

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

COMMISSION MEETING

BEFORE JAMES FALAHEE, CHAIRPERSON

333 South Grand Avenue, Lansing, Michigan

Thursday, March 21, 2019, 9:30 a.m.

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1                   Lansing, Michigan

2                   Thursday, March 21, 2019 - 9:32 a.m.

3                   MR. FALAHEE:  Let's call the meeting to order,  
4                   please.  Welcome to the March meeting of the CON Commission  
5                   which will also be the January meeting, too, in which the  
6                   Polar Vortex cancelled.  So we're gloing to combine the --  
7                   what would have been the January items with the March items.  
8                   So we have an agenda as you can see in the audience of 20  
9                   items and our goal is to finish as quickly as possible.  
10                  Some would like to say we should finish before the first  
11                  basketball game gets started.

12                  MR. MITTELBRUN:  Well, I think Tania will make  
13                  arrangements to put it on that screen over there  
14                  (indicating).

15                  MR. FALAHEE:  So there.  So let's -- let's get  
16                  started.  Thank you, everyone, for being here, both the  
17                  commissioners and the audience members.  Thank you very  
18                  much.  We've called the meeting to order.  We don't need any  
19                  introductions, so we'll move on next to the review of the  
20                  agenda.  That was in front of us this morning, and also came  
21                  out in online fashion late yesterday.  Does anyone have any  
22                  changes they'd like to make to the agenda?  Hearing none, I  
23                  would entertain a motion to accept the agenda as presented  
24                  before us, please.

25                  MR. MITTELBRUN:  Motion to accept, Mittelbrun.



1                   MR. FALAHEE: Okay. If we keep up this pace we'll  
2 be finished long before the basketball game begins. No, we  
3 won't. Okay. The first agenda item, and I'm going to call  
4 on Dr. Brian Kastner to come up to the podium, please, as I  
5 introduce what's going on. We've had, as you all know in  
6 the audience, a SAC on MRT issues and Dr. Kastner kindly  
7 agreed when I made the phone call to him, seems like eons  
8 ago, to chair that SAC. And this was his first experience  
9 with the -- the joy of the SAC and the joy of the CON  
10 process. So I want to begin by saying thank you very much,  
11 Dr. Kastner, for you and the other members of the SAC.  
12 Having been a member of a SAC and chair and co-chair, I know  
13 it's a lot of work, so thank you very much on behalf of all  
14 of the commission and the folks from the state as well.  
15 Thank you. I told Dr. Kastner that unlike other witnesses,  
16 he is not limited to the three minute mark. He will give a  
17 brief oral report of what occurred in the SAC and the  
18 recommendations coming out of it that are in our packet, and  
19 then we as the commissioners as always will have the right  
20 to ask Dr. Kastner any questions we may have. So with that,  
21 any questions from the commission? Okay. Dr. Kastner, the  
22 floor is yours. Thank you very much.

23                   BRIAN KASTNER, M.D.

24                   DR. BRIAN KASTNER: Thank you and thank you for  
25 the opportunity to serve on the SAC and to chair it. It was

1 a bit more work than I thought, but very rewarding and I  
2 enjoyed working with the committee and also working with the  
3 department who was very helpful with the work. So I'll  
4 start just by reading the report and then I have a few other  
5 comments that I'll share following the questions I  
6 anticipate.

7 MR. MITTELBRUN: Brian, can I just ask you to put  
8 the mic a little closer?

9 DR. BRIAN KASTNER: Certainly.

10 MR. MITTELBRUN: Thank you.

11 "The CON Commission gave two charges to the SAC:  
12 treatment weightings and volume requirements. The SAC  
13 approached the question of treatment weightings by  
14 first agreeing that weightings should reflect MRT  
15 utilization time. The SAC agreed to maintain a  
16 15-minute base unit for the equivalent treatment visit  
17 (ETV) to both preserve consistency with previous  
18 standards and to simplify evaluation of the impact of  
19 any subsequently proposed volume standards. Secondly,  
20 we conducted a survey to determine the standard or  
21 average time required to deliver treatments of varying  
22 complexity. Thereafter, the SAC revised the weightings  
23 to reflect the results of this survey. The SAC  
24 provided clarification to definitions regarding  
25 MR-guided radiotherapy and patient-specific quality



1 assurance for stereotactic procedures.

2 In discussion of volume requirements, the SAC  
3 discussed the changing practice patterns trending  
4 toward hypo-fractionated and accelerated treatment  
5 courses. This trend has lowered the logistical and  
6 financial burden on patients and payers while at the  
7 same time preserving, and even improving, quality.  
8 Stated differently, the adoption of hypo-fractionation  
9 is improving the metrics of cost, quality, and access.  
10 However, adoption of hypo-fractionation has also  
11 contributed to lower utilization of MRT units to the  
12 point that many centers were failing to meet minimum  
13 volume requirements. In consideration of the minimum  
14 volume, we observed that the current 8,000 ETV minimum  
15 assumed 8-hour-per-day of continuous treatment. While  
16 one may argue 8,000 to be a reasonable initiation  
17 volume, we felt this to be unreasonably high for a  
18 minimum volume. After thorough discussion considering  
19 cost, quality, and access, we agreed that any unit  
20 delivering at least 4,000 ETVs per year should be  
21 considered as meeting minimum volume. The SAC  
22 subsequently produced a consensus statement in this  
23 regard.

24 We also considered volume requirements for MRT  
25 replacement, initiation, and expansion. The discussion

1           regarding these volumes included express consideration  
2           of cost, quality, and access. The SAC concluded that  
3           further consideration of changes to replacement,  
4           initiation, and expansion volumes should await  
5           potential impact from implementation of our proposed  
6           changes to the weightings and minimum volume  
7           standards."

8           MR. FALAHEE: Thank you very much. Any questions  
9           from the commissioners? I have a few, but I wanted to see  
10          if anybody else wants to start off. Okay. Some questions.

11          DR. BRIAN KASTNER: Excellent.

12          MR. FALAHEE: Number one, what you did on the  
13          weightings I think that was tedious for one, laborious, but  
14          I applaud the SAC for that. I think that was very, very  
15          well done. I do have some questions about the reduction of  
16          the minimum from 8,000 to 4,000.

17                 And in doing my homework and making sure that  
18          Marcy transcribes everything properly, I went back and --  
19          when this first came out, it was back in August 30 of 2018,  
20          at a meeting there. And one of the physicians on the SAC  
21          said, "I think really we need our numbers to be 95 percent  
22          at least compliance." "If we have 30 percent or even more  
23          than 10 percent," meaning noncompliant, "that means we need  
24          to do something." "So the 4,000 is a very good start." And  
25          the physician went on to say, "The idea to make 95 percent

1 compliance in all numbers because that's the way it should  
2 be because those numbers should reflect the real life, the  
3 quality, quantity, comfort and so on." All right? And then  
4 you said, and this sounds like any one of the commissioners,  
5 "I sympathize with that. It's just not a rationale I would  
6 put before the CON because I don't think they are interested  
7 in just making sure everybody stays in business and to lower  
8 our bar so far that everybody does." Well said.

9 DR. BRIAN KASTNER: Thank you.

10 MR. FALAHEE: And that's what I'm going to ask  
11 questions about. Okay?

12 DR. BRIAN KASTNER: Excellent.

13 MR. FALAHEE: Because it goes on --

14 DR. BRIAN KASTNER: And I'm prepared to answer  
15 those questions.

16 MR. FALAHEE: Great. Thank you. And it went on  
17 at that same meeting one of the other physicians on the SAC  
18 was questioning the 4,000 and where any number should be  
19 said if it wasn't 8,000 and wanted to know what's a  
20 sufficient volume to ensure quality. And then the same  
21 physician that I quoted earlier at that same meeting said,  
22 "The lower the number the better." And then he went on to  
23 say, "The lower the number the better quality because the  
24 physician will have more time to think." That to me is not,  
25 in my opinion, a rationale because I don't want to take

1           what's 8,000 and go how far do we have to lower it to make  
2           sure that only one MRT is out of compliance? That -- to me  
3           that's lowering the curve so that we're in Lake Wobegon,  
4           everybody's above average, and everybody that passes but  
5           one. So those are my initial comments, and then I've got  
6           some other questions about the statement and the -- the  
7           consensus statement as well. So help -- help me out.

8                     DR. BRIAN KASTNER: Okay. Excellent. Well, as  
9           the chairman is aware, the chairman cannot control the  
10          statements of everybody in the committee.

11                    MR. FALAHEE: I'm very well aware.

12                    DR. BRIAN KASTNER: One too many members.  
13          Statements should not reflect the consensus thinking of the  
14          group. And there was a lot of healthy discussion regarding  
15          not just weightings and the basis for those weightings, but  
16          also consideration of the minimum. And so I'd like to  
17          crystallize some of those thoughts that -- that informed  
18          that decision and I'd like to root them in some  
19          considerations that are familiar to the Commission, the  
20          first being cost. And actually I'll step back from cost for  
21          a second just to talk about access because we would all like  
22          every citizen of Michigan to have access to an MRT unit  
23          within an easy drive of their home, but we recognize that  
24          the cost to do so may be prohibitive. And so whereas access  
25          would be plentiful if money were no object, we do have to

1 exercise some stewardship of our limited resources.

2 So in consideration of cost, I'd like to think  
3 first about the cost of initiation and how a -- a center  
4 comes to acquire an MRT after having demonstrated that they  
5 have sufficient volume to justify the acquisition of a unit.  
6 The center -- the hospital or the treatment center bears the  
7 initial cost of a linear accelerator, of the equipment  
8 itself, the installation, quality assurance, et cetera, the  
9 facility. The cost is recouped by the center through  
10 utilization of the unit. And the utilization cost is born  
11 by society, by the payers and their co-pays, by the  
12 insurance company, by society as a whole, by government  
13 through Medicare/Medicaid, et cetera. So to say it  
14 succinctly, society pays the cost of utilization whereas the  
15 centers bear the cost of initiation.

16 So increased utilization leads to increased  
17 revenue for a center, but it also leads to increased cost to  
18 the patient and to the insurance company and to society.  
19 And the committee is concerned that a high maintenance or  
20 minimum volume is promoting higher utilization and higher  
21 cost to society. And the committee does not believe that  
22 the CON would want to be in the position of promoting  
23 utilization. We're concerned that the current minimum  
24 standard is set in such a way that it's kind of a use it or  
25 lose it mentality. Utilize so that you can justify to your

1 continued existence. But, to again restate the primary  
2 conclusion to the cost consideration is that a high  
3 maintenance volume is perhaps inadvertently promoting higher  
4 utilization and higher cost to society.

5 MR. FALAHEE: This is Falahee. Let me ask, you  
6 talked -- so let's talk about utilization. Would the flip  
7 of that be, well, if we set it at 4,000, that's half of what  
8 we've got now, there are going to be linear accelerators out  
9 there that aren't very busy. And perhaps if a location has  
10 more than one linear accelerator, if we kept the numbers  
11 where they are, they could take one offline.

12 DR. BRIAN KASTNER: Yes.

13 MR. FALAHEE: All right. In health care, the  
14 phrase I use, "if you build it, they will come." Right? So  
15 I would look at utilization the other way around. If we  
16 set -- and this is just an argument, not argument, but  
17 position or thought. If we set it artificially low, would  
18 it keep some linear accelerators in business that really  
19 aren't truly "needed"?

20 DR. BRIAN KASTNER: Well, need is -- a need is  
21 defined by utilization to some extent and we're speaking to  
22 access on that point. Two responses there. One is that  
23 taking accelerators offline may very well reduce the access  
24 that we were trying to preserve. And since the main cost of  
25 installation has already been paid, the facility has paid

1 for this equipment, it is now just providing access and  
2 further costs are just variable costs associated with  
3 delivery. Another comment in terms of setting a minimum is  
4 that the minimum does not drive utilization unless the  
5 minimum is set too high. If the minimum is set high, then  
6 we are promoting utilization in order to achieve it. But if  
7 we set a minimum low, centers are not going to quit treating  
8 patients to drive towards a minimum. Thank you.

9 MR. MITTELBRUN: Mittelbrun. As somebody who pays  
10 for health care claims, I appreciate your argument about the  
11 4,000. I just always had the curiosity what was the  
12 rationale for the original number? Was it 8,000? I'm  
13 assuming there was a reason for that.

14 DR. BRIAN KASTNER: Okay. I can speak to that.

15 MR. MITTELBRUN: Okay. Thank you.

16 DR. BRIAN KASTNER: Even though we didn't argue to  
17 change the 8,000, but I can speak to that. And it's -- it's  
18 invoking this concept of the treatment unit, the ETV. 8,000  
19 ETVs is equivalent to eight hours of continuous treatment  
20 every day the clinic is open throughout the year. And so  
21 the -- I think the feeling when that 8,000 was adopted was  
22 that if you have enough patients that you can keep an  
23 accelerator busy 100 percent of the time, every day of the  
24 year, then that justifies a certificate. So I, you know,  
25 the Department can correct me if I'm wrong, but that I think

1 is the original thinking about the 8,000.

2 MR. MITTELBRUN: Thank you.

3 DR. BRIAN KASTNER: Some additional mathematics  
4 here just to describe how we got to 4,000. There's another  
5 number, and that is the expansion volume and that's 10,000  
6 currently. And thinking again in terms of hours of  
7 treatment, that would be ten hours of continuous treatment  
8 every day, 365 days a year to achieve the 10,000. And we --  
9 we felt that that number was reasonable because beyond ten  
10 hours of continuous treatment, we're really stretching the  
11 clinic day and asking patients to come at unusual hours for  
12 their treatments, sometimes for a course that is 45  
13 consecutive clinic days. And so we -- we were sensitive to  
14 the -- the impairment of access that is caused by having an  
15 expansion volume too high.

