1	:	STATE OF MICHIGAN
2	MICHIGAN DEPARTI	MENT OF HEALTH AND HUMAN SERVICES
3	CERTIF	ICATE OF NEED COMMISSION
4		
		COMMISSION MEETING
5		
-	BEFORE MARC D	. KESHISHIAN, M.D. CHAIRPERSON
6		
U	333 South Grand To	ownsend Street, Lansing, Michigan
7		Swiibena bereee, Lanbring, niemigan
,	Wednesday	, June 15, 2016, 9:30 a.m.
8	weariesday	, buile 13, 2010, 9.30 a.m.
9		
9	COMMITTEE MEMBERS:	SURESH MUKHERJI, M.D. VICE CHAIRPERSON
10	COMMITTEE MEMBERS:	DENISE BROOKS-WILLIAMS
10		
11		KATHLEEN COWLING, D.O. JAMES FALAHEE
1 I		
1.0		DEBRA GUIDO-ALLEN, R.N.
12		ROBERT HUGHES
		JESSICA A. KOCHIN
13		THOMAS MITTELBRUN III
		LUIS A. TOMATIS, M.D.
14		
15	MICHIGAN DEPARTMENT OF	
	HEALTH AND HUMAN	
16	SERVICES STAFF:	TULIKA BHATTACHARYA
		ELIZABETH HERTEL
17		BETH NAGEL
		TANIA RODRIGUEZ
18		BRENDA ROGERS
19		
20		
	RECORDED BY:	Marcy A. Klingshirn, CER 6924
21		Certified Electronic Recorder
		Network Reporting Corporation
22		Firm Registration Number 8151
		1-800-632-2720
23		
24		
25		

1 2 3		TABLE OF CONTENTS	PAGE
4	I.	Call to Order & Introductions	5
5	II.	Review of Agenda	5
6	III.	Declaration of Conflicts of Interests	5
7	IV.	Review of Minutes of March 16, 2016	5
8	V.	Magnetic Resonance Imaging (MRI) Services - Common Ownership - April 212, 2016 Public	
9		Hearing Summary & Report	6
10		A. Public Comment	
11		B. Commission Discussion	
12		C. Commission Final Action	7
12	VI.	Psychiatric Beds and Services - April 21, 2016	
13		Public Hearing Summary & Report	7
14		A. Public Comment	
15		Statement by Saju George	9
16		Statement by Bob Nykamp	11
17		Statement by David Walker	18
18		B. Commission Discussion	19
19		C. Commission Final Action	29
20			
21			
22			
23			
24			
25			

1	VII.	Computed Tomography (CT) Scanner Services - Workgroup Final Report
2		Workgroup Final Report
		A. Public Comment
3		
4		Statement by Dr. Mark Johnston 46, 55
4		Statement by Brent Garvin 54
5		
		Statement by Dr. Michael Kasotakis 56
6 7		Statement by Dr. Robert Langlais 60
7 8		
8 9		
10		C. Commission Final Action
11	VIII.	Neonatal Intensive Care Services/Beds & Special
1.0		Newborn Nursing Services - Draft Language 80
12		
13		A. Public Comment
Τ2		B. Commission Discussion
14		
		C. Commission Final Action 82
15		
	IX.	Bone Marrow Transplantation (BMT) Services Standards
16		Advisory Committee (SAC) - Final Report 83
17		A. Public Comment
18		Statement by Brett Jackson 98
19		Statement by Dr. Edward Peres 101, 122
20		Statement by Dr. Joseph Uberti.103, 120, 132
21		Statement by David Walker 108, 123
22		Statement by Dr. Gregory Yanik 109, 135
23		Statement by Dr. Adil Akhtar 123, 135
24		Statement by Patrick O'Donovan 136
25		

1		B. Commission Discussion 138
2		C. Commission Final Action 148
3	Χ.	Legislative Report
4	XI.	Administrative Update
5		A. Planning & Access to Care
		Section Update
6		
		B. CON Evaluation Section Update 149
7		
		1. Compliance Report (Written Report
8		& Compliance Update)
		2. Quarterly Performance Measures
9		(Written Report)
		3. Psychiatric Beds & Services
10		Compliance Project Overview
11	XII.	Legal Activity Report
12	XIII.	2016 Meeting Dates: September 21, 2016 &
		December 7, 2016
13		
	XIV.	Public Comment
14		
	XV.	Review of Commission Work Plan
15		
		A. Commission Discussion
16		
-		B. Commission Action
17		
	XVI.	Adjournment
18		
19		
20		
21		
22		
23		
24		
25		

1

2

19

Lansing, Michigan

Wednesday, June 15, 2016 - 9:40 a.m.

