

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

COMMISSION MEETING

BEFORE JAMES FALAHEE, CHAIRPERSON

333 South Grand Avenue, Lansing, Michigan

Thursday, September 19, 2019, 9:30 a.m.

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17
18
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21
22
23
24
25

TABLE OF CONTENTS

PAGE

1

2

3 I. Call to Order 5

4 II. Review of Agenda. 5

5 III. Declaration of Conflicts of Interests 5

6 IV. Review of Minutes of June 13, 2019. 6

7 V. Immune Effector Cell Therapy (IECT) Public
Hearing Summary 6

8

9 A. Public Comment

10 1. Senator Curt VanderWall 8

11 2. Bret Jackson. 18

12 3. Greg Yanik, M.D.. 21

13 4. Phillip Stella, M.D.. 29

14 B. Commission Discussion 36

15 C. Commission Final Action 42

16 VI. Psychiatric Beds and Services Public Hearing
Summary and Set Effective Date of the New Bed
Need Numbers. 43

17 A. Public Comment --

18 B. Commission Discussion 44

19 C. Commission Final Action 45

20

21 VII. Urinary Extracorporeal Shock Wave Lithotripsy
(UESWL) Services/Units Services Public Hearing
Summary 46

22 A. Public Comment. --

23 B. Commission Discussion --

24 C. Commission Final Action 46

25

1	VIII.	Hospital Beds Limited Access Areas (LAAs)	47
2		A. Public Comment	--
3		B. Commission Discussion	52
4		C. Commission Final Action	55
5	IX.	Nursing Home/Hospital Long-Term Care Unit Beds (NH/HLTC) Standard Advisory Committee (SAC)	
6		Update.	57
7		A. Commission Action	67, 87, 92
8	X.	NH/HLTC Set Effective Date of New Bed Need Numbers (written report from Paul Delamater, et al).	67
9		A. Public Comment	
10		1. Henry Boutros	68
11		2. Pat Anderson.	79
12		B. Commission Action	86
13	XI.	Computed Tomography (CT) Scanner Services (written report only)	93
14			
15	XII.	Legislative Update.	94
16			
17	XIII.	Administrative Update	
18		A. Planning & Access to Care Section Update.	95
19		1. Open Heart Surgery (OHS) Effective Date for Revised Utilization Weights for Adults & Pediatrics Numbers (written report from Paul Delamater, et al.)	
20			
21		B. CON Evaluation Section Update	96
22		1. Compliance Report (Written Report)	
23		2. Quarterly Performance Measures (written report)	
24		3. Application Process Update	
25	XIV.	Legal Activity Report (written report).	99

1 XV. Future Meeting Dates. 99

2 XVI. Public Comment. --

3 XVII. Review of Commission Work Plan. 100

4 A. Commission Discussion --

5 B. Commission Action 100

6 XVIII. Adjournment 101

7

8

9

10

11

12

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16

17

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1 Lansing, Michigan

2 Thursday, September 19, 2019 - 9:29:15 a.m.

3 MR. FALAHEE: Good morning, everybody. If this is
4 working. Hang on. Let's call the September meeting of the
5 CON Commission together. It's a little bit before 9:30, but
6 we've got a lot on the agenda so let's get started. For
7 those of you who are new to the Commission meeting, my name
8 is James "Chip" Falahee. I'm the chairman. And we won't
9 bother to introduce all the other people because of the
10 packed agenda. So get right to it, to that agenda. To the
11 members of the Commission, in front of you Brenda has placed
12 the final agenda. I would ask for a motion to approve that
13 final agenda as presented to us.

14 MR. MITTELBRUN: Motion to approve final agenda,
15 Mittelbrun.

16 MR. HUGHES: Second.

17 MR. FALAHEE: Second by Hughes. Any discussion?
18 All in favor say "aye."

19 ALL: Aye.

20 MR. FALAHEE: Opposed? That motion carries.

21 (Whereupon motion passes at 9:30 a.m.)

22 MR. FALAHEE: Next item is declaration of
23 conflicts of interest. Does any member of the Commission
24 have any conflicts of interest they wish to declare based on
25 the agenda we just approved? Okay. Hearing none, we'll

1 proceed. Next item is a review of the minutes of our last
2 meeting on June 13. I would entertain a motion to accept
3 the minutes as presented or if anyone has any changes, I'd
4 like to hear about those as well.

5 DR. WANG: Wang moves to accept the minutes as
6 previously accepted.

7 MR. FALAHEE: Do we have support for that?

8 MS. GUIDO-ALLEN: Guido-Allen, second.

9 MR. MITTELBRUN: Mittelbrun, second.

10 MR. FALAHEE: Okay. Mittelbrun, second. Thank
11 you everybody for identifying yourself. Appreciate it.
12 Motion to approve, all in favor say "aye."

13 ALL: Aye.

14 MR. FALAHEE: Opposed? Okay. That carries.

15 (Whereupon motion passes at 9:30 a.m.)

16 MR. FALAHEE: Okay. The next item on the agenda
17 is immune effector cell therapy. It's hard for me to say.
18 But I will turn it over to Brenda for our usual introduction
19 of the topic and then our first witness will be Senator Curt
20 VanderWall and I'll introduce him as soon as Brenda finishes
21 her remarks.

22 MS. ROGERS: Thank you. This is Brenda. And for
23 easier pronunciation, I'm going to use the acronym IECT.
24 The Commission took proposed action at your June 13th
25 meeting. A public hearing was scheduled and comment was

1 received. The public hearing was held on July 25th, the
2 language also was submitted to the Joint Legislative
3 Committee as well. The testimony can be found in your
4 binder. And as you can see, you received testimony from
5 several different organizations both in support and not in
6 support of the standards.

7 Today the language is in front of you for
8 potential final action. The Department encourages the
9 Commission to consider all testimony as you review it. And
10 if you decide to take final action today, the language will
11 be forwarded again to the Joint Legislative Committee and
12 the Governor for the required 45-day review period. If you
13 accept the language today with any potential amendments and
14 those amendments are deemed substantive in nature, then a
15 second public hearing would be scheduled and then brought
16 back to you in December for potential final action. Another
17 option for the Commission today is to not take final
18 actua- -- not to take final action or to postpone
19 indefinitely. And if you do either one of those, then IECT
20 would not become regulated under CON at this time. So
21 several different options for the Commission today. Thank
22 you.

23 MR. FALAHEE: Okay. This is Falahee. Any
24 questions of Brenda from anyone? Okay. For those who may
25 want to testify on this issue, in order that so I know who

1 wants to testify, you need to fill out one of these blue-ish
2 cards that you see where you sign in and turn it over to
3 Tania Rodriguez, right here, so I have an idea who wants to
4 testify. Right now, in addition to Senator VanderWall whom
5 I know wants to testify -- you don't need to submit a blue
6 card -- I have three people that would like to testify. So
7 if there are any others, please submit your blue card. With
8 that, I'll introduce my friend and good discussion mate on
9 CON issues, Senator Curt VanderWall. Senator Vanderwall
10 is -- chairs the Senate -- I always get the name wrong
11 because it's new -- the Senate Committee, the Health
12 Services and Human Services Committee or something like
13 that. Senator VanderWall is here with his chief of staff
14 Patrick. Patrick and I stopped texting each other last
15 night about 10:00 o'clock, I think. So issues going back
16 and forth. So, Senator VanderWall, Curt, you have three
17 minutes like every other witness. Senator VanderWall is on
18 a tight time line. He's got to get back to the Capitol by
19 10:00, so we'll be respectful of that. You have the floor.

20 SENATOR CURT VANDERWALL

21 SENATOR CURT VANDERWALL: Well, thank you very
22 much, Mr. Chairman, and Commission. And I -- I truly do
23 take this as a great opportunity to come in and introduce
24 myself as chair of Health Policy, but most of all to discuss
25 today on the proposed commission standards on immune

1 effector cell therapy. I wish I could stay and listen to
2 the entire testimony today and -- and see where the
3 Commission goes; however, as stated by -- I must get back.
4 We have a very hectic day as most of you know at the Capitol
5 today so I -- I must leave right away.

6 I would like to say I appreciate the dialogue that
7 we've had. Some of it's been on -- you know, back and
8 forth, but that's -- that's where good legislation and --
9 and good progress is made. And I appreciate what the
10 chairman has done and he -- I will tell you he has given me
11 an abundance of time on the subject of -- of this and
12 several other things under CON.

13 Having open communication on such a topic is
14 extremely important. The Commission has the letter that I
15 submitted along with Health Policy vice chair Bizon, Senate
16 Majority Leader Shirkey on the subject and our belief that
17 the Commission should reject the proposed new standard on
18 IETC (sic). I certainly understand the concern for patient
19 safety and share those concerns. However, I am not
20 convinced that Michigan should be an outlier requiring FACT
21 accreditation which will not be the national standard. I
22 don't believe I have seen compelling evidence that the
23 residents of Michigan would see noticeable difference in
24 treatment and success of treatment because of this proposed
25 standard as compared to the citizens in the other 49 states.

1 Because I represent so many rural counties, I am especially
2 sensitive to anything that restricts service or access in
3 these areas. And I say knowingly that it is unlikely that
4 this current treatments on this market or this service would
5 take place in my -- my communities. I know there is others
6 that are planning to speak on this, but I do ask that you
7 listen to testimony, you take careful considerations, and I
8 would request that you do not take action on this new
9 treatment. And with that, I could stay for a couple
10 questions if anybody has that, but I do truly appreciate the
11 time, appreciate everybody in this room that is giving up
12 the day to listen and learn, and, again, I appreciate the
13 Commission and everything that you do.

14 MR. FALAHEE: Okay. Thank you, Senator VanderWall
15 and I -- I saw you struggling because you probably didn't
16 know my first name was "James" because everybody knows me as
17 Chip.

18 SENATOR CURT VANDERWALL: No, I -- I never -- I
19 have -- I'm going, oh, man. What have I done here? I
20 called him Chip.

21 MR. FALAHEE: So does everybody else other than
22 salesmen. Okay. Any Commission questions? I told Senator
23 VanderWall the standard procedure is once a witness is
24 finished, I ask the Commissioners if they have any questions
25 and given your time limits, I ask if anybody has any

1 questions? Commissioner Hughes?

2 MR. HUGHES: Thanks for joining us today, Senator.
3 I think in my years of doing this, this is the first time
4 somebody has actually come down to join us. And you
5 represent one of the most beautiful areas in our state and
6 if you want to win over Chip, you should just ask him to
7 Art's for a burger and pick up the tab, cash of course.

8 MR. FALAHEE: Right. No checks. Never a check.

9 MR. HUGHES: You could never do anything there.

10 SENATOR CURT VANDERWALL: I'll remember that.

11 MR. HUGHES: Just a little bit of background here.
12 There's a lot of great expertise on the Commission from
13 various walks of life with -- with different backgrounds.
14 I'm here not because of a medical background, but because I
15 represent payers, and in my day job I work with employers
16 and employees that in a very competitive labor market are
17 trying to provide great health care benefits and as you
18 know, costs go through the roof. That's a -- an old topic.
19 But one of the big things that's been driving health care
20 costs has been prescription drugs and specifically specialty
21 drugs, and specialty drugs have been rolling out at an
22 unprecedented pace because they come out at very exorbitant
23 prices. Are you aware of the price tag of one of the drugs
24 here, the drugs in this particular category and one of the
25 ones that Celgene has not yet approved yet but would hit the

1 street at?

2 SENATOR CURT VANDERWALL: I would say I do not
3 know what the total price of any of the prescription drugs
4 are for this treatment. I will say that we are very aware
5 of the cost of many of the prescription drugs as they enter
6 markets right now and the -- the cost of what that is to
7 health plans and, of course, to the patient.

8 MR. HUGHES: Yeah. This one is projected to come
9 in around \$800,000. And so appreciate to the rural access
10 standpoint, but as you know, many years ago, not too many
11 years ago, if you needed a transplant in this state you had
12 to go over to U of M for that. Now we have one on the west
13 side of the state. This is such an expensive drug and a lot
14 of people forget when the FDA approves a drug they don't
15 talk about its effectiveness. They talk about whether it's
16 safe or not. So a lot of these drugs are unproven yet in
17 terms of their clinical trials and they get rolled out.
18 We're dealing with children here that would be getting these
19 issued. I think it's a mistake and -- and just -- I -- I am
20 from your side of the fence. I am a free market person.
21 The word "regulation" makes the hair on my back, if I had
22 some, stand up. So the problem is that health care is not a
23 free market. Half the people are covered by the government
24 and the other half it's not a consumer transaction. People
25 don't know what it costs, they don't pay for it out of

1 pocket, and so that's what causes this mess with expensive
2 prescription drugs. By doing what you're doing, you're
3 saying it's going to limit access and that anybody could
4 administer this. I think if you allow anybody to
5 administer, that's playing to the drug companies that want
6 massive distribution. If Nike can only sell shoes through
7 Nike stores verse all the other stores, they're going to
8 sell a lot less. If these drug companies can disperse these
9 drugs to anybody including rural centers that don't have the
10 expertise and the people and the specialty to deliver this
11 drug properly because it's so expensive, and you're talking
12 about children that could take it over the rest of their
13 lifetime, and you're going to get this drug prescribed for
14 people that probably it's not going to work for, you'd be
15 shocked at how many of these drugs end -- end of the day
16 don't get the clinical result that you want. I'm just
17 curious as to why you feel -- I'm looking at your comments
18 in your letter about you think this is going to limit access
19 and the FACT accreditation is a bad thing when it's a
20 voluntary thing driven by the experts in this industry.
21 I've never been a fan of matching the state's policies with
22 the feds. I think that does more harm than good. I think
23 we're better than that. So I'm just trying to understand
24 why you think this would be a better outcome both
25 financially and medically for the citizens of Michigan?

1 SENATOR CURT VANDERWALL: Well, I -- I appreciate
2 the question and the comments. As Chip and I have had many
3 discussions on this and I'm sure he's relayed to some on the
4 Commission that, you know, as we continue to limit where
5 some of this can be performed or where the access is, and of
6 course when we start getting into my area -- and I'm going
7 to say from M-20 to -- through the UP -- you know, the
8 access to care becomes critical and when we start forcing
9 folks to drive many miles to get service or potential
10 service. Do I feel that we're going to have clinics open up
11 all over the state? I don't believe that. I think that,
12 you know, the federal government has put on some pretty
13 serious standards. There's many states that have CON.
14 There's nobody that's looking at, that we know of in other
15 states, to add CAR-T cell therapy into CON. And I urge the
16 Commission to, you know, carefully consider what we do
17 because I -- I really truly believe that we struggle as we
18 continue to move forward with population in our area
19 dropping, young -- young folks moving to the south of the
20 state and more elderly in the north. And I know that most
21 of this therapy is usually done on younger folks, but I --
22 I'm just very concerned right now that we're going to limit
23 access to care. And I -- I appreciate the cost of the drug.
24 I understand that. As you know I work very hard to make
25 sure and we have things that are going to address some of

1 these drug costs. But in this situation I really feel that
2 we need to make sure that we follow the federal standard and
3 allow the free market to play and we -- we set the standards
4 to make sure that that -- that procedure is done fairly and
5 ethically and make sure that those treatments are done with
6 the most care.