16 But when we look at that expansion volume, that is  
17 the number at which a center can be justified to get a  
18 second -- a second machine, a second accelerator. Upon  
19 getting that second accelerator, their average utilization  
20 drops from 10,000 in one down to 5,000 -- 10,000 divided by  
21 two. So we thought that that was reasonable and to be  
22 expected. If you have 10,000 units and you divide it by  
23 two, you get 5,000. Note that 5,000 is below the current  
24 minimum we have established of 8,000 and we thought it  
25 illogical for the Department to maintain a minimum that was



1 above 5,000. And then there's some other considerations  
2 I'll speak to next in regards to quality as to why we  
3 adopted the -- the 4,000. So utilization we believe should  
4 be directed by medical necessity, not driven by an effort to  
5 maintain a certification.

6 Radiation oncology is undergoing what some might  
7 consider a revolution that has a dramatic impact on  
8 utilization. Whereas previous research and technological  
9 advancement in the field has led to higher utilization,  
10 think the 8100 centigray and 45 fractions for prostate  
11 cancer. More recent data is driving the field toward lower  
12 utilization. Think 4,000 centigray and five fractions for  
13 prostate cancer. This is an --

14 MR. FALAHEE: Sorry. This is Chip. Is that what  
15 you mean by hypofractionization?

16 DR. BRIAN KASTNER: Yes.

17 MR. FALAHEE: Okay. Thank you.

18 DR. BRIAN KASTNER: Yes; yes. So a treatment, a  
19 total dose is divided into fraction and if it's delivered in  
20 fewer fractions, we call that hypofractionation.

21 MR. FALAHEE: Thank you.

22 DR. BRIAN KASTNER: Accelerated fractionation  
23 would be a variation on that. A reduction from 45 fractions  
24 down to five fractions, one-ninth, is an 89 percent  
25 reduction in the utilization of the accelerator. If a

1 department has only prostate patients, early stage, being  
2 treated nine hours a day, that the adoption of this  
3 guideline would lead to an 89 percent reduction in  
4 utilization such that they were no longer treating 9,000,  
5 but were only treating 1,000 ETVs per year. The medical  
6 necessity to treat that prostate cancer is the same. There  
7 is still an indication to treat prostrate cancer with  
8 radiation. To argue that the accelerator was no longer  
9 needed because we were only treating 1,000 and we were still  
10 treating just as many patients and hopefully curing them of  
11 their cancer.

12 Now, demanding higher utilization is counter to  
13 the scientific evidence demonstrating the equivalent  
14 benefits of hypofractionation compared to fractionation. We  
15 believe that the CON may want to encourage participation in  
16 this historic change, not discourage it through high  
17 maintenance volumes.

18 MR. FALAHEE: Thank you. Other questions from the  
19 Commission on this? I see the look on your face,  
20 Commissioner Hughes. I'm just waiting for a question.

21 MR. HUGHES: Yeah. I'm not sure how to ask it  
22 because I'm kind of struggling with this, and maybe if you  
23 can just kind of respond to my thoughts and tell me where  
24 I'm going wrong? But appreciate the work that you've put  
25 into this and obviously you know this 1,000 times better

1 than I do. But dropping it to 4,000, you know, the CON  
2 limit, it makes sure we have cost, quality, access, et  
3 cetera, but make sure Chip is referring to a study by a  
4 great university a few years ago that said "if you build it,  
5 they will come." And they tend to fill beds, fill  
6 facilities if they're there, even though that care might not  
7 be necessary. So drop it to 4,000 to me almost seems like a  
8 participation medal, but on the other hand, you're talking  
9 about putting people through just to meet the numbers. And  
10 even from a medical standpoint, you would think people  
11 wouldn't do that. But under fee for service, that's the way  
12 the model works. People are encouraged to -- to order more  
13 procedures because that's how they get paid. So I'm going  
14 back and forth between you trying to say people that do it  
15 just to meet their minimums and lowering it to 4,000, which  
16 you're going to have places maybe sitting empty that  
17 shouldn't be there and have -- are going to be out there  
18 creating overhead, and then now you're bringing up the  
19 quality issue. I certainly believe that you want to be  
20 seeing people that are doing the procedures more often  
21 because the quality is going to be better.

22 DR. BRIAN KASTNER: Excellent.

23 MR. HUGHES: So I'm -- I'm juggling all of that  
24 and I'm trying to get somewhere and I really can't. So  
25 maybe you can help me?

1 DR. BRIAN KASTNER: Sure. So if they build it,  
2 they will come and quality. I will focus on those, and then  
3 you can direct me again to others. But I think the "if they  
4 build it, they will come" concept is most relevant to  
5 initiation volumes. If a -- if a facility wants to or if a  
6 entity wants to build a treatment center, their belief is  
7 that people will come once we build it. They don't have a  
8 center yet. They want a -- they want a treatment unit.  
9 They want to -- they believe that they will draw the  
10 patients and then they will hope to utilize that to a point  
11 to justify their expense. I think that most directly  
12 applies to the initiation volume which we decided not to  
13 touch. We thought 8,000 at least was reasonable for now.  
14 There was some healthy discussion regarding the -- the  
15 capacity of conversation. The 8,000 unit that we have right  
16 now is assuming 100 percent utilization of a standard clinic  
17 day and we don't believe most centers really should or can  
18 operate continuously at 100 percent capacity. It's really  
19 not necessarily healthy for the maintenance of equipment and  
20 education, et cetera, or even access. When a department's  
21 full, it's hard to fit new people in.

22 And so there was some discussion about lowering  
23 that initiation volume, but the SAC decided at this point  
24 that we shouldn't adjust too many pieces before we see the  
25 impact in reality to the -- to the changes we've proposed.

1           So that's in regard to "if they build it, they will come."  
2           We don't think that dropping the minimum has that inverse  
3           reaction as I stated earlier. We don't think that if you  
4           lower it, people will quit treating. If they do quit  
5           treating, it's in response to the data if they reduce their  
6           numbers and we believe that improves quality and it does  
7           lower the cost to society. Again, five fractions delivered  
8           instead of 45 fractions is a great savings to the patient  
9           and to society.

10                       In regards to quality and numbers, how many cases  
11           are required for a center to maintain its competence? We  
12           believe that 4,000 easily achieves that and if you compare  
13           it to something like performing a whipple procedure, removal  
14           of a portion or all of the pancreas, we would hope that the  
15           surgeon doing that has done enough of them and continues to  
16           do enough of them, maybe 15 a year to maintain competence.  
17           And at 4,000 units, that's 16 treatments per day. So we  
18           don't believe that there's any risk of losing one's  
19           competence at 4,000. Another point in regards to 4,000, it  
20           is not the ideal volume. We're not encouraging centers to  
21           drive towards 4,000 and no center would interpret this  
22           minimum in that way. We say it's the minimum. We don't  
23           want to go below this bar, but not because we think the  
24           quality will be impaired with 4,000, but we -- we are aware  
25           that perhaps the cost of just maintaining the center may be

1 not -- those costs may not be met at some low volume. We  
2 don't know they met volumes.

3 MR. FALAHEE: Other questions from the  
4 commissioners? Commissioner Dood?

5 MR. DOOD: Thank you very much. You quote a  
6 statistic on the nationwide average of between 40 and 60  
7 percent and then you guys went with 50 percent. It sounds  
8 like it's -- it's changing the utilization right -- right  
9 now. But is Michigan sort of behind the curve? I mean, is  
10 there room to drive this down even further? Or sort of the  
11 opposite argument, why should it be as high as 4,000?  
12 Shouldn't it be 3,000 or 2500 or would it be accurate next  
13 year to push it back down a little bit more?

14 DR. BRIAN KASTNER: We may be back here, yeah,  
15 next year to refine --

16 MR. FALAHEE: Will you be the chair again?

17 DR. BRIAN KASTNER: We thought 4,000 was radical  
18 enough, a 50 percent drop from what it had been has stirred  
19 enough question that we would -- we would be afraid to drop  
20 it much further but we may be having this conversation in  
21 the future if hypofractionation continues to be the norm.

22 MR. FALAHEE: And that -- this is Falahee. This  
23 hypofractionation or however you say it, is that a growing  
24 trend? Do you see it in different modalities, not just  
25 prostate, but other --

1 DR. BRIAN KASTNER: Very much so, yes. It's also  
2 happening -- has happened in breast cancer. So breast and  
3 prostate being the two chief diseases that are treated with  
4 external beam, both of them have been affective and  
5 adequate. Lung cancer as well, treating with 6,000  
6 centigray and 30 fractions, we're now treating in three  
7 fractions in some cases. So it's -- it's, I think, here to  
8 stay because the -- the results have been really quite  
9 compelling.

10 Now if I could speak to one other possibility for  
11 the CON in the future? We think that this minimum is right  
12 for now, but another concept that the CON may give to a SAC  
13 in the future as a charge is consideration of right sizing.  
14 Considering a department that may have five accelerators  
15 now, if their utilization drops and they find that their --  
16 their average across five machines is 4,000, that it may be  
17 time to right size that department rather than replacing all  
18 five. So we didn't take that up except to address the  
19 possibility at this SAC, but I think it's a reasonable  
20 consideration in the future.

21 MR. FALAHEE: Falahee. I agree with that comment.  
22 Down the road I think with hypofractionation we're going to  
23 see that inevitably happen. So we'll see -- we'll see then  
24 where it takes us. Other questions of Dr. Kastner? Well,  
25 again, thank you very much. Thank you for your service,

1 thank you for standing there and answering our questions,  
2 and at least helping this person understand it better.

3 Thank you.

4 DR. BRIAN KASTNER: Thank you.

5 MR. FALAHEE: Thank you.

6 DR. BRIAN KASTNER: Thanks.

7 MR. FALAHEE: So I will turn to Beth. Brenda is  
8 not -- I'm sorry, I should have mentioned. Brenda is not  
9 here due to a family matter. We talked to Brenda yesterday.  
10 Beth and I were on a call you'll hear about later, but she  
11 could not be here. So I will turn to Beth to lay out what  
12 the options are for us with the SAC recommendation.

13 MS. NAGEL: Okay. Good morning. This is Beth.  
14 If the Commission chooses to take proposed action on the  
15 language, the draft would then move forward to a public  
16 hearing and the Joint Legislative Committee.

17 MR. FALAHEE: So if we approve it, that's where it  
18 will go. It will go out to public hearing. This is not for  
19 final approval at this point. This is just to send it out  
20 for public hearing and to the Joint Legislative Committee.  
21 And if we wanted, we could say we would encourage anyone  
22 that has comment about any of the SAC recommendations,  
23 including the 4,000, to make those comments during the  
24 public comment period. So I would -- any discussion amongst  
25 the commissioners? If not, I'd entertain a motion.



1                   MR. MITTELBRUN: Mittelbrun. I'll make the motion  
2 to move forward with the public hearing and the Legislative  
3 Committee.

4                   DR. GARDNER: Gardner. Second.

5                   MR. FALAHEE: I have a motion on the floor. Any  
6 discussion? I would just like to encourage anyone that is  
7 making a public comment, if you want to comment about the  
8 4,000 new minimum, please do so. You heard the very good  
9 answers and questions, but if you want to make a comment, I  
10 would encourage you to do so. Any other discussion about  
11 the motion on the floor?

12                   MS. BROOKES-WILLIAMS: Commissioner  
13 Brooks-Williams. Could you repeat the motion?

14                   MR. FALAHEE: The motion is that the Commission  
15 would approve the language of the SAC and send it out to  
16 public comment, move forward to a public hearing, and then  
17 also send it as we're required to do to the Joint  
18 Legislative Committee. Any other discussion? Seeing none,  
19 all in favor of the motion please say "aye."

20                   ALL: Aye.

21                   MR. FALAHEE: Anyone opposed? The motion carries.

22                   (Whereupon motion passed at 10:03 a.m.)

23                   MR. FALAHEE: Dr. Kastner, thank you. You're  
24 welcome to stay if you want. It's scintillating stuff, but  
25 if you don't want that, go ahead. Thank you. All right.

1 Next item agenda is -- oh, I'm sorry. Wait a minute. Let's  
2 see. My fault. We have one public comment. We had one  
3 comment that I should have taken, I'm sorry, from Tracey  
4 Dietz on behalf of Henry Ford Health System talking about  
5 the MRT. And if I usurped it, I apologize.

6 MS. TRACEY DIETZ: No, that's okay.

7 MR. FALAHEE: You're all set?

8 MS. TRACEY DIETZ: Because of the vote, you can go  
9 ahead, yeah.

10 MR. FALAHEE: Okay. Thank you. We also had  
11 another comment from David Walker on behalf of Spectrum  
12 supporting the recommendation and David did not want to  
13 speak. So, mindful of the agenda item so thank you. All  
14 right. Sorry about that. Let's move forward then to  
15 Psychiatric Beds and Services. Beth, I will turn it over to  
16 you to queue up this.