3 DR. KESHISHIAN: Good morning. I'd like to welcome everybody to the Certificate of Need meeting today. 4 First item is call to order, and I don't think there is any 5 new introductions. Second issue is declaration of conflicts 6 7 of interest. Does anybody have any conflicts of interest 8 they'd like to state at this time? At any time during the 9 meeting if you have a conflict of interest, you can state it at that time. Next item is Review of Minutes of March 16th, 10 200- -- Review of Agenda. I'm sorry. Is there any changes 11 to the agenda at this point? Okay. And okay. We need a 12 13 motion to approve the Review of the Agenda.

14MR. FALAHEE:Falahee approves; motion to approve.15DR. KESHISHIAN:Do I hear a second?16DR. COWLING:Second; Colleen.

17DR. KESHISHIAN: Thank you. Any discussion? All18in favor say aye.

(All in favor)

20 DR. KESHISHIAN: Opposed? Thank you. We talked 21 about conflicts of interest. Review of Minutes of March 22 16th, 2016, you have those available. Are there any -- is 23 there any discussion? If not, if somebody would like to 24 make a motion to approve the minutes?

25 MS. BROOKS-WILLIAMS: Move to approve; Commission

1

Brooks-Williams.

2 DR. KESHISHIAN: Sec- --3 DR. COWLING: Colleen; second. 4 DR. KESHISHIAN: Any discussion? Okay. All in 5 favor say aye. (All in favor) 6 7 DR. KESHISHIAN: Opposed? Okay. Next is MRI 8 Services - Common Ownership. I'm turning it over to Brenda 9 Rogers. Brenda? MS. ROGERS: Good morning. This is Brenda. 10 And just as a general reminder today, just please identify 11 yourself before you speak for recording purposes. All 12 13 right. On MRI Services - Common Ownership, as you'll 14 recall, at the March meeting you did take proposed action to add language. We held a public hearing on March -- excuse 15 16 me -- April 21st. We received no additional testimony in 17 regard to the language, so the language today is being 18 submitted to the Commission for final action with no 19 changes. And so if the commission takes final action today, then your motion would need to include moving it for the 45-20 day review to the Joint Legislative Committee and to the 21 22 governor. If there's any questions, I'll be happy to answer Thank you. 23 those.

24DR. KESHISHIAN: Commissioner Keshishian; I do not25have any cards for public comment. Are there any public

comments? Okay. Commission Discussion: Any discussion?
 Okay. Commission Final Action: Would somebody like to make
 a motion?

4 DR. TOMATIS: Commissioner Tomatis so would move. 5 DR. KESHISHIAN: Okay. And to send it to the 6 Joint Legislative Committee and to the governor.

MR. MITTELBRUN: Tom Mittelbrun; second.

8 DR. KESHISHIAN: Thank you. Any discussion? All
9 in favor say aye.

10

7

(All in favor)

DR. KESHISHIAN: Opposed? Okay. Thank you. Next item, Psychiatric Beds and Services, April 21st public hearing, summary and comments. I do have three public comments, and I frequently forget this until after the first speaker. But there is a three-minute time limit for public comments when you provide comments. Having said that, I'll turn it over to Brenda at this point.

18 MS. ROGERS: Again this is Brenda. And you took 19 proposed action at your March meeting. We held public hearing in April. We received one piece of testimony which 20 was included in your packet, and that was from Pine Rest. 21 22 The language today -- being presented today is being moved 23 forward with no changes other than we are recommending three amendments, and those three amendments are all identical in 24 25 nature in regard to the medical psychiatric, the geriatric

and the developmental disability. All right. And so those 1 2 amendments basically would allow somebody to start a 3 psychiatric service with special pool beds in the -- in an over populated area. And what we're thinking 4 5 is this would provide better access to these particular 6 groups. The language originally was written that you had to 7 currently have a psych program before you could start a 8 psych service with these special population beds. So the 9 more we thought about it, we really think it'd be better to just allow anybody to -- and we do this same type of thing 10 in nursing homes, special population beds, so it's the same 11 type of thing. So that would be the three amendments. 12 We 13 have talked to Joe, our AG's rep, and -- who are not here They do apologize. But if any legal questions come 14 today. 15 up today, what they've asked us -- the Commission to do, put 16 those questions in writing and then they will respond to those. Again they just didn't have anybody available today. 17

18

So having said that, these three amendments would be substantive in nature. So should the Commission choose to adopt those amendments, then the language would have to be scheduled for another public hearing, and then we would bring the language back to you in September for final action. If you choose to move the language without the amendments, then today you would be moving it forward for

the 45-day review period to the Joint Legislative Committee
 and the governor. And unless you have any questions? Thank
 you.

