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

COMMISSION MEETING
BEFORE JAMES FALAHEE, CHAIRPERSON
BEFORE AMY L. MILEWSKI, M.D., VICE CHAIRPERSON
333 South Grand Avenue, Lansing, Michigan
Thursday, March 13, 2025, 9:30 a.m.

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24
25

TABLE OF CONTENTS

	PAGE
I. Call to Order	5
II. Review of Agenda	5
III. Declaration of Conflicts of Interests	5
IV. Review of Minutes of January 23, 2025	6
V. Cardiac Catheterization Services Final Report and Draft Language	7
A. Public Comment	
1. Sibin Zacharias, M.D.	35
2. Rich Cooley, DO	38
3. Jason Ricci, M.D.	44
4. Kelly Jefferson	46
B. Commission Discussion	--
C. Commission Action	49
VI. Magnetic Resonance Imaging (MRI) Final Report and Draft Language	51
A. Public Comment	
1. Abby Burnell	68
B. Commission Discussion	--
C. Commission Action	70
VII. Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services Draft Language	75
A. Public Comment	--
B. Commission Discussion	--
C. Commission Action	76

1	VIII.	Legislative Update	77
2	IX.	Administrative Update	
3		A. Commissions and Special Projects Section Update	77
4		B. CON Evaluation Section Update	78
5		1. FY2024 Annual Report	
6		2. Statewide Compliance Review for PET Scanners	
7		3. Statewide Compliance Review for OHS	
8	X.	Legal Activity Report (Written Report)	82
9	XI.	Public Comment	--
10	XII.	Review of Commission Work Plan	83
11		A. Commission Discussion	--
12		B. Commission Action	83
13	XIII.	Future Meeting Dates	83
14	XIV.	Adjournment	84

1 Lansing, Michigan

2 Thursday, March 13, 2025 - 9:30 a.m.

3 MR. FALAHEE: Good morning, everybody. Thank you.
4 Welcome. This is our first meeting of three that we didn't
5 have to either cancel or drive through a blizzard to get
6 here. So it was nice just having darkness or sunlight
7 depending on how early you got up here.

8 Good morning. Let's call the meeting to order.
9 The first item on the agenda is the review of the agenda.
10 So we've got a final agenda in front of us, and I would
11 welcome or entertain a motion to accept that final agenda as
12 presented.

13 MR. VELEZ: Commissioner Velez here. I would like
14 to make a motion to approve the agenda for today's meeting.

15 MR. FALAHEE: Thank you. Is there support?

16 DR. FERGUSON: Ferguson. Second.

17 MR. FALAHEE: Thank you. Got a motion on the
18 floor. All in favor say aye.

19 ALL: Aye.

20 MR. FALAHEE: Opposed? Thank you very much.

21 (Whereupon motion passed at 9:31 a.m.)

22 MR. FALAHEE: Next is declaration of conflicts of
23 interest. As always, if there's something on the agenda
24 that we just approved that you think poses a potential
25 conflict of interest for you, now is the time to disclose

1 that. Hearing none, we'll move forward. The next item is a
2 review of the minutes of our snowy meeting on January 23.
3 As usual, the minutes are put together very well. And if
4 you really want to get into the details, you can read the
5 transcript of all those meetings as well. Marcy does so
6 well. But I would entertain a motion to approve the minutes
7 of January 23, please.

8 MR. DRAKE: Commissioner Drake, motion to approve.

9 MR. VELEZ: Seconded.

10 MR. FALAHEE: Thank you very much. Any
11 discussion? All in favor say aye.

12 ALL: Aye.

13 MR. FALAHEE: Opposed? Great. Thank you very
14 much.

15 (Whereupon motion passed at 9:32 a.m.)

16 MR. FALAHEE: Well, we, we have three items to
17 come to the Commission today in terms of CON standards and
18 the first of those, Cardiac Catheterization Services, the
19 final report. Dr. Madder --

20 MR. CONNOLLY: Can I make a quick announcement
21 before we start?

22 MR. FALAHEE: I think so. Go ahead.

23 MR. CONNOLLY: Just wanted to let everybody know.
24 The Department would like to announce that Renee Turner-
25 Bailey has resigned from the Commission. We would like to

1 thank her for her years of service and wish her success on
2 her future endeavors. We just wanted to make everybody
3 aware that she's not present right now.

4 MR. FALAHEE: Thanks, Marcus. And that was in my
5 notes and I blew right through them. So thank you very
6 much.

7 MR. CONNOLLY: No problem.

8 MR. FALAHEE: So the first item, Cardiac Cath
9 Services. I'll turn it to the Department. And I know that
10 Dr. Madder is online. I heard his voice earlier when he was
11 signing in. So I'll go to the Department first and then
12 we'll go to Dr. Madder and I'll congratulate him when we get
13 to that point.

14 MR. EASTER: All right. The report will be given
15 by the Cardiac Cath chair Dr. Madder who is available via
16 Zoom. A copy of the report can be located in everyone's
17 binder. All recommended language in front of the Commission
18 reached a consensus. The Department is including the
19 technical edit across all standards that requires a
20 notification to the Department no later than 30 days for the
21 planned decrease or discontinuation of the CON service. An
22 extra meeting was added to finalize the language. This was
23 still within the six-month time frame required by the
24 bylaws. We have -- and if Dr. Madder wants to go into the
25 report now and then we have public comment that can follow

1 afterwards.

2 MR. FALAHEE: That would be great. And is Dr.
3 Madder going to be up on the screen here once Tiffani clicks
4 the right buttons?

5 DR. RYAN MADDER: Yeah. Hey, guys. Can you hear
6 me okay?

7 MR. FALAHEE: There you go. There you go. Dr.
8 Madder, Ryan, thanks again for willing -- time number two to
9 head up the SAC. So we really appreciate it, the Commission
10 appreciates it. Thanks, again, for all your time and effort
11 on this.

12 DR. RYAN MADDER: Sure. And I will say I'm having
13 a hard time hearing what's being stated in the room. So I
14 don't, I don't know where the microphone is there, but
15 perhaps if there are any questions, you could have whoever
16 is sitting in front of the microphone repeat the question so
17 I can hear them.

18 MR. FALAHEE: Okay. We will do that. Thank you.
19 You -- go ahead and present your report then.

20 DR. RYAN MADDER: Yeah, sure. So I'll -- as you
21 guys know, we met seven times as, as the most recent SAC for
22 Cardiac Cath and, you know, the last meeting we had was
23 November 21st of 2024. We then submitted the reports
24 thereafter. But I'll go through each of the, the seven
25 charges and I'll, I'll take a break after each one if that's

1 okay just so that I can answer any questions that, that
2 might come up.

3 But charge 1 was to review the CON current
4 standards and to make sure that they aligned with societal
5 recommendations and what CMS recommends what we'll pay for
6 regarding, you know, procedures particularly in, in FSOFs.
7 And so we formed a subcommittee to look at the CMS rules as
8 well as the societal guidelines by SCAI which is the Society
9 of Cardiac Angiography and Interventions.

10 And so the first thing we looked at were, were
11 myo-, myocardial biopsies. And so our recommendation is
12 that these only be performed in hospitals with open heart
13 surgery onsite. The exception to that is if the patient has
14 had a previous heart transplant and in that instance
15 patients we felt would be, it would be acceptable and safe
16 for those patients to have biopsies performed either in
17 hospitals or FSOFs with elective PCI programs.

18 The second thing we looked at for charge 1 was,
19 was CardioMEMS device which is a implantable device in the
20 pulmonary arteries to monitor pressures. And we are
21 recommending that those only be performed in hospitals with
22 open heart surgery onsite only because the perforation when
23 they happen, although they're rare, can be very challenging
24 to manage.

25 The third thing we looked at was a coronary

1 atherectomy. And we are recommending that coronary
2 atherectomy can be performed in hospitals without open heart
3 surgery onsite that also have elective PCI programs. And as
4 a safety measure to allowing that, we're recommending that
5 the physician performing atherectomy in such an institution
6 has at least three years and 50 atherectomies that they've
7 done post-fellowship, and that they perform at least 10
8 atherectomies per year. So we think that's a safety net to
9 ensure that the adequate level of experience is, is present
10 to do those in a facility without surgery onsite.

11 We're recommending to update the definition of
12 cardiac implantable electric devices to allow pacemaker and
13 ICD extractions, relocations and revisions in FSOFs and
14 hospitals with diagnostic cardiac cath approval except for
15 procedures involving leads greater than 12 months old which
16 are restricted only to hospitals with onsite surgery.

17 We wanted to clarify that leadless pacemaker
18 procedures are only allowed in hospitals with elective PCI
19 programs or, or that have onsite surgery, but that these
20 should not be performed in FSOFs.

21 And then we updated the standards or recommending
22 to update the standards to allow right-sided ablations with
23 the exception of ventricular tachycardia in FSOF-based cath
24 labs and this is based off of a societal recommendation as
25 well as data showing that these are safe to be performed,

1 you know, in that setting. But just of note, CMS has not
2 yet approved right-sided ablations, although there was
3 general consensus in the SAC that this is, this is
4 forthcoming.

5 And then we recommended to update the standards to
6 allow left-sided ablation procedures in hospital-based
7 elective PCI programs, and we put some procedural volume
8 requirements in place that they have at least performed 10
9 right-sided ablations in the prior 12 months, and that the
10 physicians performing the ablations have at least two years
11 of experience post-fellowship and have performed a total of
12 at least 150 left-sided ablations post-fellowship and that
13 they're Board Certified in electrophysiology. And then
14 there's a stipulation that we're recommending, these
15 physicians must also perform at least 50 left-sided
16 ablations per year. And then we wanted to clarify that
17 ventric-, ventricular tachycardia ablations can only be
18 performed in hospitals with a surgery onsite. And, again,
19 that's based off of safety concerns.

20 So I'll stop there, but I think these
21 recommendations again would, if, if put forward by the, the
22 CON Commission to update the standards, I think would, you
23 know, allow us to align with CMS as well as with current
24 professional society recommendations.

25 MR. FALAHEE: Great. Thanks. This is Falahee.

1 Any questions from the commissioners? Commissioner
2 Ferguson?

3 DR. FERGUSON: Hi. It's Eric Ferguson here.
4 Thanks for all your hard work on this. That's a lot of
5 great detail which is fabulous because that's what we're --

6 DR. RYAN MADDER: And Tiffani or Justin, is the
7 room still there?

8 MR. FALAHEE: Hang on, Dr. Madder. We're trying
9 to make some audio adjustments here. Can you hear me okay?

10 MS. STANTON: Can you hear us okay?

11 DR. RYAN MADDER: I can hear you. I wouldn't say
12 it's okay.

13 DR. FERGUSON: All right. I'll, I'll try again.
14 Can you hear me?

15 DR. RYAN MADDER: That's a little bit better.

16 DR. FERGUSON: It's Commissioner Ferguson. Thank
17 you for your hard work on this. Were any of these
18 controversial or were these all consensus or near consensus?

19 MS. GUIDO-ALLEN: Chip, can you repeat it? He
20 hears you.

21 MR. FALAHEE: Yeah. Let me repeat the question. I
22 think -- this is Falahee again. I think you can hear me.
23 We're trying to get the audio worked. The question was from
24 Commissioner Ferguson on these first sets of
25 recommendations, were they controversial at or, or were they

1 consensus or almost consensus?

2 MS. STANTON: Can you hear us better? Can you
3 hear anything? Dr. Madder?

4 MR. EASTER: Dr. Madder, can you hear me?

5 DR. RYAN MADDER: I can hear you, Justin.

6 MR. EASTER: Okay.

7 DR. RYAN MADDER: That's much better.

8 MR. FALAHEE: Go repeat. Go ahead and repeat.

9 MR. EASTER: Okay. Can you say that again?

10 DR. RYAN MADDER: That's much better. There's a
11 little bit of an echo, but the volume is so much better.

12 DR. FERGUSON: Were, were any of these
13 controversial or were they all consensus or near consensus?

14 MR. EASTER: Were any of these controversial or
15 did each of these, all consensus?

16 DR. RYAN MADDER: Yeah. I don't remember what the
17 split on the vote was for this. My general recollection
18 were that none of these were, were controversial. That we
19 had, you know, a general agreement on almost all of the
20 charges maybe except some of the conversations about things
21 taking place in, in the UP.