7 MR. HUGHES: Unfortunately this is anything but a
8 free market and that's kind of my point. And I just
9 think --

10 SENATOR CURT VANDERWALL: I understand what you're
11 saying.

12 MR. HUGHES: -- if it's that expensive of a drug,
13 then it should be delivered properly by the right people. I
14 don't think driving a couple hours to get such an expensive,
15 life-saving drug is asking too much, and a FACT
16 accreditation to me seems to make sense from a payer's
17 perspective and an outcomes perspective. So I was just
18 curious on your thoughts.

19 SENATOR CURT VANDERWALL: I appreciate that.

20 MR. FALAHEE: Other questions for Senator
21 VanderWall?

22 MR. MITTELBRUN: I guess I'll -- I'll ask.
23 Commissioner Mittelbrun. Senator, when you mentioned that
24 you -- you had a phrase "carefully consider" and we've been
25 talking about this for some time and we've been listening to

1 the experts, some of which are going to speak again today
2 after yourself, I have to agree with Commission Hughes and
3 virtually all his comments. You know, this is, you know,
4 just like many of us in this room, I've been dealing with
5 state and federal regulations for the last 30 years, many of
6 which I don't want to deal with. This is a very
7 complicated -- this -- this is very complicated and
8 dangerous procedure. And so when I'm listening to some
9 folks that are against the FACT accreditation and then I
10 went and I read some of the materials both for and against,
11 I had to go look at the definition because I figured, well,
12 I must be missing something. And the last sentence said,

13 "FACT accreditation -- FACT accredit organizations
14 voluntarily seek and maintain FACT accreditation
15 through a rigorous process demonstrating their belief
16 that the patient's needs are paramount."

17 And that was the sentence of that -- of that
18 definition that struck me the most when I was reading,
19 re-reading all this information. And I think it would be a
20 disservice to the residents of the state of Michigan not to
21 pay attention and do what we need to do here, you know, in
22 terms of this Commission. If it turns out in the end -- and
23 I remember, I'm old enough to remember when bone marrow
24 transplants started, you know, and I don't think it's any
25 different than that. And I don't think we can just stand,

1 stand aside and let things just, well, possibly turn out
2 very badly if we don't pay attention. So that's not really
3 a question, but --

4 SENATOR CURT VANDERWALL: You know what, I
5 appreciate your comments. And I will say that Chip is a --
6 projected that. We've had great dialogue and he knows -- he
7 knows where I come from and my concerns and, you know, I
8 really am -- I'm not looking that I want to destroy health
9 care in the state of Michigan and allow things to pop up on
10 corners. I understand that. I just feel very strongly that
11 the federal government has -- has put some really strict
12 standards in, especially on this therapy, and I feel that
13 we're -- we are taking the option away from some facilities,
14 potentially up north. I don't think that would probably
15 happen; however, I don't want to be that barrier and I
16 would -- I would, again, thank you for considering not doing
17 this CON on this.

18 MR. FALAHEE: Other questions? Well, to Senator
19 Vanderwall, Curt, thank you again for being here. It's a
20 pleasure. And as I'll update later, I won't see him again
21 until next week when I'm meeting with about 15 other
22 legislators about CON issues. So see you then. Enjoy the
23 weekend. Thank -- thank you for --

24 SENATOR CURT VANDERWALL: Thank you very much. I
25 appreciate the opportunity. Again, thank you, Commission,

1 for being here. Appreciate your time.

2 MR. FALAHEE: Thank you. Tania, do you have any
3 other cards on this?

4 MS. RODRIGUEZ: (Shaking head negatively)

5 MR. FALAHEE: Okay. So, just, if anybody arrived
6 late, if you want to testify on this topic, you need to
7 submit a blue card. Currently I have three. So if anybody
8 else wants to say anything, now is the time to get your card
9 over to Tania. All right. Seeing none, the next one I have
10 is Bret Jackson from the Economic Alliance. Bret's here,
11 so -- there he is. Hi, Bret. And I'll remind Bret, even
12 though he doesn't need to be reminded, there's a three
13 minute limit and then unlimited questions from the
14 Commission thereafter.

15 BRET JACKSON

16 MR. BRET JACKSON: Good morning. I am Bret
17 Jackson, president of the Economic Alliance for Michigan.
18 We represent about 900,000 covered lives, people who are --
19 have employer-sponsored health insurance around the state of
20 Michigan. And at first we were not in favor of putting a
21 standard in for immune effector cell therapy, but we -- we
22 were pushed to take a really deep dive and as we did, we --
23 we had a multi-month process, many meetings with experts
24 around the state to learn about not just CAR-T cell therapy,
25 but a lot of the cell therapies that are either in process

1 or have been approved and are into the medical marketplace
2 today. And the more that we learned, the more frightened we
3 became about the future. These are wonderful miracles of
4 science that we're seeing come before our health care
5 system. But the toxicity, the cost, the risks of doing
6 these are tremendous and we have to take steps, we believe
7 the state should take steps to ensure that every patient
8 that gets this procedure or these procedures going in the
9 future should have the best possible outcome, or the chance
10 of a best possible outcome.

11 We think FACT accreditation may not even go far
12 enough, but I think it's a good first step in trying to
13 achieve giving every patient the best possible outcome.
14 Because when you work -- if -- if -- if the new drug comes
15 out at \$800,000, that's only a fraction of the total cost of
16 the service. There is considerable testing,
17 hospitalizations, doctor visits, there's additional
18 chemotherapy that is separate from this particular drug that
19 will be administered. You know, I'm assuming these -- the
20 infusions for -- for the CAR-T cell therapy could probably
21 be done in someone's house. That's not where the cost is
22 driven from. It's all of the other things that are going to
23 have to happen pre or post-infusion that will make up a
24 large cost and will require dozens of providers and
25 services. And we -- we just think that FACT accreditation

1 is a minimal step to assure quality so that when we, the
2 payers, are making that investment in one patient, call it a
3 million dollars in one patient that could have been used for
4 thousands, tens of thousands of immunizations or tens of
5 thousands of insulin doses, that we provide the absolute
6 best opportunity for that patient to survive.

7 So I very much appreciate your time and we support
8 the actions that the Commission has taken thus far and hope
9 you continue on that path.

10 MR. FALAHEE: Thank you, Bret. Questions for Mr.
11 Jackson from the Commission members? Thank you. Next is
12 Dr. Greg Yanik. Where's -- hi, Greg. Those of you who've
13 been here before will recognize Dr. Yanik as being here at
14 least once or twice on this topic already and I believe you
15 served on the SAC as well. And I'll just explain for a
16 second. The SAC, Standard Advisory Committee, presented at
17 our June meeting and under the rules or the bylaws or
18 whatever of the Commission once a SAC presents its report,
19 the SAC disappears, all right, as a formal body, formal
20 committee. So what I have done in the ensuing months is
21 reach out to Doctors Stella and Uberti as the co-chairs of
22 the SAC. Dr. Stella is here, he'll be talking next just to
23 say here's what's happened with Medicare, with CMS, what do
24 you think, and Dr. Yanik will probably talk about it as
25 well. They all talked amongst themselves, the physicians on

1 the SAC, and you'll hear what they decided. So, but I
2 wanted you to know sort of where we were at. The SAC was
3 there, then it went away, but still those experts, those
4 physicians are still available to us and they've been very
5 engaged since about July on this topic. So I'll shut up,
6 turn it over to Dr. Yanik. Thank you for being here.

7 GREG YANIK, M.D.

8 DR. GREG YANIK: By the way, I just want to start
9 by saying that I actually support everything that
10 Commissioner Hughes and Commissioner Mittelbrun said when
11 they were questioning Senator VanderWall. You know, I have
12 several thoughts. One, will the SAC recommendations
13 restrict access to care? The SAC recommendations did not
14 limit access to care to any health care system or any
15 hospital. The SAC recommendations simply mandated that
16 those centers that provide that care provide quality care.
17 You know, reviewing the state's cancer registry, I'd
18 estimate that approximately 300 patients per year will
19 require such IECT therapy. That's not a large number of
20 patients. We're not talking 3,000, we're not talking
21 30,000. Unless do we want unregulated access where let's
22 say 100 hospitals can each treat three patients? No. I
23 really firmly believe that the SAC recommendations will
24 probably end up with 10 to 20 hospitals and those with
25 fairly large oncology group practices each treating 15 to 20

1 patients.

2 In my estimation, in case you're curious because
3 I've thought through this, just looking at the oncology
4 practices around the state, my guess is -- although I can't
5 say I've talked to them in particular -- Traverse City,
6 Midland, Saginaw, Flint, Lansing, Grand Rapids, Kalamazoo,
7 Jackson along with St. Joe's, Beaumont, Providence, St.
8 Johns in Southeast Michigan along with the existing centers
9 all will at least consider doing this.

10 The next thing is why regulate something that the
11 FDA is already regulating? The FDA only regulates the
12 manufacturer of these products. It doesn't regulate the
13 quality of the blood bank that's handling them or the
14 quality of the care delivering them. FACT is the only --
15 FACT is not a barrier to this care. In fact, FACT is the
16 only body I know, it's the only platform that will ensure
17 quality of care. Every opponent who comes up here to talk
18 about this will state that the FDA requires a "comprehensive
19 risk evaluation and mitigation strategies training site or a
20 training program for sites."

21 Well, I brought it with me, guys. For the most
22 common CAR-T product -- just pass it around -- this is the
23 certification test to become REMS certified. It's eight
24 questions. Give me ten minutes, I will have everybody in
25 this room REMS certified. If that's the most -- if that's

1 the comprehensive FDA oversight is this eight question test,
2 good heavens. REMS is a start. It's not the platform we
3 need that ensures comprehensive kind of care.

4 The other thing I want to say is that everybody
5 who's focusing on this is focusing on CAR-T. The SAC did
6 not focus on -- solely on CAR-T cells. We had to build a
7 platform for the citizens of our state not for CAR-T, but
8 for the future of all these genetically programmed blood
9 cell products; NK cell cars, tumor pulse dendritic cells,
10 any of these myriad of stem cells that are being
11 reprogrammed genetically. Don't focus on CAR-T. Focus on
12 the fact that we have to build a platform for care for all
13 of these patients, not just commercial products, but
14 investigator initiator products.

15 And I just want to end just by saying this. In my
16 30 years as an oncologist, I've never run into anything
17 quite like this group of agents. This is the most complex
18 technology that I've ever seen in my career. Period. The
19 potential benefits are high, the risks are potentially even
20 higher. We owe it to the citizens of our state to give them
21 the optimal care with the optimal quality. Thank you.

22 MR. FALAHEE: Thank you, Dr. Yanik. Any questions
23 for Dr. Yanik?

24 DR. GREG YANIK: You can ask me questions on the
25 test, too, if you want.

1 MR. FALAHEE: Commissioner Hughes?

2 DR. GREG YANIK: Yes.

3 MR. HUGHES: I was just going to say you could get
4 the other Commissioners to pass this, but probably not me.
5 But there is a multiple choice and I see -- but I just
6 wanted to -- your comments are really great and I think a
7 lot of people don't realize that there's a ton of
8 substantial information out there that shows you're in a
9 much better chance of having a good outcome by somebody that
10 does the procedure 50 times as opposed to five. If I was
11 going to go get a hair transplant, do I want the guy that
12 does two of them a year or do I want the guy that does 500?
13 And this is certainly applicable in this case and watering
14 down and diluting this type of application can't be good.

15 DR. GREG YANIK: I agree 100 percent.

16 MR. FALAHEE: Dr. Yanik, just as the layperson,
17 help me understand. You talked about, okay, there's the
18 administration of the IECT -- I say "CAR-T" because it's
19 easier for me to say, but I mean "IECT." There's the simple
20 administration of it but there's a lot that goes before that
21 and after that.

22 DR. GREG YANIK: Certainly.

23 MR. FALAHEE: Can you help explain that at least
24 to me?

25 DR. GREG YANIK: You know, just think of it this

1 way. With -- with many of these products, it means
2 genetically reprogramming your immune system to target your
3 cancer. And there's three basic tenets for all these
4 products and every one of these is scary in its own way.
5 The first basic tenet for this therapy is that the cancer
6 you're targeting ubiquitously expresses that target protein
7 on its surface. If you're treating leukemia and you've got
8 1,000 leukemia cells and only 999 have that target, you'll
9 relapse. That one cell remaining that doesn't have that
10 target will turn into two, four, eight, 16 down the road.

11 So the first tenet of all this IECT therapy is
12 that whatever you're targeting ubiquitously expresses that
13 target. The second basic premise is even scarier. That
14 target better not be on normal tissue. Ugh. If those cell
15 surface proteins you're targeting are found on myocardial
16 tissue, neuronal tissue, lungs, liver, good heavens. These
17 cells don't care what they're targeting. They just target
18 that protein. Then the third basic tenet is just as scary,
19 too. This is gene therapy. These genes have to get
20 inserted in the right place. We can't bat .300 here like
21 baseball. These genes have to get in the right place every
22 single time.

23 When IECT therapy first started in Europe in 2007,
24 they were treating a group of patients, children, with a
25 condition called SCIDs, where their immune -- they were

1 immune deficient at birth so they're putting in a new immune
2 system. Oh, those genes weren't inserted in the right place
3 at all. They're being inserted into a place that promoted
4 lymphomas.

5 You know, think about this. This therapy has to
6 target the tumor antigens 100 percent of the time, can't be
7 on normal tissue, and those genes have to be in the right
8 place. I'm fine with -- you know, pharma companies are fine
9 if they want to come up and speak, write letters about how
10 their company is fine by doing this. But what about the
11 investigator in a hospital health care system who's trying
12 to do this in his own lab? What about the guy on the street
13 who's trying to do this? We can't have cell therapy
14 programs off the street. These have to be the most highly
15 regulated products because in my mind they're the scariest
16 products I've ever seen.

17 I hope this isn't being videotaped because I
18 actually do what I'm about to show you. I'm Roman Catholic.
19 Every patient I give CAR-T or these IECT therapies to, right
20 before I treat I go like this (indicating). That tells you
21 how serious I feel about this therapy.

22 MR. FALAHEE: Thank you. Other questions?

23 MR. HUGHES: I actually have one more.

24 MR. FALAHEE: Commissioner Hughes?

25 MR. HUGHES: I am sorry. The -- the FACT

1 accreditation is kind of a big discussion of this whole
2 thing and in reviewing the thing it's put together by people
3 in the industry self-policing, it's voluntary, a very
4 thorough program and it looks at outcomes and monitoring and
5 so forth. The con against it is that it takes time, it's a
6 barrier co- -- can you put in perspective at all how big of
7 a deal or hard of a deal it is to get FACT and what it means
8 and why --

9 DR. GREG YANIK: Sure.

10 MR. HUGHES: -- why something other than a drug
11 company wants to have everybody be able to distribute it,
12 they'd be against having the FACT accreditation for people
13 that are dispersing this drug?

