no changes or we can open it up. And if we open it up, it would be whether it was a work group or a SAC. Did I concisely state that?

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

MS. CLARKSON: This is Commissioner Clarkson. I move that we move it forward with no changes.

DR. MUKHERJI: So we have a motion on the table to move forward with no changes.

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

DR. MUKHERJI: Guido-Allen, second. We have a motion and a second. We are now open for discussion. Any discussion?

MR. MITTELBRUN: Call to question.

DR. MUKHERJI: Okay. We have call to question. All in favor of the motion say "aye."

(All in favor)

DR. MUKHERJI: Any against? Okay. Motion passes. The next is psychiatric bed services. It's agenda item number eight. We had several public comment cards for this.

We will start with Lee Ann Odom from Beaumont Health.

MS. ROGERS: Dr. Mukherji, do you want a quick overview?

DR. MUKHERJI: Oh. I'm sorry. I'm sorry. I apologize. I need a quick overview. Sorry, Brenda.

MS. ROGERS: And it will be quick -- this is Brenda -- as you do have all the information in your packet. But we did receive testimony from nine different entities, all in support of continued regulation and then suggested changes to be looked at. And the department also supports continued regulation of psychiatric beds and services and would suggest or support a SAC to review the issues that have been identified in the recommendation. And again, if you have any questions, we'd be happy to answer.

DR. MUKHERJI: I apologize.

MS. ROGERS: That's okay.

DR. MUKHERJI: Okay. I'm sorry. Ma'am? Thank you.

LEE ANN ODOM

MS. ODOM: Good morning. My name is Lee Ann Odom. I'm the president of Beaumont Hospital, Taylor, and I appreciate the opportunity to provide this public comment. Beaumont Health supports the department's recommendation to establish a standard advisory committee, a SAC, to review the bed need methodology for adult and the child and

adolescent psychiatric beds, as well as to consider allowing more flexibility for adult psychiatric providers to also serve the child and adolescent patient populations. Beaumont Health currently offers adult inpatient psychiatric services at our three hospitals, so that's at Farmington Hills, Royal Oak, and Taylor. Under the current CON standards none of these units can qualify to also serve child and adolescent patient populations.

Beaumont Health also operates seven school-based clinics funded in part by the Michigan Department of Human & Health Services. These school-based clinics are often seeing and treating an increased number of young people who need mental health services. We're seeing triggers that range from bullying to depression. These clinics afford us the opportunity to spot emerging and mental health issues pretty early on.

We address these issues in the clinics, but if beds are not available we are unable to provide the full continuum of care for these children. It's putting them at a much greater risk to harm themselves or others. The need -- absolutely there. According to NAMI, the National Alliance on Mental Health, approximately 1 in 5 youth-aged children, so 13 to 18, experience severe mental disorder at some point in their life. Suicide is the leading cause of death for people ages 10 to 14, second leading cause for

those 15 to 24, and more than 90 percent of our children who die by suicide also have a mental health condition. In addition, the recently released report of the house CARES Task Force -- that's the Community Access Resource Education Safety Task Force -- recommends an increase in the number of psychiatric beds. Specifically, this report states,

> "It is important to identify and address mental illness in the early stages of life. We need to find ways to increase the availability of psychiatric beds in hospitals and facilities in certain areas of the state and to address the shortage and waiting list for individuals that need services, especially our children."

We agree with this recommendation and ask that the Commission take action to address this need. Again, thank you for the opportunity to provide public comment.

DR. MUKHERJI: Any questions? Thank you very much. The next card I have is from David Walker from Spectrum.

DAVID WALKER

MR. WALKER: I won't be as brief as last time, but those are very good comments. Again, David Walker with Spectrum Health. Thank you very much for the opportunity to provide comment on psychiatric beds and services. Spectrum Health supports continued regulation of the psych beds and

services, and we appreciate several of the recommendations made by the department including exploring options for flexibility to transfer beds and create units with existing child/adolescent and adult beds, the review of the methodology for bed need, and in reviewing criteria for special pool beds as long as there's -- increasing the current number of beds in each special pool is considered.

Spectrum believes that creating additional flexibility with transferring or creating units with existing beds, similar to the nursing home standards, will go a long way in ensuring that patients with psychiatric needs get the treatment they require and deserve. Further, the current methodology does not seem to accurately reflect the true need of the patient population. The methodology seems designed to perpetuate the status quo.

This is unacceptable as many go without the treatment they need. Therefore, Spectrum Health recommends the Commission ask the department to contract with Dr. Paul Delamater to review the bed need methodology and recommend replacement or modification. Finally, the special pool inpatient beds the Commission approved the last time these standards were reviewed were well received by the provider community. During the October public comment period Spectrum Health recommended additional beds be allocated to these pools. We especially support the department's

recommendation to include in the SAC charge the proper percentage of beds that should be allocated to the special pool. Thank you very much for your consideration. I'd be happy to answer any questions.

DR. MUKHERJI: Thank you very much. Any questions for Mr. Walker? All right. Thank you. And the last card I have is from Tracey Dietz from Henry Ford Health System.

TRACEY DIETZ

MS. DIETZ: Hi. Good morning. Thank you for the opportunity to provide comments on the psychiatric bed services. I'm Tracey Dietz with planning at Henry Ford. We support the continued regulation of psychiatric beds and services and recommend -- and the recommendation from the department to form a SAC to review the requests and comments that were received.

Currently psychiatric care is receiving a significant amount of attention at a state and federal level and the focus is around access, the quality of care, payment and support of the programs. Henry Ford is also experiencing increasing demand. We're seeing higher levels of acuity with our patients and increased volatility of our patients, and we're also experiencing a shortage of qualified workers. So we really do feel that the SAC will allow for an opportunity reviewing the recommendations and comments received to really examine the issues that have

been brought forth and to adjust the standards in a way that best supports our patients in the communities that we serve. I appreciate the opportunity to make comments. And if you have any questions --

DR. MUKHERJI: Any questions for Ms. Dietz? Thank you very much.

MS. DIETZ: Thank you.

DR. MUKHERJI: Those are all the cards I have for psychiatric beds. Would anybody like to public comment? And so we'll close the public comment section and move on to commission discussion. Brenda and Elizabeth, do you have anything else to add or give us our options?

MS. ROGERS: This is Brenda. Again, same options as you had for all the other standards. It's really your decision. If you want to open up these standards, which the department does support doing, you have your options of creating a standard advisory committee, a work group, you know, Commission, department, et cetera. So all your options are on the table.

DR. MUKHERJI: Thank you. So commission discussion.

MR. MITTELBRUN: This is Mittelbrun. I'll make the motion to establish a SAC to review the issues brought up in testimony and written comment, and to engage Dr. Delamater if the department deems it appropriate.

DR. GARDNER: This is Gardner. I'll second.

MS. GUIDO-ALLEN: Second.

DR. MUKHERJI: Seconds and thirds. Okay. Give Tressa the second there. So we have a motion with a second. Any further discussion?

MS. ROGERS: This is Brenda. So in creating the standard advisory committee -- so as part of this motion, then, is the Commission delegating to the chair to seat the SAC, draft the charge based on the recommendations approved by the Commission today? That should be part of the motion is what I'm getting at.

MR. MITTELBRUN: Yes.

MS. ROGERS: Okay. We'll add that to the motion then.

MS. GUIDO-ALLEN: Guido-Allen. Can we add to the motion that the SAC look at the ability to have flexibility between adult and pediatric populations?

MS. ROGERS: This is Brenda. That's one of the recommendations.

MS. GUIDO-ALLEN: I mention that here.

MS. ROGERS: So if you look at the recommendations -- this is Brenda -- how I would interpret this in working with the chair as it gets delegated to him in drafting the charge, the recommendations we provided to you, that's what we would use in writing, drafting the

charge. So unless there's anything that needs to be subtracted or added to that, then we would need to know that.

DR. MUKHERJI: So we have a motion on the table and a second. Any further discussion? Anybody want to call to question or --

MS. CLARKSON: Call to question.

DR. MUKHERJI: All in favor of the motion on the table say "aye."

(All in favor)

DR. MUKHERJI: Any against? Motion passes. Thank you. So the next is agenda item nine. It's megavoltage radiation therapy services. We have a little bit of a different process, if you will. Brenda or Elizabeth, do you want to give us some introduction on this?

MS. ROGERS: So on MRT services there was some testimony received during the October public comment period, but MRT services was not on the docket for this year's review. You also received some testimony at the December Commission meeting as well and you gave some assignments, specifically University of Michigan, if they could come back with a presentation on their homework, per se, and they actually are prepared to do that. So instead of waiting for the March meeting, we decided to, in conjunction with the chair, add it to this meeting since it's part of your work

plan. And so then today, after -- and there is actually two presentations today. After hearing the presentations then it's really going to be, again, up to the Commission as to what you want to do, if you want to open these standards up out of order. And if you do, then how do you want to proceed and move forward with them; department SAC, work group, et cetera; or no change to the standards.