17 MS. NAGEL: Sure. The Commission took proposed  
18 action on the draft language that is in your packet at the  
19 December 6, 2018 meeting. A hearing was held on February 6,  
20 2019. Written testimony was received from 17 organizations.  
21 The testimony can be found in your binder along with a memo  
22 providing an overview of the testimony. The Department  
23 supports the language as presented. If the Commission  
24 chooses to take final action, this language will be  
25 forwarded to the Joint Legislative Committee and the

1 Governor for the 45-day review period.

2 MR. FALAHEE: Any questions of Beth at this point?

3 Okay. I don't -- I've learned my lesson. I don't have any  
4 cards on this agenda item. Is there anyone that would like  
5 to make a public comment about the Psych Beds and Services  
6 agenda item? Okay. Seeing none, as we heard Beth say, the  
7 Department supports the language as presented and if we  
8 choose to take final action -- this is up for final action  
9 here -- the language will be forwarded to the JLC and the  
10 Governor for the usual 45-day review. Any discussion  
11 amongst the Commissioners? Any questions?

12 MS. BROOKES-WILLIAMS: Commissioner  
13 Brooks-Williams. I don't know which one works. Can you  
14 hear me? No? I can --

15 MR. MITTELBRUN: That's good. You're good.

16 MS. BROOKES-WILLIAMS: You're good? Okay. I'm  
17 sorry. Commissioner Brooks-Williams. My question was  
18 just -- so no question about the language as it's proposed.  
19 But I had asked at the last Commission meeting to just have  
20 the reeducation around what are the requirements for  
21 accepting patient populations. And so my question was  
22 really around how is that audited to confirm? I know that  
23 the standard would suggest that there's a 50 percent  
24 requirement of -- and I want to say it's indigent, I might  
25 get the language wrong -- but, yeah, public -- you know,

1 public constituents. But how is that ultimately audited and  
2 how would we be able to reflect and confirm that for anyone  
3 who, you know, was to benefit from the expanded beds, that  
4 they were living to the spirit of that intent?

5 MS. NAGEL: Yeah; sure. This is Beth. All  
6 psychiatric inpatient units, regardless of whether they  
7 apply under this language or any other language in the  
8 standard, must meet 50 percent public patient, that's  
9 defined as Medicaid. It's -- it's defined pretty broadly,  
10 "Medicaid, uninsured or those seeking involuntary  
11 commitment." And so we ask every year on our CON annual  
12 survey how many of those patients at each facility and we do  
13 go through and run compliance checks on those that come back  
14 less than 50 percent.

15 MS. BROOKES-WILLIAMS: And if an organization  
16 doesn't meet the 50 percent threshold, what is the  
17 consequence?

18 MS. NAGEL: So the compliance actions are broadly  
19 defined in the statute as under the purview of the  
20 Department. And so usually what we do is ask a lot of  
21 questions, ask for some documentation. It could range from  
22 a corrective action plan to a civil fine to expiring the  
23 Certificate of Need for that service.

24 MS. BROOKES-WILLIAMS: All right. Thank you.

25 MR. FALAHEE: Thank you, Denise. Other -- other

1 questions? Hearing none, I'd entertain a motion, please.

2 MR. MITTELBRUN: Mittelbrun. I'll make the motion  
3 to move forward with final action and forward the  
4 appropriate information to the JLC and the Governor for the  
5 45-day review period.

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

7 MR. FALAHEE: We have a motion and a second. Any  
8 discussion? Okay. All those in favor of the motion please  
9 say "aye."

10 ALL: Aye.

11 MR. FALAHEE: Opposed? That motion carries.

12 (Whereupon motion passed at 10:08 a.m.)

13 MR. FALAHEE: Thank you very much everyone. I've  
14 had many people ask me what the Commission was going to do  
15 on these standards as recently as last week and I said -- in  
16 fact, one of the legislators asked me, "What are you going  
17 to do about that?" I said, "See -- see you next Thursday."  
18 So, moving us forward. Okay. We'll now pretend we're in  
19 January and it's 30 below and we'll move to those items that  
20 were going to be covered in January. And I'll start --  
21 Beth, this is when I need your help.

22 MS. NAGEL: Yes.

23 MR. FALAHEE: So go ahead. We'll start with Air  
24 Ambulance, please.

25 MS. NAGEL: And forgive me. This is where I would

1 need Brenda's help. So items seven through 11 in your -- on  
2 the agenda are part of the public comment period and the  
3 special Commission meeting that is typically held in  
4 January. Just for a review, a public comment period was  
5 held on October 5th through October 19th of 2018. This is  
6 the annual public comment period held to determine what, if  
7 any, changes are needed to make in each standard and the  
8 need for a continued regulation or deregulation of each  
9 standard scheduled for review in 2019. The recommendations  
10 being forwarded to the Commission included analysis of the  
11 input that was provided and the Department's recommendation.  
12 These are included in your electronic binder.

13 Starting with number seven which is Air Ambulance  
14 Service.

15 "The Department recommends that Air Ambulance  
16 Service should continue to be regulated until the  
17 Department's Emergency Medical Service Licensing can  
18 update its rules to include Air Ambulance specific  
19 requirements."

20 This has been a long running issue where the  
21 Commission has looked at this specific standard several  
22 times. There is an EMS licensing that is also part of the  
23 Department of Health and Human Services that has some  
24 authority over air ambulances, but not the full scope that  
25 is included in the Certificate of Need. And so they are

1 currently working through a very lengthy and tedious process  
2 to update their licensing rules. And so the Department is  
3 recommending that until such time that those rules are in  
4 effect and being utilized, that Certificate of Need should  
5 continue to regulate Air Ambulance Services under  
6 Certificate of Need.

7 MR. FALAHEE: This is Falahee. As Beth said, this  
8 has been an ongoing constant development. We've got issues  
9 or rules from the FAA. We've got state rules and we've  
10 always deferred to those and thankfully the language is  
11 being drafted, so it shouldn't be too much longer before we  
12 see the final language. So as I understand it, Beth, with  
13 the recommendation that they continue to be regulated, do  
14 you need a motion where we would agree or disagree with that  
15 or we would just let it go?

16 MS. NAGEL: Carl?

17 MR. HAMMAKER: Motion not to.

18 MS. NAGEL: To not make judgment? Okay. A  
19 motion.

20 MR. FALAHEE: Okay. All right. Advice of  
21 counsel. Thank you, Carl. If we choose as a Commission not  
22 to make any changes, we should have a motion to that effect.  
23 But before that motion, any discussion, any questions about  
24 these Air Ambulance Standards?

25 MR. HUGHES: Just a quick curiosity question. If

1           you don't have the data now, no worries. But what do we  
2           have here, like, 11 or 12 in Michigan currently?

3                   MS. NAGEL: Oh, that's a good question. Tulika,  
4           do you know off the top of your head the number?

5                   MS. BHATTACHARYA: Sounds right, but I don't know  
6           exactly. I can give you the number.

7                   MR. HUGHES: Yeah. When is the last time you had  
8           somebody requesting a new one?

9                   MS. BHATTACHARYA: Recently, last year.

10                  MR. HUGHES: Was it a whole new place or somebody  
11          upgrading?

12                  MS. BHATTACHARYA: No. I believe it was  
13          initiation of a new service, but again I can give you the  
14          information.

15                  MR. FALAHEE: Any more questions? Commissioner  
16          Hughes, you all set?

17                  MR. HUGHES: I just -- bouncing numbers back and  
18          forth in my head between Air Ambulance costs and the  
19          standard and how many people who want air that should be on  
20          standard and just thinking about that. That's all.

21                  DR. GARDNER: A clarification? Gardner. So  
22          currently other than this Commission there will be nobody  
23          that's going to be regulating these -- they're working  
24          towards that goal, but there's nothing in place currently?

25                  MR. FALAHEE: Well, the FAA has their own rules as



1 well.

2 DR. GARDNER: Right.

3 MR. FALAHEE: And we acted in -- let's say, in  
4 concert with those and being mindful of those and then  
5 relying on what the State Department is coming up with as  
6 well.

7 MS. GUIDO-ALLEN: The MCA also would be the  
8 licensee for the air ambulances.

9 DR. GARDNER: Correct.

10 MR. FALAHEE: Other questions? So I would  
11 entertain a motion if we want to continue the standards as  
12 is or an alternative motion if someone would like to make  
13 it.

14 MS. BROOKES-WILLIAMS: Commissioner  
15 Brooks-Williams. I move that we continue the standards as  
16 is and follow the recommendation of the Department.

17 MR. FALAHEE: Is there a support to that motion?

18 MR. HUGHES: Second. Hughes.

19 MR. FALAHEE: Thank you. Any discussion?

20 MR. DOOD: Is there any public comment here?

21 MR. FALAHEE: No. Carl, thank you for reminding  
22 me to look at the cards. I've got them in order now. So  
23 thank you, Carl.

24 MR. HAMMAKER: You've already asked me that  
25 question. Thank you very much.

1                   MR. FALAHEE: Okay. No discussion, no questions.  
2 All in favor of the motion please say "aye."

3                   ALL: Aye.

4                   MR. FALAHEE: Opposed? That motion carries.

5                   (Whereupon motion passed at 10:14 a.m.)

6                   MR. FALAHEE: Thank you very much. Next one is  
7 CT and once Beth breaks it down for us, we do have at least  
8 one card on CT. So, Beth?

9                   MS. NAGEL: Sure. Again, in your packet you have  
10 a recommendation from the Department to continue regulating  
11 CT services. There were several public  
12 comments/recommendations that came in. The Department is  
13 recommending review of one which is a review of the  
14 maintenance volume requirements. In the past the -- there  
15 was a work group that looked at the weighting of the  
16 procedures, but did not change the volume requirements. And  
17 we think it's appropriate now, that enough time has gone by  
18 that we would have good enough data to look at those volume  
19 requirement. And so we are recommending a work group to  
20 review those and bring back a recommendation to the  
21 Commission.

22                   MR. FALAHEE: So I have one comment, David Bloom  
23 from Michigan Medicine, please. Good morning. Thank you.  
24 Yes, please; yes. And, Dr. Bloom, you may have heard, you  
25 may have walked in later. Witnesses have -- and I'm sure

1 Steve has already told you -- three -- three minutes. And  
2 we might give you three minutes and five seconds because  
3 you're also from a great university.

4 DAVID BLOOM, M.D.

5 DR. DAVID BLOOM: I appreciate that. Thank you,  
6 Chairperson Falahee, and thank you to the Commission for  
7 letting me speak today. My name is David Bloom. I'm a  
8 pediatric radiologist at C.S. Mott Childrens Hospital and at  
9 Michigan Medicine. And I'm here today to offer for  
10 consideration or revision to the CON standards for pediatric  
11 CT services.

12 The University of Michigan Health System supports  
13 the continued regulation of this covered service. However,  
14 Michigan strongly believes that definitional revision should  
15 be considered to more accurately clarify and classify  
16 pediatric patients.

17 Under the current CON standards, a pediatric  
18 patient is defined as any patient less than 18 years of age  
19 and a dedicated pediatric CT is a fixed CT scanner on which  
20 at least 70 percent of the CT procedures are performed on  
21 patients under age 18. UMHS suggests increasing the age  
22 limit through 21 years of age, and I will clarify that in a  
23 second. This change should be considered as it reflects the  
24 current practice of pediatric medicine. This change is  
25 critical to assuring proper health care for the entire

1 pediatric patient population. In 1988, the American Academy  
2 of Pediatrics supported this change and in a follow-up  
3 editorial in 2017, broadened that language to emphasize the  
4 importance of caring for patients 21 and under.

5 On September 1st, 2017, Michigan Medicine  
6 redefined pediatric as including all patients under their  
7 21st birthday. Patients who are 18 to 20 years of age who  
8 are new to the system are now preferentially directed to,  
9 seen, and cared for within the pediatric hospital and within  
10 pediatric clinics. This includes the majority of our 18- to  
11 20-year-olds who are local and new to our emergency services  
12 at the University of Michigan, which is the largest number  
13 of our undergraduates. To provide the highest quality,  
14 safety, and most efficient imaging for these patients,  
15 they -- we would like for them to undergo imaging studies in  
16 the pediatric environment. That's where they are and that's  
17 where the pediatric providers are.

18 To redefine pediatric as including through age 21  
19 will modernize the guidelines to reflect the current  
20 practice of pediatric and young adult medicine and ensure  
21 that pediatric patients can obtain imaging with CT proximate  
22 with their health care environment, their providers, and  
23 afford them efficient and high quality health care. We  
24 would hope that you would take this under consideration. I  
25 would like to point out during my time at Michigan Medicine

1 the volume of patients coming to our emergency room 18 to 20  
2 has increased. We are now seeing patients, fortunately  
3 through our new and advanced health care, seeing more  
4 patients surviving longer, so adult congenital heart  
5 disease, cystic fibrosis patients, oncologic patients who  
6 have long-term care. These are patients over the age of 18,  
7 quite sometimes older. And that a 70 percent cutoff will  
8 affect our numbers based on how we at C.S. Mott and other  
9 children's hospitals around the country are starting to care  
10 for our patients long-term. So thank you.

11 MR. FALAHEE: All right. Thank you. Any  
12 questions for Dr. Bloom? I'll start off. So I know there's  
13 the 70 percent threshold let's call it. Do you bump up  
14 against that now with the current definition?

15 DR. DAVID BLOOM: I don't have the exact numbers,  
16 but I do know that we anticipate it becoming an issue as our  
17 patient populations are growing and as we're starting to see  
18 more adult patients, young adult patients coming through our  
19 clinics as -- the clinics that I mentioned, just to name a  
20 few. There are even others, for example, gastroenterology  
21 clinic with patients with inflammatory bowel disease. So  
22 we're seeing patients who are older and so we anticipate  
23 with the needs for CT imaging that for our cystic fibrosis  
24 patients for a CT chest, for the inflammatory bowel patients  
25 who cannot undergo MRI and may need CT enterography, for our

1 trauma patients 18 to 20 coming in through our emergency  
2 services, that it will potentially affect that 70 percent  
3 for us to stay compliant with the CON.