14 DR. GREG YANIK: That's a very good question. So
15 we're going through our -- our re-upping of our FACT
16 accreditation this winter. It'll cost us just -- just for
17 the application for it, it'll be around \$15,000 just for all
18 the -- just to apply for FACT re-accreditation. But really
19 what it means is that we hired -- we -- we got one person as
20 one of our lead research coordinators dedicated to basically
21 24/7 ensuring that we're meeting the FACT guidelines and
22 getting all of our paperwork ready. So literally it's a 1.0
23 FTE if you think of it that way of a full-time job for
24 somebody just to ensure that our FACT accreditation is met.
25 We actually have weekly meetings every Wednesday at our

1 center with our blood bank, with our clinical research
2 coordinators, our data managers, nursing, physicians that
3 are involved in the care just to go over all of the
4 patients, to go over all of our standards, to go over what
5 we need to do to meet FACT accreditation. It literally
6 becomes a team process to get FACT accreditation. And as I
7 said, we have one lead person, 1.0 FTE, to ensure that we're
8 meeting all of those guidelines. It is a fairly rigorous
9 process. And -- but I wouldn't say that it's onerous. I
10 actually smile at it because when I look at it, it gets
11 things right. It doesn't allow us to cut corners. It
12 doesn't allow us to have people doing this care that aren't
13 properly educated. It doesn't allow us to go on to keep
14 doing therapy without having good outcomes. We have to
15 report our outcomes to FACT. So the FACT system, though it
16 does require an effort on our part, a team effort with one
17 lead person, as I look at it from top to bottom, it's a very
18 good system.

19 MR. HUGHES: Thank you.

20 MS. ROGERS: Other questions? Dr. Yanik, thank
21 you again. We appreciate all your work, effort, and
22 testimony. Thank you.

23 DR. GREG YANIK: Thank you, Chip. Thanks.

24 MR. FALAHEE: Last call for cards. I have none
25 other so I will call the last witness up and that's Dr.

1 Stella. While Dr. Stella is coming up, just to remind to
2 the Commission members, Dr. Stella was one of the co-chairs
3 of the SAC. The other co-chair, Dr. Joe Uberti, was
4 supposed to be here. He e-mailed Dr. Stella and myself late
5 yesterday afternoon saying that he could not be here. Leave
6 it to Dr. Stella and I to get even with Dr. Uberti for
7 failing to show up. We'll figure out something to do. And
8 in the interest of full disclosure, Dr. Stella and our
9 family know each other. We go way back. And the other I've
10 already disclosed. I have a nephew that is involved in
11 Boston in IECT therapy development and he's given me chapter
12 and verse, and with his Ph.D. it goes right over my head so
13 never mind. But Dr. Stella, I wanted him to be here to
14 explain what went on within the former SAC members and any
15 other comments he would like to make and then we'll open it
16 up for questions.

17 PHIL STELLA, M.D.

18 DR. PHILLIP STELLA: So, yeah, Joe Uberti and I
19 won the lottery to co-chair this SAC and -- and first of all
20 I wanted to say that I agree with everything that Greg Yanik
21 has testified to. Okay. He was a member on the SAC. The
22 SAC was well constituted actually. It has -- had the haves
23 and have not, okay, and those are that had bone marrow
24 transplant programs because, remember, we were thinking
25 should this be regulated under the bone marrow transplant

1 SAC or CON or not, and -- and so it was equally divided in
2 terms of the providers there and we had representatives from
3 payers as well as others. And -- and it was a very
4 interesting thing.

5 We were in about three meetings. We quickly came
6 to a consensus that this is a very high tech process. It is
7 fraught with risks and all, and that, that really quality
8 standards should be part of it. Even on those facilities,
9 representatives from those facilities that did not have a
10 transplant program, we felt that this should be -- that we
11 needed to have something to look at the -- to assess
12 quality, have some kind of a bar to -- that the programs
13 wanted to do this high tech procedure on, and that we could
14 then look at the quality of the procedures and the
15 treatments given at each of the facilities. We quickly came
16 to a consensus that this should not be a limiting the number
17 of sites. So that was that issue of access issue. As you
18 heard the senator talk about, there's nothing in -- we -- we
19 felt that the sites should not be limited as in the bone
20 marrow transplant world, but that if the -- a site wanted to
21 get into the immune effector cell treatments, that there
22 should be a bar that is -- that they have to pass because
23 it's a complicated procedure. And so we quickly said
24 that -- and looked at FACT accreditation, we looked
25 thoroughly at that. We talked to the people that are going

1 through it on a regular basis and have to get recertified,
2 and we all felt comfortable with the FACT accreditation as a
3 means, as a really -- a basic level or hurdle that these
4 sites would have to meet those qualifications. So that was
5 a basic.

6 In fact, in our report back, in our
7 recommendations back to this Committee, that was the only,
8 the only requirement is they meet FACT accreditation.
9 Again, it is not limiting the sites, but if some site has
10 the interest, the dollars because it's expensive to do these
11 treatments, and the patient population and they meet FACT
12 accreditation, it gave all of us as providers a reassurance
13 that if there -- these are people that know what they're
14 doing, know what they're getting into, and they'll be able
15 to provide this safely. So it's not an issue in my mind, in
16 any of our minds of -- of a access issue or not. It really
17 is safety and quality issue.

18 So when we went into this initially was the --

19 MR. FALAHEE: Dr. Stella, let me -- I think I
20 heard the beeper go off.

21 DR. PHILLIP STELLA: Oh.

22 MR. FALAHEE: But if you want to make a concluding
23 comment, but then rest assured there will be some questions
24 asked of you.

25 DR. PHILLIP STELLA: Okay. I didn't hear the

1 beeper sound.

2 MR. FALAHEE: That's all right.

3 DR. PHILLIP STELLA: So basically we -- we had a
4 recommendation, some things came out from Medicare in terms
5 of changing their initial policy on FACT accreditation.
6 We've heard from other people that had contrary views of
7 things. And so Joe and I we -- we discussed not at a SAC
8 committee meeting, but individually, the members on the SAC,
9 does anything that has happened since we reported back to
10 this Committee change what we thought and the answer was
11 "no" and that was unanimous across all those, including the
12 haves and have nots, and for the basic reasons of safety and
13 quality.

14 MR. FALAHEE: Questions of Dr. Stella? I'll go
15 first -- oh, Tom, go ahead.

16 MR. MITTELBRUN: Commissioner Mittelbrun. The
17 Senator commented on the federal government, CMS. Could you
18 explain what -- what they've done and what -- what he was
19 referring to?

20 DR. PHILLIP STELLA: Yes. CMS came up with a
21 policy or they proposed a policy initially that made our job
22 a little bit easier because they suggested that they would
23 pay for immune effector cell therapy if they -- the
24 institution that was going to do that had to have FACT
25 accreditation. That was part of their initial policy. That

1 did not come out in the final policy as it turned out and --
2 for whatever reason. Now, let me just comment that this is
3 an evolving area, just like bone marrow transplants has
4 evolved. This is a new technology. It is going to
5 involve -- we all thought that this should be revisited in
6 three years according to the -- the CON guidelines because
7 there may be things that are different. But anybody that is
8 going to get -- my view is somebody who is a have not, does
9 not have FACT accreditation, anybody that wants to get into
10 this you want to have the reassurance as a provider that
11 you're meeting certain standards and that I personally would
12 go for FACT accreditation whether it was mandated or not.
13 But I would definitely do that.

14 The problem is if there was no way, even in the
15 REMS and all the data that you had to supply to the FDA for
16 how these patients do for a long time, there's no one that
17 is really looking at that data and no assurances that --
18 that somebody will act. If you have to put in all this data
19 to the FDA and it's bad, your patients are doing poorly, who
20 the heck is looking at it, you know? We thought that the
21 CON by virtue of having to renew it and review it, at least
22 someone is going to be looking at that data. So that was an
23 important part of our deliberations as well.

24 MR. FALAHEE: Other questions? I'll just add, and
25 then I'll end with a question. I communicated both to Dr.

1 Stella and Dr. Uberti the CMS final coverage memo or
2 whatever it was called, decision memo, and sent it to them
3 and I highlighted the two instances where they said, "Some
4 commentators wanted us to preserve FACT. We choose not to."
5 That's about all they said. There wasn't a lot of rationale
6 for it. So I sent -- I copied and pasted that and sent it
7 to both Dr. Uberti and Dr. Stella and said, "Gentlemen,
8 you're the experts. We -- at least this person on the
9 Commission is not. Please help us. Please recommend what
10 to do." And so I've -- I've been impressed again with their
11 work to pull this together. They could not meet as a group
12 because of the rules, but they -- they were able to get
13 together one by one by one. I'm glad to hear it's a
14 unanimous recommendation.

15 And I'm -- Dr. Stella hit up on one issue. This
16 isn't -- in my opinion, we're at the early, early stages of
17 IECT. We, as a Commission, on any standard can say we want
18 to bring this back. Even if it's off the three-year cycle,
19 we can bring it back. If -- if we see things are moving
20 forward two years, three years, five years from now, we
21 could change it as the Commission. But I strongly agree
22 with those comments about right now for the safety of the
23 residents of Michigan to get this treatment, this is the way
24 to go.

25 In terms of Senator VanderWall's comments about

1 places where it could happen, where you could do this, as
2 you said, FACT -- anybody that thinks they can apply, they
3 can apply. It might cost \$15,000 and an FTE, but the SAC
4 recommendation doesn't per se limit where this will happen.

5 DR. PHILLIP STELLA: No, it does not. That's why
6 I say it was not a -- we quickly dispensed of the -- the
7 issue of access because we said let's take it out of the
8 Bone Marrow CON and do a specific immune effector cell
9 treatment CON and that anybody that met that criteria -- but
10 we all felt very -- we all felt the same about having at
11 least some measure of quality of a program, that is by an
12 independent body to be -- before going forward on a very
13 complex and potentially very toxic program.

14 MR. FALAHEE: Other questions? There's a certain
15 reason that there were ten physicians on the SAC and there
16 were five from each side. Some of you will recall that the
17 first time Dr. Stella was here was March of 2018, and he and
18 Dr. Uberti and others were going back and forth on the
19 witness stand and I called them the dueling physicians. I
20 ran into them after the meeting and I said to Phil and Joe,
21 "You've just made yourselves the co-chair of the new SAC and
22 rest assured the chairman of the Commission will make sure
23 that there's going to be an equal number of the haves and
24 have nots" because that's how you get things resolved. And
25 to their credit and a result of a lot of hard work, thank

1 you very much. Thank you to Dr. Yanik, Uberti, and
2 everybody else.

3 DR. PHILLIP STELLA: Thank you.

4 MR. FALAHEE: Thank you very much. So I have no
5 other witness cards on this topic and now we move into
6 Commission discussion. Sorry, I've got to wait for -- we'll
7 move into Commission discussion. I'll just -- I'll just add
8 a couple additional comments. I appreciate the comments
9 from the two Commissioners to my left and for everyone else
10 that did their homework on this. This is a complicated
11 issue and I know from dealing with many of you in between
12 the June meeting and this meeting, many of you were diving
13 into this and looking at it yourself. So thank you for
14 that. Thank you for the physician expertise on this
15 Commission. It comes in handy. Thank you.

16 And I think what's in front of us, as Brenda laid
17 out, is a few options. One is -- and, Brenda, please tell
18 me when I screw it up. One is we can approve the
19 recommendation as it was presented to us in June. That's
20 option one. Let's go 180 degrees the other way. We could
21 reject it. No, we're not going to do it at all. And then
22 there's two sort of middle grounds. One would be to table
23 it indefinitely, meaning then you could bring it back
24 whenever you wanted, or table it for a certain period of
25 time: six weeks, six months, two years, whatever. So those

1 are the four options in front of us. I'll say that based on
2 the evidence I've heard and the homework I've done, that I
3 think for the safety of the residents of Michigan we need to
4 proceed with that recommendation as it came to us from the
5 experts on the SAC. Everyone I've talked to has that same
6 opinion. I understand there are many comments that were in
7 our packet that came in from the public comment, but I think
8 our job is to look as a Commission at the quality, safety
9 and cost. When you look at all of that and you hear the
10 quote from Commissioner Mittelbrun about FACT, we're here to
11 make sure that those residents that get care get the best
12 care and the safest care they can. In my opinion, that
13 preserves the FACT requirement and that says we proceed with
14 the SAC recommendation as it was presented to us in June.
15 Discussion? Commissioner Dood?

16 MR. DOOD: Commissioner Dood. One part of the CON
17 standard that was proposed that I really appreciated that
18 impacted access was that it was required that not only
19 impacted accreditation, but it be done without regard to
20 whether the patient could pay or not, and we haven't talked
21 about that at all today, but to me that's an access issue;
22 that if we don't move forward on that, that's not a
23 requirement so that's gone.

24 MR. FALAHEE: And as one of the two hospital
25 members on the SAC, I will tell you that there are many

1 treatments out there where the treatment is in the best
2 interest of the patient. You treat the patient, you worry
3 about the payment later and sometimes your payment is zero.
4 That's part of being in the health care industry these days.
5 But it is something that I think every hospital is sensitive
6 to, every provider, every physician is sensitive to,
7 especially when as Commissioner Hughes noted, we have
8 pharmaceuticals that are very, very expensive. Other
9 discussion? Other questions? Commissioner Brooks-Williams?

10 MS. BROOKS-WILLIAMS: Yeah. Commissioner
11 Brooks-Williams. So -- so just -- just so I make sure I'm
12 clear. So we're saying that IECT if we move forward with
13 the recommendation that is before us, it really is
14 essentially saying FACT accreditation is the threshold
15 that's required for anyone to enter. Is it retrospective
16 for anyone who's doing it now? Because I'm always confused
17 with the standard if it goes back or if it -- yeah.

18 MS. ROGERS: This is Brenda. So as it was
19 discussed during the SAC and in discussions since then at
20 the Department level, so it's not retroactive, but because
21 this is a brand new Certificate of Need review standard of a
22 new covered service, we are going to require anybody
23 currently providing this service to apply once these
24 standards go into effect. It's the same as if you'll recall
25 a few years ago with the special newborn nursery. It's the

1 same type of situation.

2 MS. BROOKS-WILLIAMS: Okay. Thank you.

3 MR. MITTELBRUN: Mittelbrun. Brenda, what's the
4 time frame for compliance when you go through that process?

5 MS. ROGERS: I'm going to let Tulika address that.
6 Thank you.

7 MS. BHATTACHARYA: So -- this is Tulika. Once the
8 standards go into effect, I believe we discussed at the SAC
9 that the existing providers who are currently offering IECT
10 services will have up to six months to submit an application
11 to secure approval under the standards and we have up to 12
12 months to get the approval. Is that right?