DR. MUKHERJI: So I think I -- just thank you very much for the summary. So MRT, we do have the proton beam --

MS. ROGERS: Yes.

DR. MUKHERJI: We do have someone from the University of Michigan. We have someone from Beaumont. And then also there was some other topics that were brought up regarding weightings as well, too. So we just went ahead and took the liberty of giving ten minutes to Michigan, ten minutes to Beaumont, and then we'll have public comments after that. So Dr. Jagsi?

PRESENTATION BY RESHMA JAGSI, M.D.

DR. JAGSI: Thank you very much. It's a pleasure to be here. Thank you for the opportunity to present with you regarding megavoltage radiation therapy standards, and particularly the HMRT standards for proton therapy.

DR. MUKHERJI: And just for both these, ten minutes.

DR. JAGSI: Ten minutes. I got it. So as we all

know, radiotherapy is a critical component of the multimodal management of cancer, and those oversupply and undersupply create problems. Undersupply creates access issues and oversupply can waste resources, and your Commission is absolutely critical in protecting our citizens from these risks. And to do that, you absolutely have to ensure that your standards are current and reflecting modern circumstances.

And so there have been actually a number of material changes that include changes in patient need, including the rising incidence of cancer and emerging evidence that support broader clinical indications for proton therapy, lower costs of proton therapy centers compared to ten years, and reorganization and consolidation of care in the state.

So proton therapy is a powerful cancer-fighting tool that targets tumors more effectively and significantly lowers radiation doses to healthy tissues. Children who are being treated for cure are the most likely patients to benefit. They have lower risks of second cancers, cognitive problems, growth delays, and other forms of damage that last a whole lifetime. The University of Michigan's Mott Children's Hospital cares for the most pediatric cancer patients in our state, leveraging resources of our Comprehensive Cancer Center to offer complete care in a

patient-centric manner, and forcing families to travel for their children to receive radiation in an environment that's less specialized in pediatric cancer care creates a fragmented and ultimately suboptimal care experience. But it's not just children alone who benefit from protons. Protons deliver one-third to two-thirds less dose to healthy tissue than x-rays, and so evidence for clinical benefits are emerging for adults as well as pediatric patients.

You can see over here (indicating) an image of the very, very highly conformal dose distribution that we can achieve in a breast tumor there. See, that thing right underneath it is, of course, the heart. And so we, you know -- you can think if you had a tumor here, you would prefer for your conformal treatment not to give a low dose spray over your heart. And this is true in many, many locations; brain, head, neck, liver.

And in fact, there's growing evidence of benefits in many, many, many different types of cancers. And so ultimately there are thousands of patients in our state each year who could benefit from proton therapy. Given incidence estimates of 336 pediatric and over 50,000 adult incident cancers back in 2015, the advisory board estimates that 63 pediatric and nearly 8,000 adult patients could benefit from proton therapy. And this is not the kind of patients that you were worried about when you first came up with these

regulations. These are not prostate cancer patients getting treatment that isn't any better than standard therapy. There's 800 patients right there with head and neck cancer; individuals who will have change in their quality of life for a lifetime. If you lose your salivary gland function, that changes your life permanently. These are really important side effects. If we low dose spray over the rest of your brain when we're treating you for a curable brain tumor, that affects you for the rest of your life.

And this is true of sarcomas and liver tumors and many other kind of adult cancers. So again, strongest evidence in pediatrics, but also quite a bit of evidence now emerging in adult patients. And that 8,000 patient estimate doesn't even include potential cases of reradiation where proton therapy can be particularly effective. Half of those cases live within 50 miles of the University of Michigan and all projections are showing that cancer incidence is rising.

So I'm giving you 2015 numbers. I have the 2020 and '25 numbers. I'm trying to paint a conservative picture here. These numbers are going up, not down. The times have changed. 10 years ago radiotherapy was being provided by more and smaller facilities. There were only 5 facilities in the state that had over 30,000 ETV's, and 2 of those 5, or 40 percent, were required to have qualifying activity and form a collaborative. Back then that made a lot of sense.

Now, due to consolidation, there's actually 6 providers who have over 30,000 ETV's. And so that means that with the 40-percent rule, a new entrant actually needs a third partner. The challenge here is that 2 of these 6 providers already have facilities. Of course only one is functioning and we have no reason to believe the other will ever be.

But the existing facilities are far smaller than was anticipated when the policy was written, and those facilities can therefore treat only a small fraction of proton-eligible cases in the state. Based on guidance, these 2 providers must remain in the calculation of eligible services of greater than 30,000 ETV's, so it's really limiting the ability of a new entrant here.

Now, note that in the past activity has been the key consideration and we believe that for most services that's appropriate, including HRMT. University of Michigan has double the activity threshold on its own, over 60,000 ETV's at the U of M alone, and that a willing partner with whom to collaborate, who also has activity of over 30,000 ETV's, it has an emerging system of radiotherapy in other geographic areas, health service areas, with an expanding cancer program presence in therapeutic demand.

And so we argue that this 40-percent rule is an unreasonable third qualifier that is creating a real barrier to access required cancer care services in an integrated and

cost efficient manner. There are literally thousands of Michigan patients who could benefit from additional capacity, but existing facilities cannot meet present and future needs. I will allow my colleague from Beaumont to address Beaumont's capacity, but similarly-sized facilities can treat about 250 patients a year. We're talking about thousands of patients who could benefit.

Even if they run a second shift and double their capacity or they're much more efficient than any other center in the country, we're not getting close to the level of need that citizens of our state have here. This year we've sent over 50 of our patients elsewhere to receive proton therapy. In response to some of the questions last time, typically those cases have been sent to other comprehensive cancer centers.

That tends to be the preference of our patient population. They come to the U of M as a comprehensive cancer center, so we give them options of what's available. Beaumont's only been an option for the past few months. And many of them do still choose to travel further away. Unfortunately many of our patients lack the resources to travel even to Beaumont. If they're receiving concurrent chemotherapy, they're nauseated, they're vomiting, if their insurance won't cover them to be treated there. And so unfortunately there are many more patients that you won't

see appearing on a waiting list, but we know are there based on our activity standards and so the projections about cancer incidents. So access in our state is inadequate and we believe this does require review of the current CON requirements. The cost and scale of proton therapy is dramatically lower now. Cost containment was a very reasonable and primary driver of the standards that were currently developed.

And you know, you can look at the press coverage on this to see how things have changed; right? So there's a 2009 article that talks about the $144 million center being constructed at the U Penn as, "The most complex and expensive medical machinery ever built"; right? And this was a real concern. This was going to bankrupt all of health care. Now there's a more recent Wall Street Journal article focusing on compact proton systems that cost more on the order of 25 to $30 million, which is a truly dramatic revolution in cost and scale.

One last point is that we have to serve our citizens' needs today and tomorrow. Beyond serving the patients who benefit from proton therapy today, the University of Michigan is uniquely positioned within our state to ensure that even more patients will benefit tomorrow. We have a top five radiation oncology department in this country with the expertise that is needed to lead

the research to make proton therapy even more useful in the future and even more appropriately utilized; exactly what we all share as our priority. Many resources that we have, including our $15 million program project grant from the NCI, can actually be leveraged to help citizens in our state and beyond. And so we are really optimally positioned to lead the studies that are needed to improve the use of protons and ultimately optimize resource utilization in this setting.

So in summary, we believe that a CON standards review is necessary. Per existing standards, the University of Michigan does qualify based on activity and on collaboration. Activity has been the basis for qualification in most CON standards. There haven't been any applicants for proton centers since the current language was written, which we believe is a sign that the current standards discount patient activity as a key need criterion.

Project costs have reduced significantly over time. And therefore, we strongly recommend a standard advisory committee or work group to review the existing HMRT standards and clarify the need criteria to qualify for a proton facility and improve reasonable access to this important form of care to Michigan citizens. Thank you for the opportunity to present.

DR. MUKHERJI: Very good. Do you have any

questions for Dr. Jagsi?

MR. HUGHES: So how many of these proton beams are already in the country?

DR. JAGSI: So there are 26 functional centers, there are 16 that are being built, and about 4 to 6 more that are underway.

MR. HUGHES: And how many are already approved in Michigan?

DR. JAGSI: So there's two that have been approved, one that's functional. The other --

MR. HUGHES: Two approved.

DR. JAGSI: And the other one, just to be clear, has lost its vendor. We're not sure that it has FDA approval to actually serve as the vendor. There's many concerns about whether this will be functional at all. So I just want to throw that out there. There's two approved, but there's really only one that's functional. There's nothing up on the web site anymore about the proton center at McLaren.