4 MR. FALAHEE: And then last question from me is --  
5 this is Falahee. You talked about raising the age and you  
6 referenced the American Academy of Pediatrics and I think  
7 you said 1988 they made the recommendation?

8 DR. DAVID BLOOM: Yes, they did.

9 MR. FALAHEE: Is it generally accepted in the  
10 community or in the pediatric medical community that that's  
11 the appropriate age, or are some people saying no, keep it  
12 at 18?

13 DR. DAVID BLOOM: I think you'll find various  
14 opinions. I think the general consensus is to keep -- to  
15 have it at 21 years of age and under. Reason that I can  
16 sort of extrapolate that is that most of the large  
17 children's hospitals in the country have adopted up to that  
18 age 21 as well and they will usually capture a large  
19 referral service area for primary pediatricians. So I think  
20 we can infer that that seems to be the majority of  
21 pediatricians would agree with the AAP statement. And  
22 they -- again, they made a revision to their statement in  
23 2017 that sort of even went further. Said that it really,  
24 shouldn't really be regulated at all and, again, maybe it  
25 should be how the patient feels and the doctor-patient

1 relationship and how it drives that. If you are at 12 years  
2 old first diagnosed with cystic fibrosis but are doing well  
3 with advanced therapies, wouldn't you want to continue with  
4 your pediatric pulmonologist who is qualified to handle  
5 all -- many ages? So I think that's where it's driven. I  
6 have not heard any pushback personally for imaging services  
7 as a radiologist where I've been told for a 20-year-old  
8 patient I would prefer to have them done at the University  
9 Hospital.

10 MR. FALAHEE: Thank you very much. Other  
11 questions?

12 DR. GARDNER: Question. Gardner. Do you -- is  
13 that when you guys sign over patients at 21? You transfer  
14 them to the adult center?

15 DR. DAVID BLOOM: Yes, that is correct. Some  
16 patients may prefer to stay with their pediatric provider,  
17 especially a pediatric specialist, and so that can be up to  
18 them. And again that potentially could affect our numbers  
19 long term as well, but we're concerned about the 70 percent  
20 at this point, just with the changing demographics of our  
21 patient population and how other children's hospitals are  
22 proceeding.

23 MS. BROOKES-WILLIAMS: Commissioner  
24 Brooks-Williams. Maybe this is a question for the  
25 Department so I make sure I'm understanding. So the

1 threshold of 70 percent -- right? -- and you explained it to  
2 say that the population -- there's not a prohibition for the  
3 18 to 21 population as long as the 70 percent is achieved.  
4 I guess my question would be given what we've heard, if, in  
5 fact, that variance is there and it's less than 70 percent,  
6 again, just tell me what the ramifications are for those  
7 that have the dedicated pediatric CT.

8 MS. NAGEL: Yes. There are two dedicated  
9 pediatric CTs in Michigan. And we would look at their  
10 volumes and then we would open -- if they were less than, or  
11 over 70 percent pediatric, we would take compliance action.  
12 Again, that's broadly defined in the statute. The  
13 Department can investigate as per plan of correction, civil  
14 fine, all the way up to expiring the Certificate of Need.

15 MS. BROOKES-WILLIAMS: Thank you.

16 MR. FALAHEE: Don't leave yet. There may be more  
17 questions. Thank you. I have a question for Beth. Given  
18 Dr. Bloom's comments, would it be possible to ask the work  
19 group to look at the issue identified by the University of  
20 Michigan Health System either -- I guess there's two ways to  
21 look at it, three way: Leave it as it is, increase the age,  
22 or increase the 70.

23 MS. NAGEL: Yeah.

24 MR. FALAHEE: Would it possible if the Commission  
25 agrees that that was something the Commission wanted to look



1 at, that we could add that to what the work group is looking  
2 at?

3 MS. NAGEL: Yes; absolutely. I would just add one  
4 thing. It's the Department's perspective that changing the  
5 definition of pediatric in this standard would be -- have  
6 far reaching ramifications for our other standards. We are  
7 not opposed to making specific changes to the definition of  
8 what a dedicated pediatric CT is, but changing the  
9 definition broadly, we very much are against that. And that  
10 came up I think last year in the MRI standards, same issue,  
11 we had the same position. We do not think the definition of  
12 pediatric should be changed, but if you want to alter what a  
13 pediatric dedicated scanner is, I think that's an  
14 appropriate thing for the work group to look at.

15 MR. DOOD: Commissioner Dood. I think you'd be  
16 looking, Dr. Bloom, for a reduction in the 70 percent, not  
17 an increase?

18 DR. DAVID BLOOM: Correct; correct.

19 MR. DOOD: What would -- if that were the approach  
20 or recommendation of a SAC, what -- what would that number  
21 need to look like for you guys to feel comfortable?

22 DR. DAVID BLOOM: I'd have to go back and look at  
23 the numbers. And so if there is a work group created, we  
24 would be more than happy to furnish those numbers to you.  
25 My -- my guess would be more towards a 60/40 position. I

1 think most of our patients are still under 18 years of age.  
2 There's no question, you know, especially when we take into  
3 account our large NICU, PICU, it's for the most part, and  
4 our outpatient surgical procedures. I would still say  
5 it's -- the majority are still going to be under 18. But I  
6 think 60/40 might allow us to increase that age. But I'd  
7 have to go back and look at the numbers. I don't have those  
8 specific numbers, but I would be more than happy to have  
9 myself and Michigan Medicine provide those to you if there's  
10 a work group created for that, or at least advance this  
11 charge.

12 MR. DOOD: A follow-up question for Beth. Would  
13 the Department object to reviewing what percentage this  
14 should be going forward?

15 MS. NAGEL: No, we would not object to that.

16 MR. FALAHEE: Other questions? I have one more to  
17 comment, but I want to make sure. Dr. Bloom, thank you very  
18 much. And knowing Steve, he'll have those numbers before  
19 the day is out.

20 DR. DAVID BLOOM: That's what I was hopeful.

21 MR. FALAHEE: Thank you very much.

22 DR. DAVID BLOOM: No, thank you for allowing me to  
23 speak to you today. I really appreciate it. Thank you.

24 MR. FALAHEE: Thank you. Next comment we have is  
25 Patrick O'Donovan from Beaumont. There you are. While

1 Patrick is walking up, does anyone else have any public  
2 comments about this issue? Thank you. Patrick?

3 PATRICK O'DONOVAN

4 MR. PATRICK O'DONOVAN: Good morning. My name is  
5 Patrick O'Donovan from Beaumont Health. We had made a  
6 recommendation during the comment period to look at --  
7 there's a current requirement -- current standard that a  
8 hospital with a emergency department with a CT scanner, the  
9 first CT scanner is exempt from volume requirements and we  
10 had suggested that that exemption be extended to  
11 freestanding emergency departments. I see that there's  
12 going to be, or at least the Department is recommending a  
13 work group that's going to look at maintenance volumes,  
14 perhaps it could be covered within that. But if that issue  
15 could be added to the work group, we would appreciate it.  
16 Emergency care is by definition unscheduled. But if you are  
17 providing emergency services, you should have available CT  
18 services based on quality of care. So we would ask that  
19 that issue be added if you could. Thank you.

20 MR. FALAHEE: Any questions for Patrick? I have  
21 one, Patrick. Just freestanding EDs, how many are there, do  
22 you know?

23 MR. PATRICK O'DONOVAN: In the state?

24 MR. FALAHEE: Yeah.

25 MR. PATRICK O'DONOVAN: I'm not sure. Beaumont

1 has one. I don't think there is a lot. The Department may  
2 know. I don't know, maybe ten. I don't know how many  
3 exactly.

4 MR. FALAHEE: I just know the Joint Commission --  
5 the general counsel of the Joint Commission has said that  
6 where freestanding EDs are located is very much dependent on  
7 the CMS region you're in. In region five, the region that  
8 we're in, is very, very strict on what a freestanding ED can  
9 be and what you can have to make a freestanding ED. But if  
10 you go to Florida, they're all over the place. So it's very  
11 much dependent not so much on state rules alone, but the  
12 region that you are within CMS and our region five is very  
13 tough on this issue. That's why I asked. Just curious.  
14 Any question -- other questions of Patrick? Let me turn to  
15 Beth then, Patrick, while you're still up there.

16 MR. PATRICK O'DONOVAN: Thank you.

17 MR. FALAHEE: So following along with Dr. Bloom,  
18 is this something that could be added if the Commission  
19 sought fit to look at it in the work group?

20 MS. NAGEL: Yes.

21 MR. FALAHEE: Okay. Thank you. All right. Thank  
22 you very much.

23 MR. PATRICK O'DONOVAN: Thank you.

24 MR. FALAHEE: So -- this is Falahee. To review,  
25 the Department is recommending that the CT Scanner Services

1 should continue to be regulated but a work group should be  
2 formed at least to look at the maintenance volume, and other  
3 issues as identified either by the Commission or if you see  
4 in -- in the description in front of you, if a work group is  
5 approved by the Commission, a written charge needs to be  
6 drafted and voted on by the Commission, or the Commission  
7 could instruct the chairperson and a vice-chairperson to  
8 write the charge consistent with the language adopted by the  
9 Commission and then the chair and vice-chair would appoint  
10 the chair for the work group and we would move forward from  
11 there. So those are the options on the table for us. Any  
12 questions from the commissioners before we have any motion  
13 or vote? Okay. Anyone want to entertain or make a motion  
14 about this, please?

15 MS. BROOKES-WILLIAMS: Commissioner

16 Brooks-Williams. I move that we form a CT standard work  
17 group that will include the recommendations from the  
18 Department and add to it the review of the pediatric  
19 definition for CT scanners and allow the chair to add  
20 additional areas of review as deemed appropriate.

21 MR. FALAHEE: Is there support for that motion?

22 MR. MITTELBRUN: Mittelbrun. Support.

23 MR. FALAHEE: Let me ask Commissioner Williams  
24 before -- this is Falahee -- before a support. Would you  
25 intend to also include the issue that Mr. O'Donovan cited

1 about potential CT exemptions for freestanding emergency  
2 departments?

3 MS. BROOKES-WILLIAMS: Yes.

4 MR. FALAHEE: Okay. Thank you. Any support for  
5 the motion?

6 MS. LALONDE: Lalonde. Support.

7 MR. FALAHEE: Okay. Lalonde supports.

8 Discussion?

9 MR. DOOD: Just to clarify and I got a little lost  
10 on it, we talked about the percentage being an important  
11 number, and we talked about the definition throughout all  
12 the CON centers being very problematic and, of course, this  
13 advisory committee wouldn't have that scope. But are --  
14 when you mentioned getting into the definition, you're  
15 talking about the definition Beth mentioned of what this  
16 means within this particular context?

17 MS. BROOKES-WILLIAMS: Yes. Brooks-Williams. So,  
18 right. What I -- what I was suggesting is to not focus on  
19 the threshold of 70 percent, but to look at the definition  
20 specifically for pediatric CTs, so the two that are  
21 designated in the state as opposed to the broad definition  
22 that would affect all of the CONs.

23 MR. FALAHEE: Other discussion or questions? I  
24 have one question to Commissioner Brooks-Williams. We have  
25 the 70 percent now. Your motion would not include the

1 potential to look at making it 60/40 or 65/35?

2 MS. BROOKES-WILLIAMS: I believe if the chair  
3 decided that he wanted to expand it to include that, I would  
4 be very supportive.

5 MR. FALAHEE: Okay. Thank you. Any other  
6 questions? Okay. We have a motion and support. All in  
7 favor of the motion please say "aye."

8 ALL: Aye.

9 MR. FALAHEE: All opposed? Great. That motion  
10 carries. Thank you very much.

11 (Whereupon motion passed at 10:33 a.m.)

12 MR. FALAHEE: All right. We'll move on.

13 MS. NAGEL: Okay. All right. The next item is  
14 Neonatal Intensive Care Unit Services along with the Special  
15 Newborn Nursing Services which we call Special Care  
16 Nurseries in the standard. The Department is recommending  
17 continued regulation. We are also recommending that the  
18 Commission form a Standard Advisory Committee to make  
19 recommendations regarding specific issues that came in  
20 through the public comment. Specifically, should high flow  
21 nasal cannula treatment and/or neonatal abstinence syndrome  
22 be included as an accepted service for special care  
23 nurseries? We are also asking that the SAC look at some of  
24 the requirements and project delivery requirements on  
25 essentially what personnel needs to be on staff in a NICU

1 and consider if telemedicine can be used in some of those  
2 cases. We are also asking that the SAC review the current  
3 NICU occupancy rates across the state to see if there are  
4 any changes that need to be made to the methodology, as well  
5 as look at if there needs to be an exception for rural or  
6 micro counties that -- in the number of beds that need to be  
7 a part of the NICU. And then, finally, we are asking for a  
8 review of the definition of NICU to make sure that it is  
9 still accurate.

10 MR. FALAHEE: Thank you, Beth. We have a couple  
11 public comments so far. But before we do that, any  
12 questions of Beth of what she's laid out for us? Okay.  
13 Great. Then let's move on to public comment. From Henry  
14 Ford Health System, thank you Dr. E. I apologize. The  
15 card, I need to say -- thank you -- has Dr. E's name, but in  
16 parentheses "Dr. E," so thank you very much.