13 MS. NAGEL: I think so.

14 MS. BHATTACHARYA: Because these are going to be
15 substandard review applications. So once you submit an
16 application, there is a four-month -- four- to five-month
17 review process. So those are the timelines. And if a
18 center is truly initiating service, so there is no
19 restriction on them when they can apply. They can apply
20 whenever, you know, they want because it is a new service
21 they will start to offer. If that makes sense?

22 MR. FALAHEE: This is Falahee. I'll add I believe
23 there are two entities now that are FACT accredited:
24 University of Michigan and Henry Ford; is that right? Okay.
25 That's what I thought.

1 UNIDENTIFIED SPEAKER: Spectrum is.

2 MR. FALAHEE: Spectrum as well? So three.

3 UNIDENTIFIED SPEAKER: Karmanos.

4 MR. FALAHEE: Karmanos? Great. I'm doubling my
5 number. That's good. So we have -- the audience corrects
6 me, thankfully, there are four entities in Michigan that are
7 already FACT accredited: University of Michigan, Karmanos,
8 Henry Ford, and Spectrum. Other discussion?

9 DR. MCKENZIE: I was just going to add, if I
10 understand correctly, that the way this is written in the
11 standard, that upon CON approval, the entity would have
12 three years to obtain their FACT accreditation; correct?

13 MS. BHATTACHARYA: Yes. That will be correct. So
14 Henry Ford, U of M, Karmanos, and Spectrum, they are
15 currently offering IECT services, so they'll have six months
16 to submit an application and up to 12 months to secure
17 approval. And then after approval, let's say they did not
18 have FACT accreditation, they'll have three years after
19 approval to obtain that FACT. Now, let's say a new
20 provider, for example, Beaumont wants to apply to initiate
21 service, there is no restriction that they'll have to file
22 within six months. They can file whenever they want. But
23 after they secure approval, they'll have three years to get
24 their FACT accreditation for this service.

25 DR. MCKENZIE: Thank you.

1 MR. FALAHEE: I see the look in Commissioner
2 Brooks-Williams eyes, so I know there's a question coming.

3 MS. BROOKS-WILLIAMS: Commissioner
4 Brooks-Williams. So if we approve it and it goes to JLC --
5 and Chip and I had an opportunity to talk a little bit about
6 this before this meeting -- given the testimony against the
7 standard that we've seen in writing and here today, just
8 remind us what that JLC review looks like in a circumstance
9 where we've had one person come forward to speak to their
10 dissension on the topic.

11 MR. FALAHEE: This is Falahee. I just happen to
12 have the language in front of me in case that question came
13 up because I wanted -- and I was going to talk about it
14 anyway. Thank you. When we go and we approve these, we
15 always say, "Well, we'll send it to the JLC and the
16 Governor." Well, what's that mean? All right. I know that
17 over the course of the summer some members of the
18 legislature were approached and said -- and told, "You
19 remember the JLC?" And they went, "What's the JLC? Never
20 knew I was on it." Okay. The way it works, it says once
21 we -- let's say we approve a standard or this standard --
22 okay? -- it goes to the Joint Legislative Committee and the
23 Governor. The Governor or the legislature may disapprove
24 the proposed final action within 45 days after the date of
25 submission. There's some language about how many

1 legislative days you have to have within that 45-day period.
2 Then the legislative disapproval, I'm going to read the
3 language. I'll quote it.

4 "Legislative disapproval shall be expressed by
5 concurrent resolution which shall be adopted by each
6 house of the legislature. The concurrent resolution
7 shall state specific objections to the proposed final
8 action."

9 That's the language. That's how it works
10 internally at the capitol. And Senator VanderWall's chief
11 of staff is still here, so if I get it wrong, I'm sure
12 Patrick will say something about it. So there. So that's
13 right out of the statute. So Commissioner Brooks-Williams,
14 that's how it works, let's say, behind the scenes.

15 MS. BROOKS-WILLIAMS: Thank you.

16 MR. FALAHEE: Any other discussion? If not, I'd
17 entertain a motion.

18 MR. MITTELBRUN: Mittelbrun. Based on the
19 description and the answer to the questions in terms of the
20 process of going through the FACT accreditation, it looks
21 pretty liberal and I don't want to say lenient, but
22 certainly plenty of time to get that. I'll make a motion we
23 approve the standards as presented in June in accordance
24 with the recommendation of the SAC and that the standards
25 proceed through its normal course with being reviewed by the

1 JLC and then the Governor.

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

3 MR. HUGHES: Commissioner Hughes, second.

4 MR. FALAHEE: Any discussion? All in favor say
5 "aye."

6 ALL: Aye.

7 MR. FALAHEE: Any opposed? Carries.

8 (Whereupon motion passes at 10:25 a.m.)

9 MR. FALAHEE: Thank you very much for all your
10 work. Thank you to Dr. Stella, Uberti in absentia and Dr.
11 Yanik. Express our concern or thanks to the other
12 physicians and the other members of the SAC. Thank you
13 very, very much. Next item on the agenda is psychiatric
14 beds and services and I'll turn it over to Brenda Rogers for
15 her usual summary for us. Please, Brenda.

16 MS. ROGERS: Again, this is Brenda. You do have
17 the material in your packet. You took proposed action at
18 your June meeting. A public hearing was scheduled in July.
19 Testimony was received from five different organizations and
20 can be found in your material. There was testimony both in
21 support of the language and -- yeah, I'm looking -- I'm
22 making sure I'm looking at the right one here so, sorry. We
23 have a lot of standards this time. In there -- so,
24 therefore, the Department supports the language as you
25 passed it in June and if you take final action today, again,

1 it will move forward to the Joint Legislative Committee and
2 the Governor for the 45-day review period along with the
3 language. As you'll recall a -- an updated bed need
4 methodology is part of this draft language. Those numbers
5 had already been run as a part of the review. The
6 Commission does need to set the effective date of those bed
7 need numbers and since the Commission typically asks the
8 Department if we have a recommendation or suggestion, we
9 would suggest making the effective date of the new bed need
10 numbers the same as the effective date of the new standards
11 once they become effective assuming you take final action
12 today. Thank you.

13 MR. FALAHEE: Any questions of Brenda? All right.
14 I have no cards for anything else on the agenda. So if
15 anybody wants to say anything about any of the future agenda
16 items, please submit a blue card. Having no blue cards on
17 this agenda item, no public comment, we move right into the
18 Commission discussion. I think Brenda laid it out exactly
19 what the options are in front of us. Is there any
20 discussion amongst the Commission? Any questions of the
21 Commissioners to the members of the Department here? If
22 not, I'll -- sorry. Beth Nagel has a comment.

23 MS. NAGEL: Thank you for allowing me to comment.
24 I wanted to make a comment. There was a bit of testimony
25 that was received about high acuity beds in your packet and

1 I just wanted to say that we've done some due diligence,
2 worked back with the chair of the work group, Dr. Laura
3 Hirshbein, and just wanted to make it clear that testimony
4 was essentially saying if the new high acuity pool, if a
5 patient goes into the high acuity pool, the goal should be
6 to raise their acuity, and so then what happens to them
7 there? Are they still eligible to be in that bed? And the
8 work group is very clear that that's a clinical decision;
9 that the physician should be able to decide whether they
10 should go to a general psych bed or whether that patient
11 should stay in the high acuity bed. And the language and
12 our interpretation of the language supports that. So we
13 didn't see a conflict based on that testimony and I just
14 wanted to make that clear.

15 MR. FALAHEE: Thank you, Beth. That's an
16 important clarification. Thank you. Questions?
17 Discussion? If not, I'd entertain a motion, please.

18 MS. BROOKS-WILLIAMS: I'm laughing because I'm,
19 like, I should have this right by now; right? I move that
20 we accept the psych standards as presented and move them
21 onto the JLC and the Governor for the 45-day review.

22 MR. FALAHEE: And I'm sure you also want to set
23 the effective date at the same date that the standards are
24 effective?

25 MS. BROOKS-WILLIAMS: Absolutely. I want to do

1 that as well.

2 MR. FALAHEE: I knew that.

3 MS. BROOKS-WILLIAMS: Commissioner
4 Brooks-Williams.

5 MR. FALAHEE: Thank you. Support for that motion?

6 DR. GARDNER: Commissioner Gardner, support.

7 MR. FALAHEE: Thank you. Discussion? All in
8 favor of the motion say "aye."

9 ALL: Aye.

10 MR. FALAHEE: Opposed? That motion carries.

11 (Whereupon motion passes at 10:30 a.m.)

12 MR. FALAHEE: Thank you, everyone. Next, the
13 always on the agenda topic lithotripsy. I'll turn it over
14 to Brenda Rogers.

15 MS. ROGERS: This is Brenda. Again, you took
16 Commission -- the Commission took action at your June
17 meeting. Public hearing was scheduled. We received one
18 piece of testimony which you have in your packet. And so
19 the recommendation today is to move the language forward for
20 final action to the JLC and the Governor for the 45-day
21 review period. Thank you.

22 MR. FALAHEE: Any questions of Brenda? Again, I
23 have no public comment cards for this agenda item so we move
24 right into the Commission discussion. Any Commission
25 discussion? If none, I'll entertain a motion.

1 DR. WANG: Commissioner Wang moves that we accept
2 the proposal as previously stated and that we move it for
3 JLC consideration and the 45-review standard period or
4 something to that effect.

5 MR. FALAHEE: And we'll include the Governor in
6 that as well?

7 DR. WANG: And we will include the Governor in
8 that as well.

9 MR. FALAHEE: Support for that motion?

10 MS. BROOKS-WILLIAMS: Support, Brooks-Williams.

11 MR. FALAHEE: Thank you. Any questions or
12 discussion? All in favor of the motion say "aye."

13 ALL: Aye.

14 MR. FALAHEE: Opposed? Motion carries.

15 (Whereupon motion passes at 10:32 a.m.)

16 MR. FALAHEE: Next topic, hospital beds limited
17 access areas, and I'll let Beth Nagel explain this confusing
18 to me topic. Should we put you on a two-minute limit?

19 MS. NAGEL: Please. I'd love that. If you don't
20 mind, I'll come up here because I'm going to want to point.
21 I'm sorry that it's confusing to you. It's also a little
22 bit confusing to us as well.

23 In the hospital bed standards there is a section
24 called limited access areas and it was created about 15
25 years ago for the purpose of making sure that the hospital

1 bed need methodology didn't miss any areas of the state that
2 might have extra circumstances for need. Now it has been in
3 the standard for 15 years. Every time we renew the hospital
4 bed, bed need numbers, we give you a new map of the limited
5 access areas that have been identified, but we, as the
6 Department, has never received an application for a limited
7 access area facility ever until this year. And so the
8 language was challenged for the first time. We went through
9 as a Department the language with the bed need and we found
10 an issue that we need to bring to the Commission and ask for
11 your help in resolving it.

12 Just for some background, this is directly from
13 the hospital bed standards. These are the definitions in
14 the definition section. The first one is an "underserved
15 area" and that's an area that -- that with -- in that area
16 you have to drive 30 minutes to reach, 30 minutes or more to
17 reach the next critical or acute care hospital with 24/7
18 emergency room services. The "limited access area" is a
19 subset of the underserved area and it means within that
20 underserved area, it's an area where the patient day demand
21 meets or exceeds the statewide average for 50,000 residents.

22 So if it'll help if I show on the map? This is
23 your map that we show every time we redo the hospital bed
24 need. And the red areas are the limited access areas and
25 the yellow areas around it are the zip codes that touch a

1 limited access area -- okay? -- and so we assign a bed need
2 to each of those as well. I keep walking away from the
3 microphone. You probably don't like that. So like the
4 limited access area 1 is in the UP and that has a bed need
5 of 306 beds. So in this area, all the red areas in the UP
6 are more than 30 minutes from the next hospital that has
7 24/7 emergency room service and has a patient day demand for
8 50,000 people that meets or exceeds the statewide average.
9 And as you can see, the little plus hash marks are hospitals
10 and so around those hospitals you can see the 30-minute
11 drive time is kind of in the yellow. And then, you know,
12 there's a part of the upper part of the mitten that's a
13 limited access area, and then there are some that have been
14 added more recently which are down here (indicating) below,
15 limited access area 4, 5, and then 6 as well. And we
16 projected based on the methodology in the hospital bed
17 standards the bed need based on those -- on those specific
18 areas.

19 So there is the definition of the limited access
20 area which I -- I just told you about and the map. And then
21 within the standard itself there are specific requirements
22 that you have to meet in order to build a hospital in these
23 limited access areas. And one of them, the one that's most
24 salient to today's discussion, is that the hospital, if it's
25 in a metropolitan area, has to be within the limited access

1 area; that limited access at a point where it can hit 50,000
2 people within a 30-minute drive time of that hospital --
3 okay? -- and if it's in a rural or micropolitan, they get
4 60-minute drive time. So if you look back at -- the UP is
5 kind of the best example. So if you were to place your
6 hospital here (indicating) at this very tip limited access
7 area, at the very tip of the western UP, you would have to
8 in a 30-minute or 60-minute drive time has to hit 50,000
9 people within that area. And so you -- you -- that wouldn't
10 be eligible; right? But maybe if you had it somewhere else,
11 like in limited access area 2, you might be able to do that.

12 So when we looked more specifically at limited
13 access area 4, which as you remember was just east of
14 Muskegon, you can see the zip codes here (indicating), these
15 two zip codes. Together those two zip codes have a
16 population of 50,600 people, but the limited access area
17 that was identified, that small area there actually has zero
18 residents in it. And so that's slightly perplexing. When
19 we looked at -- when we looked at access area 6, there are
20 three zip codes as well that have about 60,000 people in it,
21 but the actual block itself has 7,600 people in it.

22 So essentially in those two limited access
23 areas -- and we hadn't done -- we haven't done this analysis
24 on all of them, but at least in these two there would be no
25 place to put a hospital where you would get 50,000 people

1 inside the limited access area and within a 30- or 60-minute
2 drive time. So essentially the problem that I'm bringing to
3 you is that there's an issue with how the limited access
4 areas are being identified in the methodology. We're
5 finding these areas, but they don't meet the standards and
6 so we're putting out a bed need that can't actually be taken
7 advantage of. Does that -- should I stop here for
8 questions?