I'm quite concerned that if you're considering that second center as providing access, you should really speak to the folks at McLaren about what provisions they have to make sure that they can actually open.

MR. HUGHES: And on previous discussions we talked about the actual cost of these being closer to $50 million.

Would you agree with that?

DR. JAGSI: Actually, I said 35 when we talked and that was including housing for the unit. But they tend to be 25 million for the machine, and then 35 including --

MR. HUGHES: And the staff?

DR. JAGSI: Yeah. And then of course everything has staff costs that come along with it.

MR. HUGHES: And then when you're referring patients now, are you having a problem getting access and them having to wait when you try to send them in-state currently?

DR. JAGSI: So we've only had an in-state option for a few months, so I don't think that that has reached a stable equilibrium. And we're still trying to sense what number of patients we can send who will be accommodated. I think we need to hear from Beaumont about how many of the patients that are being sent there for protons are actually being treated with photons, if they're shifting patients who are being referred for proton therapy to photon therapy which you wouldn't see as a wait, but would actually be not then accommodating them with protons. I think we need to hear from Beaumont about that.

MR. HUGHES: Yeah. And I think it's also fair to mention that several of these have failed throughout the country, too, financially?

DR. JAGSI: Absolutely, and that's the old model where the idea was that you would crank through a whole lot of patients with prostate cancer who are really fast to treat, and who actually don't get a meaningful benefit as compared to photon therapy in many cases. And so that was a bad business model, and indeed it was -- and that's the reason that you're seeing those failures. It was also when the cost of this technology was much higher.

This is before the evidence that's come out that has really shown that, again, you know, if you had a tumor in one part of your brain and we could say, "Well, we can treat that tumor fairly conformally, but we'll spray some low dose radiation to the rest of your brain. And, oh, yeah, now we have evidence that doing that is actually not so good in the long term for your cognitive capacity, but that's okay. What's the cost of a little bit of your cognition?"

That's the challenge, is that, you know, when we're talking about treating several hundred patients at one of these smaller centers -- we're not talking about treating thousands of patients at a larger center -- we actually should be able to have several of these centers, or at least certainly when you have a facility with over 60,000 ETV's and another partner with over 30,000 ETV's, be able to treat several hundred of their patients who clearly -- with over,

you know, 800 patients alone with head/neck cancer who are going to have meaningful quality of life benefit, we should be able to accommodate that need.

MR. HUGHES: A lot of this is based on projected need of people. And so my last question -- and then I'll shut up -- you said that half the people were within --

DR. JAGSI: 50 miles.

MR. HUGHES: -- 50 miles. So how many of those people are within 50 miles of the two places already approved in the state versus the rest of the population?

DR. JAGSI: So I don't know the answer to that question. But again, I don't think that the two places -- even if the second one does miraculously become functional, I don't think that the capacity at those two centers is anywhere near the numbers that we're seeing in terms of the need. And so I think there's still a demonstrated need.

MR. HUGHES: By -- what? -- wait times?

DR. JAGSI: Not by wait times, by incidence numbers and benefits. So based on the clinical benefits that have been demonstrated for proton therapy in minimizing dose to organs that have now been demonstrated to show meaningful, long-term quality of life impact and by the incidence projections of those cancers.

MR. HUGHES: Thank you.

DR. JAGSI: Thank you.

DR. MUKHERJI: Any other questions? Thank you very much. The next presentation is from Craig Stevens from Beaumont.

PRESENTATION BY CRAIG STEVENS, M.D.

DR. STEVENS: Thank you very much for the Commission hearing my testimony. And Reshma, please send me your business because we have space on our machine, so we'd love to see your patients. So I'm the chair of radiation oncology at Beaumont Health and I oversee the radiation oncology at all of our centers. I'm the former chair at Moffitt Cancer Center in Tampa where I was chair for eight years, and was at MD Anderson when they were bringing up their proton center.

I'm a lung cancer guy and I was actually working on the treatment planning standards for lung cancer back 15 years ago when I was there, so I've been looking at protons for a long time. So Beaumont safely and successfully installed the commission of the first proton therapy center in Michigan which has allowed us to treat the first adult patient, the first pediatric patient, and also to develop a fair bit of new knowledge and clinical research that we're using that will impact the future applications of radiation therapy with protons throughout the world. In fact, we have new intellectual property on delivering rotational protons just like we've been delivering rotational intensity

modulated x-rays now for some years. And that intellectual property is, again, owned by Beaumont. So Beaumont has a long track record of developing novel technologies. We patented the Cone Beam CT technology that's involved in every linear accelerator that's manufactured. We developed adaptive radiation treatment planning, active radium control and the like. We've had significant funding from NIH, intellectual property and other sources and, in fact, last year we published over 90 papers in our department.

So we really are an academic radiation oncology department and that's going to become relevant as you see our center. It actually requires a fair bit of academic rigor in order to make these things work. This (indicating) is the beautiful building that we have. It's -- actually the whole center was $42 million. We have a state of the art treatment room and some beautiful spaces as well.

So the reason that protons are important is they go in and they stop. That allows us to paint dose and avoid normal tissue complications. I'd like to focus on the pediatric example here. There's a number of others as was mentioned. But basically if you look at what x-rays do to this young child getting cranial/spinal radiation, you can see a fair bit of dose goes to basically all of the organs of the pelvis, the abdomen and the chest in comparison to protons where essentially no dose goes to those areas. It

reduces the chance of second malignancies, heart disease, esophageal strictures, a variety of other lay complications in our most vulnerable patient populations. So our center has pencil beam scanning which adds dose like a 3D printer, so it's very conformal dose distribution. So pencil beam scanning allows you to deliver dose very precisely. We have three different types of in-room imaging that allows you to not only deliver dose, but know where you're delivering the dose into the patient and that's also an important piece.

And all of this allows you to deliver more dose to the cancer with less side effects. We also put our pediatric oncology center on the second floor of the proton center so that our most vulnerable patients would have immediate access should they need it. We recruited quite well for our staffing needs. Our physicians come from Harvard, University of Florida Proton Center, and one of my colleagues from MD Anderson who treated patients, treated lung cancer patients there for seven years as a faculty member.

We also recruited medical physicists that were extremely well trained and the lead proton physicist actually had installed and commissioned a similar unit, a standalone and single bolt unit in Louisiana. We recruited folks from MD Anderson and the University of Pennsylvania on the physics staff as well. We then sent our staff for

dedicated training at two different functioning proton centers. And what we found during all this is that there's really a limited talent pool for experienced staff in proton therapy, and we actually had to pay almost a 20 percent additional surplus for our physics staff to get them to move. So there's quite a learning curve and there's a lot of activity in proton centers right now around the country, and so it's difficult to recruit trained staff.

You have to really train them up yourself. Proton therapy commissioning is not like a winnock. So radiation therapy is a fairly straightforward type of treatment to commission. It takes a few months and you're done. Protons is not that way. In fact, each disease site has to be commissioned separately and requires robust development of immobilization for each site. It takes into account the density of the tissue and the density of the immobilization through which the beam has to pass and the reproducibility of that density.

And so the dose painting that we can do is dependent on the energy of the incident beam, which obviously we control, and the density of the tissue through which it passes, which we don't always control. Patients lose weight during the course of treatment. Patient may get a sinusitis during the course of treatment which causes fluid density instead of air density and that can shift your

proton dose distributions by a centimeter or two. And so all of those things have to be looked at daily and you need to develop a robust immobilization and robust abilities to deal with those day-to-day changes in density that can affect your proton distribution so much. We also had to requeue all of our CT devices to make sure our Hounsfield units were right. Those radiologists in the audience know about Hounsfield units.

DR. MUKHERJI: Careful.

DR. STEVENS: But we actually had to make sure that those were quite correct because of the criticality of that in our treatment planning. We also had to develop a daily and weekly imaging plan. So do they need crossfire x-rays every day or do they need three-dimensional volume metric imaging every day? As I mentioned with sinus, they may actually need daily imaging and even daily replanning to account for changes in soft tissue density.

So we needed to develop an adaptive planning strategy, again, for each disease type, each disease site. The way that you would deal with adaptive planning in the lung is very different than the way you deal with it in the head and neck, and you don't have to deal with it in the brain for the most part. It requires multiple dry runs, and on top of that you have to do a separate case for pediatrics. Some of the cases require anesthesia. And in

fact, we're still in the process of commissioning the treatment of tumors that move over half a centimeter because we don't like the way it's done nationally. But the bottom line is that we were able to treat our first patient on June 28th of 2017, and it was a patient with a brain tumor and his treatment was 37 seconds long as we painted the dose into his brain. As was mentioned, there's 26 operational centers in the US. Ours is the 25th.