17 SUDHAKAR EZHUTHACHAN, M.D.

18 DR. SUDHAKAR EZHUTHACHAN: I prefer you not go  
19 through all the alphabets in my name. I'm grateful for the  
20 opportunity to speak here and we actually have for the Henry  
21 Ford Health System, its NICU and three special care  
22 nurseries, we would like two items to be included in the SAC  
23 charge. And one of them -- in fact, both of them are  
24 primary to allow us to keep appropriate babies well within  
25 the scope of the CON guidelines, at their mother's place so



1 that we don't provide maternal-child separation. The two  
2 issues are this. One of them I think you're addressing, but  
3 we only ask you to consider that on occasion we may make  
4 every effort to transfer a baby who requires specialty care,  
5 but unfortunately some circumstances don't permit an  
6 instantaneous manufacturing industry finished product to be  
7 transferred. We often are in the situation where parents  
8 are trying to decide where they want their baby to go and  
9 respecting that, sometimes the decision is delayed, not  
10 intentionally by our transport services. Sometimes  
11 ambulances are not available and sometimes the receiving  
12 hospital or the hospital that the parents chose after they  
13 have discussion, they are not open to transfer for whatever  
14 reasons they might be. So sometimes this time frame of  
15 exactly 24 hours is often not meetable. We will make every  
16 effort ahead of time, and as all of you will know, babies  
17 behave differently at different times and our expectations  
18 are often not met when we expect them to improve wonderfully  
19 and progressively so that parents can also be happy. It  
20 doesn't happen that way. So we want you to please consider  
21 that when you make your assessments.

22 The second request, once again from the standpoint  
23 of trying not to separate babies who are brief feeded, and  
24 then having to transfer them back to their mother, the  
25 hospital their mom has delivered. And this is in relation

1 to the provision of TPN, that is Total Parenteral Nutrition.  
2 In the past, each individual unit used to formulate and  
3 calculate and prepare these solutions for baby and available  
4 to purchase. In fact, all units, especially K units, for  
5 instance, after having identified where exactly this has to  
6 go.

7 MR. FALAHEE: If you can hold on for a second? We  
8 want every word you're saying to be transcribed, so we'll  
9 have to wait for the microphone to get back up there.

10 DR. SUDHAKAR EZHUTHACHAN: I have got a bad habit  
11 with my hands.

12 MR. FALAHEE: Okay. Thank you.

13 DR. SUDHAKAR EZHUTHACHAN: Yeah. So if we are  
14 permitted to provide a brief duration of nutrition which is  
15 actually mandated in today's science, in other words, the  
16 antigen nutrition that the mother is providing through the  
17 placenta, it does immediately stop as soon as the blood to  
18 the baby is -- but in a specialty care setting, we should  
19 start TPN on these babies, not depriving them for more than  
20 a couple of hours until we can start the TPN. On the other  
21 hand, if a baby who is born at 32 and one week and is 1560  
22 gram, we cannot achieve the nutritional level that we need  
23 for several days. And in some babies who are back and forth  
24 with their feeding, it may take longer.

25 MR. FALAHEE: Thank you. Your time is up.

1 Anything you'd like to say to sum up?

2 DR. SUDHAKAR EZHUTHACHAN: I -- I would say that  
3 these two would help us keep mothers and babies together,  
4 avoid transfer, and very minimal number of babies would be  
5 affected insofar as the issue is concerned.

6 MR. FALAHEE: Thank you, Dr. E.

7 DR. SUDHAKAR EZHUTHACHAN: Thank you.

8 MR. FALAHEE: Don't leave. We may have some  
9 questions for you.

10 DR. SUDHAKAR EZHUTHACHAN: Oh, sure.

11 MR. FALAHEE: Any questions? Okay. Thank you  
12 very much.

13 DR. SUDHAKAR EZHUTHACHAN: Thank you.

14 MR. FALAHEE: We have one other public comment  
15 card from Sparrow Health System, Dr. Karna.

16 MARLENA HENDERSHOT

17 MS. MARLENA HENDERSHOT: I am not Dr. Karna.  
18 Unfortunately, if she had spoken to you, and be able to make  
19 it, but the agenda is moving a little quickly today. Good  
20 morning. My name is Marlena Hendershot. I'm with Sparrow  
21 Health System. Dr. Karna is one of our top neonatologists.  
22 She was hoping to come, but I will read her statement in her  
23 absence.

24 "Thank you for this opportunity to provide  
25 comments regarding Certificate of Need Review Standards

1 for NICU and SCN Services. You will find a detailed  
2 comment letter in your packet but to summarize, Sparrow  
3 Health System feels strongly that allowing Special Care  
4 Nurseries to perform treatments outlined in many of the  
5 public comment letters would be detrimental to the  
6 smallest and most fragile of our patients.

7 Sparrow Health System is licensed for 33 bassinets  
8 at our Lansing hospital. Babies come to Sparrow with  
9 very special needs and unfortunately these needs are  
10 sometimes greater if facilities in which these babies  
11 are born do not have the proper resources to care for  
12 them.

13 We support the department's recommendations to be  
14 consistent with AAP standards as they relate to Medical  
15 Vents and TPN.

16 We also support the department's recommendation of  
17 the formation of a SAC to review the current standards  
18 for NICU and SCN based on comment letters received."

19 Again, thank you for the opportunity to provide  
20 this statement. I will try to answer any questions that you  
21 have.

22 MR. FALAHEE: Thank you. Any soft questions?

23 MS. MARLENA HENDERSHOT: Thank you.

24 MR. FALAHEE: All right. Thank you very much.

25 MS. MARLENA HENDERSHOT: Thank you very much.

1                   MR. FALAHEE: Appreciate it. So Commission  
2 discussion. I think Beth laid out well what the options are  
3 in front of us, with the recommendation that a SAC be seated  
4 and the Department through Beth has listed at least five  
5 items that the SAC can look at. As before, there are  
6 options in front of us as a Commission. Just to lay those  
7 out for us as Commissioners, if we vote to seat the SAC --  
8 that's hard to say -- you could draft a charge right now or  
9 you could instruct the chair and vice-chair to put the  
10 charge together working with the Department, and then the  
11 SAC as always would expire six months from when it gets  
12 together first time and the people on the SAC would be --  
13 nominate themselves and then the chair and vice-chair look  
14 through that with the Department to figure out who would be  
15 appropriate to sit on the SAC. So that's all before us  
16 today. I wanted to lay it out for you and I'll entertain  
17 any discussion. If no discussion, then we should go right  
18 to a motion.

19                   MS. NAGEL: I have a comment.

20                   MR. FALAHEE: Beth, what did I miss?

21                   MS. NAGEL: No, you didn't miss anything, just a  
22 Department comment. We have some serious concerns about  
23 deviating from the national guidelines that are currently in  
24 the standards today. We did a full, comprehensive review of  
25 the Special Care Nurseries and certainly there were

1 instances where the 24 cutoff could not be made. Every  
2 single provider with the exception of one provider was able  
3 to give us documented reasons why that the mother and the  
4 baby should be kept together. It was not a hard and fast 24  
5 hours, you know, you need to follow these standards instead  
6 of having patient -- you know, good patient care. We did  
7 not see a widespread problem with this. Everyone is pretty  
8 much in compliance with it. Again, those that weren't had  
9 very good reasons why. We see a major -- this could be a  
10 major departure from national guidelines both with keeping  
11 the -- the two issues that were mentioned with CPAP and  
12 ventilation for 24 hours and with TPN as well.

13 MR. FALAHEE: Okay. Thank you.

14 DR. PADMANI KARNA: May I make a comment? I'm  
15 sorry. I'm Dr. Karna.

16 MR. FALAHEE: Excuse me.

17 MR. MITTELBRUN: It's Dr. Karna.

18 MR. FALAHEE: Oh, oh, Doctor, yes. You may make a  
19 comment very briefly. If you'd step to the podium, please?  
20 And I'm allowing this because she was not here when it was  
21 her public comment card. So please limit your comments to  
22 three minutes, please. Thank you.

23 PADMANI KARNA, M.D.

24 DR. PADMANI KARNA: Sorry. I didn't realize it  
25 was moving pretty fast. So I was involved in original NICU

1 guidelines that were made in 2009 at Michigan and there was  
2 a very strong sentiment that we should stay with AAP  
3 guidelines are or what the national guidelines are. And  
4 keeping those in mind, I think there will be some deviations  
5 as you were saying. So far they are reasonable and they are  
6 documented, I think that can be there. But if it's going to  
7 inch more -- because it's really the safety of the baby.  
8 Yes, you want to keep the parent tied together, parent and  
9 the baby, but it's a safety. And it's not just having a  
10 physician who's capable of taking care of it. You need the  
11 other people. You need the respiratory people, you need the  
12 pulmonologist (phonetic), you need to monitor all those kinds of  
13 things. So I think it's really the extended support that's  
14 needed with it. That's what my concern is and that's what  
15 the concern was of the committee at the time that we were  
16 talking about it. So that's the main point I really would  
17 like to say. Thank you for allowing me.

18 MR. FALAHEE: One second. Any questions?

19 DR. OCA: This is Oca. I agree with Dr. Karna's  
20 comments as a neonatologist myself as well. It's all --  
21 it's a very specialized group of people on every level that  
22 need to be able to care for these babies. So thank you,  
23 Doctor.

24 MR. FALAHEE: Thank you very much. I figured we'd  
25 hear from you.

1 DR. OCA: I've been trying to stay quiet.

2 MR. FALAHEE: Thanks very much. Okay. Any other  
3 discussion? Any other questions? If not, I'd entertain a  
4 motion about the -- the SAC and all of that.

5 MR. MITTELBRUN: Mittelbrun. I'll make the motion  
6 for the Department to seat the SAC and for the chair and  
7 vice-chair to sit the charge of the SAC.

8 DR. OCA: Oca. I second the motion.

9 MR. FALAHEE: Discussion?

10 MS. BROOKES-WILLIAMS: This is Commissioner  
11 Brooks-Williams. So the way that our vice-chair made the  
12 motion I'm comfortable with. And I just want to ask the  
13 question if you look at the three items that the Department  
14 recommended "no," and I appreciate Beth's comment about the  
15 "no" being affirmative related to national guidelines, is  
16 there strong concern from the Department that if the chair  
17 and the vice-chair decided to allow the SAC to discern that,  
18 that that is a problem? I mean, we would ultimately take  
19 action on those recommendations. And I don't know -- I just  
20 don't have the expertise that if I look at the comments that  
21 came, you know, from public comment, you've got a variation  
22 of people that are kind of raising this question about  
23 practicality. And so I hear you saying that we'll create a  
24 variance if someone, you know, has an exception and we don't  
25 want to make it the rule, and I concur with that 100



1 percent. But I also wonder why we would restrict the group  
2 of experts from simply discussing it so that we have their  
3 wisdom. And they would probably come out, it sounds like,  
4 exactly where you are coming out. But I just want to make  
5 sure that in the motion that that's allowed, that if the  
6 chair and the vice-chair did include the three "noes," that  
7 that would be okay.

8 MS. NAGEL: Certainly it's the Commission's  
9 purview to include things that we didn't recommend  
10 including, certainly. I think just for our rationale it was  
11 one of efficiency, one that, you know, that the staff should  
12 focus just on the tall order that they have with the ones  
13 that were a "yes" essentially. That was the rationale.

14 MR. FALAHEE: So we have a motion and support. We  
15 have a motion before us. Any further discussion about this?  
16 Okay. All in favor of the motion please say "aye."

17 ALL: Aye.

18 MR. FALAHEE: All opposed? Okay. That motion  
19 carries. Thank you very much.

20 (Whereupon motion passed at 10:48 a.m.)

21 MR. FALAHEE: And I apologize for moving so  
22 quickly through the agenda, but I'm glad we're moving  
23 quickly through the agenda. So thank you. Moving on to  
24 agenda item ten. And so far for public comments I have  
25 one -- one card that wants to speak and one does not need to

1 talk. So let's move on to Nursing Home and Hospital  
2 Long-Term Care Unit Beds.

3 MS. NAGEL: Okay. For the Nursing Home Standards,  
4 the Department recommends that the Commission should  
5 continue regulation and form a Standard Advisory Committee  
6 to make recommendations on some of the items that were  
7 outlined in our statute. There were a couple -- or that are  
8 outlined in the recommendation that we gave you. There were  
9 a couple of items that came in, one relating to fees for  
10 Certificate of Need, one was relating to the threshold for  
11 Certificate of Need, and we don't recommend that those get  
12 reviewed because those are statutory issues and can't be  
13 affected by a Standard Advisory Committee. So those two,  
14 that was our rationale there. We are recommending that  
15 there is a full review of the bed need methodology. This is  
16 something that we talked about at previous CON Commission  
17 meetings and we think we are due for that full review. We  
18 are also asking that this Standard Advisory Committee look  
19 at special populations and look at project delivery  
20 requirements and a couple of technical changes from the  
21 Department.

22 MR. FALAHEE: Any questions of Beth before we open  
23 it up for public comment? Okay. The card I've got, Walt  
24 Wheeler. Walt, over the years I'd love to know how many CON  
25 Commissions you've attended. Probably a record. For those

1 of you that don't know, Walt was the head of the CON  
2 Department for how long?

3 MR. WALT WHEELER: Twenty-five years.

4 MR. FALAHEE: Yeah; right.

5 MR. WALT WHEELER: Yeah, a long time.

6 WALT WHEELER

7 MR. WALT WHEELER: Thank you, Mr. Chairman, and  
8 members of the Commission. I'm representing Oakland Senior  
9 Living operations which is involved in the acquisition and  
10 replacement of nursing homes, two older nursing homes. The  
11 issue that we're raising is that -- deals with the  
12 application of the nursing home standards in a situation  
13 where a nursing home is temporarily closed for renovation or  
14 replacement under a building program agreement issued by the  
15 Department of Licensing and Regulatory Affairs, the  
16 licensing program. The problem is that a plain reading and  
17 the accurate reading of the current standards says that a  
18 nursing home is -- to be eligible for CON, has to be in  
19 operation and "operation" means actively admitting patients  
20 or serving patients; and that they -- they -- to be eligible  
21 for CON to replace a nursing home or to renovate and acquire  
22 in these situations, the applicant has to assure that the --  
23 the nursing home is currently an active operation and will  
24 continue to be an active operation while the facility is  
25 being renovated or replaced.