9 MR. FALAHEE: Any questions of Beth at this point?
10 You'll get your other chances later.

11 MR. MITTELBRUN: I'll wait for the solution.

12 MR. FALAHEE: Okay. Yeah; yeah.

13 MS. NAGEL: Okay. Yes. Because the solu- --
14 thank you.

15 MR. FALAHEE: Now what is what we're waiting, yes.
16 Now what?

17 MS. NAGEL: Thank you. I appreciate your
18 confidence. The solution is next. So what we'd like to ask
19 you for, your permission to work with Dr. Paul Delamater
20 from the University of North Carolina who does most -- does
21 all of our analysis for updating the bed needs and was
22 integral in bringing this issue to our attention. He
23 believes that there are potentially just some tweaks that
24 can be made to identify these areas better so that we're
25 actually looking for the 50,000 people first and then the

1 drive time as opposed to the kind of -- it's kind of the
2 other way around now. And that may involve some changes to
3 the language in the methodology and the standard. It may
4 not. We need to explore that further. But I also wanted to
5 bring to your attention as well that the hospital bed
6 standards are part of the -- their annual review cycle or
7 three-year review cycle is next year and so we will be
8 taking public comment on hospital beds this fall like we
9 normally do. It'll come back to you at your special
10 Commission meeting. You know, from our perspective you
11 could do one, both, or the other. We're concerned with
12 having this bed need out there and knowing this conflict.
13 And so from our perspective, this Department's perspective,
14 we want to be able to fix it and find a solution as soon as
15 possible, but also at the same time know that it's going
16 through it's going through its regular process as well.

17 MR. FALAHEE: So this is Falahee. Beth, question.
18 Do you need a formal motion from the Commission to say yes,
19 proceed with the proposed solution?

20 MS. ROGERS: I'm going to turn to Carl on that.

21 MR. HAMMAKER: I think that would be the best,
22 yes.

23 MR. FALAHEE: I don't want to shortcut any
24 questions we might -- I just want to figure out what -- what
25 the end game is here. Commissioner Brooks-Williams?

1 MS. BROOKS-WILLIAMS: Yes. So, Beth, just to
2 clarify, I followed you 'til the end, but you said -- so the
3 proposed solution is to allow the Department to work on the
4 fix, which I totally understand, but it would be folded into
5 the regular bed need process or would you -- would -- if we
6 said fix it and you identified the fix, it would come back
7 sooner or --

8 MS. ROGERS: Yeah. So, yes. So potentially if
9 you said, yes, fix it, we would come back to you with a fix
10 as soon as we have that information, and at the same time,
11 if you want to take a whole comprehensive review of the
12 limited access area concept in full, you could also do that
13 at -- in next year.

14 MS. BROOKS-WILLIAMS: Okay. So when the fix would
15 come back, the fix would come back and then it still would
16 go through the normal comment period? I'm just trying to
17 make sure how it gets reviewed. Right?

18 MS. ROGERS: Yes. Absolutely. Yup.

19 MS. BROOKS-WILLIAMS: Okay.

20 MR. FALAHEE: Commissioner Dood?

21 MR. DOOD: I wasn't here 15 years ago, but
22 presumably our predecessors or maybe some people left over
23 knew what they were doing. So what -- what exact -- I mean,
24 if more people moved into these areas it wouldn't be a
25 problem. Was that the intent all along or is it -- is it

1 really a problem or I'm missing a part?

2 MS. NAGEL: The problem is that we're identifying
3 need, but the standards -- a need that can't be accomplished
4 given the criteria in the standards. Neither was I here 15
5 years ago and our researcher wasn't here 15 years ago
6 either. But what he believes happened is that when it was
7 these large areas, like the UP and part of the mitten, it
8 made sense. But now that we're identifying these smaller
9 areas it might -- it doesn't make as much sense and needs to
10 be fixed.

11 MR. FALAHEE: This is Commissioner Falahee. I
12 wasn't on the Commission 15 years ago, but I've been
13 attending Commission meetings for at least 25 years, so I am
14 a leftover. Okay. I will say that Beth is exactly right.
15 When we started to look at this -- and I see Mr. Wheeler
16 over here so he may add to it -- but when we started to look
17 at this, we were identifying large area. I recall looking
18 at the Alpena area going, oh, my gosh, that's an area where
19 you don't get easy access to care, and the same with certain
20 areas of the UP. But we were looking at much larger blocks,
21 if you will. We didn't have the finiteness that we can do
22 now and I can say we didn't have Professor Delamater to help
23 us either, so I can see how this could happen. But that's
24 why we did the best we -- or the Commission then did the
25 best it could given the data it had. Any other questions

1 for Beth? If not, I'll entertain a motion.

2 MS. ROGERS: Excuse me. This is Brenda. Do you
3 have public comment?

4 MR. FALAHEE: No.

5 MS. ROGERS: Okay.

6 MR. FALAHEE: No public comment on this issue.

7 MR. MITTELBRUN: Mittelbrun. Oh, don't take my
8 slide away. Motion to proceed with the proposed solution as
9 identified in items one and two in the slide presented by
10 Beth.

11 MR. FALAHEE: Support for that motion?

12 MR. HUGHES: Second.

13 MR. FALAHEE: Commissioner Hughes supports.

14 Discussion? All in -- sorry.

15 MS. BROOKS-WILLIAMS: Commissioner
16 Brooks-Williams. Because I'm not going to say I can't fully
17 read that slide, but I just want to make sure that before we
18 take action that the question that I asked before about what
19 that means in terms of time line, does the -- does the
20 proposal say how it comes back to us and how it
21 ultimately -- whatever the fix is; right? So I'm supporting
22 the fix. I'm not sure that I'm understanding the process
23 after you have resolution.

24 MS. NAGEL: Yeah. That's a good -- so if -- let's
25 just say hospital bed is not part of the next review cycle

1 at all. I would say we'll go back, we'll look at this fix,
2 and then we'll bring it back to you at, you know, the next
3 meeting or the meeting after that. That was going to be our
4 proposal, but then we noticed that the hospital bed standard
5 is up for review. And so essentially what we're saying is
6 that we can bring you back a solution and we'd like to do
7 that, and also you can have that solution checked, double
8 checked, re-tuned whatever needs to be by the hospital, as
9 the hospital bed standard gets reviewed next year, too. So
10 we're not taking away any option for this to be reviewed. I
11 just wanted to highlight another way that it can be
12 reviewed, too.

13 MS. BROOKS-WILLIAMS: Okay. So at this point it's
14 just the fix and then we figure out what to do with the fix
15 once you bring it to us?

16 MS. BHATTACHARYA: Standards need to be updated
17 with the fix.

18 MS. NAGEL: Yeah; yes. And that's a good point.
19 So what may happen -- what potentially could happen is that
20 we come back to you in December with a fix and you take
21 proposed action and it moves to final action, and then the
22 hospital bed, let's say you have a SAC next year, would look
23 at the new version of those standards. Or we could bring
24 you a fix and you don't like it and you say have the SAC do
25 this next year.

1 MS. BROOKS-WILLIAMS: Okay. Thank you.

2 MR. FALAHEE: Commissioner Gardner?

3 DR. GARDNER: Commissioner Gardner. So you said
4 that this is the first time you've ever had an application
5 for it. What happens to that application during this
6 process?

7 MS. NAGEL: I'm looking at my legal counsel
8 because I do not believe that I can comment on an
9 application that's pending right now.

10 MR. HAMMAKER: Yeah. That application is
11 currently pending and it'll be -- you know, a decision will
12 be made when the Department issues the decision, which is
13 due at the end of the month, so --

14 MR. FALAHEE: So we have a motion on the floor,
15 it's been made and seconded. All in favor of the motion say
16 "aye."

17 ALL: Aye.

18 MR. FALAHEE: Opposed? That motion carries.

19 (Whereupon motion passes at 10:47 a.m.)

20 MR. FALAHEE: Let me take this time to publicly
21 acknowledge the people sitting around the table that
22 Commissioner Mittelbrun and I work with extensively in
23 between these meetings, whether it's Tania, Tulika, Beth,
24 Brenda, or Carl. We are in constant communication with them
25 and they with us, and I want to thank them publicly for all

1 the excellent work they do. Keeping Commissioner Mittelbrun
2 and I on our toes and up to speed is not an easy task. But
3 thank you very, very much for all you do for us. Thank you.

4 Next we'll move on to the nursing home/hospital
5 long-term care unit beds Standard Advisory Committee update
6 and that's got my name next to it. So I'll go back a little
7 bit in time. In March of '18 -- = '18, we first talked
8 about nursing home and beds and a bed need methodology was
9 presented and attached to the minutes of the March of '18
10 meeting. I think it was Exhibit F, I think, or H. I
11 forget. I looked at it last night as I was communicating
12 with Patrick from Senator VanderWall's office. And then
13 that was March of '18. And we did not set a date on the bed
14 need methodology at that point. We held off on it and the
15 people to my right will tell me if I get any of this wrong.

16 In March of '19, so this year, we said that we
17 would like to appoint a SAC to look at a number of issues in
18 the nursing home area. One of those issues, the first
19 charge, was the new bed need methodology, March of '19. And
20 so we as the Commission approved that SAC, that a SAC be
21 established. And then what happens behind the scenes is we
22 work -- the chairman and the co-chair work with Brenda and
23 Beth to send out nominations for any SAC including this one
24 to get the people on it, to nominate themselves, to get
25 people to nominate themselves to be on the SAC. And as I do

1 with every attempt to put together a SAC, Brenda or Beth
2 will send me a note. "We've sent out the first round of
3 nominations, only three people applied, or five people, not
4 enough numbers." I'll send -- I'll say, "Okay. Send it out
5 again a second time." That happened here first time it went
6 out, not enough people, second time it went out, not enough
7 people, and I believe at this June meeting I said at the
8 Commission meeting we're not getting people in the Nursing
9 Home SAC to submit names to be on the SAC. And as I do with
10 every other SAC, I give it three times. We sent it out the
11 third time, didn't get sufficient nominations. Three
12 strikes and you're out. So there was no SAC created in
13 spite of the Commission and the Department's best efforts to
14 put one together.

15 So the update is that there isn't a SAC and if
16 anybody has any questions about that or Brenda or Beth, if
17 I've misstated anything, please correct me, because the
18 attempt was there, three attempts, nothing happened. That's
19 the discussion on the SAC. I think that's the end of that
20 agenda item. I do have three cards, but one has the same
21 person twice, that's because Pat Anderson is so good she can
22 be here twice.

23 MS. ROGERS: Can I comment on that?

24 MR. FALAHEE: Oh, sure. You can, yeah.

25 MS. ROGERS: Okay. So, yes, this is Brenda and

1 Chip is accurate in his analysis. So now what we are going
2 to be looking for from the Commission is how do you want to
3 proceed and maybe you were going to get to that. But I just
4 want -- so the Commissioners aren't left hanging, okay,
5 what's the next step? We are going to be asking you what is
6 that next step. Do you still want to proceed moving and
7 looking at the charge that was originally set up for the SAC
8 and that could be via a work group, via the Department, via
9 yourselves as the Commission, or do you see no need to do
10 that at this point in time and wait 'til the next review
11 period in three years? So just -- just as FYI as you
12 continue the discussion. Thank you.

13 MR. FALAHEE: Thank you, Brenda. This one
14 Commissioner -- this is Falahee. We tried three times to
15 get the SAC for the substantive issues, I mean, bed need
16 methodology and the other issues. I don't think a work
17 group is the best thing to do. But failing to get a SAC
18 after multiple attempts to do it, we can't be stymied. We
19 need to move forward. To me the most important thing to
20 move forward on is to see the next agenda item which is
21 the -- set the effective date of the new bed need numbers
22 which were first I think published or discussed in late
23 2017, then they were attached to the March 2018 CON
24 Commission minutes, so it's not as if people didn't know
25 about them. So that's just one person's opinion.

1 MS. ROGERS: Okay. So, again, sorry, Chip.

2 MR. FALAHEE: No, that's --

3 MS. ROGERS: This is Brenda. So having said that,
4 the numbers for the next agenda item that you have today is
5 a result of its -- it was time to run the new need numbers
6 again this year, 2019. So the numbers are slightly
7 different than what you had two years ago so I just want to
8 make that clear for the Commission members.

9 MR. FALAHEE: So the --

10 MS. ROGERS: So these have been rerun based on the
11 standard that it's required that the Department run the
12 numbers every two years. Having said that, had a SAC been
13 seated, we still would have been doing that and we still
14 would have been bringing these numbers to the Commission
15 because according to the standard it's your responsibility
16 to set the effective date of the bed need numbers. But the
17 SAC could have still continued its work, okay. So I just
18 want to make -- make clear in what we're doing here as far
19 as the process goes.

20 MR. FALAHEE: Got it.

21 MS. ROGERS: Thank you.

22 MR. FALAHEE: So this is Falahee again. So
23 Brenda, to confirm, the numbers we have, or the bed need
24 numbers we have in front of us are the most current
25 available?

1 MS. ROGERS: This is Brenda. That is correct.
2 And so, and also in case you didn't -- we had both of Paul's
3 reports in there, the one for this time plus we provided the
4 one from two years ago. And the reason we did that is
5 because when you look at the bed need numbers that came out
6 in this run, they are higher than what's currently in place.
7 Two years ago they were higher than what was currently in
8 place. So when you looked at it, it does, it looks like a
9 significant increase in the number of beds. Having said
10 that, had the last run been put into effect and then
11 comparing it to what the run is now in 2019, you would have
12 seen a decrease of 400 plus beds. So I just want to make
13 sure that you're -- when you're looking at these, that
14 you're comparing and that type of thing.

15 MR. FALAHEE: Thank you.

16 MR. MITTELBRUN: Mittelbrun. Brenda, what was the
17 recommended effective date by the Department?

18 MS. ROGERS: The Department is suggesting an
19 effective date of November 1st as that is when the next
20 scheduled publication of the bed need inventory is provided.
21 And then also what that does, will give any applicant
22 seeking to apply for new beds time because the next window
23 date to apply is February 1st.

24 MR. MITTELBRUN: Thank you.

25 MS. ROGERS: So it will just make it even for all

1 players.

2 MR. FALAHEE: Thank you. So, and like I said
3 before, at least I rely on all these people to my right and
4 across, so thank you, Brenda, for those clarifications. I
5 think that I'll move to the next -- well, I guess, is
6 there -- is there any Commission action that we would like
7 to take having not been able to seat a SAC? Commissioner
8 Dood?

9 MR. DOOD: You made a comment that you didn't
10 think a work group would be best, that a SAC would have been
11 best and that's what we were looking for. But is a work
12 group a possibility or you're saying hey, since that's --
13 would be far inferior to having a SAC. We couldn't get a
14 SAC, so we should just give up on the issues that we had
15 wanted addressed?

16 MR. FALAHEE: That's up to the entire Commission
17 to decide.

18 MR. DOOD: Yup. I was just looking for your
19 opinion on that.

20 MR. FALAHEE: I have the charge for what the SAC
21 would have looked at had it been able to come together.
22 Number one, bed need methodology. There are six total. I
23 think one was the most important. Two, whether adequate
24 access exists for Medicaid patients; three, specialty
25 population beds; four, language changes as presented by the

1 Department regarding minimum occupancy requirements to
2 section 6 and 8; five, language changes regarding technical
3 edits; six, any other technical edits or changes. So those
4 are the six charges. And the language about -- the four,
5 five and six about language changes, you often see that when
6 SACs are put together. To me, of those six, the most
7 important was the bed need methodology. To be able to have
8 a SAC, look at it, much like with the IECT SAC, you put
9 people from both sides of the issue on it so there can be a
10 robust debate one way or the other. My issue with work
11 groups, other may disagree, is you don't know who's going to
12 be there that morning or that afternoon when you hold the
13 work group. You don't know if you're going to get 10 people
14 or 20. You don't know if those 10 or 20 are all evenly
15 split on the issue or happen to be on one side of the issue.
16 So you could get a skewed result. That's why when it comes
17 to issues like a bed need methodology, this -- this one
18 Commissioner says no, you need the formal SAC and that's why
19 the legislature in 2002 set up the SAC process, so there can
20 be a robust discussion amongst experts that then those
21 experts can report to us Commission members so that we can
22 help understand what's going on. And sometimes work groups
23 do work when there aren't substantive issues, things that
24 need to be worked through. We've just went through one.
25 But on this one at least, this one Commissioner doesn't

1 think a work group is the best way to look at the issue.