There's 11 under active construction. We still have the capacity to treat additional patients. We've heard that the center in Flint is going to open this year. We don't have confirmation of that. And since our center isn't full, the addition of three additional vaults is likely to quadruple the state's capacity. We're happy to provide tours. We've done a number of knowledge hearing events both at the center and around the state.

Everybody is welcome to come see our center. It's pretty cool. I'm positive about protons. A little ion -- sorry about that. It's always that kind of sad laugh. I think it's funny. Anyway, so we're serving our patients across Michigan. Our first patient treated was from Saginaw and we basically have been treating patients from around the state and around the region, from Illinois, Indiana, and Ohio. You can see that most of our patients that we've done consults on have come from the Detroit metro area, but we've

had a number from around the country, around the world. We also had a call from -- they have phones in Afghanistan it turns out. We had a call from there. We had a patient from Australia call us as well, and we have a patient from California that's starting next week. So our center has been open for 6 months and we have treated 47 patients, and we went slowly intentionally so that we could get lots of experience with treating patients and we commissioned our center with really great care.

You can't suck the protons out if you deliver them incorrectly, and so we wanted to make sure that we were doing it correctly. But now our center with a single shift is running 12 to 20 patients a day over the last 2 months. We've treated 10 children and we just started our second patient with anesthesia, a 2-year-old. And again, we've had patient referrals from around the state.

We also developed a proton therapy access center to sort of speed the ride of our patients so they have a single point of call for all their appointments. Any imaging, testing, consultations, are all arranged through our access center. Importantly, too, we don't want to provide care and then have financial toxicity delivered to our patients, because we will treat no patients without preauthorization or enrollment in the Beaumont imaging care process. We don't want our patients to be sicker from --

financially from the therapy than they are from their cancer. And so far, even though one patient required seven peer to peers, so far we've only had one patient that we couldn't get authorization for. So we've actually been pretty relentless and the folks at Acord do not like us, which I'm really fine with. We also have biweekly proton therapy chart rounds where every single patient that's recommended for proton therapy is reviewed.

Often they're preplanned on their pretreatment imaging and we can actually do comparison plans of protons versus photons so we can see how much the patients are actually likely to benefit. And if they don't proceed to proton therapy, we present them with other options. In fact, one of the best things for our brachytherapy program has been the proton therapies. So we've actually treated 15 patients that came for prostate radiation with the single fraction HDR.

DR. MUKHERJI: If you could wrap it up, we're --

DR. STEVENS: Okay. We have an ethics committee and we've also done a lot of publishing. So thank you.

DR. MUKHERJI: Thank you very much. So if you're positive about protons, how do you feel about electrons?

DR. STEVENS: I just had one. Can be negative.

DR. MUKHERJI: All right. So thank you. Any

questions for Dr. Stevens?

MR. MITTELBRUN: Mittelbrun. The previous speaker had some recommendations. Did you have anything to add to that or --

DR. STEVENS: Well, what I can tell you is we're in the process of staffing up for our second shift. We're also in the process of a large community outreach program that will, I'm sure, increase the referral base of our center. But right now our center isn't full. We've been using a lot of word of mouth and I think with advertising it will fill up nicely. But if you add three more vaults, I'm not certain that -- I'm not certain what's going to happen.

I'm fairly certain that back in 2007 we didn't need a five-room center, which is what we had originally proposed. And I don't know how much more proton therapy centers you need in Michigan, how many more vaults you need.

DR. MUKHERJI: Any questions?

DR. STEVENS: And there's only 66 pediatric patients, so it's not a huge volume. And we can treat -- we estimate that we'll be able to treat somewhere around 350 patients a year. And one of the other things that's really interesting, having looked through a bunch of head and neck plans, I'd say only about a third of head and neck plans actually benefit from protons. So it's not like every head and neck patient needs a proton plan. Again, I'm a lung

cancer guy. I actually looked at an IMRT plan on one of my patients and elected to treat the patient with x-rays because I felt the plans were equivalent. So yes, there's times when you absolutely need protons. Retreatments, I think it's very important. But you know, many patients -- and without the comparative plans you wouldn't know. But with comparative planning, which is required for most insurance authorizations, you can really see that not everybody benefits.

DR. MUKHERJI: Any other questions?

MR. HUGHES: Just a quick one. This is a totally unfair question. It's like asking you how much snow we're going to get this weekend.

DR. STEVENS: More.

MR. HUGHES: If you had to guess -- is it your opinion, is the other place going to open in 2018, if you had to guess?

DR. STEVENS: I truly have not enough knowledge to base an educated guess on. You know, the center received FDA approval -- I don't know how, but they did -- but then they've elected not to treat any patients. So I'm not sure what the issues are. I've heard a lot of rumors, but it's rumors and speculation. I haven't talked to the principals about it and I think maybe that's something you guys should talk to them about. And you know, if they're never going to

open, then it's probably worthwhile to open the issue again because, you know, I'd certainly consider another center for us. But if that center's never going to open, yeah, I think you have to. But you got to know that and you have to look at it with actual data. Speculation isn't fair to them.

MR. HUGHES: Thank you.

DR. MUKHERJI: Any other questions? All right. Thank you very much. So what we tried to do is give two centers the opportunity to talk about proton beam and we understand that there's a difference in opinion there. The next -- yes?

MS. NAGEL: We can weigh in on the progress of the second one.

DR. MUKHERJI: Yes, please. Yeah, thank you.

MS. BHATTACHARYA: So this is Tulika. As part of our regular follow-up process we did reach out to McLaren-Flint and asked for an update on their proton beam therapy project. The equipment has been installed. The center has been constructed. And as of January 22nd of this year, they have reported to the department that they expect to start patient treatment in June of this year.

DR. MUKHERJI: Thank you very much. We do have public comments. So next is Arlene Elliott on behalf of Trinity Health.

ARLENE ELLIOTT

MS. ELLIOTT: Good morning. My name is Arlene Elliott and I am here on behalf of Mary Boyd of Trinity Health. She is the chief integration officer of Mercy Health and St. Joe's, which collectively make Trinity Health in Michigan. I'm going to read her comments since she couldn't be here.

"On behalf of Trinity Health-Michigan, I would like to thank the CON Commission for taking into consideration our comments regarding the current MRT CON standards.

Trinity Health-Michigan offers radiation therapy services in Muskegon, Grand Rapids, Chelsea, Ann Arbor, Brighton, Livonia and Canton. Our seven centers serve thousands of patients annually and provide nearly 10 percent of all radiation therapy treatments in Michigan. Our centers include non-special MRT units as well as special purpose MRT units.

Across our locations, we have not identified an unmet need for access to proton beam therapy. Specifically, we have not experienced any difficulty coordinating consultations or treatments for our few patients who have required this treatment. We believe that the high cost of proton beam therapy centers, combined with the small number of conditions for which proton beam therapy is the standard of care, requires

our profession to use caution in expanding the number of proton beam therapy centers. Therefore, we would encourage this CON Commission to maintain the current CON standards for proton beam therapy until a specific unmet need is identified and that any future change assures proton beam therapy is geographically dispersed in Michigan.

Based on the findings from MDHHS' 2017 review of MRT services, we are concerned that the minimum maintenance volume requirement of 8,000 equivalents may not accurately reflect the way radiation therapy is being delivered at some busy facilities. In the short term, and prior to any follow-up compliance actions, we would encourage this CON Commission to establish a lower minimum maintenance volume requirement to ensure that the existing MRT programs are not negatively impacted by anachronistic regulations. Given the very narrow and immediate nature of this specific issue of maintenance volumes, we believe it is appropriate for the CON Commission to make such a change without a workgroup or a SAC.

In the long term, Trinity Health-Michigan would support the CON Commission establishing a SAC during the normal review cycle of 2020 to more carefully consider expert opinion and data on current practices

and technology including proton beam therapy. An expert panel is necessary to make thoughtful revisions to both the equivalent treatment weights and the volumes required for initiation, expansion relocation and maintenance. We strongly believe that any changes to the equivalent treatment weights must also include a simultaneous review of all volume requirements to avoid significant and unforeseen negative consequences." Thank you.

DR. MUKHERJI: Thank you. Any questions for Ms. Elliott? Thank you very much. The next is Dr. Salim Siddiqui from Henry Ford Health System.

SALIM SIDDIQUI, M.D.

DR. SIDDIQUI: Good morning. As Dr. Mukherji said, I'm Salim Siddiqui from Henry Ford Health System. I'm the senior staff radiation oncologist. I'm also the director of our department's quality assurance committee. I'm also the MR simulation program director and the stereotactic radiation director for the Henry Ford Cancer Institute. I also serve as the medical director for physician partnering.

I want to begin by thanking the Commission for this opportunity to provide comments on the CON standards for MRT services, and for considering review of the MRT standards earlier than scheduled. Over the past six to

eight months we've realized that the current MRT standards have not kept up with the changes in delivery of care and technology that have occurred in radiation therapy over the past five years. In an effort to deliver the highest value of care, the selection of the most cost effective treatments as -- has resulted in a significant shift from IMRT to complex treatments.