22 DR. FERGUSON: Perfect. Thank you.

23 MR. EASTER: Thank you.

24 DR. RYAN MADDER: Are there, are there any other
25 questions on charge 1?

1 MR. FALAHEE: I don't think so, so move ahead to
2 charge 2.

3 DR. RYAN MADDER: Justin, was that go ahead to
4 charge 2?

5 MR. EASTER: Yes.

6 DR. RYAN MADDER: Okay. So charge 2 was to
7 consider whether it's appropriate to, to modify the
8 definition of diagnostic Cardiac Catheterization Services in
9 order to allow permanent pacemaker and ICD implantation
10 procedures to be performed in ambulatory surgical centers to
11 align with CMS. And we're recommending that, yes, we, we
12 modify the definitions of, of cardiac cath procedure and
13 diagnostic cardiac catheterization procedures to make it
14 clear that all implantable devices, you know, as, you know,
15 according to the stuff we talked about in charge 1, would be
16 allowed to be performed in ORs at both hospitals and FSOFs.
17 And so that was just, I think, cleanup that, that
18 definition. Are there any questions about, about that?

19 MR. FALAHEE: Any questions from the
20 Commissioners? So Justin --

21 MR. EASTER: No questions.

22 DR. RYAN MADDER: Great. Charge 3 was to review
23 the current standards and determine whether cardiac cath
24 procedures can be performed safely and in which settings and
25 under what conditions or requirements based on societal and

1 federal guidelines. We really felt that this third charge
2 was, you know, very similar to charge 1 and so all of the
3 recommendations that the SAC made for charge 1 also apply to
4 charge 3. So we don't have anything additional to add for,
5 for charge 3. Are there any questions about that?

6 MR. FALAHEE: No. Go ahead, Justin.

7 MR. EASTER: Go to 4 please.

8 DR. RYAN MADDER: Sure. So charge 4 is to
9 consider whether revisions to the standards are appropriate
10 to allow certain cardiac cath procedures to be performed in
11 hospitals without onsite open heart surgery and under what
12 conditions and requirements. And, and we felt also that
13 most of the recommendations here would fall under the same
14 things that we recommended in charge 1. There was one
15 exception to this and this was that,

16 "The SAC is recommending deletion of Section
17 4(1)(m)(iii) which removes a limitation on the
18 initiation of new hospital-based elective PCI programs
19 unless the applicant can demonstrate that there are no
20 other existing PCI programs within 60 miles of the
21 applicant site."

22 There, there was quite a bit of discussion, I
23 think, about this point. Nobody on the SAC really had I
24 think any understanding of, of where this initial 60-mile
25 radius came from. We suspect that it was added probably

1 more than a decade ago to, to make sure that we don't delete
2 out or, excuse me, thin out PCI volumes at existing centers.
3 I think there was general belief that with the opening of
4 FSOFs to allow elective PCIs at FSOFs that this 60-mile
5 radius becomes somewhat, has become somewhat obsolete. And
6 so there was a vote and the vote was to recommend removing
7 the 60-mile radius.

8 The other thing is I think there was a very good
9 clinical case made for, for, you know, how this impacts
10 patients in its current state. There are hospitals
11 currently performing primary PCI within the state of
12 Michigan and in the setting of primary PCI, it's become best
13 practice to open up any non-, non-culprit lesions, meaning
14 lesions that did not cause the heart attack but which are
15 severe. Those are generally opened up either in the same
16 procedure or in the same hospital stay because it reduces
17 the risk of subsequent mortality and, and heart attack. And
18 for pat- -- for places that are currently only doing
19 elective PCI, those patients are having to be transferred --
20 excuse me, that are only doing primary PCI, those patients
21 are having to be transferred for those elective procedures
22 in order to reduce their risk of, of mortality and future
23 heart attack. And, and we felt that that was a limitation
24 for patients in those communities. And so the
25 recommendation was to eliminate this 60-mile radius. Are

1 there any questions about that?

2 MR. EASTER: One question.

3 DR. FERGUSON: It's Commissioner Ferguson again.

4 I want to make sure I understand the rules. Am I correct in
5 understanding that a hospital can't open a program within 60
6 miles under the current rules, but an FSOF could?

7 MR. EASTER: So can a hospital that can open --
8 say that one more time. I'm sorry.

9 DR. FERGUSON: If I understand correctly under the
10 current rules, the 60-mile rules, a hospital could not open
11 a new program, but if they were an FSOF within 60 miles,
12 they could? Is that --

13 DR. RYAN MADDER: Yeah, I think I understood the
14 question. So FSOFs actually have a requirement to be within
15 a certain radius of an existing hospital as a safety measure
16 and we put that in the, the last SAC cycle during the
17 pandemic. And, and that was to ensure that if a
18 complication arose at an FSOF, that that patient could be
19 efficiently transferred to a hospital that could manage that
20 complication and so that, that again was a safety
21 requirement. So, yes, an FSOF can open up within a 60-mile
22 radius of, of a hospital. In fact, has to have, I think, a
23 tighter radius than that for, for opening up an, an FSOF. I
24 don't -- did that answer the question?

25 DR. FERGUSON: Yeah, it does. Thank you. And

1 then with respect to the 60 miles, was there any, is there
2 any appropriate limit or is -- this is really difficult.

3 This is extraordinarily hard to have a meaningful con- --

4 MR. FALAHEE: Could we -- would it possible if we
5 took a short break to figure this out? Because it, it's not
6 going to function well. Because it worked well when we had
7 Professor Delamater.

8 MS. STANTON: It's the same settings. Doctor --
9 Dr. Madder, can you hear us at all? Can you --

10 DR. RYAN MADDER: I can hear you fine. There's a
11 little bit of an echo, but when I mute my audio it's, it's a
12 little better.

13 MS. STANTON: Is it -- can you hear us now?

14 DR. RYAN MADDER: I can hear you now fine.

15 MS. STANTON: Okay. Dr. Ferguson, can you try
16 speaking?

17 DR. FERGUSON: So --

18 MS. NAGEL: Can he speak without the microphone?

19 MR. EASTER: Sorry. I will mute.

20 DR. FERGUSON: Try that without the microphone.

21 MS. STANTON: There. No, go ahead. You can turn
22 your mic on. Sorry. Can you --

23 DR. FERGUSON: Do you want the mic on or off?

24 MS. STANTON: Yeah, it was -- it was Justin's
25 speaker.

1 DR. FERGUSON: How's that?

2 MS. STANTON: Can you hear him?

3 MR. FALAHEE: Better.

4 DR. FERGUSON: All right.

5 MS. STANTON: Dr. Madder, can you hear Dr.
6 Ferguson?

7 DR. RYAN MADDER: I can hear him much better and
8 the echo is gone.

9 DR. FERGUSON: Great. So going from 60 miles to
10 zero miles is a big change. I'm not necessarily opposed to
11 it. Was there any consideration -- is there any appropriate
12 restrictive mile limit to meet the overall desire to the
13 state and the CON to provide appropriate services but not
14 spread too thin, et cetera, et cetera. Or is the right
15 answer truly zero limit?

16 DR. RYAN MADDER: And I, my own opinion about this
17 is that I'm not sure there, there is a right answer. You
18 know, the more programs that we open up, you know, that will
19 dilute out elective PCI volumes. There's, there's no
20 question about that. We are not recommending any changes at
21 least outside of rural settings to the number of PCIs that
22 have to be performed per year in order to, to keep a program
23 open. And so our hope is that, yes, although this could
24 dilute out, you know, PCI volumes, that most programs will
25 not fall below that, that 200 PCI threshold per year, again,

1 outside of rural settings where, where, you know, this would
2 become a safety concern.

3 DR. FERGUSON: Thank you.

4 DR. RYAN MADDER: But I think, I think it is, you
5 know, one of those things -- and, again, this was not
6 something from the SAC, but just my own opinion that, you
7 know, if this change is accepted, that it's something that
8 could be tracked and, you know, looked at again at the next
9 cycle to see, see the impact that this has had on, on PCI
10 volumes across the state.

11 MR. DRAKE: This is Commissioner Drake. Question
12 for you. So in the 60-mile radius I, I go to access. So
13 were there discussions during the SAC that the current 60-
14 mile radius was prohibiting access or what really drove the
15 need to touch that? What problem were we trying to solve by
16 removing the 60-mile radius?

17 DR. RYAN MADDER: Yeah. Great question. And, and
18 I think my understanding of this from those that were very
19 much in favor of this had to get back to this example of
20 patients with, with STEMI, so primary PCI. And so there are
21 programs that have, primary PCI programs that have opened
22 that are currently functional doing, you know, a good volume
23 of primary PCIs per year. And if you go back ten years ago,
24 you know, the current best practice pattern in the United
25 States was that you would only fix with PCI the culprit

1 lesion that caused the heart attack. Based on, you know, a,
2 a dozen or more randomized control trials that have come out
3 in the past ten years, we now recognize that the thing that
4 is best for patients when they come in and need a primary
5 PCI, is that we also do elective PCIs either in the same
6 procedure or during that hospital stay to fix non-culprit
7 lesions that, that are severe and, and that by doing so we
8 can reduce patients' risk of mortality and subsequent heart
9 attack. And so right now those primary PCI programs that
10 only have primary PCI are having to transfer a subset of
11 their patients who need additional work done and that
12 creates challenges, I think, for that patient as well as
13 for, for the patient's families and the patients in that
14 community that they can't get all of that work done at the
15 hospital that they initially present to.

16 MR. DRAKE: So to take that further then, so I
17 understand the issue we're trying to solve. Was there
18 discussion of solving that by giving the primary centers
19 more if they've got the patient, why couldn't they --
20 what -- did you look at giving those centers the opportunity
21 to do the additional work during the hospitalization or
22 doing more during their procedure?

23 DR. RYAN MADDER: Yeah. We did not talk about
24 creating, you know, a special set of circumstances for, for
25 those patients to do, you know, to have elective PCIs done

1 in that, that same hospital setting. And, and I think one
2 of the concerns at least that I would have would be that,
3 you know, we know that when elective PCI numbers -- or PCI
4 numbers at any given institution fall below 200 per year,
5 that that can impact safety for patients. And so there's,
6 there's a balance there I think that if you do make that
7 exception for those hospitals to do it, I think you probably
8 want to put something in place to ensure that their PCI
9 volumes remain, remain adequate.

10 MR. DRAKE: That concludes my questions. I'll
11 reserve more maybe depending on, on the public comment.

12 MR. FALAHEE: Okay. Thanks, Commissioner Drake.

13 MS. GUIDO-ALLEN: Guido-Allen. Can the Department
14 weigh in on what they think about the deletion of the
15 60-mile radius and tell us what, what was the premise behind
16 the 60-mile if, if anybody remembers?

17 MS. BHATTACHARYA: Thank you. This is Tulika. If
18 I can -- before I answer the direct question. So I want to
19 say that we are maybe talking about two different things.
20 So when there is a PCI program where they're in a hospital
21 or FSOF without onsite open heart surgery, that facility
22 needs to have a written agreement with an open heart surgery
23 hospital within a 30-minute's travel time for FSOF/ASC and
24 for hospitals within a 60-minute's travel time. That is
25 still there. This change is not affecting that. What this

1 language was doing in the current standard is this. So if
2 you are a primary PCI hospital and you want to start
3 offering elective PCI service, you'll have to meet all of
4 the requirements, plus you have to show that they are no
5 other PCI programs within 60 whatever minutes/mile of you.
6 So this change is eliminating that provision in the
7 standard. And if you think of the entire state as a whole,
8 there are, according to the 2023 annual survey, there are 15
9 elective PCI program and only two primary PCI programs at
10 two hospitals. So this change will allow those two
11 hospitals if they meet all other requirements to start
12 offering elective PCI services. And also, when an FSOF/ASC
13 wants to start offering diagnostic cath and elective PCI
14 service, there is no mile radius or additional requirements
15 for them to show we have nobody within, you know, 60 minutes
16 or 60 mile radius.

17 So, Commissioner Guido-Allen, did I answer your
18 question?

19 MS. GUIDO-ALLEN: You did. And all of that,
20 though, when they fill out their annual surveys, would have
21 to meet the minimum volume requirements; correct?