2 MR. DOOD: Commissioner Dood. So the options are
3 to -- since a SAC could not be established would be either
4 to do a work group that has some disadvantages to the SAC or
5 to do nothing -- right? -- and just let it go, or you
6 mentioned something about the Commission itself could have
7 its own work group and -- was that something you said two
8 minutes ago or no? Okay.

9 MR. FALAHEE: No; no. The Commission couldn't do
10 its own work group. The Commission always has the ability
11 to take a standard off cycle, if you will. We look at every
12 standard every three years and as we discussed with IECT, we
13 could always say, hey, we need to look at any standard out
14 of -- out of cycle, out of sync. Am I correct on that?

15 MR. HAMMAKER: Yeah.

16 MR. FALAHEE: Okay.

17 MR. DOOD: And if we don't do anything, there's no
18 work group established? That's not a default to when a SAC
19 is not established? It would just -- is that correct?

20 MR. FALAHEE: You mean if you can't get one then
21 you're stuck with the other?

22 MR. DOOD: I'm wondering or is the default nothing
23 happens if we don't fill a work group?

24 MR. FALAHEE: The Commission decides what the
25 "default" is.

1 MR. DOOD: You were going to move onto the next
2 agenda item. I was trying to decide what that would mean.

3 MR. FALAHEE: Right. Well, they're kind of tied
4 together.

5 MR. DOOD: I -- yeah, I agree.

6 MS. ROGERS: This is Brenda. Just in my side
7 conversation and partly in answer to your question there, I
8 think if the Commission decides that no work group is going
9 to be required at this point in time, I think it would be
10 just for making it clear and clean for the Commission to
11 take -- make a motion to -- I don't even know if it has to
12 say "not seat a work group," but just to in lieu of not
13 seating a SAC or a work group, the standards will be put out
14 for the next review period in three years or something to
15 that effect just to make sure that it's clear and on the
16 record.

17 MR. FALAHEE: Okay.

18 MS. ROGERS: Thank you.

19 MR. FALAHEE: Commissioner Dood, anything else?

20 MR. DOOD: Not at this time.

21 MR. FALAHEE: Thank you. Other questions? I
22 don't have public comment specifically on this. I've got
23 public comment from two individuals on the bed need. Pat,
24 did you want to speak about this specific issue as well,
25 Pat, on the SAC?

1 MS. PAT ANDERSON: Well, HCAM is in support of the
2 SAC if it can be called and we'd be willing to help approve
3 members.

4 MR. FALAHEE: Yeah. Okay. Pat Anderson from HCAM
5 is in the audience and for the sake of the record, she said
6 that HCAM is in support of a SAC. I knew that. They've
7 always been in support of a SAC, we still didn't get a SAC.
8 Okay. So with that, I have two cards, but that's on the
9 next issue, the bed need numbers. So I think what we're
10 left with is if there's no further Commission discussion, as
11 Brenda just said, I'd entertain a motion if someone wants to
12 make it along the lines of what she was just discussing or
13 something else if you want to do that.

14 MR. DOOD: Could we -- Commissioner Dood. Could
15 we wait on that until we have the next discussion since they
16 are tied together or --

17 MR. HAMMAKER: Yeah, you can move on the agenda,
18 suspend, you'll make a motion to suspend debate on this
19 until after the bed need.

20 MR. DOOD: Make a motion to suspend this until we
21 have the discussion on the bed need.

22 MR. FALAHEE: Support for that motion?

23 MR. MITTELBRUN: Second, Mittelbrun.

24 MR. FALAHEE: Motion made and supported. All in
25 favor say "aye."

1 ALL: Aye.

2 MR. FALAHEE: Opposed? That carries.

3 (Whereupon motion passes at 11:03 a.m.)

4 MR. FALAHEE: So now let's move to agenda item
5 ten. Set the effective date for the new bed need numbers.
6 And as I said earlier, there are two cards I have for that
7 and I will mess up his name, but Henry Boutros from
8 Illuminate. Are you here? Good timing. I don't think you
9 were here earlier. With any witness, you're limited to
10 three minutes time and then the Commission members can ask
11 you one or 100 questions after that.

12 MR. HENRY BOUTROS: Within the three minutes?

13 MR. FALAHEE: No. You have three minutes and we
14 can make you --

15 MR. HENRY BOUTROS: You have all day?

16 MR. FALAHEE: -- yeah, we can make you stay here
17 all day, so, yes.

18 MR. HENRY BOUTROS: Terrific. I might need a
19 bathroom break after a few questions, but we'll go on.

20 HENRY BOUTROS

21 MR. HENRY BOUTROS: Chair Falahee and
22 Commissioners, thank you for the opportunity to speak today
23 regarding the new bed need numbers for nursing homes and
24 hospital long-term care units. My name is Henry Boutros.
25 I'm the vice president of Illuminate HC, which operates 16

1 skilled nursing facilities in the state of Michigan. For
2 the last three years I've served as the chairman of the
3 board of directors for the Health Care Association of
4 Michigan and have recently been appointed by Governor
5 Whitmer to the Veterans Facility Authority Board.

6 I'm here today to respectfully request that the
7 commission not adopt the bed need projection and instead
8 continue to work to form a Standard Advisory Committee, SAC,
9 to review the basic methodologies used to determine the bed
10 need going forward. HCAM and it's 348 skilled nursing
11 facility members have been willing to serve on a SAC to
12 review the bed need methodology. In fact, HCAM's vice
13 president of reimbursement as well as HCAM's members applied
14 to participate in the SAC in the early spring of this year
15 following the first call for participation. Applicants did
16 not receive any information in return about the status of
17 the SAC. Convening a SAC for nursing facilities has proven
18 to be difficult over the past few years, but we certainly
19 understand and we support the need of a SAC to review the
20 important issues. In recent years HCAM has provided chairs
21 to the work group when a SAC was not able to be formed.
22 HCAM is willing to continue to identify individuals to serve
23 on the SAC or on a work group.

24 The August 2019 updates of the nursing home and
25 hospital long-term care unit bed need reports a 6,797 bed

1 increase over the current bed need. That's a 17 percent
2 increase moving from 39,391 to 46,188. The current
3 methodology for determining nursing facility bed need
4 projected this dramatic increase which does not appear to be
5 reasonable as it's inconsistent with occupancy trends,
6 contradicts real life experience of providers and does not
7 reflect the rapid changes incurring in how people are
8 interacting with the segment of the health care system which
9 is integrated on the continuum of care -- long-term care
10 supports and services. The continuum of long-term care
11 supports and services provide alternate settings and
12 programs for individuals to receive long-term care services
13 that at one time were provided within the skilled nursing
14 environment. The primary goal of the CON is to help control
15 costs by preventing excess capacity in health services. The
16 cost implications of having thousands of nursing home beds
17 in Michigan are significant. Following the assumptions
18 provided by the current CON methodology, Medicaid program
19 would be over \$45 million of state's general fund dollars
20 year over year if we were to go forward with this program.
21 The work force providing care --

22 MR. FALAHEE: Sum up your remarks, please.

23 MR. HENRY BOUTROS: Pardon?

24 MR. FALAHEE: Your three-minute timer is going
25 off, so if you could sum up your remarks, please?

1 MR. HENRY BOUTROS: Great. Yup. So summing up.
2 I'm here today to respectfully request that the Commission
3 not adopt the bed need projection and instead continue to
4 work to form a Standard Advisory Committee to review the
5 basic methodologies used to determine the bed needs going
6 forward.

7 MR. FALAHEE: Thank you very much. Questions from
8 the Commission members of Mr. Boutros?

9 MR. MITTELBRUN: Mittelbrun. I'm a little -- your
10 comments about the SAC, what would be different than what
11 just happened where we tried to seat the SAC three times and
12 failed because organizations like yourself didn't
13 participate? And two, I'd like Brenda maybe to give that
14 explanation on the bed need numbers or the calculation that
15 you just gave the Commission before the gentleman walked in.
16 He didn't get the chance to hear that.

17 MR. HENRY BOUTROS: So, as far as HCAM and our
18 facility membership within the Health Care Association of
19 Michigan, we are very interested in participating on any
20 level by providing names to participate on the SAC itself,
21 and -- and I think once the application is made, I believe
22 it's out of our hands so we can't force the CON, you know,
23 this Commission here to appoint somebody. All we've done is
24 applied and have waited for a response and we've not had
25 that response come back. And so it's a disappointment on

1 our end not to have this go forward.

2 MR. FALAHEE: This is Falahee. I'm going to
3 respectfully disagree. As the one -- as the chairman, I
4 work with Brenda and Beth very closely on these, on any SAC,
5 and there was notice that we weren't getting adequate
6 nominees.

7 MR. HENRY BOUTROS: Well, I believe that
8 this spring --

9 MR. FALAHEE: And there was -- there were -- there
10 were one, two, three attempts to get adequate nominations.
11 And in fact, I'm pretty certain if you look at the minutes
12 of the June meeting of this Commission, I said something
13 right there at that June meeting about we're having trouble
14 getting nominations. If you want to do that, get your name
15 in. So I think there was more than adequate notice and
16 three attempts to put the SAC together. Brenda, if I'm
17 wrong, please correct me.

18 MS. ROGERS: Brenda. That is correct.

19 MR. HUGHES: I get the e-mails, too; right?

20 MR. HENRY BOUTROS: So, and I don't know where the
21 disconnect may have happened. I do know that the vice
22 president of reimbursement for HCAM applied as did other
23 members within HCAM, as -- as members have, and they applied
24 during the first round, the invitation in early spring, and
25 we did not hear anything back. So obviously there's a

1 disconnect and it's -- I'm -- I'm hoping standing here
2 before you today we can hopefully try to clear that up, that
3 our intention -- we believe that there is a good value in
4 putting the SAC together and to have our representation
5 there to provide input to this Commission. Truly, it
6 sounded that we didn't -- that we somehow we -- we
7 disconnected on this issue which is important to all of us
8 here.

9 MR. HUGHES: Wasn't done in secret.

10 MR. HENRY BOUTROS: Oh, no, and I apologize.

11 MR. MITTELBRUN: Brenda, would you go through
12 those numbers again, please? Mittelbrun. The explanation
13 of -- that you gave the Commission?

14 MS. ROGERS: This is Brenda. Maybe, yeah. Get
15 this thing turned around. Okay. Yeah. So as far as the
16 bed need numbers that are in front of you today, as I stated
17 earlier, so this is part of the requirement of the standard
18 for the Department to run the bed needs every two years. So
19 it was ran in 2017, it was due again here in 2019. When we
20 ran it in 2017, the Commission decided -- and it's the
21 Commission's responsibility to set the effective date of
22 those bed need numbers. And at that time there was
23 discussion and the Commission decided to not put an
24 effective date on the bed need numbers and to postpone them
25 indefinitely knowing that the standards were going to be

1 coming up for review in 2019 and to seat a SAC and take a
2 look at that bed need methodology. So, therefore, those
3 numbers didn't go into effect. Now, doing due diligence,
4 the Department, because of they're due again in 2019 and we
5 would have done this as I stated earlier even if a SAC or a
6 work group would have been seated, the Department asked Paul
7 Delamater, because that's who does the calculations for us,
8 to run the bed need numbers. And so you have them in front
9 of you today for -- again, for you as the Commission to
10 determine the effective date of those bed need numbers or
11 you can do as you did two years ago, decide to postpone or,
12 you know, whatever you want to do with the effective date.
13 And, again, as I stated earlier, I don't know if you -- did
14 you want me to cover this, too, Tom, as far as the
15 comparison of the numbers?

16 MR. MITTELBRUN: Yes, please.

17 MS. ROGERS: Okay.

18 MR. MITTELBRUN: That was important.

19 MS. ROGERS: So -- so when we ran the numbers in
20 2017, it showed a significant increase in beds compared to
21 what was in effect at that time. A lot of that had to do
22 with the one prior. There were questions because the
23 numbers were so low, so we've done some cleanup. We
24 found -- we did some digging, founded that -- found out that
25 there was a lot of reporting issues on the numbers. So the

1 last two runs now we are working with -- on my term -- good
2 data from what we had over years past. Okay. So as a
3 result of that, though, it is showing an increase in bed
4 need numbers.

5 So when you're looking at the numbers today and
6 comparing it to what's in place, keep in mind you did not
7 set an effective date on the last run, so it is looking like
8 it's a large increase. Had you set the effective date two
9 years ago, it would have been a large increase at that time
10 again because of all the -- you know, the cleanup of the
11 reporting, et cetera. But comparing that to today's run,
12 you would be see -- you actually see a decrease of 400 plus
13 beds. So it depends on how you want to look at it. And I'm
14 in agreement, because of the numbers that are in effect
15 right now which were last run in 2015, you're going to see
16 that discrepancy or change. I hope that helped.

17 MR. MITTELBRUN: Now, go on. That's a good job,
18 but that's why I wanted him to hear that.

19 MR. HENRY BOUTROS: May I -- may I respond? Thank
20 you, sir. So in 2015 we believe that the report, as you
21 said, Ms. Rogers, was bed need was far too low and HCAM
22 brought that information forward recognizing as you said and
23 identified that not all of the providers are actually
24 providing data as an input for the basic methodology that
25 Paul has put together. And then in 2017 and 2019, the

1 report projected that the numbers were too high. So while I
2 believe there has been some sort of cleanup that's been done
3 by having providers report, we still don't know and we're
4 still not assured ourselves that providers are reporting the
5 exact data that is needed for the methodology. In addition,
6 what we've noticed since 2015, occupancy rates in the state
7 of Michigan have actually been on a decline and so it seems
8 alarming that by 2017 and 2019 the bed numbers have gone up.
9 Irrespective of where you have your cutoff, we know from
10 2015 to 2019 occupancy rates have declined throughout the
11 state. And so it just does -- and so -- and part of that
12 may due to having outside supports and services that
13 normally would have been fulfilled by the long-ter- -- by
14 skilled nursing are now being fulfilled through programs
15 like PACE, the waiver programs, other type of home health
16 programs where individuals who are actively moving
17 individuals who no longer meet the requirements for
18 long-term care for skilled nursing are now being moved back
19 into their home. And that's an active -- a active program
20 that all the providers here in the state of Michigan are
21 participating in to put individuals in the right place.