This shift decreases cost to patients and payers while maintaining the highest quality and has been supported by the statewide Michigan Radiation Oncology Consortium, also known as MROC. Our commitment to such high value care has earned Henry Ford the MROC's gold card status. However, in the current standards, such as shift decreases ETV's, as IMRT is weighted at 2.0 ETV's and complex is weighted at 1.25 ETV's.

Now, this may be a disincentive to appropriately offer complex treatments over IMRT. Moreover, improvements in technology have resulted in essentially the same treatment time for IRMT and complex treatments. So the current weightings no longer accurately reflect their relative treatment times. In addition, the volume requirements need to be reevaluated. Currently the MRT service operating 5 days a week, 8 hours a day must generate at least 4 ETV's per hour just to meet the minimum volume requirement of 8,000 ETV's per year. As most treatments

today are either complex or IMRT, the average facility cannot meet the minimum volume requirements as revealed during the compliance audit last year when the department found that 30 percent of the existing service is well below minimum volume standards. Finally, we at Henry Ford are honored to have the first realtime MRI guided radiation therapy on the ViewRay MR Linac, a new FDA-approved technology now at our Henry Ford Cottage site.

This novel technology is being pursued by other systems in Michigan as it will significantly decrease the risk of toxicity while improving outcomes for patients that are treated. However, it requires significant additional time as it involves realtime MR tracking such that the radiation beam turns on only when the tumor is within the treatment field and turns off when the tumor moves out, thereby protecting surrounding normal organs.

The current weightings need to be updated to accommodate this additional time. It's also important to note that treatments on the ViewRay MR Linac are not more expensive than treatments in other units, so thereby providing even higher value care for cancer patients in the state of Michigan. For these reasons, we would like to request a reevaluation of the weights and volume requirements that account for changes in technology and to high value care and ensure health care resources are

utilized efficiently. We believe this work is perfectly suited for a work group and we'd engage with other MRT services across the state and have received very positive feedback and a strong interest to work together to find a best solution. Therefore, we ask for your support in forming a work group in the coming months with the plan to bring back recommendations before the end of this year. Thank you again for your time and I'd be happy to answer any questions.

DR. MUKHERJI: Thank you very much. Any questions for Dr. Siddiqui? Okay. Thank you. The next card I have is from Marlena Hendershot from Sparrow Health System.

MARLENA HENDERSHOT

MS. HENDERSHOT: Good morning. My name is Marlena Hendershot. I am the director of strategic planning at Sparrow Health System. I'm new in this role, so this is only my second CON Commission meeting, so I apologize in advance if I'm just a little nervous. Thank you for this opportunity to provide comments regarding the CON standards for MRT services.

The administrative director of our cancer center had planned to be able to speak to you today but unfortunately had to stay back for a survey, therefore, I'm going to try to do my best to deliver his message. We at Sparrow believe the MRT weightings and volume requirements

are in need of review and updating due to significant changes in technology and patient care over the last five years. Based on the compliance review conducted last year, almost 30 percent of existing providers had to enter into compliance settlement agreements based on low-weighted volumes in 2015. Luckily Sparrow was not one of those, but only because the department determined we were trending upward and close enough to the minimum volume.

The facilities that weren't so lucky have until the end of 2019 to meet minimum volumes, but because the weightings are so outdated it is extremely difficult to meet that deadline without an update to the standards before then. We realize these are not scheduled for review until 2020, but ask that you form a work group to review them early. Thank you for your time. I'd be happy to try to answer any questions you would have.

DR. MUKHERJI: Thank you very much. Any questions for speaker? Thank you. The next I have is Sean Gehle from Ascension.

SEAN GEHLE

MR. GEHLE: Good morning, Mr. Chairman. Thank you for the opportunity to provide some additional comments regarding MRT Standards. I won't repeat what's already been said, and I think Dr. Siddiqui did a nice job of explaining the issue for you. On behalf of Ascension Michigan, I am

the chief advocacy officer. We support the formation of a work group to look at the weightings. The weights and volume requirements in the MRT Standards have not been updated, as has been said, in some time. And as a result, we don't believe that the current weights accurately reflect the amount of time the various procedures take on the machine due to significant changes in technology in patient treatment plans since the last time they were reviewed.

In addition, it would at least appear that the minimum volume and expansion volume requirements are perhaps too close together and should be evaluated to ensure that the standards measure as accurately as possible the utilization of these MRT units. We believe all of these updates would be suitable for a work group where all interested parties could come together to build consensus around the appropriate weights and volume requirements.

We also believe that this work group should be limited in scope to just this issue. Thank you for your time. I'd be happy to answer questions.

DR. MUKHERJI: Thank you very much. Any questions of the speaker? Thank you, sir.

MR. GEHLE: Thank you very much.

DR. MUKHERJI: The next speaker is Thomas Lanni from Beaumont Health.

THOMAS LANNI, JR.

MR. LANNI: Good morning, Mr. Chairman, commissioners. My name is Thomas Lanni. I'm the vice president for oncology medicine and rehab services at Beaumont Health. We understand that some MRT providers are requesting an early review of MRT Certificate of Need standards to review the equivalent treatment visit weightings for MRT visits. This request was prompted by the department's compliance review of MRT volumes across the state.

While it's beneficial to periodically review these weightings, Beaumont does not believe there's an immediate need to do so and does not support moving the review up from its regular three-year cycle. All of Beaumont's MRT facilities were part of the department's compliance review and will be closing due to low volume. The other facilities, however, all meet minimum volumes in 2015, '16 and '17. Thank you for the opportunity to provide public comment and I'll be happy to answer any questions.

DR. MUKHERJI: So I guess I'll ask why do you think there's a big discrepancy between -- we've heard two systems ask for moving the process up and forming a work group to look at weightings, but your system appears not to -- have a different opinion regarding that.

MR. LANNI: I think for us at this point we are seeing growth in volumes and so we're making up for

potentially some of those changes. But we do provide treatments similar to standard of care that have reduced fractionation (pronouncing) for patients, but at the same time we have also grown. So we have not seen that drop in volume overall.

DR. MUKHERJI: So is it a growth in actual patients coming in, in your opinion, or is it a shift to a higher weighting of IMRT versus complex?

MR. LANNI: We actually shifted from IMRT to more complex care over the last couple of years based on some differences of clinical data that has come up. So we have actually reduced IMRT treatments over the course of time.

DR. MUKHERJI: Do you participate in the MROC?

MR. LANNI: Yes, we do.

DR. MUKHERJI: You do. Do you know where you stand in your MROC data at all?

MR. LANNI: I do not at this time. I'm sorry.

DR. MUKHERJI: Any questions? All right. Thank you.

MR. LANNI: Thank you.

DR. MUKHERJI: Next speaker is Tony Denton from Michigan Medicine.

TONY DENTON

MR. DENTON: Thank you and great to be back again. I feel like I'm kind of the bogeyman in the room with

regards to the proton conversation. In December Dr. Lawrence and I came and made some comments about what he thought was important. And I just wanted to bring us back to what we thought was a need to clarify the intent of the existing standards, because, as you know, at Michigan we did wait, to your point about cost, wanting the cost to come down.

And the way that the standards are written do seem to focus on need, looking at activity thresholds as the basis as prime criteria number one. As Dr. Jagsi mentioned, we have double the threshold. So as we looked at the standards and tried to apply them to our situation, we said, "Yes, we need it." When we looked at the collaboration requirement, we found a partner and said, "Yes, we meet it."

So when we then embarked upon trying to pursue application, we were told that there was a 40-percent threshold, 40-percent rule, which meant that if you have a partner, you and the partner have to be 40 percent of those providers that exceed 30,000 ETV's. For as long as anyone can count, there were 5. So we thought, "Yes, we meet it." Then we found that there was actually a sixth in the most recent year reported. So we went from 40 percent to potentially 33 percent. So we're talking about plus/minus 7 when we've already demonstrated that we've exceeded the threshold on our own and with a provider to meet what we

thought was the overall intent of the Certificate of Need as written. So the question that we raise is why is the 40-percent rule there? If activity can demonstrate need and collaboration can demonstrate an intent to try to reduce costs, what is the reason for that third qualifier as Dr. Jagsi mentioned? That's the point of what we were trying to get at in terms of suggesting that it might be a need for early review, because for ten years there have been no applications for a proton.

Cancer as an incidence disease is growing. It takes 2 or 3 years after approval to get a center up. So if you wait 'til 2020, and if we weren't so lucky to then be able to qualify and get one approved, we're now talking about 2023 to 2025 before we provided access to care for patients who need it in our integrated comprehensive cancer care center. So I ask you to think about those particular aspects of how you would delay need if you choose to delay review in considering the question regarding the proton beam. Thank you.