22 MS. BHATTACHARYA: Yeah. Within two years of
23 starting to offer their services.

24 MS. GUIDO-ALLEN: Thank you.

25 MR. FALAHEE: Thanks, Tulika. And I think we can

1 then, with no more questions, move on to the next charge.

2 Thanks, Dr. Madder.

3 DR. RYAN MADDER: Yeah. No, thank you to Tulika
4 for always making it easier to understand for everybody.
5 Yeah, thank you.

6 Yeah. So charge 5 was considering provisions to
7 include access to cardiac cath services in rural areas,
8 including initiation requirements for elective PCI. And so
9 we, we formed -- the SAC did form a subcommittee to review
10 issues within rural areas in the state and the SAC is
11 recommending the following four things. The first is that
12 we modify cardiac cath maintenance volumes for hospitals
13 located in either rural or micropolitan areas to measure
14 total cardiac cath volumes instead of splitting out
15 diagnostic.

16 The second is to reduce PCI volume requirements
17 for hospitals located in rural or micropolitan areas to --
18 from 200 which is the current standard to, to 100 procedures
19 per year. And, you know, I, I just have to say. I, I
20 always -- we receive a lot of transfers from, you know,
21 rural areas to our hospital in, in Grand Rapids and you
22 always feel for the patients and families in, in those areas
23 that they don't have a lot of these services close to them.
24 So I think anything -- you know, I think there was a general
25 consensus in the SAC that things that we could do to, to

1 help maintain access for patients in those rural areas, you
2 know, would be considered favorable. And so that was kind
3 of the rationale behind that one.

4 The third one was to allow for inclusion in PCI
5 projection of all registered patients transferred from the
6 applicant hospital to another hospital for PCI rather than
7 just allowing the counting of inpatients. And the reason
8 for that is that, that emergency room patients who get
9 transferred currently aren't count-, counted because they're
10 not registered and -- or, sorry, they're not inpatients and
11 so, but they are registered. And so by including them,
12 again, I think that may increase access for, for patients in
13 some of our communities in Michigan.

14 And then the final one under this charge was to
15 allow for commitments of patients who receive diagnostic
16 cardiac cath at the applicant facility and received an
17 elective PCI at another cardiac cath services within 60
18 days. So expanding that to 60 days rather than the current
19 30 days if that applicant facility is, again, located in a
20 rural or micropolitan area. And all, again, all of these
21 changes, the rationale was to try to improve access.

22 So I'll stop there and answer questions related to
23 this one.

24 MR. FALAHEE: Any questions from the
25 Commissioners? I'll ask any comments from Tulika? Okay.

1 Thanks. Okay.

2 MS. GUIDO-ALLEN: I just have one question.
3 Guido-Allen. Registered patients for moving from just
4 inpatient, are we also including observation patients?
5 Because many of these folks will not meet inpatient status
6 even if they were "admitted." So is that ER, obs and
7 inpatient?

8 MS. BHATTACHARYA: When you remove the term
9 inpatient, it's any patients at the hospital. Seen at the
10 hospital.

11 MS. GUIDO-ALLEN: Thank you.

12 MR. FALAHEE: This is Falahee. The reason we ask
13 that when we're in the hospital community, more and more
14 patients are not inpatients even though they're in the
15 hospital. They're observation patients. They're still
16 occupying a bed, but that's why I'm sure that question was
17 asked. So, thanks. All right. Dr. Madder, next one,
18 please. Thank you.

19 DR. RYAN MADDER: Sure. Charge number 6 of 7.
20 Charge 6 was to review provisions and definitions for hybrid
21 ORs and cath labs and to recommend any changes, you know,
22 for facilities that can have those. And so the SAC is, is
23 recommending that we modify the standards to allow any
24 facility that has approval for surgical services and, and
25 cardiac cath services to qualify for a hybrid OR and cath

1 lab. And the, the rationale behind this is that the, the
2 concept of the hybrid OR/cath lab really came about when,
3 when transcatheter aortic valve therapies became clinically
4 available and, you know, these are done with -- it's an
5 endovascular procedure with, you know, percutaneous access,
6 but a certain percentage of those patients will require, you
7 know, emergent open heart surgery. And so having a combined
8 OR/cath lab, you know, really made sense. However, we, the
9 SAC, did not believe that there was any reason at this point
10 in time that that should, you know, only be, be limited to,
11 to, you know, TAVR procedures. That we thought any facility
12 that wanted to, to install cath lab equipment in an
13 operating room so that they could use their facilities more
14 efficiently should, should be able to do so. And we also
15 felt that there be no drawback in expanding the use of, of a
16 hybrid OR/cath lab, you know, to facility, you know, for
17 instance, the FSOFs which would allow them to use theirs
18 also more efficiently. So I'll stop there and take
19 questions about this one.

20 MR. FALAHEE: Any question -- any questions from
21 Commissioners?

22 DR. DELANO: Commissioner Delano. Ryan, thanks
23 for all your hard work on this. I'll echo that without the
24 echo at some point this time. I, I was wondering if there's
25 a cost analysis done. If it's OR space, usually it's more

1 expensive than another lab. Is there any difference?

2 DR. RYAN MADDER: Oh, I agree with you that I
3 think it's, you know, an OR is in general more expensive
4 than a cath lab. But I think if facilities, you know, want
5 to use, you know, OR space, for instance if it's not being,
6 you know, fully utilized and, and they put a C-arm in there
7 and, and use it as a cath lab, it may increase the
8 appropriate or more, you know, increase the usage of that
9 space. And I think also that business can have implications
10 for FSOFs which, you know, have to have an, an OR is my
11 understanding. And so to be able to do both cardiac cath
12 procedures as well as, you know, OR-based procedures in that
13 I think it's going to increase the utility of these spaces.

14 DR. DELANO: I'll just add I didn't doubt the, the
15 practical nature of that. It's just about if there's
16 preferential placement of, of elective procedures into an OR
17 space, are they going to be billing OR facility fees when
18 they could be, you know, scheduling the patients elsewhere?
19 So there could be an unhealthy incentive to use those spaces
20 efficiently so to speak.

21 DR. RYAN MADDER: Yeah. And I think that's a
22 great question, and I, I don't know enough about how those
23 are billed out to know the immediate impact. But I think
24 it's a, a very relevant, a very important question.

25 MR. FALAHEE: Okay. Any other questions? Moving

1 on.

2 DR. RYAN MADDER: And then charge 7 was just
3 consider any other technical changes from the Department,
4 you know, regarding any modifications to the, the standards.
5 And so there were a whole bunch of, of kind of just
6 technical updates, we fixed some typos, and rewriting some
7 of the sections just to make them more easy to understand.
8 And, and the SAC did not feel that any of these although
9 very important, were really -- that they weren't that
10 substantive in, in nature. And so I think that's all we
11 have on, on charge 7. Any questions about that?

12 MR. FALAHEE: No questions about that. So --

13 DR. RYAN MADDER: And we included --

14 MR. FALAHEE: -- hang on. One, sorry, one, one
15 more.

16 DR. RYAN MADDER: Sure. Go ahead.

17 MR. FALAHEE: Commissioner Delano?

18 DR. DELANO: I was just going to circle back to 6.
19 I'm struggling with this. I'm just thinking of the
20 situation where we put MRIs in ORs and, you know, the cost
21 for that is a lot more than, for example, an outpatient
22 facility with an OR -- with, with an MRI. I, I just
23 don't -- we, we're acknowledging that there's a potential
24 conflict of interest in how they're utilized, endorsing its
25 use for practical purposes to make sure that there's optimal

1 utilization, but it's reliant entirely on, on goodwill, I
2 think. And, and I'm hoping that everybody looks at it in a
3 cost effective manner which "hope" isn't really a good CON
4 standard. So I was wondering if there should be any further
5 discussion of that. I don't have a solution myself, but
6 sounds like the workgroup didn't really specifically address
7 that.

8 MR. FALAHEE: And this is, this is Falahee. I
9 would say that we need to look at this separately from a CON
10 perspective and then a billing perspective. And hospital
11 billing -- Tulika knows a lot, but she's not going to know
12 about hospital billing. And hospital billing is very
13 complicated. I think that's outside of the purview of the
14 CON Commission. But I think from a, what we look at as the
15 quality, access, yes, cost of it, but I think there are ways
16 that hospital billing itself separate from CON can handle
17 the questions that you raise.

18 DR. FERGUSON: This is Ferguson. So I agree
19 details of hospital billing is not our purview, but cost is.
20 And if this is a move that has a -- maybe it has meaningful
21 risk, maybe it doesn't. But if it has a meaningful risk of
22 driving up cost, I think it does become our purview. I'd be
23 interested in hearing some type of...

24 DR. MILEWSKI: So I agree that cost does sit
25 within our purview. I have mixed feelings about this

1 because we do hear that hospitals are looking for ways to
2 re-task spaces as more volume moves out. So there's the
3 opportunity for increasing efficiency. There is a billing
4 aspect of this. I think that it is incumbent upon the
5 facilities to only bill for the services that they are
6 providing. So if they're not using the OR space and then
7 it's incumbent on insurance companies as fiduciaries to make
8 sure that that is compliant.

9 DR. FERGUSON: So what do you recommend? Sorry to
10 put you on the spot because --

11 DR. MILEWSKI: Yeah.

12 DR. FERGUSON: -- you have a lot of insight on
13 this and --

14 DR. MILEWSKI: Yeah. My thoughts are that it is,
15 you know, I think from an efficiency standpoint -- and I
16 don't sit in the facility space. From an efficiency
17 standpoint, from a patient care standpoint it can make some
18 sense. Will it create some billing issues? Potentially
19 that will have to be guarded against.

20 DR. FERGUSON: Thank you.

21 MR. FALAHEE: Thank you. Good discussion. Thank
22 you. Any other questions on that? Okay. Moving on.

23 DR. RYAN MADDER: Yeah. And then just the last
24 thing that's in the report is just an initiative that came
25 up that we talked about as it would impact the UP.

1 And so one of the hospital systems in the UP
2 currently has a team of cardiologists and cath lab staff
3 members that travel there several days a week to provide
4 cardiac cath services, diagnostic cardiac cath services, to
5 that community in that hospital. And the rationale to, to
6 do that is that a large portion of the population in the
7 lower aspect of the UP is apparently traveling to Wisconsin
8 to get cardiac cath services done when they need them. And
9 in order to try to keep those patients closer to home, this
10 program was initiated where they're, again, doing diagnostic
11 cath services there with a team from, from Wisconsin.

12 The, the possibility was brought up of allowing
13 that institution to do a pilot where they would do, you
14 know, elective PCI or even potentially primary PCI on the
15 days that, you know, that, that team was there. And there
16 was a lot of discussion about this. You know, ultimately I
17 think there was a ton of support for this, but I think we,
18 we, you know, felt that, that we ran out of time before
19 being able to iron out all the details to allow this to, to,
20 to recommend this going forward at this point. But we do
21 think at a minimum that this is, you know, deserves further
22 discussion at the next SAC to address whether this is
23 something that, that could go forward and certainly would
24 encourage additional discussion between now and then if
25 there's a way to, to allow this to move forward only because

1 I think it has a tremendous potential to improve access to
2 cardiac cath services and PCI in the UP.

3 MR. FALAHEE: Okay. Falahee again. Any questions
4 about that? I know we have public comment on this issue,
5 but before we do that, any questions from the commissioners?

6 MR. DRAKE: This is Commissioner Drake. That's a
7 great idea on the pilot. I do remember in the previous
8 meeting that we've talked about pilots before, and I'd be
9 supportive if there was a way to do a pilot, to figure out
10 how that could be achieved.

11 DR. RYAN MADDER: Yeah. And I, I, I'm glad to
12 hear that. And, and I, I will say, you know, there's a lot
13 of -- there are a lot of existing data on, you know,
14 cardiovascular outcomes in, in rural populations in the U.S.
15 compared to, to ur-, the urban counterparts. And, you know,
16 as additional background for this, you know, 62 percent of
17 counties in the United States don't have a cardiologist.
18 And when you don't have a cardiologist, you don't have
19 cardiac cath or PCI services. And so there are also very
20 strong data that, you know, if you are a patient in a rural
21 community right now in the United States and you present to
22 a rural hospital with a heart attack, you are significantly
23 less likely to get a cardiac cath and significantly less
24 likely to get a PCI compared to, to, you know, if you
25 present to an, an urban or suburban hospital. And, and so

1 there's this concept which is really unfortunate but
2 continues to exist, that where you live determines if you
3 live. And there are very strong data showing that if you
4 live in a rural population within the United States
5 including the UP, that your cardiovascular mortality is
6 higher; and a good chunk of that is because you don't have
7 access to services. So, again, I think things that we can
8 do as a state to try to improve access to, to those services
9 in those counties, I, I personally believe would be very
10 favorable if we can find a way to do it safely.