22 So, you know, we don't know if the formula that we
23 are using today actually takes into account how supports and
24 services are actually being utilized. So the real data of
25 from a provider level have seen our rates drop. The

1 occupancy rates drop. Seems inconsistent with the notion
2 that we have more beds that are available. Especially like
3 in Oakland County or some of the other very specific
4 counties that we've identified in our report that we
5 submitted to the Commission here earlier, it was suggesting
6 that Oakland County is going to need another 1100 beds.
7 Well, Oakland County's occupancy rates have dropped below 80
8 percent. And as all of you are well aware, that the 85
9 percent occupancy rule is this structure for providers where
10 you start being penalized anything less than 85 percent
11 occupancy. So adding more beds to the system, it's not
12 going to meet any more needs, it's just going to add more
13 costs to the state. As you projected, it's about a \$45
14 million increase -- potentially an increase of \$45 million
15 year over year.

16 So all we're asking is can we step it back and
17 take a look at what are the new inputs? Is it comprehensive
18 enough? Should we be looking at data of individuals being
19 now actively being placed outside of the system? And can we
20 be really assured that the information that providers are
21 providing today as part of an accepted formula, is that
22 accurate information? Just because we have greater
23 participation of data being put in, is it accurate
24 information that's being put in?

25 MR. FALAHEE: This is Falahee. One would hope

1 that when that data is submitted it is accurate. And I
2 also -- you said the numbers were too high. Well, the
3 numbers are the numbers based on the data that's submitted.
4 Maybe individual people or individual entities think the
5 numbers are too high, but I think when Professor Delamater
6 runs the numbers, he bases it on the data that's submitted
7 to him.

8 MR. HENRY BOUTROS: Correct. And so we're --
9 we're -- yes, sir.

10 MR. FALAHEE: And -- and the point -- and the
11 point is here you are asking again give us another chance to
12 put a SAC together. We tried. It didn't happen.

13 MR. HENRY BOUTROS: I can commit that this will
14 happen rather quickly --

15 MR. MITTELBRUN: Mittelbrun -- oh.

16 MR. HENRY BOUTROS: -- absolutely within a short
17 period of time. So, but, I mean, have we taken into
18 consideration the decreased occupancy? That's also a hard
19 fact. That's easy numbers that regardless of whether we
20 argue it or not, it's a fact that occupancy levels have
21 dropped significantly throughout the state.

22 MR. MITTELBRUN: Okay. Mittelbrun. Henry, just
23 as a followup, I think that might be a little -- well, I
24 don't know if I'm confused or not. We're talking about the
25 data that's submitted?

1 MR. HENRY BOUTROS: Yes; yes.

2 MR. MITTELBRUN: Isn't it the members of your
3 association that are submitting the data?

4 MR. HENRY BOUTROS: That is correct.

5 MR. MITTELBRUN: And I'm -- and I'm assuming
6 you're helping them to make sure it's -- it's correct and
7 accurate?

8 MR. HENRY BOUTROS: Well, to the extent that they
9 reach out and to the extent that they listen to the advice
10 that we've provided that is correct and, as we found out in
11 2015, that was not happening. And so we, too, are saying
12 let's take a look at this. Let's step back. Is this really
13 the right kind of data that should be collected?

14 MR. MITTELBRUN: Well, you've got to correct the
15 rep, Henry, that's all I can tell you because I --

16 MR. HENRY BOUTROS: Point taken. Please give us
17 the chance to put this SAC together. I mean, this can be
18 taken care of extremely fast.

19 MR. MITTELBRUN: Thank you.

20 MR. HENRY BOUTROS: Thank you, sir.

21 MR. FALAHEE: Any other questions? I have one
22 more comment card. Thank you. Last card, Pat Anderson --
23 oh, Pat, you moved. Thank you. Okay.

24 PAT ANDERSON

25 MS. PAT ANDERSON: I'm Pat Anderson with the

1 Health Care Association of Michigan and I did apply for the
2 SAC. I understand that you're looking for payers. In the
3 nursing facility arena, 63 to 65 percent of the payers --

4 MS. NAGEL: Purchaser.

5 MS. PAT ANDERSON: Purchasers. Okay. Purchasers?
6 How do you define a purchaser?

7 MS. NAGEL: Typically it's been an employer,
8 someone who purchases --

9 MS. PAT ANDERSON: An employer base? Okay. Most
10 of the nursing facility services are paid by Medicaid. They
11 would be the purchaser. The other big chunk is Medicare and
12 that represents probably 80 percent of our business. I
13 guess one of those would have to be at the table? I don't
14 know. Medicaid doesn't usually participate.

15 MS. ROGERS: This is Brenda. Typically for
16 purchasers, it's a purchaser of health care services.
17 That's if you look at the statute. So typically what we've
18 had in the past is your union -- your union organizations
19 have been the biggest, but a purchaser of health care
20 services. I mean, that's repre- -- that type of
21 representation. And not only did we not have purchaser
22 organizations, we were also short on the expert side of
23 nominations as well.

24 MS. PAT ANDERSON: We have access to many experts.
25 Purchasers is a little more difficult. A lot of health

1 benefits don't include long-term care. That's not a benefit
2 there, so that's not -- they're not a purchaser of it so
3 that is a little more difficult. But Henry has made the
4 commitment we would be willing to help with that.

5 The only other comment is I wanted to support what
6 Henry said about the bed need and the methodology. And,
7 yes, we've worked with the CON staff over the last probably
8 five years to correct the filing report to get that
9 information more correct and it has done a better job. Some
10 of the terminology about five years ago was more on what a
11 hospital would be used to as versus a nursing facility. So
12 miss -- data was missed. It is much better data today. It
13 can always get better. But the big point is our occupancies
14 are still going down. Like Henry pointed out there are
15 alternatives to going to the nursing facility and somehow
16 they need to be measured in the methodology. The numbers
17 will come out and it'll look like that the population is
18 getting older, it grows and grows, but there's alternatives
19 and I think that's what's being missed in the methodology.
20 Thank you.

21 MR. FALAHEE: Any questions from the Commission
22 members? Okay. I don't have any other comment cards on
23 this topic. So let me see if I can figure out where we're
24 at. In front of us now is whether we as the Commission want
25 to set the effective date for the new bed numbers. Whatever

1 action we take on that, then we need to go back to the prior
2 agenda item where we -- agenda item nine to figure out what
3 if any Commission action we want to take on that. Am I
4 stating that correctly, people to my right?

5 MR. HAMMAKER: That's correct.

6 MR. FALAHEE: Okay. So on the agenda item ten,
7 setting the effective date. There is a recommendation from
8 the Department to set the effective date as of November 1 of
9 this year, 2019. And what, Brenda, what other -- or anybody
10 else -- what other options are there? We could just not set
11 an effective date and just keep it as is? What are our
12 options there?

13 MS. ROGERS: Yeah, this is Brenda. As I stated
14 previously, or you can do like you did two years ago, you
15 can postpone setting indefinitely the effective date of the
16 number so then the bed needs remains the same so there would
17 be no change in the bed need numbers.

18 MR. FALAHEE: So then if we took that action, the
19 bed need is based on 2015 data?

20 MS. ROGERS: And actually when it was run in 2015,
21 I think it was based on -- I don't have that information in
22 front of me -- I want to say probably 2013 or '14 because
23 it's always like a year off, behind.

24 MR. FALAHEE: Okay. All right.

25 MR. MITTELBRUN: Mittelbrun, a question. So based

1 on your comments, Brenda, and actually the comments of the
2 test- -- both who provided testimony, that the data is
3 better than it was in 2014 or '13, whenever it was run
4 before. So it makes sense to me that this is more accurate
5 than it was in the past. So I don't know -- I guess my --
6 my thought process is why would we keep pushing it off when
7 we know we're working off of inferior data or not, or less
8 accurate data than we have today?

9 MS. ROGERS: This is Brenda. That is correct. I
10 think we at the Department -- and Beth or Tulika can correct
11 me if I'm wrong -- that we have done due diligent and the
12 data that we have today as far as what the facilities are
13 reporting is much significantly better data than what we had
14 in the past. And I will just say that even if you decide to
15 set an effective date for this current run, that does not
16 preclude you as the Commission to still form a work group or
17 something to still take a look at the methodology. So it
18 does not preclude you from doing that. So I just want to
19 make sure that you're aware of that as well.

20 MR. FALAHEE: This is Falahee. Thank you, Brenda,
21 for that explanation. Questions about setting effective
22 date? If not, I think we need to proceed to see if we can
23 have a motion on that issue one way or the other. Any
24 questions? Commissioner Dood?

25 MR. DOOD: Commissioner Dood. Yeah, kind of a

1 question, kind of a comment. But we've got the data and
2 then we have a methodology and the two together presented
3 this result that we're talking about setting effective date.
4 In my mind the, from what I've heard from the testimony,
5 what I know of the industry, it creates kind of an illogical
6 result. You have very low occupancy and we'd be increasing
7 the supply rather dramatically. And the data is good,
8 everybody's saying that, so it seems like it's the
9 methodology is the issue. Jumping ahead on the agenda item,
10 you know, that's the problem. We didn't get anybody in time
11 to opine on the methodology to look at that to figure this
12 out. But setting an effective date, because that didn't
13 happen, to create an illogical result is -- doesn't make any
14 sense to me.

15 MR. FALAHEE: This is Falahee. In some people's
16 minds it may be illogic, in some they would say the data is
17 the data and derived, the numbers are driven by it and the
18 data is what it is and it was the data that was submitted by
19 the nursing home community.

20 MR. DOOD: But it's the data times the
21 methodology -- right? -- that -- it's the two together that
22 produces the results, not just the data. It's the
23 methodology and the methodology we all agreed in March
24 needed to be looked at and it -- it -- it hasn't been. I
25 understand the frustration with that.

1 MR. FALAHEE: Other questions or comments? If
2 not, I think we need to proceed to a motion if possible.

3 MS. BROOKS-WILLIAMS: Commissioner
4 Brooks-Williams. So when we -- I just want to make sure
5 what's on the table -- right? -- because we had two
6 considerations that we kind of said we were going to wait
7 and combine them and so as we look to take a motion, it's on
8 what?

9 MR. FALAHEE: Setting the effective date for
10 these -- the nursing home bed methodol- -- the numbers.

11 MS. BROOKS-WILLIAMS: So setting a -- setting a --
12 a -- a date for the numbers. What about the methodology?
13 We're just saying because we couldn't seat the SAC we're not
14 dealing with that one now? Because we --

15 MR. FALAHEE: Not --

16 MS. BROOKS-WILLIAMS: -- we set it aside to
17 address them together, so I'm just trying to make sure I
18 understand what we're -- do we have two items we need to act
19 on or one?

20 MR. FALAHEE: I would say the answer is two.
21 Okay. Because we need to set the effective date as Brenda
22 explained a few minutes ago.

23 MS. BROOKS-WILLIAMS: Yes; uh-huh.

24 MR. FALAHEE: Then we need to go back to the prior
25 agenda item --

1 MS. BROOKS-WILLIAMS: We go back. Okay.

2 MR. FALAHEE: -- and say, okay, given what we did
3 or did not do on the effective date, do we as a Commission
4 want to try again to do a SAC, do we want to do a work
5 group, do we want to do nothing?

6 MS. BROOKS-WILLIAMS: Okay.

7 MR. FALAHEE: So I look at it they're connected,
8 but they're two separate issues.

9 MS. BROOKS-WILLIAMS: Okay. Thank you.

10 MR. FALAHEE: Fair enough? Okay. So I think
11 what's before us now is setting the effective date of the
12 new bed need numbers.

13 MR. DOOD: Commissioner Dood. I make a motion
14 that we postpone indefinitely the setting an effective date
15 for the new bed -- the need methodology.

16 MR. FALAHEE: Is there support for that motion?
17 Hearing none, that motion fails.

18 MR. MITTELBRUN: Mittelbrun. Taking into account
19 Commissioner Dood's comments, which I completely understand,
20 by the way, but on the other -- on the other -- other side I
21 don't think it's right to continue to kick the can down the
22 road. So I'm happy to make both motions, but the first one,
23 we've got to take care of that first. Make the motion to
24 set the effective date as November 1st, 2019. I'll stop
25 there, but there will be a part two. I don't know if it'll

1 satisfy --

2 MR. FALAHEE: Is there, is there support for that
3 motion?

4 MS. LALONDE: Lalonde. Support.

5 MR. FALAHEE: Okay. Thank you. So there's a
6 motion on the floor and supported to set the effective date
7 for the bed need numbers as of November 1 of 2019. Any
8 discussion? Questions? All in favor of that motion say
9 "aye."

10 ALL: Aye.

11 MR. FALAHEE: Opposed?

12 MR. DOOD: Aye.

13 MR. FALAHEE: One opposed, all others in favor,
14 the motion carries.

15 (Whereupon motion passes at 11:31 a.m.)

16 MR. FALAHEE: Now we will go back to the prior
17 agenda item. Do we need a motion to go back to the prior
18 agenda item?

19 MR. HAMMAKER: Why not?

20 MR. FALAHEE: Okay. Always follow what the
21 attorney general tells you to do. Okay. We need a motion
22 to go back to the one we motioned to go ahead from.

23 MS. BROOKS-WILLIAMS: Brooks-Williams. I move
24 that we go back to the agenda item that we moved --

25 MR. FALAHEE: Nine.

1 MS. BROOKS-WILLIAMS: -- yeah, agenda item nine.

2 MR. FALAHEE: Support?

3 MR. HUGHES: Support.

4 MR. FALAHEE: All in favor?

5 ALL: Aye.

6 MR. FALAHEE: Opposed? Okay.

7 (Whereupon motion passes at 11:32 a.m.)

8 MS. ROGERS: Excuse me. This is Brenda. Who was
9 the support?

10 MS. NAGEL: Hughes.

11 MR. FALAHEE: Oh, Mr. Hughes.

12 MR. HUGHES: Commissioner Hughes. Sorry. Sorry
13 about that.

14 MR. FALAHEE: Okay. So now we're back at nine.
15 Any discussion? Otherwise, I think Commissioner Mittelbrun
16 has something to say.

17 MR. MITTELBRUN: Well, I will do -- I -- I will do
18 part two of my thoughts. Is that I make a motion that we
19 attempt once again for the last time hopefully to seat
20 another SAC in this matter to address all of Commissioner
21 Dood's comments and the comments of our presenters today.

22 DR. GARDNER: Support.

23 MR. HUGHES: Second. But jeez, oh Pete's.

24 MR. FALAHEE: Well, hang on. One second.

25 MR. HUGHES: All right.

1 MR. FALAHEE: So we have a motion -- we have a
2 motion and support by Commissioner Gardner.

3 DR. GARDNER: Gardner. Support.

4 MR. FALAHEE: And then I think Commissioner Hughes
5 has something to say.

6 MR. HUGHES: Strike me from the record.

7 MR. FALAHEE: Anything?

8 MR. HUGHES: It's already been said. Let's just
9 get it done.

10 MR. FALAHEE: And let me suggest that a friendly
11 amendment to your motions would be that if the Commission
12 decides to approve that motion, that the chair and the vice
13 chair are authorized to develop the charge for that SAC and
14 to do whatever we can do to encourage, strongly encourage,
15 coerce membership on the SAC. "Coerce" was said in jest.
16 All right? So I would assume you meant -- you included that
17 in your motion?