DR. MUKHERJI: Any questions for the speaker?

MR. HUGHES: Could you articulate to me how this is going to reduce cost?

MR. DENTON: Well, we have an integrated cancer center. And our patients, they come for all kinds of diseases and they're treated onsite. When we have to go

through a process of transferring them to another facility, there's costs to the patient and the family, there is cost of the care modality, because we now have to coordinate care with other providers. If other issues come up, there's fragmentation in the care of going from one to the other, so the transition costs and having to have a different level of coordination when we can't keep the patient onsite to treat all of their needs at one facility.

MR. HUGHES: So this third one would be located where? Within how many miles of the other two?

MR. DENTON: For us it would be in Ann Arbor.

MR. HUGHES: Yeah. The rest of the state?

MR. DENTON: We treat patients in every county of the state of Michigan and have patients come from all over the state.

MR. HUGHES: And that's okay for them?

MR. DENTON: Well, it provides access to the whole state.

MR. HUGHES: Just seems to spend $50 to make it a little bit more convenient for people in Ann Arbor versus anywhere else in the state where we already have two, I'm having a hard time -- I'm not even full understanding the cost savings there, but I could be missing something.

MR. DENTON: Well, I think what we're all missing is why did we put the standards in place the way that they

are with regards to the activity? As I said, we treat over double the threshold which shows and demonstrates the need. We're not able to provide that level of care for patients who need it. And integrated care for us is patient-centered and an important philosophy. I do agree with what you said earlier about the cost of the business model, but that's why I said we waited for the cost to come down to integrate it so that it's across a broad population, how to treat the care of that population.

In regards to other providers, I think you heard earlier that Beaumont is going to a second shift. It's projected that they're going to be full at some point. We're saying that we have demonstrated the Certificate of Need standards that we have the activity to take care of a number of patients at our site.

MS. GUIDO-ALLEN: I'm going to take you back to our -- Guido-Allen -- to our discussion earlier in the meeting, the fragmentation of care, having to leave the health system, move to -- it's okay for the bone marrow transplant patients to have to go to other systems, but not for your proton beam patients. Can you explain why the standards are different?

MR. DENTON: I will try.

MS. GUIDO-ALLEN: From the patients and families perspective, yeah.

MR. DENTON: Yeah. It's hard to make the distinction between the two. I don't want to try to argue one versus the other, but there's a difference in terms of the history, the evolution of the standards for both. For proton therapy as a form of radiation therapy, it's been in existence for a long time. And the way that the BMT came about, it was based on other providers already being in that space.

I can tell you that I hesitated for a long time about how do you make that juxtaposition between the two topics. But for us, it really is about fragmentation for a population that is in greater numbers.

DR. MUKHERJI: Any other questions for the speaker? Thank you very much.

MR. DENTON: Thank you.

DR. MUKHERJI: That is the last public comment card I have for MRT. Would anybody like to speak on any of the topics that we heard? Hearing none, I guess we move on to the commission discussion. So I will give my opinion as to where we are in space. My understanding is this is not supposed to come up for review until next year; is that correct, Elizabeth?

MS. ROGERS: This is Brenda. 2020.

DR. MUKHERJI: 2020. Okay. So the reason it was put on the agenda for this meeting of this year is that one

of the options for the Commission is to do nothing and wait until it comes up for its normal review. The other option is -- well, I should say the reason it was moved up was because of the testimony we heard at the last meeting for proton beam from some of the health systems in the state, and then also there was public testimony that was brought to everyone's attention regarding the weighting. So we opted to at least put it on the agenda for this meeting.

So my understanding is that we could wait until next year, until the normal cycle, or we as a Committee have the option to open the standards -- I think I have the terminology correct -- open the standards to either a work group or a SAC. Did I summarize that correctly?

MS. ROGERS: Uh-huh (affirmative).

MR. MITTELBRUN: Is it next year or two years?

DR. MUKHERJI: Two years. I'll open it up for discussion.

MS. BROOKS-WILLIAMS: Commissioner Brooks-Williams. My question is to the department. So the concerns about the weights and the volume seem compelling to me for a work group action, but I think it's compelling because it seems to be that the organizations that are struggling with that feel that they're at risk if we were to wait until that 2020 because I'm assuming they continue to go under compliance review. Is that accurate, that if we

did nothing and the standard was as it was related to the weights and the volumes, that there's risk for programs?

MS. NAGEL: So many of the providers that were under compliance action are now in a settlement agreement to meet that volume. So it's hard to say risk, but we do enforce the standards as they're written. And so I don't know that I can -- if you're asking if we're going to continue compliance --

MS. BROOKS-WILLIAMS: Maybe a different way to ask it is there are consequences in this window of time. So to do nothing now means between now and '20 there could be more people that fall out and are noncompliant.

MS. NAGEL: Yeah.

MS. ROGERS: But also keep in mind even if the Commission opens this up and makes changes to the standards, it's proactive. It does not -- it's not ret- -- prospective. It's not retroactive.

MS. BROOKS-WILLIAMS: Understood.

MS. ROGERS: So unless they come in for some reason under the new set of standards, they're going to still be subject to the standard that they're under. So just so everybody's aware.

MS. CLARKSON: This is Commissioner Clarkson. What does the department recommend?

MS. NAGEL: I'm sorry. I --

MS. CLARKSON: What does the department recommend?

MS. NAGEL: We did not make up a formal recommendation on this topic because it wasn't part of the normal review and so we don't have a prepared recommendation on whether to open the standard and look at the weights now or to not.

MS. CLARKSON: Thank you.

MR. MITTELBRUN: Mittelbrun. I'm a little confused. You mentioned the compliance audit and the settlement. And when does the settlement period end? I'm assuming it's before the 2020?

MS. BHATTACHARYA: For most of the providers, without looking into individual agreements, I believe it's end of calendar year 2019.

MR. MITTELBRUN: Okay. Which is before the review. And I'm just trying to -- Brenda, if I understood you correctly, because the settlement agreement period ends the end of let's say 2019, if we do the work group and make some changes, it wouldn't affect them under that settlement agreement? It'd have to wait until after the settlement period ends?

MS. BHATTACHARYA: So what Brenda said is correct. So any CON approval and the current settlement agreements for Cardiac Cath and MRT are under the current review standards. But there is also a clause in one of the terms

of the settlement agreement, if there is a new standard that goes into effect before the end of calendar year 2019, the provider has the choice to request to come under that new standards.

MR. MITTELBRUN: Okay. That makes sense to me. Thank you.

MS. BHATTACHARYA: It's not automatic.

MR. MITTELBRUN: Right. That makes sense. So this is still Mittelbrun. So the 40 percent, I'm trying to understand it. You know, we've heard some comments. Why is the 40 percent there and what is the rationale for that additional measure, I guess?

DR. MUKHERJI: For proton.

MS. ROGERS: Yes, for proton.

MR. MITTELBRUN: Yeah, based on the test- -- I'm sorry.

MS. ROGERS: This is Brenda. Just going back historically -- and I think we had this discussion. This came up, I believe, at the December meeting as well. It was a SAC/work group, et cetera, that worked on this and I believe it was a SAC at the time that worked on those standards and it was a collaboration of everything that was available at the time. This was a mechanism that they felt was important. If you're going to provide this service in the state of Michigan, this is one of the things, one of the

requirements you need to meet, and the Commission agreed.

MS. GUIDO-ALLEN: So this is Guido-Allen. I'd like to make a motion that we keep the standards as is and review at the regular scheduled time, 2020.

DR. MUKHERJI: Okay. So we have a motion on the table suggesting that we keep the standard as is and then review at the normal cycle. We have a motion on the table. Anybody like to second?

MR. HUGHES: I'll second.

DR. MUKHERJI: We have a second. So we have a motion on the table and we have a second indicating that we keep the standards as is until 2020. So Commission discussion?

MS. BROOKS-WILLIAMS: Commissioner Brooks-Williams. So I guess I'm just speaking to the fellow commissioners. Not really discussion, but just a comment. I would hope that we would look to have a work group to -- not on the proton, because I realize we've got several issues that are here. I don't have the path or the answer to that.

But I do think that if we have organizations that are saying that there has been change to the weights related to the complexity and that we could be incenting (sic) delivering the care in such a way to get to a certain weight or volume -- again, not to suggest that I fully know

everything that's said. But I think if there's agreement and once that group -- to have a work group which could come back to us and say there is no path that's different than the one that's there today, 2020 feels far to me to defer that conversation. So obviously vote how you feel, but I would hope that we wouldn't support the motion as stated and at least allow the work group. And I respect that the motion is the whole activity and not speaking on the proton section, but I would like to at least have a work group on the MRT.