11 MR. VELEZ: Commissioner Velez here. I am really
12 interested with the idea of having a pilot program, but I
13 would like to be more educated on the requirements,
14 limitations, and outcome.

15 DR. RYAN MADDER: Yeah. I agree with you
16 completely. I, I think -- and that was part of the reason
17 the SAC did not agree to, to recommend this at this time is
18 that, that those details about how, how this would be
19 enacted and, you know, what data would be tracked to prove,
20 you know, the safety and efficacy of this, you know, just
21 were not presented. And so I think additional time was
22 needed to put that type of proposal together.

23 MR. FALAHEE: Seeing no hands I think that's it
24 for the commissioners. Dr. Madder, I don't know if you have
25 the time to stick around to hear what witness or people

1 coming up to the podium have to say -- I always say
2 witnesses and that's not (inaudible). So, but if you, if
3 you need to leave, we understand. I want to thank you again
4 on behalf of the Commission and personally because when I
5 reached out to you and asked if you would do it again, you
6 readily said yes. And I congratulated Darryl Amucci as well
7 on that. So thank you again. If you have the time, you're
8 welcome to stick around and we hope you can hear people, but
9 if you need to leave, we understand.

10 DR. RYAN MADDER: Yep. I'm happy to stick around.

11 MR. FALAHEE: Great. Thank you. Okay. We have
12 some cards. So, Justin?

13 MR. EASTER: So we've received public comment from
14 McLaren in support of the language. This has been included
15 in your electronic binder. They have also submitted a blue
16 card to come up to speak. Katherine?

17 MS. TUCKER: We have Dr. Zacharias from McLaren.

18 SIBIN ZACHARIAS, M.D.

19 DR. SIBIN ZACHARIAS: Good morning. On behalf of
20 my colleagues at McLaren, thank you for the opportunity to
21 speak here today. My name is Dr. Sabin Zacharias. I am an
22 interventional cardiologist with the McLaren cardiovascular
23 institute, practicing out of our hospitals in Pontiac and
24 Mount Clemens, and our standalone ERs in both Clarkston and
25 Oxford. I am one of several physicians who provide primary

1 PCI with emergency heart stenting for patients at McLaren
2 Oakland.

3 We currently can only offer primary PCI to
4 patients who come to the hospital with an acute -- with
5 acute chest pain caused by an emergent heart attack.
6 However, there are many clinical situations in which it is
7 necessary to provide PCI to these patients on a non-urgent,
8 elective basis. Practically speaking, if a patient with an
9 acute heart attack has coronary disease that involves more
10 than one heart artery which requires additional stenting or
11 has an abnormal inpatient or outpatient stress test which
12 ultimately will require heart artery stenting, we are unable
13 to provide immediate stenting treatment based on the current
14 CON rules. Unfortunately, these patients must be
15 transferred to another facility for elective PCI. This may
16 result in delays in care, added costs, and patient or family
17 inconvenience among others.

18 We are eager to advance the cardiac care in our
19 community which includes Pontiac, Waterford, Oxford,
20 Clarkston, and the surrounding regions, and provide greater
21 continuity with the ability to offer elective PCI. We
22 believe this will facilitate more efficient health care
23 delivery thereby improving quality of care and decrease in
24 costs to the benefit of our patients.

25 I am here to support the proposed language that

1 Dr. Madder and other members of the Cardiac Cath SAC
2 committee have recommended. Currently the standards
3 prohibit a hospital that was not approved as a primary PCI
4 center before 2015 from offering elective PCI if it is
5 within 60 minutes or 60 miles from the nearest PCI center.
6 The Cardiac Cath SAC committee has recommended removing that
7 rule from the standards. We agree with the proposed new
8 language and respectfully request that the CON Commission
9 consider adopting this recommendation to help improve health
10 care delivery in our community. We are very proud of the
11 primary PCI program and advancement in cardiac care that we
12 have brought to patients in northwest Oakland County, in the
13 McLaren Oakland region, and we are eager to build on that
14 foundation by offering elective PCI. Thank you again for
15 the opportunity to speak today.

16 MR. FALAHEE: Thank you, Doctor, for being here.
17 Appreciate it. Any questions or comments from the
18 commissioners?

19 MR. DRAKE: I'll make a comment. I was waiting to
20 hear some public comment. That answers my question on the
21 60-mile rule. So thank you for clarifying that.

22 DR. SIBIN ZACHARIAS: No problem.

23 MR. FALAHEE: Other questions? Great. Thank you
24 for being here.

25 DR. SIBIN ZACHARIAS: Thank you.

1 MS. TUCKER: Next we have public comment from Dr.
2 Cooley, OSF HealthCare.

3 MR. FALAHEE: I had the pleasure of speaking to
4 Dr. Cooley yesterday. Thanks to the Escanaba team from fly,
5 for flying down here today. Welcome to the joys of the CON
6 Commission. I, I forgot to add two things. Number one,
7 there's a new person sitting to my right. Some of you may
8 recognize Carl, Carl Hammaker, from the Attorney General's
9 Office. Carl was here before and then had the gall to leave
10 the Commission and Brien was here. Brien is moving into
11 other areas that were mainly his chief function and he
12 needed more time to do that. So we're happy to have Carl
13 back. For those of you that don't know, Carl is an M.D.
14 J.D. So we can approach him with medical issues and legal
15 issues. Carl, welcome. And then the other thing I'll add
16 is that -- and Dr. Cooley knows this, but for those of you
17 that don't, when we have folks come up and speak from the
18 podium, there's a three-minute time limit and then if we ask
19 you questions, there's no limit on the length of questions
20 or the answers to those questions. So with that, Dr.
21 Cooley, the floor is yours. Thank you.

22 DR. RICH COOLEY: Thank you, sir.

23 RICH COOLEY, D.O.

24 DR. RICH COOLEY: Thanks, everybody. I was able
25 to participate in the SAC that Dr. Madder led, and he asked

1 me to chair the rural subgroup that started to work through
2 some of the discussions that you had just had presented. I
3 started my practice in the Upper Peninsula of Michigan. I
4 trained down in the Detroit area and was a primary care,
5 do-it-all internal medicine doc in a small critical access
6 hospital in Ishpeming, Michigan, where I did inpatient
7 medicine, outpatient medicine, rounded at nursing homes,
8 took care of my own ICU, and was theologist for a whole lot
9 of patients in the small Upper Peninsula community of
10 Ishpeming. After that, I started the hospital medicine
11 program in Escanaba and have had various leadership roles
12 across northern Michigan really from Grayling, Alpena,
13 Traverse City, and up into Escanaba, Ishpeming, and
14 Marquette. So I know the northern Michigan landscape quite
15 well from a health care standpoint.

16 So I learned a lot in participating in the SAC and
17 in chairing a rural subgroup, and I'm still continuing to
18 learn more. When we wrapped up our work in November, I was
19 disappointed that we couldn't get further in getting access
20 to cardiac catheterization, particularly PCI for the rural
21 communities in the Upper Peninsula. And within the first
22 few weeks of wrapping up our work on the CON, I had event
23 reporting in our system when there's a safety concern that
24 roils up to me. I currently serve as the chief medical
25 officer in addition to working as a hospitalist, now and

1 again clinical. We had events come in to our event
2 reporting system on some adverse patient outcomes that
3 direct, directly go to this work.

4 The first one was a 50-year-old man, you know,
5 very rigorously healthy guy who presented to our hospital
6 with a heart attack. It was an inferior infarct. He did
7 not meet the criteria for emergent intervention, the STEMI
8 program that requires us to fire up the helicopter sitting
9 in our, in our parking lot. But he had an on STEMI. He had
10 EKG changes, he had compatible symptoms, he had elevated
11 troponin, and he needed attention. He was accepted and
12 transferred to Marquette, and we discharged him from our
13 emergency department five days later because there was no
14 bed available in Marquette. The echocardiogram done two
15 days before his discharge showed that the inferior wall of
16 his heart stopped working completely, his ejection fraction
17 dropped to 40 percent, and this man is going to have
18 ischemic cardiopathy and congestive heart failure the rest
19 of his life because we didn't have access to cath.

20 The next one was an 80-year-old man who also had a
21 similar presentation, accepted to Marquette, and died eight
22 hours later without a bed.

23 These are avoidable things. The things to fix
24 both of those patients was three minutes down the hall in
25 our new cath lab and with all of the folks that we bring up

1 from Wisconsin. And so I felt compelled to see what it is
2 that we could do. So I have the workgroup proposal in front
3 of you, and I'd be happy to entertain any questions.

4 MR. FALAHEE: Are there any commissioner questions
5 of Dr. Cooley, or, Dr. Madder, if you want to make any
6 comments you can as well. I told Dr. Cooley yesterday when
7 I spoke that the chair doesn't like it when things are
8 headed, handed out at the last minute. This was not last
9 minute sort of. It was handed out in front of you when they
10 got here after the plane landed so you can see that there.
11 But I think it discusses some of the issues that came up as,
12 as Dr. Madder said at the last meeting of the SAC. And if
13 I'm reading, or hearing and reading and interpreting
14 correctly, there just wasn't enough time to get into the
15 details of what would a pilot look like if that was the
16 decision. So, and that's why I believe -- and, Dr. Madder,
17 correct me if I'm wrong -- that's why the SAC did not
18 recommend anything but did say next time this is up for
19 review, perhaps this should be considered as part of the
20 next SAC that looks at these issues. Do I have that right,
21 Dr. Madder?

22 DR. RYAN MADDER: Yeah, that, that's correct. Is
23 that, yeah, there was, there was considerable support for a
24 pilot, just the, the details had not been flushed out. But,
25 yeah, I just wanted to comment on Dr. Cooley's two examples.

1 It's, it's really disheartening to hear, you know, examples
2 like that of which I'm sure he has, you know, a lot of such
3 examples just because, you know, again, to my comments
4 earlier, had, had those patients presented to a hospital
5 having, you know, cardiac cath services, I think those
6 outcomes would have been very different. And, yeah, it's,
7 it's just unfortunate to hear that the individuals in our
8 state based on the county that they live in, you know, they
9 don't get the treatment that the rest of us do and, and it's
10 just, it's too bad.

11 MR. FALAHEE: Thank you very much. Any questions
12 from the commissioners? Commissioner Ferguson?

13 DR. FERGUSON: A process question. So I'm hearing
14 that the SAC ran out of time to address this particular
15 topic. Would this topic have fit under one of the
16 prescribed charges? Meaning if there had been time, would
17 it have been addressable? Because I -- if I recall
18 correctly, you don't or we don't like the SACs and the
19 workgroups to expand and make up their own charges without
20 direction. So if -- I know it's kind of a technicality and
21 I'm not trying to undermine the spirit of -- this sounds
22 like I think we ought to be looking at. But from a process
23 perspective, in my mind, it becomes quite easy if this fits
24 under a charge and we ran out of time, I would suggest we
25 figure out a way to give them some more time.

1 MR. FALAHEE: Number one, we can't give them more
2 time. The SACs are alive for six months and then by rule
3 they go away. Number two, this would have fit in, under
4 either charge 4 or charge 5.

5 MR. EASTER: Charge 5.

6 MR. CONNOLLY: Charge 5.

7 MR. FALAHEE: Thank you. All right. And then I
8 think that if it comes up at the last meeting, that's an
9 issue we're trying to get details worked out. But, yeah, we
10 can't extend the length of the SAC.

11 DR. FERGUSON: So I, I -- that I understand, but
12 the alternative is can -- if we wanted to, could we create a
13 workgroup now or do we have to wait the three years or
14 whatever? Three years is a long time. Isn't it, isn't it a
15 three-year cycle for the next review?

16 MS. STANTON: We --

17 MR. FALAHEE: No, it -- no.

18 MR. EASTER: So we're taking public comment on it
19 this October. So it could come up for the next year as a
20 SAC or a workgroup depending on what the Commission decides.