1           We recommend that the standards be reviewed and  
2           for consideration for possible revisions of the language to  
3           allow a Certificate of Need application to be processed when  
4           a nursing home is temporarily closed for renovation or  
5           replacement in the limited circumstances where the nursing  
6           home is licensed under a building program agreement issued  
7           by the Department of Licensing and Regulatory Affairs. This  
8           is to address a problem and that is in we have a whole  
9           generation of nursing homes built in the 60's and the 70's  
10          that are wearing out and some even later than that, and the  
11          licensing program will find significant physical plant  
12          deficiencies that require it to be terminated or closed for  
13          renovation or replacements. In those instances they enter  
14          into a building program agreement. But to proceed with the  
15          renovation or replacement, you need a Certificate of Need.  
16          And we don't argue with the -- the current interpretations  
17          that's a reading of these things. We just think that the  
18          standards ought to be reviewed for -- for revisions to allow  
19          this to happen.

20                 MR. FALAHEE: Thank you, Mr. Wheeler. Questions?  
21          Walt, a question. This is Falahee. So you're talking --  
22          I'm trying to make sure I understand this. All right?

23                 MR. WALT WHEELER: Yeah.

24                 MR. FALAHEE: So you've got a building program  
25          agreement from the licensing department.

1 MR. WALT WHEELER: Yes.

2 MR. FALAHEE: All right. That says the nursing  
3 home is temporarily closed for renovation or replacement;  
4 right?

5 MR. WALT WHEELER: Yes.

6 MR. FALAHEE: So does that put that nursing home  
7 in sort of, like a holding pattern in terms of CON?

8 MR. WALT WHEELER: Right. It's what we used to  
9 call zero occupancy. It's on the books but it's -- but it's  
10 not admitting patients and it's recognized as licensed, but  
11 it is not actively admitting and caring for patients because  
12 in some cases that would pose a -- a danger or a great  
13 inconvenience. And that's a call that the licensing people  
14 make and that's what happens and why you end up with a zero  
15 occupancy home for -- for a period of time until it's fixed.

16 MR. FALAHEE: Okay. That anticipated my next  
17 question. Still Falahee. When you say "period of time,"  
18 you and I when we worked together we always figured out how  
19 to game the system. On my side I would try to game the  
20 system and I would -- thank you. How long do these building  
21 program agreements last?

22 MR. WALT WHEELER: Well, they'll last until --  
23 part of the -- part of the ability to replace or renovate is  
24 to obtain a Certificate of Need. That takes -- typically if  
25 it's a substantive review, it takes six months, maybe ten.

1           Then you have a period of time to get the, you know,  
2           enforceable contract, two years to -- to start renovation or  
3           to start construction because you've got to find the land,  
4           you've got to get the financing, you've got to do the design  
5           work, and then it's a period of time after that that the  
6           facility actually opens. So it's a period of -- of years,  
7           but it -- but that's true of any time you're trying to build  
8           a nursing home under CON.

9                       MR. FALAHEE: So if I understand, your  
10           recommendation is that, assuming we put together a SAC to  
11           look at this, this would be one of the items that's looked  
12           at by the SAC?

13                      MR. WALT WHEELER: Yes.

14                      MR. FALAHEE: Okay. Commissioner Dood?

15                      MR. DOOD: Commissioner Dood. Hi, Walt.

16                      MR. WALT WHEELER: Hi.

17                      MR. DOOD: Nice to see you again. Does this  
18           provide an incentive for a -- a holder of a CON to let their  
19           building deteriorate by giving them the ability to -- to get  
20           another CON versus --

21                      MR. WALT WHEELER: Well, that -- that's  
22           something --

23                      MR. DOOD: -- isn't that just a -- I'm sorry,  
24           isn't that just kind of a logical consequence to letting  
25           your building get that bad that you should lose your CON?

1                   MR. WALT WHEELER:  If -- if there's not an ability  
2                   to replace because it's off the table, a nursing home  
3                   operator, potentially -- and I'm not saying this happens --  
4                   but will be inclined to keep operating until it's bad enough  
5                   to be -- the license to be revoked because it's not possible  
6                   to close it, you know, to do the renovations or to find a  
7                   means to do the renovation.  And so I don't speak -- you'd  
8                   have to ask the licensing people currently, you know,  
9                   whether that could happen.  In my experience, you know,  
10                  it's -- it's possible and you see these older homes that  
11                  are -- really should have been fixed, especially in urban  
12                  areas, a long time ago that are just getting by and each  
13                  year they get less able financially to make the major  
14                  investments to fix the physical plant or replace it.

15                 MR. FALAHEE:  One other question.  If you have a  
16                 building program agreement, does that mean those nursing  
17                 home beds are still in existence and, therefore, if someone  
18                 wanted to build a nursing home in that area it would still  
19                 be over bedded because of those --

20                 MR. WALT WHEELER:  Right.  Because that nursing  
21                 home -- the typical building program agreement will say, you  
22                 say you're going to fix it or an -- an acquiring entity is  
23                 going to fix it, these are the steps, and if it doesn't --  
24                 if you don't get a -- if you don't apply for a CON within a  
25                 certain amount of time, those beds are gone.  If you don't

1 build within a certain amount -- you know, if you don't  
2 actually build it, those beds are gone. So the idea is, you  
3 know, replace it or renovate it or lose it. But until, you  
4 know -- so it isn't -- that's how they handle it, to make  
5 sure that it actually happens. But the beds stay in the  
6 inventory until that.

7 MR. FALAHEE: Other questions?

8 MS. NAGEL: We have a couple of questions. The  
9 question I have is couldn't the nursing home replace --  
10 apply to replace before they closed?

11 MR. WALT WHEELER: They -- yes. At any time a  
12 nursing home can. This is just in a situation where they  
13 may not have done it and they -- they end up with a  
14 citations or a situation where the licensing program comes  
15 in and says you may not have wanted it, but it has to  
16 happen.

17 MS. NAGEL: So there is the ability for the  
18 nursing home before they close to preplan and file a  
19 replacement application?

20 MR. WALT WHEELER: Any nursing home at any time  
21 can file to do that.

22 MS. NAGEL: Tulika has a question.

23 MS. BHATTACHARYA: Hi, Walt. Just one question  
24 from the patient care point of view. So let's say this  
25 is -- this is an older home per se and they decide to close



1 down. So what happens to the residents in those beds at  
2 that home?

3 MR. WALT WHEELER: Typically in a building  
4 program -- and, again, I don't speak for lic- -- I know my  
5 own experience. The licensing program will oversee -- if  
6 it's an enforcement situation, they will actually send in  
7 temporary managers to -- to -- to oversee the evacuation of  
8 those patients. If it is voluntary, they have a process for  
9 voluntary closure which includes patient rights and making  
10 sure that everybody is -- is taken care of. In other  
11 situations -- a home is approaching this -- they will seek  
12 voluntary closure and go through attrition bringing that  
13 volume down. But there is -- the state oversees the, you  
14 know, bringing that population down to zero and making sure  
15 rights are held, you know, respective.

16 MS. BHATTACHARYA: So, in summary, those residents  
17 will be placed appropriately in that community in other  
18 available beds?

19 MR. WALT WHEELER: Yes. That's -- the licensing  
20 oversees that.

21 MS. BHATTACHARYA: Okay.

22 MR. FALAHEE: Other questions? Thanks, Walt.  
23 Appreciate it very much.

24 MR. WALT WHEELER: Thank you very much for your  
25 time.

1                   MR. FALAHEE: Thank you. Commission discussion.  
2                   Let me confirm. Wait a minute. Pat Anderson, but she did  
3                   not want to speak. Still the same, Pat?

4                   MS. PAT ANDERSON: Yes.

5                   MR. FALAHEE: Okay. Thanks. Any other public  
6                   comment? Okay. Thank you very much. Commission  
7                   discussion, questions, comments?

8                   MS. BROOKES-WILLIAMS: Commissioner  
9                   Brooks-Williams. So I just want to ask Beth. So in the  
10                  noes -- right? -- that -- for consideration where you  
11                  indicate that it cannot be really addressed within the CON  
12                  standards because it's state statute?

13                  MS. NAGEL: Uh-huh (affirmative).

14                  MS. BROOKES-WILLIAMS: Just maybe -- not like  
15                  that's not self-explanatory, but for those that are  
16                  suggesting I guess that it's a problem or concern, how would  
17                  they address it if not through the standard review?

18                  MS. NAGEL: Sure. The state statute is under the  
19                  purview of the legislature and so it would need to be a  
20                  legislative change.

21                  MS. BROOKES-WILLIAMS: Thank you.

22                  MR. FALAHEE: This is Falahee with another  
23                  question for Beth. The issue raised by Mr. Wheeler, is that  
24                  something also that would require a legislative change or is  
25                  that something that if the Commission chose to put together

1 a SAC, that that's something the SAC could look at?

2 MS. NAGEL: Yes. It is certainly the change that  
3 Mr. Wheeler was talking about would be in the Certificate of  
4 Need standards. However, I will say that then the  
5 Department would not support that type of change.

6 MR. FALAHEE: I understand. Other questions?  
7 Okay. Commission action. I'll enter -- well, as before  
8 I'll serve -- I'll lay it out. It's much like the others  
9 where we appoint a SAC, you could if you so chose instruct  
10 the chair and vice-chair to put together, working with the  
11 Department, what that charge would be and then we would ask  
12 for nominations for the SAC. The chair and the vice-chair  
13 working with the Department would then select the people to  
14 serve on the SAC and the chair or vice-chair, co-chairs for  
15 that. So that's -- that's an option in front of us today.  
16 I'd entertain any motion.

17 MR. DOOD: This is Commissioner Dood. I'd  
18 recommend that the Commission form a SAC to make  
19 recommendations regarding the -- the issues that are on  
20 here, the bed methodology, the definitions on the  
21 nonoperational, unavailable, I would exclude that one. So  
22 that -- that -- that would be the change to -- to what's on  
23 here. And I have a couple comments, too. That's my motion.

24 MR. FALAHEE: Support for motion?

25 MR. MITTELBRUN: Mittelbrun. Support.

1 MR. FALAHEE: Questions, discussion?

2 MS. BROOKES-WILLIAMS: This is Commissioner  
3 Brooks-Williams. So if you can just clarify? So this is --  
4 one, two, three, four -- the fourth item is what you're --  
5 so the Department recommended "yes" to advance it to the  
6 SAC, but we're taking it out? Is that the one?

7 MR. DOOD: Yes, that was my motion.

8 MS. BROOKES-WILLIAMS: Okay.

9 MS. GUIDO-ALLEN: So your motion is to exclude  
10 which?

11 MS. BROOKES-WILLIAMS: I'm calling it four because  
12 I don't -- they're not numbered, but maybe if you read it to  
13 us?

14 MS. GUIDO-ALLEN: Which -- yeah, can you read to  
15 us --

16 MR. DOOD: That's the one, the message the  
17 Department would not support. So,

18 "Review the definitions of nursing home beds and  
19 other parts of the standards to make it clear that  
20 existing nursing home beds include nursing homes and  
21 nursing home beds that are non-operational."

22 MR. MITTELBRUN: We must be looking at a different  
23 page.

24 MS. BROOKES-WILLIAMS: We may have a different --

25 MR. MITTELBRUN: Because our number -- okay. What

1 page are you on? Just look at the top and just tell me --

2 MS. NAGEL: 133, page 133 of 181.

3 MR. DOOD: It's -- it's top of 134, I guess, but  
4 then it keeps going.

5 MS. BROOKES-WILLIAMS: Okay. Catch us up, sorry.  
6 First of all, our document --

7 MR. FALAHEE: Different page numbers for different  
8 people depending on the current volume, the first set and  
9 second set.

10 MS. NAGEL: 133 is the second set.

11 MS. BROOKES-WILLIAMS: Okay. And, again, if you  
12 could just confirm that this is, then, what I'm calling  
13 four, it really isn't; it's seven. So it's, "Review  
14 relocation of nursing home beds under Section 8," is that  
15 it, that we're excluding?

16 MR. MITTELBRUN: No.

17 MS. NAGEL: No.

18 MR. DOOD: No. It would be three above, two above  
19 that I guess. It starts, "Review the definitions for."

20 MS. BROOKES-WILLIAMS: Okay. So Commissioner  
21 Brooks-Williams. I'm going to ask my question again. So  
22 regardless of what page it's on, the document that I have is  
23 suggesting that,

24 "Review the definitions for nursing home beds and  
25 other parts of the Standards to make it clearer that

1 existing nursing home beds include nursing homes and  
2 nursing home beds that are non-operational or  
3 unavailable for occupancy when they are licensed under  
4 a building program agreement approved by the Michigan  
5 Department of Licensing and Regulatory Affairs pursuant  
6 to section 20144 of the Public Health Code."