DR. KESHISHIAN: Thank you, Brenda. Three cards,
Saju George from Garden City Hospital.

MR. SAJU GEORGE: Good morning. My name is Saju 6 7 George, and I am the CEO for Garden City Hospital. We 8 really appreciate the effort put forth by the workgroup on 9 Psychiatric Bed Services and support the direction 10 Commission has taken to create a statewide pool for both geriatric psychiatric patients as well as medical 11 psychiatric patients. We also support the recommendations 12 13 of the Department to expand the pool to include new 14 applicant facilities as well.

As a community provider, Garden City Hospital sees 15 16 approximately six to eight patients per day in our ER that 17 requires inpatient psychiatric services. Many of the 18 psychiatric patients that we see in our ER are seniors. 19 Often we have difficulty placing these patients, and some of these patients stay in our ER for up to seven to ten days. 20 This situation is not ideal for the patient, their families 21 22 or the acute care providers. In many instances, patients are sent to a facility a long distance away putting further 23 24 burden on the patient and their loved ones.

25

Studies show majority of adults with mental

illness have at least one medical condition. Comorbidity is 1 2 associated with elevated symptom burden, functional impairment, decreased length and quality of life and 3 increased costs. The pathways causing comorbidity are 4 complex and bidirectional. Medical disorders may lead to 5 mental disorders, mental conditions may place a person at 6 7 risk for medical disorders, and medical and mental disorders 8 may share common risk factors.

9 Recognition of the needs of this patient 10 population is essential to our community and population 11 health management. Our community would greatly benefit from 12 the initiation of both medical and geriatric program. We 13 hope to provide geropsychiatric services at Garden City 14 Hospital to encompass a greater demographic than the 15 traditional programming.

16 According to the report prepared by Milliman, 17 Inc., for American Psychiatric Association, integrated 18 treatment models such as geropsychiatric programming 19 proposed at Garden City Hospital are a cost-effective approach to healthcare delivery for complex patients. After 20 tracking total healthcare costs for more than 21 22 four-year period, researchers determined that collaborative care costs were on average 70 million less than the costs 23 for providing care for using usual care. This represents 24 25 approximately a 10 percent Medicare cost savings in the

total healthcare cost. The report indicated that collaborative care had lowered the costs in every category that was observed. Ultimately patients in a collaborative care program was 87 percent more likely to have lower healthcare costs than those receiving the care.

The creation of a statewide pool for both 6 7 geriatric psychiatric patients and medical psychiatric 8 patients by the Commission as well as the inclusion of new 9 applicant facilities will benefit communities throughout 10 Michigan. Adopting the proposed rules will increase eligibility and decrease healthcare costs benefitting 11 patients, providers and other stakeholders. Thank you for 12 13 your time and consideration.

14DR. KESHISHIAN: Thank you. Are there any15questions? Thank you. Next Bob Nykamp from Pine Rest.

MR. BOB NYKAMP: Good morning. Thank you. My name is Bob Nykamp. I'm the chief operating officer at Pine Rest Christian Mental Health Services in Grand Rapids, Michigan. Pine Rest has over 300 beds under management throughout the state including Grand Rapids, St. Joseph, Battle Creek and Lansing and Muskegon.

I want -- I have submitted a written comment, and so I will not belabor the Committee with any more of that information. What I did want to express is that adding these special population beds may absolutely be great public

policy, but we at Pine Rest don't know. And I venture to 1 2 guess that the Department doesn't know. We have been developing this information in the workgroup based on 3 anecdotal information. There has not been statewide 4 5 research in terms of the type of disease that is plaguing 6 our state in terms of ER boarding for patients identified 7 with psychiatric issues. It is a real problem. It is a 8 prevalent problem in the state of Michigan.