21 DR. FERGUSON: Oh, very good. Thank you. That's
22 very helpful.

23 MR. FALAHEE: Commissioner -- I had the same
24 question, Commissioner Ferguson, on timing. So that we'll
25 be back in October with public comment and then, yeah. And

1 pers-, my personal thought is when we get there and talk
2 about it, this is one of those where my hunch is there are
3 opinions on both sides of the issue and that would not merit
4 a workgroup, it would be another SAC. Other questions from
5 the commissioners? Dr. Cooley, thank you very much.
6 Appreciate your time.

7 DR. RICH COOLEY: Thank you.

8 MR. FALAHEE: Do we have other public comment?

9 MS. TUCKER: Yes. Next we have Dr. Ricci from
10 Bellin Health.

11 JASON RICCI, M.D.

12 DR. JASON RICCI: Good morning. Thank you for the
13 opportunity to speak. So my name is Jason Ricci. I'm an
14 interventional cardiologist at Bellin Health in Green Bay,
15 but I do have strong Michigan ties. For the first nine
16 years of my career I was a interventionalist in Petoskey,
17 Michigan, in Northern Lower and I'm a byproduct, I grew up
18 in the Western UP. So this, this topic rings home for me.

19 I was asked to sort of comment on a similar
20 program that's being proposed potentially as a pilot that we
21 currently run with a rural hospital in Wisconsin, about 45
22 miles from where our home base is. We provide similar
23 kinds, types of services that was proposed. So we provide
24 complete interventional services Monday through Friday 8:00
25 to 4:00 o'clock. Within that, there are both elective cases

1 as well as primary PCI, as well as patients who come into
2 the hospital that have more urgent needs. And I think
3 overall the program has been an overwhelming success on, on
4 both ends, both for the rural hospital and for us. And I
5 think there's some tenets that make that successful and I
6 think a couple of things I want to comment on.

7 First and foremost is both organizations have to
8 have clear understanding of what is required and what is
9 needed and what can be done at each hospital and that
10 patients' needs have to be put first. This can't be an
11 ownership type thing, that this is our patient or their
12 patient. I think secondly you need a team of experienced
13 interventionalists that have high volumes that can do these
14 cases and are comfortable knowing what can be done at a more
15 rural hospital where we may have limited access to all the
16 tools we would typically use versus what type of patients
17 need more extended care where they should be transferred. I
18 think the other thing that's super important is there has to
19 be tremendous education at the rural hospital because,
20 again, you maybe take care of these patients for 45 minutes,
21 an hour, hour and a half and then their care is left to
22 nursing staff, ancillary staff, and there has to be
23 continued dialogue and continued education at that rural
24 hospital so the nurses, the technicians, everybody can
25 continue to take care of those patients once the

1 interventionalist leaves.

2 And then I, I think the last thing is like any
3 specialty care, the cardiologists have to be available. We
4 have -- you know, there's, there's the two As of being a
5 good specialist: you got to be available and you've got to
6 be applicable. And I think, you know, that although we're
7 not there all the time, we do provide 24/7 call coverage to,
8 to in the proposal that allows these patients and the
9 hospitals that are taking care of them to have continuous
10 access to us with questions or complications as they arise.
11 So I appreciate your time, and I'm happy to answer any
12 questions.

13 MR. FALAHEE: Thank you very much. Any questions
14 from the Commissioners? Doctor, thank you very much.

15 DR. JASON RICCI: Great. Thank you.

16 MR. FALAHEE: Thanks for being here. More cards?

17 MS. TUCKER: We have one. Next we have Kelly
18 Jefferson from St. Francis Hospital.

19 MR. FALAHEE: This is Falahee. I also spoke to
20 Kelly yesterday, so --

21 KELLY JEFFERSON

22 MS. KELLY JEFFERSON: Good morning, everyone. I'm
23 Kelly Jefferson, president of St. Francis Hospital in
24 Escanaba, Michigan, and I just want to kind of drive home
25 some points that you've already heard here today.

1 I want to thank you first for assembling the, the
2 SAC on Cardiac Cath Services. It's such an important topic,
3 especially to us in the Upper Peninsula, and for allowing
4 Dr. Cooley to participate on that incredibly important work.
5 The topic of access to interventional cardiology services in
6 rural areas is incredibly important, specifically in the
7 Upper Peninsula. We really appreciate the opportunity to
8 explore new ways of addressing this issue.

9 So just to educate, there are two cath labs in the
10 Upper Peninsula. One is in Marquette at UPHS. They do
11 both diagnostic and PCI. And then we just opened our cath
12 lab in July of 2024, in Escanaba, and we perform diagnostic
13 only.

14 I did hand out a trend graph that was seat, put at
15 your seat earlier today. In looking at this graph, you'll
16 see that access or having limited access to PCI services in
17 the UP is not a new issue. So this graph shows a historical
18 trend here of PCI sessions that originated from UP zip
19 codes. In the last five-year look back here, you'll see
20 that the cardiac cath PCI sessions that were performed on
21 individuals originating from a UP zip code, that more than
22 50 percent of them occurred in Wisconsin. And the majority
23 of those patients, the dark counties on your map here, the
24 dark on the bottom are from Menominee and Delta County, both
25 which are served by St. Francis Hospital. Access to PCI

1 services is not getting better in the Upper Peninsula and
2 there's really no hope that it will get better. And thus,
3 looking at these historical trends, there's no hope that it
4 will improve unless we make changes to our Certificate of
5 Need standards.

6 We need to be open to new models of care like the
7 one Dr. Ricci just discussed in which we have strong
8 partnerships where we work with larger centers that can
9 bring PCI services to the Upper Peninsula, that bring their
10 highly skilled teams that also have the levels, the volume
11 levels that are required to establish confidence and
12 maintain your confidence and to meet high quality standards.
13 I mean really, thinking across the -- looking across the
14 state what other parts of the state of Michigan do we have
15 that have such limited access for such an expansive
16 geography? It is very discouraging to our care teams to
17 know that we have the PCI -- the resources needed found
18 onsite to perform PCI, but yet we have far too many patients
19 that sit waiting in the emergency room for extended periods
20 of time due to lack of availability of beds and PCI centers.
21 We are eager, eager to help and eager to be a part of the
22 solution if given the opportunity.

23 I am requesting that the Commission consider
24 assembling a SAC or a workgroup to address the unique
25 challenges of PCI in the Upper Peninsula. And with that

1 I'll take any questions or comments. Thank you.

2 MR. FALAHEE: Any questions from the
3 commissioners?

4 MS. KELLY JEFFERSON: Thank you.

5 MR. FALAHEE: Thank you very much. No more cards?

6 MR. EASTER: No more cards.

7 MR. FALAHEE: Okay. Great. Thank you. Any --
8 I'll start with any questions based on what our folks have
9 said, based on what they said, any further questions of Dr.
10 Madder? Okay. Great. Commission discussion about any
11 items? And then there's a potential motion we'll have. But
12 I wanted to see if there's any discussion first, general
13 discussion about the topic. Okay. As usual we've got a SAC
14 recommendation in front of us, and the normal process is
15 that we would look at the recommendation and if a motion was
16 introduced, approve it and send it on for further comment.
17 I wanted to make sure there wasn't any other discussion
18 items first. If not, I'll entertain a motion to that effect
19 on the SAC.

20 DR. MILEWSKI: This is Commissioner Milewski. I
21 will make a motion that the Commission take proposed action
22 on the language, the draft to move forward to public hearing
23 and the Joint Legislative Committee.

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

25 DR. FERGUSON: Ferguson. I'll second that.

1 MR. FALAHEE: Thank you. Any discussion amongst
2 the commissioners on that motion? If not, all in favor of
3 the motion please say aye.

4 ALL: Aye.

5 MR. FALAHEE: Opposed? That motion carries.

6 (Whereupon motion passed at 10:34 a.m.)

7 MR. FALAHEE: Dr. Madder, if you're still there,
8 thank you once again for everything and for willing, being
9 willing to do this a second time. So thank you very much
10 for the time and the effort. And with the other members of
11 your SAC, it was very good discussions, great report.
12 Thanks again.

13 DR. RYAN MADDER: Yeah. Great. Thank you,
14 everybody.

15 MR. CONNOLLY: Thank you, Dr. Madder.

16 MR. EASTER: Thank you.

17 MR. FALAHEE: Thank you.

18 MR. EASTER: The Commission's proposed action will
19 move the language for a public hearing and to the Joint
20 Legislative Committee. A report and language for final
21 action will be brought back to the CON Commission at the
22 June meeting.

23 MR. FALAHEE: Okay. Let's move on to the next
24 item, MRI. And we'll first turn to the Department for any
25 comments.

1 MS. TUCKER: No public comments for --

2 MR. FALAHEE: No; no. Any introductory comments
3 on MRI?

4 MS. TUCKER: So the report will be given by Randy
5 Parker on behalf of the MRI workgroup chairperson Dr. Masch.
6 A copy of the report can be located in the electronic
7 binder. All recommended language in front of the Commission
8 reached a consensus. The Department supports the language
9 as presented, and it is included, included in the technical
10 edits across all standards that requires a notification to
11 the Department no later than 30 days after any planned
12 decrease or discontinuation of the CON service. An
13 additional meeting was added to allow more time to finalize
14 the language presented today. We have not received public
15 comment from any organizations. Proposed action from the
16 Commission will require a motion, a second, and a vote to
17 approve. The Commission's proposed action will move to the,
18 remove the language to the public hearing and the Joint
19 Legislative Committee. A report and language for final
20 action will be brought back to the Commission at the June
21 meeting. And with that, I'll hand it over to Randy to give
22 the report.

23 MR. FALAHEE: Okay. Thank you very much. Thank
24 you for being here on behalf of others.

25 MR. RANDY PARKER: Of course, yeah. Good morning.

1 Thank you, Chairperson Falahee and Members of the
2 Commission. My name is Randy Parker, and I'm the lead MRI
3 safety officer at Corewell Health West. Dr. Masch is
4 unavailable to attend today, so he asked me to go through
5 the workgroup's recommendations on his behalf.

6 We met five times and concluded our work on
7 November 7th, 2024. This workgroup was tasked with eight
8 total charges. And if it's all right with the Commission,
9 I'll just go through all of them and then take questions or
10 any discussion at the end. Certainly if there's any, you
11 know, urgent questions or clarifications needed to be had,
12 please feel free to stop me.

13 So the first charge was related to the revision or
14 revising the definition of a teaching facility to clarify
15 who can be allowed to get additional teaching, get the
16 additional teaching factor. The recommendation from the
17 workgroup was the definition of a teaching facility be
18 revised to the following:

19 "Teaching facility" means a licensed hospital
20 site, or other location, that provides either fixed or
21 mobile MRI services at which residents or fellows of a
22 training program in diagnostic radiology engage in care
23 of a patient (including protocoling and interpretation
24 of studies), and that is approved by the Accreditation
25 Council on Graduate Medical Education or American

1 Osteopathic Association. A teaching facility shall be
2 identified as meeting the definition if at least one of
3 the following are true:

4 (i) Participating -- the participating hospital
5 site of other location's facility's name is listed on
6 the Accreditation Council on Graduate Medical Education
7 or American Osteopathic Association Accreditation
8 letter as having a training program in diagnostic
9 radiology.

10 (ii) The participating hospital site or other
11 location is owned by an entity that is listed on those
12 letters "as having a training program in diagnostic
13 radiology.

14 The definition change better clarifies what
15 constitutes a teaching facility easing the state's
16 ability to confirm teaching facility status without the
17 continued need for annual facility self-attestations.
18 This change also liberizes -- liberalizes the number of
19 sites that will qualify for the additional teaching
20 factor as it now will allow for teaching factor to be
21 applied to sites in which radiology trainees are
22 participating in care remotely. The subgroup members
23 argued that even remote involvement of trainees
24 lengthens the scan time, and the 0.15 weighted (sic)
25 factor is important for encouraging facilities to

1 participate in the radiologist training."

2 Charge 2 --

3 MR. FALAHEE: Let me, let me interrupt there.

4 MR. RANDY PARKER: Yes.

5 MR. FALAHEE: Number one, just like we did with
6 Dr. Madder, let's go one by one by one to see if at the end
7 of each charge there's any question from the commissioners.