MR. MITTELBRUN: This is Mittelbrun again. I agree with that completely. That was kind of my thought because obviously the treatment has changed between what it was to more complex and so on. And is there any harm of having a work group look at it and report back? I mean --

DR. MUKHERJI: I'll just go ahead and chime in. I guess I've been in this room for many years -- not this room, but several rooms. Years ago there was a work group that was formed. I think Commissioner Keshishian was the chair of that work group and I think I was vice chair of that group in which we tried to tackle the weightings through a work group. And I think a year later there were some unintended consequences of doing that through the work group, and it's something that has been gone on back and forth. And we had to make some -- I don't know what the --

I forget what we call those amendments, but they were you would say important amendments that were made off cycle. We also -- when we look at weightings, I know there are some challenges here with nursing beds as well, too. And so my only concern is that -- or I guess concerns. If we do open up the standards, I would rather see it be a more formalized process.

I'm not sure how many of the commissioners have actually been in a work group, but typically it's anywhere from two to three meetings, and it's interested parties that show up and those interested parties typically, if you will, already have the methodology worked out. It's almost having the answers to the test already before you've actually seen the test. So my personal thought is if we're going to open it, I would rather do it through a SAC process because it's set by state statute, it is transparent, and we know the individuals that will be on that committee with a formal chair and eventually vice chair.

MR. HUGHES: If we did the SAC, can we limit the scope of what they're looking at in the standards?

DR. MUKHERJI: We can put that in the charge.

MS. ROGERS: Absolutely.

MS. GUIDO-ALLEN: Then I amend my motion to include a SAC to look at just the MRT standards weighting.

DR. MUKHERJI: So you're amending your motion to

have a SAC. And when would the SAC -- if you limit to move -- are you suggesting open the standards up?

MS. GUIDO-ALLEN: Yeah, open the standard.

DR. MUKHERJI: And then that opening the standards would be a SAC?

MS. GUIDO-ALLEN: For the MR weighting; MRT weighting.

DR. MUKHERJI: For look at MRT weighting only?

MS. GUIDO-ALLEN: Uh-huh (affirmative).

MS. ROGERS: This is Brenda. Weights and volume? Because those are the two issues that were brought up.

MS. GUIDO-ALLEN: Yes; yes.

MS. ROGERS: And then no change to the proton beam part?

MS. GUIDO-ALLEN: Correct.

DR. MUKHERJI: So I just have a question for the department before we -- I think you have a motion. If a SAC meets and the chair or the group -- I'll take whatever the group wants me to do -- and we set up an agenda, does the SAC have the flexibility to discuss any other topics that it sees fit if it's -- we've had that conversation before, I think.

MS. ROGERS: This is Brenda. I'll turn to Joe, but typically in the past when you've written the charge up, the charge is specific, but sometimes there is some leeway

written into it. But if you are going to make the charge specific, then they are going to be limited to that.

MR. POTCHEN: And you can also direct the charge the SAC is not supposed to look at X, Y or Z.

MS. ROGERS: Right.

MR. POTCHEN: So you can limit it that way. We have gone broader, but if you say, "You can look at this, but you cannot look at that," that would be specific on limiting what they can look at.

MS. ROGERS: Right.

MS. CLARKSON: This is Commissioner Clarkson. If we do this, does it still come open again in 2020? Would it still be reviewed in 2020?

MS. ROGERS: This is Brenda. Yes. It remains on the same cycle of review and that's what happened with BMT, just as an example.

DR. MUKHERJI: So one other question for the commissioners because I want to be as transparent and as concise as much as I can. Can the Commission actually vote on the charge of a SAC if it heads to a SAC?

MS. ROGERS: This is Brenda. Yes, the Commission does not need to delegate drafting the charge to the chair. I mean, the Commission as a whole can vote on that charge. So it could be they could delegate you to draft it, but then bring it back to approve.

DR. MUKHERJI: So just to the current state as to what's on the table, my understanding is that we have a motion on the table that initially then was amended which says that -- to form a SAC. And I think we did have a second, so I think the second carries over because it was a friendly amendment; correct?

MS. ROGERS: Yes.

DR. MUKHERJI: So the question I would ask, since we're in the discussion period, is does the group want to limit the charge of the SAC or is it going to be up to me or what do we want to do? How strongly? Because the two main issues are volumes/weight on proton.

MR. HUGHES: I would like to specifically limit it to not include the proton.

MS. LALONDE: I agree.

DR. MUKHERJI: Okay. So does that require a separate motion or --

MS. ROGERS: This is Brenda. I mean, that's actually what your motion already states, so --

MR. MITTELBRUN: So this is weighting and volume issue, all those things that --

MS. ROGERS: Your motion already states to make no changes to proton beam therapy requirements, but review the volumes and weights by a SAC.

DR. MUKHERJI: And limit that?

MS. ROGERS: Correct.

DR. MUKHERJI: I just want to be as clear and --

MS. ROGERS: Yup; yup.

DR. MUKHERJI: -- as transparent as we can be. So just to summarize, we have a motion on the table with a second to reopen the standards off cycle, if you will, and the specific charge would be to look at the weightings and volumes through a SAC. That's the motion on the table. Is there further discussion?

MR. MITTELBRUN: Call for the question.

DR. MUKHERJI: Okay. We have call to question. All in favor of the motion on the table say "aye."

(All in favor)

DR. MUKHERJI: All against? Okay. That motion carries. We just have a couple -- so we're right at 11:30. Is this going to go quickly or should we take a biologic break or are we --

MS. ROGERS: I think it'll go quickly.

DR. MUKHERJI: Okay. All right. So next is the -- agenda item number ten is FY 2017 CON Annual Activity Report.

MS. BHATTACHARYA: This is Tulika. So this is the department's 29th annual report to the Commission. The detailed report is in your packet. And since I was told to be quick, I'm not going to go over the whole report. So I

just want to point out, as you can imagine and you probably know, there are lots of activities that goes on in the CON program starting from processing LOI's to applications, issuing decisions on time, following those projects up to make sure they're being implemented on time, and if they are not being implemented on time, what's going on, if you need extension, and then finally the compliance and monitoring of those established facilities and services.

So just on page 98 of your packet, you can look at table one. It tells you that we are on time in terms of processing letters of intent. Although our numbers are down compared to the previous years in terms of LOI's and applications -- but we continue to be on time. On page 100 of the packet, you do see we issue all the decisions within the required time frame for nonsubstantive and substantive reviews, which are 45 and 120 respectively.

The numbers are a little higher this year because we also have seen a lot of complicated projects where the applicant requested more time to give us enough information so that we can approve their project instead of denying them on the 45th or 128th day. Then on page 101, again, just the decision chart. We have issued all those decisions on time. There wasn't any comparative review legally or technically, but we did have a big group of psychiatric special floor bed applications for geriatric projects. The applicants kind of

cooperated and coordinated with each other to reduce the number of beds requested so that they don't get into a comparative review. So technically we didn't have to do a scoring, but there was a lot of work involved in that and we thank the applicants for their cooperation through the process. We have successfully awarded all of the geriatric special pool beds throughout the state and to psychiatric hospitals and waiting for those to be established.

On page 102 it's a nice figure where you can see in the map, like, where most of the projects are and obviously southeast Michigan is -- has the most number of projects. So if you look at page 104, that's the activity comparison table. And as I had said, the number of applications are down, but still the number -- the dollar amount that we have approved as a total for Michigan's health care system, it's about $104 billion in capital expenditure as we have seen more and more big capital expenditure projects last year.

The last table I would like to point out is table 13 on page 105. So that's a comparison, what is the existing capacity in our state and what need services we have approved. You will see we have approved two new FSRF's in the state. There are two hospitals, but those are not two acute care hospitals. Those are long-term acute care hospitals which utilizes existing beds from a hospital and

set up patients typically are only needing long-term acute care under specific CMS rules. We approved 3 new nursing homes. We approved 7 new psychiatric hospitals or units in the state last year. That's quite a bit. And then the next chart, table 14 -- I know compliance has been a hot topic last year, so we continue to follow up projects to ensure they're being implemented. And if they don't -- if they're not being implemented, we expire them.

So you see the numbers. There have been 78 projects that we have expired. The compliance orders, they include the settlement agreements and some other incidents, specific compliance actions that I report to you in your quarterly report, so 54 in total. And that's about it. If you have any questions on any of this data, I'll be happy to answer.

MR. HUGHES: Just curious. Who is the other air ambulance?

MS. BHATTACHARYA: Air ambulance?

MR. HUGHES: Yeah. There was one of two.

MS. BHATTACHARYA: I can double check and give you that information. I don't have the background data with me today.

MR. HUGHES: Okay. Just curious. Thank you.

MS. BHATTACHARYA: Yeah.

DR. MUKHERJI: Any other questions? Do we need an

approval for this or that's information?

MS. ROGERS: This is Brenda. This is simply information for the Commission.