9 I want to share with you recent research that Pine Rest, Priority Health and Helen DeVos Children's Hospital 10 performed on all Priority Health Medicaid and Priority 11 Health commercial payers that had boarding in Helen DeVos 12 13 Children's Hospital specifically to the children's 14 population. 87 percent of that population had explosive 15 personality or conduct disorder issues, not autism or 16 developmental disabilities issues. Pine Rest along with the 17 Department has begun to identify special need populations 18 for short-term residential care that we think is the primary 19 solution to the access problem it relates for these families and these kids who are suffering with these issues. So I 20 wanted to bring that to the Commission's attention as a 21 22 potential alternative to special population beds.

I also want to remind the Commission that today -- there are 80 adult beds and 80 child and adolescent beds available in the state to be opened today. Those beds

have not been opened. It is my assumption -- it is Pine 1 2 Rest's assumption, that those beds have not been opened because of the economic impact of treating this specialty 3 population. They are tough to treat. They require 4 intensive staffing, intensive care. And today the payers, 5 6 both Medicaid as well as the commercial payers, currently do 7 not offer some kind of intensive care rate. So again that 8 is not the Commission's purview, and I understand that. It 9 is the Department's purview. And would encourage the 10 Commission to consider asking the Department along with the Michigan Hospital Association and all the psych providers in 11 Michigan to engage in definitive research as to what are the 12 13 access issues that are causing our ER boarding issue today with psych patients. It is critical. That is apart from 14 the decision you make today regarding these special 15 16 population beds, but it is critically important that we 17 define this population and we develop the right services for 18 this population. Thank you.

19DR. KESHISHIAN: Thank you. Are there any20questions?

21 MR. FALAHEE: Bob, this is Commissioner Falahee. 22 So Pine Rest is in support of the proposed language; right? 23 MR. BOB NYKAMP: We are not opposed to the 24 proposed language.

25 MR. FALAHEE: All right.

MR. BOB NYKAMP: I can't tell you if we're in 1 2 support of it, because I don't know if it fixes the problem. 3 MR. FALAHEE: Okay. 4 MR. BOB NYKAMP: Is that a fair answer? 5 MR. FALAHEE: That's your answer. The special residential you're talking about, that would go beyond what 6 7 we're talking about here in the proposed language? 8 MR. BOB NYKAMP: It would. 9 MR. FALAHEE: Okay. And that's for these kids 10 that have explosive personalities or whatever? 11 MR. BOB NYKAMP: Exactly; yup. Short-term, acute psychiatric care minimally helps these kids with explosive 12 13 personality and conduct disorder issues. Research proves that short-term residential is a much more effective way to 14 impact in a lot of cases trauma care that is required for 15 16 these children. 17 MR. FALAHEE: So what you're recommending if I get 18 it right is, Commission, if you approve these standards, 19 that's great. But go the next step either with the Department or MHA or others to do some analytical data on 20 how many are in the EDs, how many get sent to psych units 21 and how do we invent psychiatrists? 22 23 MR. BOB NYKAMP: Absolutely. MR. FALAHEE: Okay. 24 25 DR. KESHISHIAN: Are there other questions?

1 Commissioner Brooks-Williams, go ahead.

2 MS. BROOKS-WILLIAMS: Commissioner Brooks-Williams. You indicate in your written testimony a 3 couple of suggestions around incentives for loan forgiveness 4 5 for psychiatrists. And I'm just curious, are you suggesting that the Commission would have impact on that or maybe it's 6 7 a follow-up to Jim's question, how do you --8 MR. BOB NYKAMP: It's public policy. I don't 9 think it's --10 MS. BROOKS-WILLIAMS: Okay. MR. BOB NYKAMP: -- again within the Commission's 11 purview. 12 13 MS. BROOKS-WILLIAMS: Okay. 14 MR. BOB NYKAMP: But I think that, in 15 collaboration with the Department, we have the opportunity 16 to impact psychiatric resources of the state. 17 MS. BROOKS-WILLIAMS: Okay. DR. KESHISHIAN: This is Commission Keshishian. 18 19 Just a broad comment. We have over the year that we've talked about this, we talked about registries. And in every 20 state that has a registry, in fact, it is legislated by the 21 22 Legislature. It isn't something that's done by the 23 Commission. Because even if we were to mandate a registry for new applicants at this point, all the old applicants we 24 25 couldn't do anything with. So it would have to go through

state Legislation. Having said that, I do think it's -- we 1 2 provide recommendations to the state Legislature. We can do it at any time during the year. We do it once a year just 3 to give them an overview. We could, if we decide, to either 4 5 write a statement at this point that would be approved at 6 the next Commission meeting requesting a registry and we 7 could expand it to requesting loan forgiveness for 8 psychiatrists. It would just bring the issue to the state 9 Legislature that this body believes in this. Or we could do 10 it in our annual report to the state Legislature, which I 11 think --