8 MR. RANDY PARKER: Sure.

9 MR. FALAHEE: If we can do that. Any questions?
10 Commissioner Ferguson?

11 DR. FERGUSON: Ferguson. So sound principle. I
12 agree with the principle. Practical question, I don't
13 understand quite enough how everything enrolls. What I
14 would not want to see happen is a large health care system
15 that happens to own hospitals all over the state, all over
16 the country, suddenly identifies and says oh, all of these
17 other sites where the teaching really isn't occurring count
18 because it's all owned by the same parent company. So if
19 the residents are actually actively involved in that guided
20 reading, that makes perfect sense to me. I, I am completely
21 supportive. I just don't want to see an end run here and I
22 don't quite know how the enrollments for sites necessarily
23 occur and/or what the restrictions on that are so that it
24 doesn't get taken sideways. And maybe somebody else who
25 understands enrollment categories better than I can comment

1 on this.

2 MS. GUIDO-ALLEN: Guido-Allen. My question is
3 same as Commissioner Ferguson's. You may be listed on the
4 ACGME letter as being a teaching clinical, but, but are we
5 going to be looking at actual programs? Will it have to say
6 radiology? So I think that's a little loose and it needs to
7 be a little tighter.

8 MR. RANDY PARKER: Yeah. Understandable. I
9 appreciate the feedback on that, too. And, and I know that
10 that was -- just kind of being a participant in that group,
11 that was kind of or apparently somewhat of a participant in
12 that group, that was one thing that was questioned quite a
13 bit in the discussions with and with regards to a teaching
14 hospital and kind of how all of that. So, yeah, both of
15 your questions are, are certainly valid for sure.

16 MR. FALAHEE: And so when commissioners have
17 questions about a report, what normally happens is, is when
18 we do the motion, we will say we would specifically request
19 public comment on the charge 1, in this case, and the
20 recommended solutions to charge 1 so that we would get that
21 public comment back in June or September.

22 DR. FERGUSON: I might also be interested not only
23 in the public comment, but perhaps the Department comment on
24 how to tighten the language as well.

25 MR. FALAHEE: Thank you. And then I'll have one

1 general comment. Don't feel the need to read everything
2 that's in the report because we've got the report in front
3 of us and it's about ten pages single-spaced.

4 MR. RANDY PARKER: Yeah.

5 MR. FALAHEE: All right? So unless you get the
6 bad eyes from people, you can like Dr. Madder did, summarize
7 the report and then we'll ask questions as needed.

8 MR. RANDY PARKER: Yeah. Perfect.

9 MR. FALAHEE: Okay? Thank you.

10 MR. RANDY PARKER: All right. Thank you.

11 MR. FALAHEE: If that's okay with the other
12 commissioners. Okay. Thank you.

13 MR. RANDY PARKER: There's a few charges in here
14 which I know are quite lengthy that I plan to keep high
15 level, so -- all right. So charge 2, revise section
16 2(1)(jj), the definition of a mobile MRI unit to operate at
17 once per quarter. So as you can see, the recommendation was
18 that there was -- recommends no change to the current
19 definition of a mobile MRI unit to operate on a regular
20 basis. The workgroup believed that requiring the quarterly
21 service to maintain a mobile MRI unit could decrease access
22 to MR, the MRI sites and also may not take into account the
23 utilization or operational needs and also may burden sites
24 with additional costs or operational down time as a result
25 of that. So the proposed change to operate a minimum of

1 once per quarter could also increase the cost, as I
2 mentioned, as well as approval for insurance policy and
3 requiring quarterly service regardless of the need of that
4 particular site. Any questions or comments on that charge?

5 MR. FALAHEE: Any questions of the commissioners?
6 Okay. Move on.

7 MR. RANDY PARKER: All right. Charge 3, revise
8 section 4(4)(b) to add MRI and mobile host site has been in
9 operation for at least 12 months. The workgroup recommended
10 the adoption of the Department's proposed change to that
11 section. This change clarifies the existing terms within
12 the review standards of the mobile MRI host site
13 relocations. The host site should be operational for at
14 least 12 months.

15 MR. FALAHEE: Any questions about that? All
16 right.

17 MR. RANDY PARKER: Charge 4, review section 9(6),
18 to consider if additional criteria can be added to allow
19 non-surgical diagnostic studies to be performed in an
20 intraoperative MR-, or IMRI unit. The workgroup recommended
21 adding the following language:

22 "The patient is having a diagnostic or therapeutic
23 procedure performed using an IMRI unit to target
24 specific areas of the body, including biopsies,
25 injections, ultrasounds, and other procedures."

1 Essentially the rationale behind this was that the
2 exemption allows for the MRI units to be used for other
3 non-surgical procedures which may increase patient access
4 for not only those procedures themselves, but also increase
5 patient access for other clinical MRI studies to be
6 performed. Typically right now, these studies, these
7 procedures are being formed, being performed on the MRI
8 units that are typically seeing outpatients/inpatients and
9 these procedures can take several hours at a time. So to
10 block off a particular scanner, that would decrease access
11 to several patients potentially within a day who need their
12 MRI diagnostic studies to be performed. So being able to
13 utilize an intraoperative MRI suite to take up that block of
14 time would give that access back to those other patients.

15 MR. FALAHEE: Any questions from the commissioners
16 on that?

17 MR. DRAKE: Yeah, I have a question on that.
18 Remind me -- this is probably for, for the, for the
19 Department. Does the IMRI require anesthesia services? Was
20 that one of the requirements for that one? Because it's
21 intraoperative. Or did it not?

22 MS. NAGEL: We're looking.

23 MR. DRAKE: Okay. Because what, what's being
24 proposed here, those wouldn't necessarily require
25 anesthesia; is that correct?

1 MR. RANDY PARKER: It would depend, but I -- yeah.

2 MR. DRAKE: It wouldn't be a hard requirement for
3 somebody --

4 MR. RANDY PARKER: Right; right; yes.

5 MR. DRAKE: I'm just curious if that would --

6 MR. CONNOLLY: Marcus from the Department. From
7 what I recall at the actual meeting -- and I'll give them
8 time to look it up -- it wasn't something that was
9 addressed.

10 MR. DRAKE: But the current standard, though.
11 Does the current --

12 MR. CONNOLLY: Yeah, the current standard I'm not
13 sure. But I know it wasn't something that they considered
14 during the, the workgroup.

15 MR. DRAKE: Okay. Okay.

16 MS. BHATTACHARYA: So in the current standard it
17 does say that nonsurgical diagnostic studies shall not be
18 performed unless the patient is having a study performed on
19 an outpatient basis, but is in need of general anesthesia or
20 deep sedation as defined by the society.

21 MR. DRAKE: Okay. I thought that. Okay.

22 MR. FALAHEE: Any other questions? Okay.

23 MR. RANDY PARKER: All right. Charge 5, add
24 project delivery requirements to Section 15 for MRI services
25 CON standards to include mobile host site patient safety,

1 similar to Section 15(1)(h) for the CT CON standards. So
2 the workgroup recommends adopting the Department's proposed
3 change to Section 15 adding the following: Each host MRI --
4 each host facility must provide a properly prepared parking
5 pad sufficient load bearing capacity to support the vehicle,
6 a waiting area for the patients, and a means for the
7 patients to be able to enter the vehicle without going
8 outside such as a canopy or enclosed corridor. Each host
9 site facility must also provide the capability for
10 processing the images and maintaining the confidentiality of
11 patient records. As well as a communication system between
12 the mobile vehicle and each host facility should there be
13 any sort of emergency medical situation. This aligns and
14 mirrors the language in the CT standards.

15 MR. FALAHEE: Thank you. Questions? All right.
16 Move on.

17 MR. RANDY PARKER: All right. Charge 6, it was to
18 review Sections 15 -- Section 15(2)(e) to consider
19 clarifying the term "immediately available." The workgroup
20 recommends the change the last sentence to the following:

21 "A physician, nurse practitioner, physician
22 assistant, or -- physician assistant, or RN trained in
23 the management of hypersensitivity and physiological
24 drug reactions to MRI contrast shall be onsite when
25 patients are receiving intravenous contrast."

1 The rationale for this was that there are several
2 situations where a patient is receiving an MRI without
3 contrast. And so this work actually aligns with the
4 professional guidelines published by the American College of
5 Radiology that only require them to be present for
6 contrasted studies.

7 MR. FALAHEE: Any comments? Questions? I will, I
8 will add one. This is very important practically because
9 right now if you don't have a physician onsite, and that's
10 getting much more difficult, then you have to either stop
11 doing it or try to get physicians to cover it. So this is
12 helpful language out in the field. So thank you.

13 MR. RANDY PARKER: Yep.

14 MS. GUIDO-ALLEN: Guido-Allen. I have one
15 question. Sorry. Guido-Allen, one question. Did the CMS
16 conditions of participation allow for an RN?

17 MR. DRAKE: That's a very good question.

18 MS. GUIDO-ALLEN: Previously back when, when I had
19 some oversight of that it did not include an RN.

20 DR. FERGUSON: And are the -- and are the ACR
21 guidelines allowing for an RN? I guess I'm thinking mostly
22 about meds; right?

23 MS. GUIDO-ALLEN: Yeah; yeah.

24 DR. FERGUSON: All right.

25 MS. GUIDO-ALLEN: Because we can't order.

1 DR. FERGUSON: Right.

2 MS. GUIDO-ALLEN: Right. They can be
3 protocolized, but we can't order. But I would have to look
4 at the CMS COP around that, around oversight.

5 MR. DRAKE: Yeah, that's a very good point.

6 MS. GUIDO-ALLEN: Maybe it changed, but I don't
7 know.

8 MR. FALAHEE: Right. And --

9 DR. DELANO: I'll just -- this is Commissioner
10 Delano. Thank you for your hard work on this.

11 MR. RANDY PARKER: Nice to see you.

12 DR. DELANO: Nice to see you again. I'd echo
13 that. I think I guess maybe during the public comment
14 period, is that when it would be appropriate to readdress
15 that? But I think that could be cleared up. It's my
16 understanding that registered nurses aren't to do that. It
17 brings in scope of practice issues, too, that are -- may not
18 be acceptable.

19 MR. FALAHEE: We, we may find that we'll add that
20 to the proposed motion to be presented to the Commission.
21 But I think it's a great point. Thank you.

22 MR. RANDY PARKER: All right. So charge 7.

23 MR. FALAHEE: You do not need to read this
24 whole --

25 MR. RANDY PARKER: Oh, no, not at all. So, yeah,

1 just try to keep it high level here but just kind of still
2 give you the, the picture of what this group did. So the
3 charge was to review Section 16(1) to consider adjustments
4 to the additive factors for patients with implants or other
5 metallic foreign bodies. The Department reviewed the
6 current weighting adjustments in Section 16. A subgroup was
7 formed to consider if a new weight should be added for
8 procedures on patients with implants or other metallic
9 foreign bodies. The workgroup accepted a proposal to add
10 four additional weightings for patients with implants or
11 other metallic foreign bodies. And the proposal will
12 include adding definitions in Section 16 as you can see in
13 the packets defining low, medium, and high complexity;
14 active implants, so exactly what those are; and then MRI
15 exam safety evaluations, as well as off label imaging of
16 active implants.

17 Additionally, the proposal suggests adding
18 weighting increases. The four additional weighting
19 increases are, range anywhere from 0.75 to be added up to
20 1. -- or, I'm sorry, up to 1.5 for high level and then also
21 1.75 for any patients that have multiple active implanted
22 devices or if the scan is being done off label and requires
23 a risk versus benefit analysis. It was clarified that the
24 definition to define metallic foreign bodies as things like
25 screws in the ankles or things like that were not really of

1 concern and didn't really apply to this request. So there
2 was language that was defined to help prevent confusion
3 also; each level of complexity as well as some of the more
4 technical things like SAR and Bl+rms were defined in order
5 to prevent confusion between the levels and the terms.

6 Regarding the quarterly data entry reporting for
7 MRI utilization, it was suggested that each level of
8 complexity be given a number rating of zero to four for the
9 ease of reporting. There were no objections to the language
10 with the addition to the language adding "with appropriate
11 trained personnel" to the definition for MRI exam safety
12 evaluations.