DR. MUKHERJI: Okay.

MS. BHATTACHARYA: I'd just like to take a couple minutes to thank Abigail Burnell, our project coordinator, for collecting and analyzing all this information from our online application system, and also thanks to Jack Ho and Katie Timer for diligently following up and making sure the annual server data is correct. So that's why we can get to you the most recent -- last year's data and review of our application and advise the Commission on, you know, the trends and the numbers and things like that and what needs to be changed.

And also, last but not the least, my review team of Joette, Matt and Perry. And, like, the track record of never being late in issuing a decision, all the credit goes to them and they do an excellent job in making sure we are approving what needs to be approved and the hundreds of hours that we spend in consultation in order to achieve that goal. So I just wanted to thank my team for that.

DR. MUKHERJI: Are they here?

MS. BHATTACHARYA: Stand up.

DR. MUKHERJI: All right. We have one public comment card from David Walker from Spectrum.

DAVID WALKER

MR. WALKER: Again, I'll try to be very brief. I realize I'm one of the last key things standing between you and lunch. Again, David Walker with Spectrum Health. I'm going to take you back down memory lane here. During the December meeting, the Commission voted to reject draft language updating the CON review standards for surgical services. My impression was that the Commission's concern with the language was largely due to the changes related to vascular access centers.

However, included in that draft was a modification to the previously approved changes to the standards that would allow health care systems to initiate new surgical service facilities based on current system resources. As you may recall, Spectrum Health had concerns that without this additional modification, systems would still experience an administrative burden by having to navigate identifying specific physicians and their cases to commit to a new facility and ensuring physicians understood the new process.

The department presented language that would address our concerns by exempting applicants from sections 11(2)(a) and 11(2)(b) of the standards. My understanding is that the department did support this change. Further, based on conversations during previous CON Commission meetings, it also seemed the Commission was supportive of this change.

As such, Spectrum Health respectfully requests that the Commission allow the department to bring back this language exempting applicants, initiating a new surgical facility under common ownership, from sections 11(2)(a) and 11(2)(b) of the CON review standards for surgical services for consideration at the Commission's March meeting.

In doing so, the previously approved surgical standards would be improved to ensure the administrative burden imposed on health systems is relaxed while ensuring access to quality care. Thank you very much for your time. I would be happy to answer any questions.

DR. MUKHERJI: Any questions for Mr. Walker? Thank you.

MR. WALKER: Thank you.

MS. ROGERS: Have you decided what you'd like to do?

DR. MUKHERJI: Maybe you can provide me some context as to what our options are?

MS. ROGERS: This is Brenda. I mean, it's really up to the Commission. As Mr. Walker stated, you did vote down the entire set of standards at the time, but there was some language in there that was carryover from the previous set of language that did move forward on the surgical. This exemption piece was kind of an afterthought, but instead of delaying the surgical standards, we moved it through, and

then the second piece to follow was going to be the vascular access and that exemption -- that added exemption language. So we have the language. We just have to take it and retract the vascular access out. So it could be brought back to the Commission if the Commission chooses to do that and we can bring it back for potential proposed action. So it's really up to the Commission.

DR. MUKHERJI: Does the department have an opinion on this?

MS. ROGERS: We're neutral as far as I know.

MS. NAGEL: Well, we do have a comment actually.

MS. BHATTACHARYA: And I don't know if it needs to be amended or not. That's not my comment. I just have a question for Dave. The Commission did make the changes that are needed to avoid submitting individual position commitment forms and they asked the department to develop a form, institution specific. We have developed that. It's on our website and it does list what is required and what is not required. Have you reviewed that and do you still have concerns?

MR. WALKER: Thank you. I have reviewed the language.

MS. BHATTACHARYA: In the form?

MR. WALKER: Excuse me. Yes, the form. My concern would be that it seems, though, if you read the

standards, it will technically say that you have to provide that although the form is not included. And I'm not saying that the Commission -- or excuse me -- the department is going to hold anyone to that standard because of the form. But let's say 10, 15 years from now there's a change, the department's brand-new and they look at the language. They're going to see that and say, "Well, they should have been supplying this information."

It's a very technical -- it's a very technical change. But that's just my concern. I do appreciate the form. I did look at it. I think it was -- I liked it. But again, my concern would be for another interpretation down the road.

DR. MUKHERJI: So is this a substantial change or is this something that can be done offline? Because it sounds like overall you're okay, you're just worried about a small syntax.

MS. ROGERS: This is Brenda. There is no offline. If you open up the standard even for a technical -- I'm going to say "technical" -- technical edit, it still has to go through the full process of Commission taking proposed action, putting out for public comment, coming back to the Commission for final action, going to the JLC, you know, as appropriate, and the governor as appropriate. So it's got to go through the full process regardless of the -- minor

the change may seem.

DR. MUKHERJI: So is this a substantial change or nonsubstantial change?

MS. NAGEL: I mean, but I think Brenda's point is it doesn't matter if it's substantial or not substantial.

MS. ROGERS: Right.

MS. NAGEL: It's going to go through the same process.

MS. ROGERS: Right. And it sounds -- and I think -- and Tulika can even correct me -- but I think their interpretation of the standard, they have handled it through the form process. So having said that, I think it is more of a technical edit in nature versus a substantive change because we've made the substantive change as far as not requiring all of the individual -- right; yeah. So you could -- that's the other thing.

It could be the next time the standards get opened in its next review, it could be clarified at that point in time if it's still necessary. So I think it is. I think it's more of a clarifying, technical edit than anything because I think we're already handling it on the department side of it, I believe.

MR. POTCHEN: When is this up again?

MS. ROGERS: 2020.

MR. POTCHEN: So we can see what happens in two

years?

MS. ROGERS: Uh-huh; yeah.

DR. MUKHERJI: Is that okay with you?

MR. WALKER: I will survive.

DR. MUKHERJI: You will survive?

MR. WALKER: I ran this by some attorneys and that's why there's all the technical concern. No offense, Joe. Thank you.

DR. MUKHERJI: Thank you. Thank you very much. So do we have to vote on that or we're just --

MS. ROGERS: There's no motion, so --

MR. MITTELBRUN: Probably another two years.

DR. MUKHERJI: Okay. Very good. The next is review of commission work plan. Brenda?

MS. ROGERS: Okay. This is Brenda. You do have the draft work plan in front of you. Based on the action taken today -- all right? -- BMT services will be open just for the specific purpose of removing "stem" from the definition of BMT service and the department will bring that draft language to you for proposed action. Heart/lung and liver, no revisions needed at this time, so those standards will be moved forward for the next review period in 2021.

The same thing for MRI services, no changes at this time. The next review period is 2021. MRT, we will be seating a SAC specifically for looking at the volume and

weights only. And for psychiatric beds and services, we will be seating a SAC to look at all of the items in the department's proposed recommendation and as accepted by the Commission today. Thank you.

DR. MUKHERJI: So I'll just have one comment from the chair. We try to make this Commission as open and as transparent as we can. All the statutes are written. They're for anyone to view. When we go to a SAC process, I would encourage all of you to talk, either you -- if you are the stakeholder or there are a few different constituents, to please encourage your constituents to participate in the process.

You know, historically sometimes there's challenges just seating SAC's, but the only way we're going to be successful is if we become the "they." You know, if you don't like something, you always blame it on "they." Well, part of this process that we're trying to incur is that you can be the "they." So please encourage the people that you represent to participate. And also, I've worked with the department to try to identify consumers as well, too, so we have different groups that we try to engage as well.

So also, if you know other consumers that are interested -- and again, we just want people to participate in this process. I think it is important work we do. We do

determine public health policy for the state, and all of us in this room I think play an important part. Next, I guess, is me again. Future meeting dates --

MS. ROGERS: Whoops. We need a motion to accept the plan.

DR. MUKHERJI: Oh. I'm sorry. Motion. We need a motion to accept the work plan. I apologize.

MR. MITTELBRUN: Mittelbrun. Motion to accept the work plan as presented.

MR. HUGHES: Second.

DR. MUKHERJI: We have a motion and a second by Mr. Hughes. Any discussion? Anybody want to call to question?

MR. MITTELBRUN: Call to question.

DR. MUKHERJI: All in favor?

(All in favor)

DR. MUKHERJI: Did I do right? Okay. All right. Future meeting dates now. Okay. They're listed on the sheet. Is there anything else that people would like to talk about? All right. One last -- if I'm forgetting anything before I get to item 14? Okay. All right. We have an adjournment. Anybody want to make a motion to adjourn?

MS. GUIDO-ALLEN: So moved.

DR. MUKHERJI: So moved. Second?

MR. MITTELBRUN: Second.

DR. MUKHERJI: All in favor?

(All in favor)

DR. MUKHERJI: Thank you very much.

(Proceeding concluded at 11:52 a.m.)

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