7 I thought that the Department was supporting it  
8 moving forward with a "yes."

9 MR. MITTELBRUN: Ours says yes, supports it.

10 MS. BROOKES-WILLIAMS: Are you -- that's saying  
11 the Department does not support that?

12 MS. NAGEL: I am and I do apologize for the  
13 misinformation listed in your packet.

14 MS. BROOKES-WILLIAMS: Thank you very much. Would  
15 there be any other clarifications for the early printers or  
16 confirm that we're acting -- or know what the scope is that  
17 we're acting on?

18 MS. NAGEL: There are no further clarifications  
19 that I am aware of in this document.

20 MR. FALAHEE: And then this is Falahee. Let me  
21 ask for a further clarification because the item that  
22 Commissioner Dood and the other that supported the motion  
23 is -- is taking out under the motion is what Mr. Wheeler was  
24 just talking about; correct?

25 MR. DOOD: Correct.

1                   MR. FALAHEE: Right. And then I want to  
2 understand the Department's position. So, Beth, if you  
3 could rephrase it? It sounds like the Department is saying  
4 that's a different department.

5                   MS. NAGEL: Yes. One, it is. The building  
6 program agreements are completely under the jurisdiction of  
7 a different department. Also, our concern is that at any  
8 time a home can -- there are -- there are standards already  
9 in the Certificate of Need standard for Nursing Home for  
10 replacing their nursing home. They have multiple  
11 opportunities to replace aging, unsafe nursing homes. We  
12 also strongly believe that if the residents are moved out  
13 and absorbed into other nursing homes, that a new operator  
14 should be able to take advantage of the Certificate of Need  
15 standards and build a new nursing home if those beds are  
16 then returned to the pool. Essentially, in this case it  
17 would -- someone who for whatever reason the nursing home  
18 closed, they were sort of held in limbo until that operator  
19 can decide what to do with it.

20                   MR. FALAHEE: Thank you. So is everyone clear on  
21 what's in the motion and what's not? Okay. Any discussion?

22                   MR. DOOD: I, just --

23                   MR. FALAHEE: Commissioner Dood?

24                   MR. DOOD: -- just a couple of other items then.  
25 Review the bed methodology and I'm sure the SAC will get

1 into this, but there are some things going on with the state  
2 in terms of moving to a managed care model. There's a  
3 definite time frame now put out. There's PACE programs  
4 and -- and other things going on. So I -- I just would  
5 encourage the charge that you guys write to, to think about  
6 how that will change. It's not just populations and just  
7 looking back. But you have a -- really a fundamental change  
8 in who gets cared for in an institutional setting.

9 MR. FALAHEE: Fair warning. The chair is not  
10 adverse to calling on commissioners that have expertise to  
11 help rode the charge. Any other questions or comments? So  
12 we have a motion in front of us that's been supported. All  
13 in favor of that motion please say "aye."

14 ALL: Aye.

15 MR. FALAHEE: Opposed? That motion carries.

16 (Whereupon motion passed at 11:09 a.m.)

17 MR. FALAHEE: I'm going to keep plowing ahead  
18 here. The next agenda item is agenda item 11, Lithotripsy.  
19 It seems like we just finished Lithotripsy. Some things  
20 just take awhile and then they come back up for their normal  
21 cycle. So, Beth, I will turn it over to you, please.

22 MS. NAGEL: Okay. The Department is recommending  
23 that Lithotripsy should continue to be regulated and we are  
24 asking the Commission to request the Department bring back  
25 language, making some -- two technical edits and one



1 technical-like edit to these -- to these standards. The one  
2 technical-like edit -- you'll remember the reason why you  
3 just got done with the Lithotripsy standards -- was that we  
4 put in a requirement -- put in requirements for a fixed  
5 Lithotripsy. We, the Department and the Commission -- the  
6 Commission voted on a MAI- -- initiation volume for the  
7 fixed lithotripter, but we did not look at the maintenance  
8 volume for that fixed lithotripter. So we are recommending  
9 that those two numbers match.

10 MR. FALAHEE: I have one card, Marlena Hendershot  
11 from Sparrow as we know.

12 MS. MARLENA HENDERSHOT: I'll try and make a  
13 better entrance.

14 MR. FALAHEE: This time we'll be able to ask you  
15 hard questions, not the soft questions.

16 MS. MARLENA HENDERSHOT: We'll see.

17 MR. FALAHEE: Thank you.

18 MARLENA HENDERSHOT

19 MS. MARLENA HENDERSHOT: Good morning. Thank you  
20 again for allowing me to present comments this morning. To  
21 be respectful of the agenda, I'll be just really quick. We  
22 support the Department's recommendation to revise the  
23 project delivery requirements from 1,000 to 500 procedures  
24 annually. We also support the Department's recommendation  
25 for the replacement and acquisition volume to be reduced

1 also to that 500. This will keep in line with the  
2 initiation changes that were made last year reducing those  
3 volume requirements to 500. Thank you again for the  
4 opportunity. Do you have any questions?

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

6 MS. MARLENA HENDERSHOT: Thank you.

7 MR. FALAHEE: Thank you. I don't have any other  
8 comment cards. Is there anyone else that would like to  
9 comment on this item? Okay. So let me turn to the people  
10 to my right. It's a recommendation you're bringing to the  
11 Commission, so my thought is you're looking for a motion to  
12 either say yes, we support the recommendation or no, we  
13 don't?

14 MS. NAGEL: Correct.

15 MR. FALAHEE: Or have one of our own?

16 MS. NAGEL: Yup.

17 MR. FALAHEE: All right. Okay. All right.  
18 Comments, questions, discussion or a motion?

19 MS. BROOKES-WILLIAMS: Commissioner  
20 Brooks-Williams. I move that we support the Department's  
21 recommendations as presented.

22 DR. MCKENZIE: McKenzie. I'll second.

23 MR. FALAHEE: Thank you. Motion made and  
24 seconded. Any questions or comments from the commissioners?  
25 All in favor of the motion please say "aye."

1 ALL: Aye.

2 MR. FALAHEE: Opposed? Motion carries. Thank you  
3 very much.

4 (Whereupon motion passed at 11:12 a.m.)

5 MR. FALAHEE: Moving on, the next item is a  
6 written only report from the Psych Beds and Services work  
7 group and that's in our packet. I don't know if anyone has  
8 any questions? If so, you're welcome to direct them not to  
9 me, but the people to my right. So if you have any  
10 questions?

11 MS. BROOKES-WILLIAMS: Commissioner  
12 Brooks-Williams. My question for the Department is just we  
13 earlier -- right? -- advanced and approved the -- the Psych  
14 Bed recommendations and I'm just curious if the work group  
15 recommendations have any incongruence with what we approved,  
16 what would the process be to reconcile that?

17 MS. NAGEL: I don't see any -- there isn't any  
18 incongruence that jumps to my mind. If there is, you will  
19 hear the report in June from the Psychiatric work group  
20 chair and you could make any recommendations to the --

21 MS. BROOKES-WILLIAMS: Okay. So we just would  
22 take it as it comes.

23 MS. NAGEL: Yup.

24 MS. BROOKES-WILLIAMS: Okay. Thank you.

25 MR. FALAHEE: Any other questions? Great. Next

1 item, agenda 13, is the Bone Marrow Transplantation Services  
2 Standard Advisory Committee (BMTSAC) Interim Report, it says  
3 verbal. And that's -- that's me to provide the verbal  
4 report. Let me give you some background on that. As you  
5 know, we seated the SAC. They've had two meetings. They  
6 had a conference call with some of us yesterday, with Beth  
7 and myself and Brenda, and the two from the SAC were the two  
8 co-chairs, Dr. Stella and Dr. Uberti. And they wanted to  
9 give us an update so then I could give it to you. And  
10 anyone that knows Doctors Stella and Uberti would not be  
11 surprised when they said that they want to be finished and  
12 not do this in six months, but do it with one more meeting.  
13 They are overachievers. I knew that. There's a reason  
14 they're the co-chairs. Here's where they're at so far.

15 Let me read to you an e-mail that Dr. Stella sent  
16 to myself, Dr. Uberti, Brenda, and Bath.

17 "Chip, as you recall, the BMT SAC was charged to  
18 evaluate whether CAR-T cells should be regulated under  
19 the BMT CON standards, a separate CON, or remain  
20 unregulated. The SAC has met twice and there has been  
21 general consensus on the following points."

22 And there's -- there's four points that Dr.  
23 Stella -- Stella points out here in his e-mail and that he  
24 talked to us about yesterday on the call. First is FACT, F-  
25 A-C-T, which stands for the Foundation for the Accreditation

1 of Cellular Therapies. So, "FACT accreditation under the  
2 immune effector cell pathway should be required for the safe  
3 delivery of CAR-T cells." I think the reference there is  
4 "should be required." I would, based on our call yesterday  
5 say "must be required." So step one, FACT accreditation.  
6 And Dr. Stella told us yesterday currently the accreditation  
7 runs about 350 pages.

8           Next, number two, "This should be regulated under  
9 a separate immune effector cell CON, new standard, with the  
10 only requirement being a site interested in administering  
11 CAR-T cells be FACT accredited." So that sort of ties back  
12 to number one. Number three, "We specifically did not think  
13 the number of approved sites should be limited by the CON."  
14 By that he means currently there are BMT providers in the  
15 state of Michigan. My recollection is there are five, that  
16 CAR-T would not be limited to those five sites. If you're  
17 FACT accredited, as the consensus is right now within the  
18 SAC -- if you're FACT accredited you can get CAR-T approval  
19 as of right now under general consensus. Okay? And number  
20 four, "As the panel is not constituted to evaluate other  
21 cellular adoptive therapies, we will be restricting our  
22 recommendations to CAR-T cell and similar therapies." What  
23 Doctors Stella and Uberti told us on the call yesterday is  
24 this is a rapidly evolving medical field, if you will, for  
25 cellular therapies and who knows where it will be six months

1 from now, six years from now. The SAC was specifically  
2 designed to look at CAR-T cell and similar therapies, so  
3 that's their charge. That's what they're going to do,  
4 that's what they feel most competent and qualified to do,  
5 and not comment on what else may be coming down the pike  
6 with cellular therapies.

7 So Dr. Stella concluded by saying, "But we believe  
8 these statements represent the general consensus of the  
9 Committee, we have not taken a formal vote of approval yet."  
10 So that's their status. I believe they meet -- is it in  
11 April next time?

12 MS. NAGEL: Uh-huh (affirmative).

13 MR. FALAHEE: Right. So they may be concluded,  
14 who knows, but that would be their intention so far with the  
15 consensus that they've reached. Any questions? They have  
16 been very responsive --

17 MR. DOOD: Commissioner Dood. If they're saying,  
18 hey, the only requirement to get a CON is to be accredited,  
19 and I don't have the history on this, but is there any  
20 reason to have it subject to CON at all?

21 MR. FALAHEE: The chairman would express his  
22 personal opinion, absolutely, yes.

23 MR. DOOD: And just help me understand why. I'm  
24 sure I'm missing the obvious here.

25 MR. FALAHEE: I would have missed the obvious

1           until we talked to Doctors Stella and Uberti yesterday  
2           because the concern is that if you don't put some  
3           requirement in there about FACT and CON, there are literally  
4           machines out there now that cost about \$20,000 that Dr.  
5           Stella told us about yesterday that can generate the  
6           necessary cell therapies. Not through a drug company.  
7           Okay. And they could be generating this without any CON,  
8           without any FACT accreditation. So that's why the -- the  
9           consensus in the committee is we don't want that rampant  
10          technology growth going on uncontrolled, unfettered. That's  
11          why they felt quality reasons there should be that control  
12          built on.

13                   MR. DOOD: That's -- that's not otherwise covered  
14          by a licensure or a standard of medicine or something?

15                   MR. FALAHEE: No. Beth, did you have anything to  
16          add on my attempt at an answer to Commissioner Dood?

17                   MS. NAGEL: No. I think you covered it quite  
18          well.

19                   MR. FALAHEE: Okay. Thank you. And I'm sure when  
20          they're here to present their final report, you're welcome  
21          to ask that or any variation of that. Other questions?  
22          Thank you. I will say they've been very responsive when  
23          we've had questions and I'm pleased but not surprised that  
24          they're moving fast through these issues. Okay. Looking  
25          ahead at one of our last items, public comment, I don't have

1 any other public comment cards yet, so if you do want to  
2 make any public comment, please make sure you get the cards  
3 to Tania within the next few minutes. Okay. We'll move now  
4 to the Administrative Update starting, Beth, with you, I  
5 believe.

6 MS. NAGEL: Yup. We finished and wrapped up the  
7 Psychiatric Bed work group. We're working on the language  
8 now to bring to you in June. And as we just discussed, we  
9 are currently working with Bone Marrow Transplant Standard  
10 Advisory Committee as well. Based on what you've done  
11 today, we will work to get a work group for CT and then a  
12 SAC for NICU and a SAC for Nursing Home as well.

13 MR. FALAHEE: Thank you, Beth. And then, Tulika,  
14 you go ahead will you please? Thank you.

15 MS. BHATTACHARYA: Thank you, Mr. Chairman. So  
16 there are three reports in your packet. The first one is  
17 about the programs activities and the number of LOIs,  
18 applications, decisions we have issued in the first quarter  
19 of the fiscal year and just we continue to maintain the  
20 timeliness of all of our decisions as you can see from the  
21 report. The second report is about compliance activities.  
22 Just, I mean, if you have any questions, I'm happy to  
23 answer. There were three facility specific actions that we  
24 took. We also completed the statewide compliance review for  
25 NICU, Special Care Nursery, and Lithotripsy Services. The



1 summary findings are in your packet. And this year, in  
2 2019, the Department proposes doing statewide compliance  
3 review for MRI and PET scanner services.