13 So the rationale behind this is the patients with
14 these types of implants or foreign bodies, any time that you
15 are having to restrict or change your parameters in order to
16 kind of decrease the level of energy that the patient is
17 exposed to, 9.9 out of 10 times that's going to increase the
18 amount of time -- sorry -- that's going to increase the
19 amount of time that the patient is on the table. Also, a
20 lot of those implants require services that are, you know,
21 utilized in other MRI procedures like anesthesia and
22 sedation, so there's nurse involvement, there's physician
23 involvement with a lot of those in order to be able to scan
24 those patients' devices safely. So those were all factored
25 into the proposal that we did.

1 MR. FALAHEE: Any questions on charge 7?

2 MR. RANDY PARKER: I'm ready. Here we go.

3 MR. FALAHEE: Yeah, right.

4 MR. DRAKE: No, this is Commissioner Drake. No
5 question, but a comment. Great, great job, great work.
6 Because I definitely appreciate the difference in some of
7 the complexity of these scans.

8 MR. RANDY PARKER: Yep.

9 MR. DRAKE: So nice work.

10 MR. RANDY PARKER: Thank you.

11 DR. DELANO: I'm going to be redundant and say the
12 same thing. It's remarkable and I'm grateful for that.
13 It's an incredible amount of work that I know falls on lots
14 of people's shoulders, especially yours. So good, good job.

15 MR. RANDY PARKER: Thank you. Appreciate that. I
16 also appreciate -- I want to call out the Department's
17 involvement in those discussions because they were very
18 helpful in providing very good feedback for us as to how the
19 language needed to be laid out within these standards. So I
20 really appreciate the Department's involvement as well.

21 MR. FALAHEE: Next charge. Charge 8.

22 MR. RANDY PARKER: All right. So charge 8 was to
23 review the CON standards and consider if changes are needed
24 to improve the access for MRI in rural and micropolitan
25 statistical counties. So the workgroup recommends

1 incorporating "sole community hospital" into the multiple
2 sections of the standards. The sections are listed out. I
3 graciously will not go through them all. You can see those
4 there. But essentially the rationale behind that was to
5 help just increase, help change the improvement of MRI
6 access at sole community hospitals, most of which are
7 located in those rural counties. And so these charge --
8 these changes also mirrored the language in the surgical
9 service standards.

10 MR. FALAHEE: Thank you. Yeah, this is a very
11 detailed report which means there was a great deal of
12 detailed work that went on in this workgroup and this is
13 just the, the tip of the iceberg. So thank you to you and
14 everybody else. It's wonderful.

15 MR. RANDY PARKER: Absolutely.

16 MR. FALAHEE: Any questions? Any public comment?

17 MS. STANTON: Before we do go to the public --
18 this is Tiffani -- to Commissioner Guido-Allen's point,
19 they, they did discuss the, the charge 6. So the American
20 College of Radiology, that is kind of where they actually
21 did find that term around. It does include the nurse,
22 registered nurses.

23 MS. GUIDO-ALLEN: I'm asking about CMS.

24 MR. FALAHEE: CMS. It's, it's --

25 MS. STANTON: Okay. So it's more than just the --

1 MS. GUIDO-ALLEN: Yeah.

2 MR. FALAHEE: Yeah, it's the, --

3 MS. STANTON: Okay. From the April 2024.

4 MR. FALAHEE: -- it's the conditions of
5 participation established by CMS that are critical when
6 you're in the hospital world.

7 MS. STANTON: They're a lot deeper.

8 MS. GUIDO-ALLEN: Yeah, and very difficult to
9 find.

10 MS. STANTON: Yes.

11 MR. CONNOLLY: Yep.

12 MR. RANDY PARKER: Something like 1,000 or 1100
13 pages, I think.

14 MS. STANTON: Yeah. Plus.

15 DR. FERGUSON: I guess in my opinion it's, it, it
16 is CMS, but there's also a what do we think is right for
17 patient care and patient safety. We need to be at least as
18 tight as CMS, but we're allowed to have even higher
19 standards than CMS.

20 MR. FALAHEE: Yes, we are.

21 MR. EASTER: We do have one public comment from
22 Abby Burnell from McCall Hamilton in regards to charge 1 and
23 6.

24 MR. RANDY PARKER: Thank you.

25 MR. EASTER: Thank you.

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ABBY BURNELL

MS. BURNELL: Good morning, everyone. Abby Burnell with McCall Hamilton and I will be brief. I just wanted to add some additional context to charges 1 and 6, of which I both participated.

For charge 1 you had asked about the ACGME certification stating only the -- maybe the owner entity hospital name, and there was some concern that there might not actually be patients participating in the program but them still getting the .015 credit if the owner entity is listed on the AC-, ACGME certification. And it was the intention of the group that it is only facilities and hospitals where the residents are actively participating in the care of the patients. And so we did write the definition that way. We added language to say "engage in the care of the patient including protocoling, interpreting of studies." And then you demonstrate that by showing that either that site or the owner site is listed on the ACGME certification. But it would be up to the facility to be honest and truthful that there are patients -- participating in the active care of patients. And so it was the intention that it would be active care. Happy to answer a question about that if there is one.

MR. FALAHEE: A question I've got, Abby. When you say "engaged in," once -- one day a year? Is that engaging

1 in?

2 MS. ABBY BURNELL: Good question. Very lawyer
3 question of you. We can -- we didn't set a standard. I
4 think the expectation of it was regular engagement, but we
5 can circle back to -- Henry Ford led charge 1, so we can
6 circle back to the leader of the subgroup and, and see if we
7 can fine tune that for you. But it was meant to be regular
8 engagement. It's just that especially with residency
9 programs, they're not always physically located at every
10 single ancillary site. They might be at the main hospital,
11 but I regularly do the scans for Sparrow Ionia even though
12 I'm not located there physically.

13 MR. FALAHEE: Maybe that can be submitted during
14 public comment if the motion --

15 MS. ABBY BURNELL: Sure. Makes sense.

16 MR. FALAHEE: -- talks about that. Okay.

17 MS. ABBY BURNELL: And then if there's nothing
18 else on charge 1? Charge 6 I wanted to briefly just say I
19 don't believe that we discussed the CMS regulations,
20 Commissioner Guido-Allen. We specifically looked at the ACR
21 recommendation. I think there was -- if it's not in CMS, I
22 think there was some hope that it might be coming and we
23 might be ahead of the game not having to change the
24 standards afterwards. But we can also kind of put the
25 brains back together on that subgroup 6 and see if we can

1 get some additional clarity and answer for you.

2 MS. GUIDO-ALLEN: I just don't want to set anybody
3 up to be violating the COP.

4 MS. ABBY BURNELL: Understood.

5 MR. FALAHEE: Any questions for Abby?

6 Thanks a lot.

7 MS. ABBY BURNELL: Thank you.

8 MR. FALAHEE: Any other commission discussion? If
9 not, I'll turn it back to the Department before we tee up a
10 motion.

11 MR. EASTER: No more public comment.

12 MR. FALAHEE: No more? Okay. All right. So we
13 have in front of us a very detailed report from the
14 workgroup. And, again, thanks to the people on the
15 workgroup. Any commission discussion about it? If not,
16 based on the discussions we had, I'll entertain a motion
17 with some, probably some additions to that normal motion.

18 DR. MILEWSKI: This is Commissioner Milewski.
19 I'll take the first stab here in a motion to, for the
20 Commission to take proposed action on the draft language
21 which will move it forward to a public hearing and to the
22 Joint Legislative Committee with a specific request for
23 public comment on charge 1 on the best way to identify
24 training facilities and whether modifications are needed to
25 the existing lang-, proposed language, as well as to charge

1 6 with specific feedback on the language related to
2 inclusion of registered nurses and whether that meets CMS
3 guidelines.

4 DR. ENGELHARDT-KALBFLEISCH: Commissioner
5 Engelhardt-Kalbfleish. Second.

6 MR. FALAHEE: Thank you very much. Any
7 discussion?

8 DR. DELANO: I'd like to -- I'm not sure the
9 right -- I fully endorse what you said, but I'd like to also
10 have charge 4 be brought up for a similar consideration as
11 we look at OR space and if there's financial implications of
12 that at least to be considered during the public comment
13 period within from, from a cost as well as access
14 standpoint.

15 MR. EASTER: Is that in relation to Cardiac Cath?

16 DR. DELANO: It's similar. I'm trying to have a
17 parallel consideration for that because it's an OR device
18 that has OR charges. And if it can -- if procedures can be
19 done in other facilities cheaper, is -- are there -- is
20 there going to be a tendency to put patients to the OR
21 rather than to a less expensive route to have that done.
22 And a lot of that falls onto insurance I suppose, but --

23 MR. FALAHEE: Yeah, it's -- this is Falahee. This
24 is it sounds like similar to the concern we had with Cardiac
25 Cath --

1 DR. DELANO: Exactly.

2 MR. FALAHEE: -- and using an OR for a cardiac
3 cath procedure and how that is billed. Similar billing
4 issue; correct?

5 DR. DELANO: Overall cost of care issue, yes.

6 MR. FALAHEE: Right. Okay. And so this on MRIs,
7 it sounds like the same concern, issues, question?

8 DR. DELANO: Yeah. It's a procedure that's done
9 in a machine that's in a space that you want to utilize to a
10 greater extent rather than have it sit idle, but the added
11 cost for that patient may be considerably higher.

12 MR. FALAHEE: Right. And so if I understand you
13 correctly, Commissioner Delano, what potentially an addition
14 to the motion to say we would also welcome comment regarding
15 charge 4 on whether this will increase patient cost by using
16 nonsurgical diagnostic studies performed on an IMRI unit,
17 and the billing for those procedures.

18 DR. DELANO: Thank you for your re-wording.
19 That's good.

20 MR. FALAHEE: Just try to make it simple --

21 DR. DELANO: Educate me.

22 MR. FALAHEE: -- and so the people that are
23 looking at what we decided know what we expect public
24 comment back on. If, if, if, if those that support -- made
25 the motion and supported it, I could -- I think we could

1 take that as a friendly amendment if they agree.

2 Commissioner Drake?

3 MR. DRAKE: I want to ask a clarifying question on
4 both the MRI and the cath lab. So let's presume on the cath
5 lab side I have a OR/cath lab and I also have a cath lab.
6 If I do the cath procedure in the hybrid room, does that
7 count in OR volume or cath lab volume?

8 MS. BHATTACHARYA: So the CON standards say you
9 can either count it as a cardiac cath procedure or a
10 surgical case. You cannot count it as both. Now the
11 standards and the Department do not dictate how to count it.
12 It's left to the providers depending on the nature of the
13 procedure performed.

14 MR. DRAKE: So, for example, an MRI, if I can do
15 the same procedure -- to his point -- in the OR or in the
16 regular MARS suite, how does the IMRI volume count? Is it
17 the same count for those? If I do them in the OR, is it a
18 MRI count or no?

19 MS. BHATTACHARYA: No. So, so a hospital have
20 their diagnostic MRI scanners, right, the fixed MRIs in the
21 MRI suites. IMRI is the special MRI scanner that is not
22 included in your diagnostic MRI scanner count.

23 MR. DRAKE: Okay.

24 MS. BHATTACHARYA: So when this MRI scan is being
25 performed in the OR or in an adjoining room, it is counting

1 as a volume for the IMRI unit, not for your diagnostic MRI
2 scanner.

3 MR. DRAKE: Okay. It doesn't solve your billing
4 issue, but at least it's being counted in the right place
5 for MRI.

6 DR. DELANO: And last, can you clarify for me? I
7 don't believe we really need to -- there aren't standards
8 that require certain volumes on IMRIs. So there isn't a
9 procedural -- so the only motivation would be to free up
10 your --

11 MR. DRAKE: Correct.

12 DR. DELANO: -- fixed scanners that you can
13 optimize their use rather than have prolonged all day long
14 procedures under anesthesia, that sort of thing.

15 MR. DRAKE: Correct.

16 DR. DELANO: So -- all right. Thank you.

17 MR. FALAHEE: So let me ask if Commissioner
18 McKenzie (sic) will agree to a friendly amendment.

19 DR. MILEWSKI: This is Commissioner Milewski and I
20 will agree to amend adding the language proposed by
21 Commissioner Falahee around comments related to charge 4.