MS. ROGERS: This is Brenda. That will be
actually due in January 2017 so --

DR. KESHISHIAN: Right. So we could either wait 14 'til January 2017. I do believe talking to Commissioner 15 16 Cowling and -- you know, that we should be pushing for a 17 registry. I have not thought much about whether we should 18 be pushing for loan forgiveness of psychiatrists. That 19 would be something that a -- there is a shortage. Someplace in all this material I read there are only ten 20 child/adolescent psychiatrists in the state. I was amazed 21 22 when I read that number.

23 MR. BOB NYKAMP: No; no. Inpatient psychiatric
 24 providers.

DR. KESHISHIAN: Pardon me?

25

MR. BOB NYKAMP: The units. 1 2 MS. BROOKS-WILLIAMS: Facilities. 3 MR. BOB NYKAMP: There are ten facilities. 4 MS. BROOKS-WILLIAMS: Facilities. DR. KESHISHIAN: Oh, okay. I'm sorry. I read --5 Thank you. So any other questions, comments on this? 6 okav. 7 MS. BROOKS-WILLIAMS: Commissioner 8 Brooks-Williams again. So I guess if we need to officially say that we would work -- I don't know who would work on 9 10 that communication to the Legislature -- I would agree that there probably are many other things that we could recommend 11 the Department or the Legislature to look at that are 12 13 outside of our purview but I think are very important. So I would support that. I'm looking at Commissioner Cowling, 14 15 because she probably could lead the charge on that, but --

16 DR. KESHISHIAN: My recommendation would be for 17 this Commission to give broad overview to develop a letter 18 so that we can take a vote on it as a Commissioner either in September or in the annual letter in January and then to ask 19 the Department to work with Commissioner Cowling if she's 20 willing to accept the responsibility to draft the language 21 so we could review it if we decide to do that. I think the 22 idea of what the concepts, is it registry, is it loan 23 forgiveness, is it -- where do we want to go with this 24 25 letter? Any other questions? Okay. Thank you. Last,

1

David Walker, Spectrum.

2 MR. DAVID WALKER: Good morning and thank you. My 3 name is David Walker from Spectrum Health. And with regard 4 to psych beds, Spectrum Health appreciates all the hard work 5 dedicated to this important access issue by the workgroup 6 last summer as well as the Department's (inaudible) and 7 especially by Commissioner Cowling as the worker chair.

8 We do believe that allowing existing acute care 9 hospitals that don't currently have psych beds the 10 opportunity to initiate inpatient psych services with the 11 med psych beds from the proposed special pool would create 12 more opportunities to improve access and therefore strongly 13 support the Department's proposed amendment. Thank you very 14 much.

DR. KESHISHIAN: Are there any questions? The Department has some quantitative data that they supplied us. And I'm going to ask -- they were going to provide it later in the meeting, but I'm going to ask them to supply it now so, as we discuss this, we can know at least the research that they have done so far. So I'm going to turn it over to Beth at this point.

MS. NAGEL: Sure. And, Tulika, I'm going to put you on the spot in a moment. But this is Beth. And I would just like to say the Department has been very active in these discussions not just particular the Certificate of

Need but in general how can we alleviate the problem of the 1 2 shortage of inpatient psychiatric services. As part of 3 that, we developed a pilot with one of the prepaid inpatient health plans in the state to collect denial data so that we 4 5 can have quantitative data that shows how long a patient spent in the emergency room, which diagnoses spend longer, 6 7 what is the hardest to place. And we started that process 8 in March. Tulika has a interim report on that data 9 collection process. We planned to provide it later in the agenda, but it seems like it's germane to this discussion, 10 so I'd ask Tulika to share that now. 11

MS. BHATTACHARYA: Sure. You should have this 12 13 one-page summary in your packet if you could make reference to that. So first of all, I would like to thank Mid-State 14 Health Network, Region 5, for willing to collaborate with 15 16 the Department to establish the pilot program. And not only that, they developed an online web-based tool for all of the 17 CMH functioning in that region to be able to enter live data 18 19 as the denials are happening in these hospitals. And also, I mean, thanks to the Department administration and 20 especially Andrea Moore, our compliance analyst, for kind of 21 22 doing most of the work for this pilot program.