18 MR. MITTELBRUN: I amend my motion to include all
19 of the above.

20 DR. GARDNER: And I support.

21 MR. FALAHEE: Thank you. All right.

22 MR. DOOD: Quick question. So you're not bound by
23 the earlier charge that we work through in -- in March then?
24 With your friendly amendment you're -- you're starting from
25 scratch on that?

1 MS. ROGERS: Yeah, this is Brenda. That's how I
2 read Chip's amendment.

3 MR. DOOD: Would you anticipate the bed need
4 methodology still being on the charge or not?

5 MR. FALAHEE: That would be my anticipated charge
6 number one, two, three, and four, yes. And then whatever
7 other charges are appropriate given anything that's
8 transpired between March of this year and now, when we set
9 the first charge on March 21 of this year. Other questions?
10 Okay. We have a motion on the floor. All in favor of the
11 motion say "aye."

12 ALL: Aye.

13 MR. FALAHEE: All opposed? The motion carries.

14 (Whereupon motion passes at 11:34 a.m.)

15 MR. FALAHEE: Let me say in the strongest possible
16 terms. We've been through this before, we have not been
17 able to form a SAC. Let's put a SAC together. Because I,
18 too, do not like kicking the can down the road. Thank you.

19 MS. LALONDE: Can I propose a five-minute break?

20 MR. FALAHEE: That -- you've read my mind. Okay.
21 We'll take a five-, ten-minute break and we'll come back for
22 the last few minutes of our meeting. We're on, next agenda
23 item is CT.

24 (Off the record)

25 MR. FALAHEE: This is Commissioner Falahee. We're

1 going to go ahead and get started again. I notice far fewer
2 people in the room, so that's okay. We've had a discussion
3 in -- in the break with some real fine tuning we may need to
4 go through to make it easier to put this SAC together and
5 I'm going to let Mr. Hammaker explain the details and then
6 get ready, Commission members, I think we may need to do
7 another motion to fine tune what we just did. Carl?

8 MR. HAMMAKER: Okay. So what we were just
9 discussing, the administrative process of forming the SAC
10 and typically when someone applies to be a member of the
11 SAC, their application stays in the pipeline. So when the
12 Commission moved to form a SAC back in the March meeting,
13 there are applications that are already received. If the
14 Commission -- when the Commission voted to form a SAC now,
15 that would restart the process and the Department would lose
16 those applications that were already in the pipeline. So
17 rather than doing that, I would recommend to the Commission
18 that someone bring a motion to reconsider the previous vote
19 to form a new SAC and, instead, direct the Department to
20 continue to work off the charge that was previously
21 developed as a result of the vote from the March Commission
22 meeting, and then we'll go -- the Department will proceed to
23 try to put the SAC together, you know, for a -- put a fourth
24 callout on the same previous charge.

25 MR. FALAHEE: Which -- this is Falahee -- would

1 then keep those that are in the pipeline still in the
2 pipeline; right?

3 MR. HAMMAKER: Correct.

4 MS. BHATTACHARYA: Yes.

5 MR. FALAHEE: Okay.

6 MR. DOOD: Make a motion that we reconsider our
7 earlier vote. Do a -- do we need to vote on that first or
8 can we --

9 MR. HAMMAKER: Yeah.

10 MR. FALAHEE: Yeah; right. Yeah, we do -- right;
11 right.

12 MR. HAMMAKER: We need a second, too.

13 MR. MITTELBRUN: Second. Mittelbrun.

14 MR. FALAHEE: So we have a motion on the floor.

15 At this point all the motion is, is just to reconsider the
16 prior vote. Any questions? All in favor say "aye."

17 ALL: Aye.

18 MR. FALAHEE: All opposed? That motion carries.

19 (Whereupon motion passes at 11:46 a.m.)

20 MR. DOOD: I make a motion that we continue the
21 process of filling the SAC with the charge from the March
22 meeting.

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

24 MR. FALAHEE: Motion made and seconded. And by
25 the "March meeting," you mean the March 2019 meeting?

1 MR. DOOD: Correct.

2 MR. FALAHEE: Any questions?

3 DR. MCKENZIE: Yeah, I have a question. Would --
4 would those that have applications in the system be notified
5 that there's going to be a new call for a SAC so that
6 they're aware and ready if they applied months and months
7 and months ago? Or if they're already part of the community
8 and might be able to solicit additional support -- because I
9 did hear that -- you know, I heard from the testimony that
10 there was a lack of awareness and I'm not sure if you're not
11 part of the Listserv maybe they're not receiving that --
12 that information that there's yet another round. So is that
13 an option or what's the expectation around that?

14 MS. NAGEL: So the people that have already
15 applied wouldn't have to reapply again. Is that what -- did
16 I miss --

17 DR. MCKENZIE: Yeah. Would they be notified,
18 though, that we're now going to seek -- we need additional
19 applications, we still have your application, we're going to
20 move it forward, you know, but we'd still need additional
21 participants?

22 MS. NAGEL: We certainly can do that. Brenda,
23 reminds me, yes, that is something that we do.

24 DR. MCKENZIE: Okay. Thank you.

25 MR. FALAHEE: Other questions? So we have a

1 motion on the floor. All in favor of the motion say "aye."

2 ALL: Aye.

3 MR. FALAHEE: Opposed? That motion carries.

4 (Whereupon motion passes at 11:48 a.m.)

5 MR. FALAHEE: Okay. Next agenda item is a written
6 report, it is in our packet, on the CT scanner services, the
7 work group and there's a written report there. There's
8 really no formal action required, just to notice that the --
9 be aware of the written report. Brenda, anything else on
10 that?

11 MS. ROGERS: This is Brenda. I don't believe so.
12 Although I believe the chair had a comment in the report
13 about seeking the Commission's opinion, but I don't know
14 that that was something he necessarily was asking for at
15 this meeting. But I just -- I do draw you to that attention
16 as to his comment, and I'm sorry I don't have it right here
17 in front of me. And then just to let the Commission know,
18 they've actually only held one meeting at this point, so
19 they've really just gotten into the discussions. And I --
20 and the comment that's in there about the question to the
21 Commission, I do know at the end of that very first meeting
22 they were throwing out a lot of different things and so I
23 think, I believe -- and Beth can correct me if I'm -- might
24 be not remembering this correctly -- but I think that's
25 where that came from.

1 MR. FALAHEE: This is Falahee. I guess we just
2 wait to see as they have additional meetings and maybe fine
3 tune what they're working on and if they want to ask
4 question of the Commission even after they fine tune it,
5 that's fine. So Brenda, are we all set on that then?

6 MS. ROGERS: Yes. Thank you.

7 MR. FALAHEE: Okay. Let's move on then to agenda
8 item 12, the legislative update. That has my name, Falahee,
9 next to it. As you can tell from listening to Senator
10 VanderWall today, he and I have met four times since
11 February and about IECT, CON in general, and most recently
12 potential CON reforms that he has talked with me about and
13 others. No legislation has yet been introduced on those
14 reforms and I don't know whether any or all of those will be
15 introduced as legislation. So I think it's premature to
16 talk about what might happen. But we've had robust
17 discussions, he and I. And going forward over the next two
18 weeks I'll be meeting with I think 15 legislators in my role
19 as chair of the CON Commission and another hat I wear is on
20 the board of the Michigan Hospital Association, to talk with
21 them about CON. Because with the term limits, many of our
22 legislators, through no fault of their own, we talk
23 Certificate of Need to them and they don't know exactly what
24 that is, how it works, and what our job is and what their
25 job is. And so it's -- and I've done this before, prior

1 chairmen have done this, Ed Goldman did it, Mark Keshishian
2 and I did it, to go educate the members of the legislature.
3 So I'll be meeting with all the members of the JLC and other
4 members of the legislature and leadership to -- just to tell
5 them, you know, let's talk about CON, what it is, what it
6 does and answer any questions they may have. And then if
7 they want to talk about potential reforms, happy to do that
8 and whatever happens, I'll report back at our next meeting
9 in -- in December. And if there's anything that comes up
10 urgently, I always can get out by e-mail information or
11 phone call. So that's where we're at on that. Any
12 questions? Okay.

13 Administrative update, a couple reports here.

14 Beth, for the planning and access to care section update?

15 MS. NAGEL: Yes. I wanted to update you that the
16 open heart surgery standards has in it the need to -- I
17 think it's every -- I'm looking at Brenda -- five years?

18 MS. ROGERS: Open heart is three.

19 MS. NAGEL: Open -- every three years we update
20 utilization weights for adult and pediatric numbers. Those
21 are not in the statute that we need the Commission to set an
22 effective date. The Department sets the effective date and
23 we are -- I'm just notifying you that those will be updated
24 on our web site. I believe the effective date is October 1.

25 MS. ROGERS: Correct.

1 MS. NAGEL: I also just wanted to note -- to note
2 that our notice of public comment period will be going out
3 soon for the standards to be updated in 2020 to the
4 Commission and that will be held from October 4th to October
5 18th. It's how we generate all of the information that you
6 look at at your special Commission meeting in January.
7 Those standards that we're specifically asking for feedback
8 on are: cardiac catheterization, hospital beds, MRT, open
9 heart surgery, PET scanners, and surgical services. That's
10 it.

11 MR. FALAHEE: Any questions of Beth? We'll move
12 on then. Tulika?

13 MS. BHATTACHARYA: Hi. There are two reports in
14 your packet: the performance measures for the program and
15 the compliance report. We are doing the MRI and PET
16 services compliance. We have made progress. We have sent
17 out letters of appropriate actions or a proposal for
18 settlement agreement to the providers based on our
19 investigation and our conference calls with the providers.
20 There are just a few providers that we are still working on
21 to figure out appropriate actions.

22 The third one is an application process update.
23 So under the statute, the Department frequently monitors the
24 processes and develops forms in order to promote
25 administrative efficiency of the application review process.

1 So the Department has developed this new form
2 called Certification of Planning Area Bed Need, a form 200C.
3 So all applications for new beds for which the Department
4 maintains the bed inventory, so hospital beds, nursing home
5 beds, psych beds, NICU beds, for those applications the
6 applicant will need to submit this form. So when providers
7 file their letters of intent, we will assign this form to
8 their application so that they know they're required to fill
9 out this form. So basically what this form says is based on
10 the Department inventory, if the planning area shows no bed
11 need or a negative bed need which means there is a surplus
12 of beds, the Department is not going to accept applications
13 for new beds in those planning areas. Any questions?

14 MS. GUIDO-ALLEN: Can you repeat that one more
15 time?

16 MS. BHATTACHARYA: So this form will be applicable
17 to proposed projects that are requesting new beds from the
18 Department inventory. We maintain the Department inventory
19 for hospital beds, nursing home beds, psych beds, and NICU
20 beds, and we publish a new report every two months, January,
21 March, May, the odd months, July. So what we are saying
22 is -- and the applications for new beds can only be
23 submitted three times a year: February, June, and October
24 under the statute and the rules. So what this form is
25 saying, if a planning area does not show that there are

1 available new beds, then an applicant cannot submit an
2 application for those beds in that planning area.

3 MS. GUIDO-ALLEN: Got it.

4 MR. FALAHEE: Commissioner Dood?

5 MR. DOOD: Commissioner -- so if there's another
6 basis for needing a Certificate of Need, let's say replacing
7 a facility which would be allowed even if there was excess
8 inventory, this form would prohibit that now and it didn't
9 in the past? I'm confused on the language.

10 MS. BHATTACHARYA: No. So when you are replacing
11 beds or acquiring existing facilities or relocating beds
12 from one existing to another existing facility, you are not
13 requesting new beds from the Department inventory.

14 MR. DOOD: So this is just for new?

15 MS. BHATTACHARYA: This is just for new beds.

16 MR. DOOD: Thank you. So this is a process you do
17 internally now. You're asking people, hey, make sure you
18 looked at it, fill out the form beforehand?

19 MS. BHATTACHARYA: We are making it public. It
20 was kind of informal because if there are no new beds, why
21 would you apply for it? But now we are making sure that the
22 applicant certifies they have reviewed the bed inventories
23 and they have made sure that there are available beds before
24 they apply for those.

25 MS. NAGEL: If I could just add? Even though it

1 does seem strange that someone would apply for new beds when
2 there are no beds, it does happen and so we are trying to
3 fix the problem.

4 MR. FALAHEE: Other questions? Okay. We'll turn
5 next to the legal activity report.

6 MR. HAMMAKER: So there's not much of an update
7 from our last meeting. I put a -- there's a written report
8 in the packet. There is still one administrative case
9 ongoing. That's through discovery and it's been adjourned
10 until next month.

11 MR. FALAHEE: Any questions? All right. For
12 those in the audience, future meeting dates for next year if
13 you don't have them, this year our last meeting will be
14 December 5. Then for next year January 30, that'll be our
15 usual special Commission meeting, then March 19, June 18,
16 September 17, and December 10th. So those are the meetings
17 for next year. I'll do it quickly again: January 30, March
18 19, June 18, September 17, and December 10th. Okay.

19 The next agenda item is public comment. I do not
20 have any cards in front of me and I don't see anyone
21 approaching the podium, so I'm going to assume no public
22 comment. Brenda, turn it over to you for Commission work
23 plan review.

24 MS. ROGERS: This is Brenda. You do have the
25 draft work plan in your packet. I'm not going to go -- read

1 through everything, but if you have a question on it, please
2 let me know. We will just need to have a motion to accept
3 the work plan as presented. And the only modification made
4 today is that we are going to continue to work on the
5 nursing home SAC, so we will update it accordingly. Thank
6 you.

7 MR. MITTELBRUN: Motion to accept work plan as
8 presented.

9 DR. MCKENZIE: Second.

10 MR. FALAHEE: Second by McKenzie. Discussion?
11 All in favor say "aye."

12 ALL: Aye.

13 MR. FALAHEE: Opposed? All right.

14 (Whereupon motion passes at 12:01 p.m.)

15 MR. FALAHEE: That brings us to adjournment. I
16 would entertain a motion to adjourn.

17 MS. BROOKS-WILLIAMS: Brooks-Williams. I move
18 that we adjourn the meeting.

19 MR. FALAHEE: Okay. Support?

20 MR. HUGHES: Second.

21 MR. FALAHEE: All in favor?

22 ALL: Aye.

23 (Whereupon motion passes at 12:01 p.m.)

24 MR. FALAHEE: Thank you, everyone. Thanks for all
25 your diligence on getting through the agenda and our packet.

1 Thank you very much.

2 (Proceedings concluded at 12:01 p.m.)

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