4 A little bit about the NICU and SCN compliance.  
5 There are 14 Special Care Nursery services in the state and  
6 we reviewed all 14 of them. Based on our preliminary  
7 findings, we set up five conference calls to discuss our  
8 findings and give them an opportunity to explain the  
9 deviations or deficiencies that we noticed. And based on  
10 additional information and documents they provided, we were  
11 able to close out four of them and only one resulted in a  
12 settlement agreement where the Department felt we didn't see  
13 proper justification of the deficiency that we observed in  
14 their service. There were 21 NICU hospitals in the state,  
15 all six of them are grandfathered so they are not held under  
16 any standards and project delivery requirements. So based  
17 on our preliminary findings, there was one facility we had a  
18 conference call with and that facility is in a rural area.  
19 And when we looked at their deficiency where they had less  
20 than 15 NICU beds, that's the minimum in the standard, but  
21 again, it's a rural area and they are not able to provide  
22 onsite neonatal ophthalmology, but they have made  
23 arrangements and they demonstrated satisfactory to the  
24 Department so that we -- we actually deemed them compliant  
25 based on, you know, the rural area of that hospital because

1 they're the only provider that's offering NICU service in  
2 that area.

3 The Litho compliance review statewide, so there  
4 are a total of 89 facilities, seven of them are mobile  
5 networks and 82 host sites. All but one of the networks are  
6 meeting their volume requirement of 1,000 Litho procedures  
7 per unit. And every network is required to project and  
8 maintain 100 procedures in each planning area that they  
9 serve. Three of the networks are not meeting that  
10 requirement, the other four are. There were five host sites  
11 that were not able to offer or they did not have blood  
12 products available onsite, but the most recent standard  
13 allows them to have a contract for those products so we are  
14 able to bring them up to compliance by, you know, doing the  
15 settlement agreement with those host sites.

16 And then there is the annual report for fiscal  
17 year 2018 which is October 1, 2017 through September 30th,  
18 2018. I'm not going to go over all of the pages, but just a  
19 few of the charts. So in total we reviewed 371 letters of  
20 intent, 296 applications, and issued 275 proposed decisions,  
21 and the capital expenditure in those approved projects were  
22 about approximately \$2.1 billion. There were 18 amendments  
23 that were submitted to the CONs that we approved. And of  
24 those 371 LOIs, 99 percent of them were processed on time,  
25 within 15 days, 73 of them resulted in waivers where the

1 Department determined that the project does not require our  
2 review. Then on the type of application, you know, we  
3 continue to receive substantive and non-substantive  
4 applications as usual, but in last fiscal year we did not  
5 receive a comparative group or a comparative review  
6 application group where we had to score them out to make a  
7 decision on who is the best applicant. We had enough beds  
8 to approve all the applications.

9 So we are busy as you can tell from the numbers  
10 and that doesn't count the countless hours we spend  
11 consulting with our providers even before they file their  
12 Letter of Intent or the application, just to make sure they  
13 are planning the projects appropriately so that we can  
14 approve it and things like that. So out of the 174 non-  
15 substantive decisions we issued, the average review cycle  
16 was 36 days and the statute allows us 45. Of the 107  
17 substantive application, the average review period was 102  
18 days and the statute allows us 120 days. So we are able to  
19 meet the timeline and then, you know, shorten it a little.  
20 We do -- there is a process for expediting reviews and the  
21 applicants file those forms with their justification. And  
22 while the Department tries to honor all of those requests,  
23 but sometimes, depending on our decision queue and we end up  
24 sometimes prioritizing those, so we are not always able to  
25 approve all expedite requests, but we try our best and it

1 depends on the justification. And we always take into  
2 account, like, if it is going to affect patient care, that  
3 rises to the top of our priority.

4 On -- sorry. I didn't mention any page number.  
5 On page 159, that's the chart of decisions of how many we  
6 approved -- approved with conditions and disapproved. The  
7 two disapprovals that you see, one of them was for a nursing  
8 home project, and the other one was for a new hospital  
9 project in HSA1, so those are the two denials last fiscal  
10 year.

11 This next chart that I would like to point out is  
12 on page 162, table 11. That just shows, like, the increase  
13 and the trend in the number of projects that we review. So  
14 as you can see compared to last year, our LOIs jumped 16  
15 percent, but the capital expenditure in those LOIs jumped 43  
16 percent. So we are receiving more and more big capital  
17 expenditure projects compared to the previous years. The  
18 applications were increased by eight percent and the costs  
19 in those applications 61 percent. The decisions in terms of  
20 numbers pretty much stayed the same. But, again, if you  
21 look at the capital expenditure for all of the decisions we  
22 issued, that jumped 70 percent.

23 The next one is next page, the table 13. It is a  
24 good measure of, you know, the capacity in the state and  
25 what we have existing and the new capacity that we added.

1           So just to point out a few, there were nine new surgical  
2           centers, two new hospitals, but those are long-term acute  
3           care hospital. So not new beds, but -- so Air tax utilizes  
4           existing beds so they didn't at a host hospital. One new  
5           nursing home, but 58 additional nursing home beds, one new  
6           psychiatric unit but in terms of psychiatric beds, 134 new  
7           psychiatric beds in the state were approved last year.

8                       Next one, page 164, our compliance activities. We  
9           are busy, both in terms of following up on approved projects  
10          to make sure they are being implemented within the required  
11          time frame, or they're requesting extension for justifiable  
12          reasons. Our follow-up analyst Gay Huddle (phonetic) does  
13          an excellent job in doing that. And, actually, I would like  
14          to give a shout out to my team of nine. They do an  
15          excellent job with their -- for reviewing applications,  
16          consulting with the providers or doing the compliance and  
17          that's how the Department is able to maintain the timeliness  
18          for all of our processings.

19                       The compliance orders that you see on the chart,  
20          48 of them, that would include the statewide compliance  
21          reviews for Cath and MRT and the individual compliance  
22          actions were related to Air Ambulance Services, Litho, and  
23          one capital expenditure project.

24                       And then the last table is on page 165, table 16,  
25          it's about the funding and the revenues for the program. I

1 would say we are doing well in terms of meeting all of our  
2 expenditures through our fee revenues. So that's the last  
3 one and I'm happy to answer any questions you have.

4 MR. FALAHEE: Any questions of Tulika?

5 MS. BROOKES-WILLIAMS: Commissioner  
6 Brooks-Williams. I don't think I've ever talked this much.  
7 But we -- earlier on in your -- and I was late so I had to  
8 catch up. That's what it is. I missed the first minutes.  
9 But on the report around NICU, it was noted that there were  
10 some that were grandfathered and as a result of the  
11 grandfathering they weren't able to be reviewed under any  
12 standard. Are they not held to the standard that was there  
13 when they existed? I just was confused by that. Like  
14 how -- how are they monitored?

15 MS. BHATTACHARYA: Yeah. So what that means is  
16 the Commission developed a NICU standard -- and I have to  
17 look what was the first date of the standard. So these NICU  
18 units at these six hospitals were already in  
19 existence before the --

20 MS. BROOKES-WILLIAMS: When the standard was to  
21 form?

22 MS. BHATTACHARYA: -- yeah, when the Commission  
23 adopted the regulations for NICU.

24 MS. BROOKES-WILLIAMS: Okay. And so but going  
25 forward -- I appreciate and understand grandfathered. Just

1           curious what -- I understand they can't be reviewed perhaps  
2           under those standards because they existed, but does it mean  
3           they are basically unregulated then? They're just not held  
4           to the standards? I don't know if I'm making sense in my  
5           question.

6                       MS. BHATTACHARYA: No, you are. So two things.  
7           So for example there was one grandfathered hospital but they  
8           went through a change of ownership project so they were  
9           brought under the then current review standards. So that's  
10          one way of bringing them under a standard. Second, if you  
11          are applying for high occupancy or you want to add more  
12          beds, you have to apply under the current standards and then  
13          we will monitor them in the future.

14                      MS. BROOKES-WILLIAMS: Uh-huh (affirmative).

15                      MS. BHATTACHARYA: But let's say these six  
16          hospitals they never came back to the Department for any  
17          sequential or, you know, projects so they're still  
18          grandfathered and legally they're not held under any project  
19          delivery requirements under the CON regulation.

20                      MS. BROOKES-WILLIAMS: Understand. But their  
21          licensure, all those other compliance elements still stand?

22                      MS. BHATTACHARYA: Right; yes.

23                      MS. BROOKES-WILLIAMS: Okay. Thank you.

24                      MR. FALAHEE: This is Falahee. I will give my own  
25          shout out to Tulika and the whole team. As one of the

1 hospital representatives on the Commission and one who's --  
2 I think we've got ten CONs in the pipeline now with the  
3 Department. It's our pleasure at least at Bronson to work  
4 with Tulika and her team. I see one of the members in the  
5 team back there right now and they show up at the meeting  
6 now and then. They do a great job and they do a very good  
7 job, Tulika called it countless hours of consultation. We  
8 find those to be very valuable for us and we hope for the  
9 Department so that we know what to say, whether it will be  
10 granted, denied, whatever, what we need to tweak. And so I  
11 want to say thank you, Tulika, to you and the whole  
12 Department, even the compliance people. You don't want to  
13 get a phone call from some of them, but they're doing their  
14 job and I will shout out. Given the history of the CON that  
15 the compliance function is much, much better than it used to  
16 be and that's to the good of this Commission, the  
17 encouragement of this Commission, the hard work of the  
18 Department, and I think it keeps the health care better in  
19 the state to have an effective compliance program. So thank  
20 you for that. In spite of the phone calls that we all as  
21 providers get, so thank you. Any other comments? Okay.  
22 Great. We'll turn it over to Carl for the legal activity  
23 report, please.

24 MR. HAMMAKER: Yeah. Carl Hammaker from the  
25 Attorney General's Office. I included our legal activity



1 report in your packet. There's currently two open  
2 litigation files regarding CON decisions. Otherwise, the  
3 Attorney General's Office is available as always to continue  
4 helping develop standard language and answer any of the  
5 Department's questions. I would open it up to the  
6 Commission if you have any questions for me.

7 MR. FALAHEE: Any questions? I'm going to give a  
8 shout out to Carl and his predecessor. You may not see it,  
9 but when we're working with them as the chair or the  
10 vice-chair, very, very helpful on these issues. I'll give  
11 the most current example. Carl is both a J.D. and an M.D.  
12 So when we were trying to put the standards together for the  
13 CAR-T, he was very helpful wearing both hats. So thank you,  
14 Carl, for all that you've done and your -- the whole team at  
15 the Attorney General's Office. Thank you.

16 MR. HAMMAKER: Thank you.

17 MR. FALAHEE: Okay. Moving on -- we might make  
18 the basketball game yet. The future meeting dates, just to  
19 confirm it for people out there: June 13, September 19, and  
20 December 5. Those are the meeting dates for the remainder  
21 of 2019, weather permitting. Next, public comment. I don't  
22 have any cards for any other public comment. Is there  
23 anyone out there that would like to make a public comment at  
24 this time, please? Seeing none. Next we'll turn it over to  
25 Beth for the ever revising Commission work plan.

1 MS. NAGEL: Yes. So the work plan that you have  
2 in your packet was the one that was approved at the December  
3 meeting which is why you still see a good chunk of 2018 on  
4 it. We will revise this work plan to show all of 2019, and  
5 we will add in what the Commission has done today with the  
6 changes that you've made to CT, NICU, and Nursing Home as  
7 well as Lithotripsy. So we will reflect those going  
8 forward. This does require approval from the Commission.

9 MR. FALAHEE: Entertain a motion to that effect?

10 MS. GUIDO-ALLEN: Guido-Allen. Motion to approve  
11 the work plan.

12 MR. FALAHEE: Support?

13 MS. BROOKES-WILLIAMS: Brooks-Williams. Support.

14 MR. FALAHEE: Discussion? All in favor say "aye."

15 ALL: Aye.

16 MR. FALAHEE: Opposed? That motion carries.

17 (Whereupon motion passed at 11:39 a.m.)

18 MR. FALAHEE: Moving on. Anything else, Beth, on  
19 that?

20 MS. NAGEL: (Shaking head negatively)

21 MR. FALAHEE: Okay. Thank you very much. Next,  
22 election of officers. We elect officers every March. It's  
23 a one-year term. The current officers are myself as chair  
24 and the gentleman to my left, Mr. Mittelbrun, as vice-chair.  
25 Entertain any motion out there for that?

1 MS. GUIDO-ALLEN: Guido-Allen. I'd like to make a  
2 motion that Commissioner Falahee continue in the chair role  
3 and Commissioner Mittelbrun continue in the vice-chair role.

4 DR. GARDNER: Support. Gardner.

5 MR. FALAHEE: Thank you Any objections?

6 MR. MITTELBRUN: No, but I'll make the motion to  
7 adjourn.

8 MR. FALAHEE: Okay. All in favor of the motion to  
9 before us please say "aye."

10 ALL: Aye.

11 MR. FALAHEE: Opposed? Thank you.

12 (Whereupon motion passed at 11:40 a.m.)

13 MR. FALAHEE: Thank you both.

14 MS. GUIDO-ALLEN: Thank you.

15 MR. MITTELBRUN: Any other business? I'll make  
16 the motion to adjourn.

17 MR. FALAHEE: Second?

18 MS. LALONDE: Second. Lalonde.

19 MR. FALAHEE: All in favor?

20 ALL: Aye.

21 MR. FALAHEE: Motion carries. Thank you everyone.

22 Thanks to those in the audience and thank you to the  
23 commission members and the Department.

24 (Proceedings concluded at 11:40 a.m.)

25 -0-0-0-