23 So we are not at a point to give you a detailed 24 analysis or trends in, like, what are the root causes behind 25 these denials. What's happening out there? But we do see

some trends, and we can make some conclusions based on that. 1 2 And that's what I am presenting to you today. We are in the 3 process -- we not only collect the complaints from the providers, depending on what those complaints are, we do 4 5 send those back to the hospitals and give them a chance to tell their side of the story. Like if you denied a patient, 6 7 what was the reason? Or do you agree with this? Because 8 sometimes, you know, things get lost in conversation and the 9 way -- who is entering the information and how it is being entered. So there is a process of that background check in 10 -- built into the system. 11

12 So what are we collecting? So the PIHP provides 13 the basic information about the denial; so who is the patient, the date and time the hospital denied the service, 14 15 the hospital name that denied the service and the reason 16 service was denied. We have a predefined drop-down list that we have worked internally to populate, and they select 17 one of those but we do also have an "other" category that's 18 a catchall category so -- and if the patient had any co-19 morbidities along with the psychiatric diagnosis. 20

21 So we started collecting data in March of this 22 year. To date, the PIHP has reported 3,047 denials. But if 23 you look at the unique number of patients behind these 3,000 24 denials, it's 360. So you can imagine or calculate how many 25 denials at an average each patient is receiving. So that

1 was an eye opener. Without this system, we always heard 2 about the denial but we didn't know if 3,000 denials means 3 3,000 patients, 1,000 patients or what's that ratio. But 4 now we know.

5 If we look at the age, it ranges form 7 to 73 6 years; 18 percent being child/adolescent and 62 percent are 7 adults. And if we do look at the gender, male patients 8 account for 62 percent and female patients account for 38 9 percent.

10 So if we do a straight calculation for average number of denials per patient, 3,047 divided by 360, it's 11 eight denials per patient. But that is a little misleading. 12 13 It doesn't tell you the whole picture. So if we look at 14 more closely what is happening, so the patients are 15 receiving denial over several consecutive days, like June 1, 16 2, 3, 4. But on the other hand, we have noticed not all denials are over consecutive days like one this week, 17 another one next week or waiting two, three days for the 18 19 same patient, which indicates some issues with the diagnosis and treatment or readmission for the same patient, because 20 it's not consecutive denial over number of days. So of 21 22 these 360 unique patients, 60 of the patients received denials over two consecutive days, 12 of them received 23 denials over three consecutive days, three patients received 24 25 denials over four consecutive days and there was one patient

who received denials over five consecutive days, meaning the 1 2 patient -- either it was ER boarding or some other method --3 was not placed in an inpatient psychiatric bed and did not have the psychiatric treatment that he or she needed. 4 Additionally 15 patients received denials over non-5 6 consecutive days indicating multiple different events for 7 seeking psychiatric treatment, and the maximum numbers of 8 denials a single patient received prior to admission was 62 9 denials over a four-day period. We are also noticing peaks and valleys in the number of denials that we receive, which 10 we are analyzing those, because we do not have a large 11 12 enough set of data to say why those peaks are there, what is 13 causing those influx in the number of denials. So the maximum number we have noticed in a week was 390, and the 14 15 minimum weekly total was 170. So there's also, like, 16 similar variants that we have noticed at denials on a daily basis so with a daily peak of more than 90 denials for a 17 single patient on a single date to like less than 10 denials 18 19 on other dates. So certain dates we are seeing that peaks --or those peaks in the number of denials. 20

21 So there are established categories for 22 classification of the denial that the CMH providers are 23 entering. So when they are calling the hospitals, they want 24 to place the patient, whether you admit them or you say why 25 you cannot admit them, and those are the reasons. So if we 1

2

look at the categories, currently 70 percent of the denials are associated with the facility being at capacity.

3 Now, I need to explain a little about that. So being at capacity means many different things. So I have 25 4 5 beds, and all 25 beds are currently occupied today. So if I receive a call from the CMH, I cannot place any more 6 7 patients. So that's one category. The second category that 8 we have noticed is that male/female in the same room. So I 9 may have 25 beds and I have maybe 22 patients, but the empty beds are in rooms where -- and the new patient is male or 10 female who cannot be put in that same room, so therefore I 11 have a bed available, but I cannot really accept that 12 13 patient. And sometimes it is -- let's say I have a room with two beds but because of the nature of that patient in 14 15 that room and by the doctor's order you cannot put a patient 16 in that same room. So therefore I have a bed, but I cannot 17 accept that patient.