22 DR. ENGELHARDT-KALBFLEISCH: Commissioner
23 Engelhardt-Kalbfleisch. Second.

24 MR. FALAHEE: Commissioner Ferguson?

25 DR. FERGUSON: A proposal hopefully viewed as

1 friendly. With respect to the ask around charge 6 and the
2 use of registered nurses and the check with CMS regulations,
3 I would ask, you know, some version of just as the
4 appropriateness of the use of RN in a situation per CMS
5 guidelines and other safety considerations. I would just --
6 I'd like to open it up beyond simply to CMS if you're open
7 to that.

8 DR. MILEWSKI: Commissioner Milewski. Agree with
9 adding the additional language around safety considerations.

10 DR. ENGELHARDT-KALBFLEISCH: Commissioner
11 Engelhardt-Kalbfleisch. Agree as well.

12 MR. FALAHEE: Other comments, friendly amendments?
13 It's -- no, the fine tuning is great. Okay. We have a
14 motion on the floor. All those in favor please say aye.

15 ALL: Aye.

16 MR. FALAHEE: All those opposed? That motion
17 carries. Thank you very much.

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

19 MR. FALAHEE: I'm going to keep moving on. All is
20 hopeful. Next one, Lithotripsy Services. And I'll turn it
21 over to Tiffani.

22 MS. STANTON: Yes. Great. Thank you. Okay. So
23 at the January 2025 CON Commission meeting, the Department
24 was charged with some technical edits including the
25 technical edit for the 30-day language that is being added

1 across all standards. In addition, the Department is adding
2 a technical edit to the Section 4 to include the term
3 "renewal of lease" as defined in Section 2. A copy of the
4 draft is included in your electronic binder. We have not
5 received any public comment today from any organizations.
6 Proposed action from the Commission will require a motion,
7 second, and a vote. The Commission's proposed action will
8 move the language to a public hearing and the JLC, and the
9 report for the final action will be brought back to the
10 Commission at the June Commission meeting.

11 MR. FALAHEE: Thank you. Any questions of
12 Tiffani? And confirming no cards then; right?

13 MS. STANTON: Correct.

14 MR. FALAHEE: Thank you. Any discussion? If not,
15 a motion?

16 DR. MILEWSKI: Commissioner Milewski. I would
17 make a motion that the Commission move forward the proposed
18 action on the language, and that the draft go to public
19 hearing as well as to the JLC.

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

21 MR. VELEZ: Commissioner Velez. Second that.

22 MR. FALAHEE: Thank you very much. Commission
23 discussion? All in favor of the motion please say aye.

24 ALL: Aye.

25 MR. FALAHEE: Opposed? All right. That motion

1 carries as well. Thank you.

2 (Whereupon motion passed at 11:11 a.m.)

3 MR. FALAHEE: Thank you all very much. It's a lot
4 of details to get through those three agenda items, so thank
5 you. Let's move on then to legislative update. Justin,
6 please?

7 MR. EASTER: We are monitoring bills and there
8 have been none introduced pertaining to CON.

9 MR. FALAHEE: We like those short reports. Thank
10 you. Administrative update. Marcus, begin with you,
11 please.

12 MR. CONNOLLY: Yes. Just want to give an update
13 on the Heart, Lung, Liver. Everything is going well as of
14 right now. We have two more meetings to finalize the
15 language, but nothing has come up so far that's anything
16 that's contentious. So we'll keep you posted on that at the
17 June meeting. For Psych Beds, we're down to one last
18 meeting and we're also in the process of finalizing the
19 language, and we'll vote on that this next week, a week from
20 today. County designation, that is really going well. The
21 chairs have done a really good job of formulating a plan to
22 implement the new county designations. We will meet
23 potentially one more time. We'll see how that final meeting
24 goes and if we need an additional, but that's going well.
25 So we'll just see how that goes, the last meeting. And we

1 have started the CT nominations, and we're currently getting
2 feedback from that. Is there any questions?

3 MR. FALAHEE: Great. Thank you, Marcus. Tulika,
4 we'll turn it over to you.

5 MS. BHATTACHARYA: Thank you, Chairman Falahee.
6 This is Tulika Bhattacharya. So I am going to -- I'm not
7 going to read from my annual report. I will just touch up
8 on some of the highlights. But I want to start my
9 presentation with a note of appreciation for the CON
10 evaluation section team and Marcus's team. Excellent job
11 for one more year.

12 So if you look at page 5 of the report? Just in
13 summary, how was FY 2024? We processed 255 letters of
14 intent, 189 application resulting in 195 proposed decisions,
15 and approval of almost \$2.7 billion dollar in new capital
16 expenditure for Michigan's health care system. There were
17 also 66 amendments processed and as part of our annual
18 survey, we surveyed 1,099 health facilities.

19 So out of the 255 letters of intent, 100 percent
20 were processed within the 15-day time frame, and 49 of them
21 issued a, a -- received a waiver from review because the
22 projects were not reviewable. Of the 193 applications
23 received, 99 percent of those were processed within the
24 15-day deadline.

25 Now, another thing I wanted to bring to your

1 attention in table 4 we always, you know, we say we are on
2 time in issuing our decisions. We are just not on time, we
3 do it in less amount of time than allowed by the
4 legislature. So for a non-substantive review, the average
5 was 34 days versus 45 that we have, for substantive 98 days
6 versus 120 max days, and for comparative 92 days instead of
7 150. We also received four emergency CON applications
8 compared to hundreds during the pandemic, but it's -- and
9 that's what we want to see, not too many emergency CONs.
10 Then another, so in table ten out of the 190 final decisions
11 there were 161 approval, 29 approvals with conditions, and
12 no final disapproval this year. If you look at table 11
13 like the comparison of activities, you do see there is a
14 decline in terms of number of LOIs and applications, but in
15 terms of decision, we are about the same compared to last
16 year.

17 Another table that we like to present which is
18 table 13 which tells you like what was the new capacity in
19 last year's cycle. So just some of the examples, there was
20 one new cardiac cath service for new cardiac cath labs
21 approved; eight new surgical services facilities meaning
22 FSOF/ASC, no new hospital surgical service, but 42 new
23 operating rooms, no new hospital, but 192 new hospital beds
24 to a high occupancy. But when it comes to psychiatric
25 facilities, mainly due to the special pool of beds that are

1 in the standards now, there were three new psychiatric
2 facilities and 179 new psychiatric beds were approved.

3 And then finally table 16 is the revenue and
4 expense report to the CON Commission. We didn't quite make
5 it to 100 percent coverage for our expenses, but our budget
6 tells us we are, we are still in good shape.

7 And then kudos to you, a long list of CON
8 Commission activity and I'm not going to read through them.

9 MR. FALAHEE: You could try but we would tell you
10 to be quiet, so, no. Beth?

11 MS. NAGEL: If I could just take one second here?
12 You know, in -- I've been in state government a long time
13 and I have seen many, you know, public facing services that
14 we have in state government. I have never seen one that
15 runs this high volume with this efficiency. This team is
16 really fantastic. Their dedication to I guess I'll call it
17 customer service is really second to none. It, it -- you
18 know, that, that I've seen anyway. I mean, I, I really just
19 can't say enough how proud I am of the work that they do and
20 just so grateful for Tulika and her leadership in making it
21 all happen. And I think this report does a really great job
22 of highlighting just how much they do on an annual basis.

23 MR. FALAHEE: You took the words right out of my
24 mouth. This is Falahee. I've been working with the CON
25 Department since the 1980s. This is a great team led by a

1 very, very good leader. I don't always like what Tulika
2 tells me, but I always know whatever she tells me, darn it,
3 it's right. So kudos to the whole Department. Tulika,
4 continued great work even with the change in people within
5 the Department. So really this, this is just a snapshot of
6 what goes on and I thank you very much.

7 MS. BHATTACHARYA: Thank you. And I take it on
8 behalf of my team. Without them I, I am not doing anything.
9 It's just really them. And, and special thanks, I have to
10 mention one person's name, Ashley Mayor. Credit goes to her
11 for compiling this report, and truly is thanks to her.

12 The other announcement I had for Commission
13 members and for the applicants or providers, excuse me. So
14 this year the Department is planning to do the statewide
15 compliance reviews for Open Heart Surgery services and PET
16 Scanner services. So there are 33 hospitals with adult
17 services and one with pediatric only for Open Heart Surgery,
18 and for PET Scanners, there are 10 mobile networks serving
19 91 host site locations and there are 12 fixed sites. So we
20 will take a look at their CON standards approvals, project
21 delivery requirements, their data reported to us. We will
22 send out the questionnaire for the missing items that we
23 don't collect through the annual survey, and then once we
24 have our assessment, we will probably schedule meetings with
25 them if we need to discuss certain things in their, in their

1 review that came up, and then we will bring back the report
2 to the CON Commission probably towards the end of the year.

3 MR. FALAHEE: Thank you. And for those on the
4 Commission that aren't in the health care business, I can
5 assure you that the Department is very thorough when they do
6 their compliance reviews. And if you miss something by one,
7 you will hear from Tulika and the team. And as she said,
8 they will then "discuss certain things" with those people.
9 So I can assure you that happens. Tulika, anything else?

10 MS. BHATTACHARYA: No. That will be all. Thank
11 you.

12 MR. FALAHEE: Any questions of Tulika? Great
13 report. Thank you. Legal activity report. Carl?

14 MR. HAMMAKER: Hello. Well, first of all, thank
15 you, Chip, for your warm welcome back. I'm very glad to be
16 back. My -- there's a written legal activity report in your
17 packet. It's fairly unremarkable. We don't have any
18 current litigation going on. Otherwise, myself and the
19 folks from Corporate Oversight Division are always here to
20 assist the Department and any of the CON Commission members
21 with any questions you may have.

22 MR. FALAHEE: Any questions of Carl? Great.
23 Thank you very much. Any other public comment at this
24 point?

25 MS. TUCKER: No additional public comment.

1 MR. FALAHEE: Okay. Thank you very much. Review
2 of Commission work plan. Tiffani?

3 MS. STANTON: Yep. Same as what we had in
4 January. We were able to start the CT nominations, so
5 everything was how we presented in January moving forward.
6 We have no changes, so it looks the same as what we
7 approved.

8 MR. FALAHEE: So since there are no changes,
9 there's no need for any Commission action then; correct?

10 MS. STANTON: I would still prefer if we could
11 just to approve it as is presented as no changes requested
12 by the Commission.

13 MR. FALAHEE: Okay.

14 MS. STANTON: But, I mean, we are on track at
15 least.

16 MR. FALAHEE: All right.

17 DR. MILEWSKI: Commissioner Milewski, I move to
18 approve the work plan as it was presented.

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

20 DR. ENGELHARDT-KALBFLEISCH: Commissioner
21 Engelhardt-Kalbfleisch. Support.

22 MR. FALAHEE: Thank you. Any friendly amendment?
23 If not, all in favor of the motion please say aye.

24 ALL: Aye.

25 MR. FALAHEE: Opposed? That motion carries.

1 Thank you.

2 (Whereupon motion passed at 11:22 a.m.)

3 MR. FALAHEE: Future meetings dates for those that
4 don't have them or need to be reminded: June 12, September
5 18, and December 4. Any other items to come before the
6 Commission? If not, I'd entertain a motion to adjourn the
7 meeting.

8 DR. MILEWSKI: Commissioner Milewski, motion to
9 adjourn.

10 DR. ENGELHARDT-KALBFLEISCH: Commissioner
11 Engelhardt-Kalbfleisch. Second.

12 MR. FALAHEE: Great. Thank you, everyone.
13 Appreciate it.

14 MS. STANTON: Thank you, everyone.

15 MR. CONNOLLY: Thank you.

16 (Meeting concluded at 11:22 a.m.)
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CERTIFICATE

I, Marcy A. Klingshirn, a Certified Electronic Recorder and Notary Public within and for the State of Michigan, do hereby certify:

That this transcript, consisting of 84 pages, is a complete, true, and correct record given in this meeting on March 13th, 2025.

I further certify that I am not related to any of the parties to this action by blood or marriage and that I am not interested in the outcome of this matter, financial or otherwise.

IN WITNESS THEREOF, I have hereunto set my hand this 25th day of March, 2025.

Marcy A. Klingshirn

Marcy A. Klingshirn, CER 6924
Notary Public, State of Michigan
County of Eaton
My commission expires: March 30, 2029