18

DR. COWLING: Don't forget staffing.

MS. BHATTACHARYA: Yes, staffing also; yes. So I
have beds available and male/female match, but insufficient
staffing, and therefore the bed is not usable.

And the next category is failure to return a phone call. And ever since we started monitoring these denials, I think the hospitals now -- many of the hospitals did tell us that, yes, we really do not have a good

follow-up or tracking system to tell you why we denied that 1 2 patient. And ever since, they have developed systems or enhanced their processes to capture those information and 3 give us better data and information as to what was the 4 5 specific reason for not returning that phone call or things like that. And so that accounts for 8 percent, and the 6 7 facility being at capacity accounts for 70 percent of the 8 denial. The patient did not fit the milieu of the unit 9 accounts for 8 percent of the denial. And the next is the other category and we are analyzing, like, what specific 10 reasons under that other category. 11

So at this point, we continue to collect data and 12 13 monitor the denial process. And we appreciate the willingness of the providers to give us those background 14 information. I understand it is -- it is a hardship on 15 16 them, because it is a lot of work as much as for the 17 Department and the providers. So I really appreciate that. 18 So at a later date when we have a large data set and we have 19 done more analysis on the reason and the background information and the rationale, we hope to give you another 20 presentation and provide you with those analysis. If you 21 have any questions? 22

23 DR. KESHISHIAN: Thank you very much, Tulika. 24 That was an excellent report. Appreciate it. Are there any 25 questions? And just I want to make sure. This is only

prepaid Medicaid plans. So this does not include commercial or Medicare or any other members; is that a correct understanding?

4

MS. NAGEL: Yes.

5 DR. KESHISHIAN: Okay. So we are only dealing 6 with a small percentage of the population when we're looking 7 at this. Any other questions or comments on -- Commissioner 8 Cowling?

9 DR. COWLING: Yes, this is Commissioner Cowling. Thank you, Tulika. Because actually I think you're starting 10 to get a grasp of how difficult this problem is to frame 11 from a research standpoint to get definitive numbers. 12 13 Because just while I'm listening to you and you're talking 14 about why there's only a few days where they're documented that they're being denied and there's other factors that 15 16 enter into that which is, once a social worker, for example, is given the information on a Friday night that there's not 17 18 going to be any beds until Monday, they'll stop calling over 19 the weekend, because what's the point of wasting their time? So that won't be denied on Saturday and Sunday because 20 they're not going to try again until Monday. So even though 21 22 the patient is still there in the ED, there's nobody calling to say, "Oh, by the way, did you have a magic bed open up?" 23 24 Doesn't happen.

25

Second thing is, is that there are those of us

that can be incredibly persuasive of our hospitalists who 1 2 beg and plead for, for instance, an elderly patient that really is having a difficult time sitting on a hospital 3 GURNEY in the Emergency Department waiting for a bed and we 4 convince them to admit them for 23-hour observation, which 5 is totally -- I get it -- wrong. Everybody in the room, I 6 7 understand this. Okay. The problem of it is, is that my 8 heart goes out to these people, because those beds are not 9 meant for somebody that has, you know, spinal stenosis that 10 doesn't deserve to be in the ER for three days. So that's another reason why, for instance, they're not going to show 11 up on that list is because now they're in the inpatient pool 12 13 or the observation pool, which gets extended for days and days and days which obviously is costing the hospitals on a 14 different front. 15

16 So I think this problem has so many different 17 angles and variables to it that whatever we can do to get 18 that research is very valuable, but that's where I think, if we're going to do anything, it's the registry that I think 19 we could at least go forward. Because if the social workers 20 could get online, live data in terms of what beds are 21 22 actually open and able to take patients, I think that would really help where we can actually make a difference now. 23 Building new beds is great, but the registry actually would 24 25 be something very helpful at this point. So thank you.

1

DR. KESHISHIAN: Any other comments?

2 MR. HUGHES: Commissioner Hughes. Tulika, great 3 info. Just I don't know if you got any sense for it or 4 going forward we could try to get an indication of when they 5 say they're full and there's no access, is it result of the 6 beds being full or not enough staff?

7 MS. BHATTACHARYA: We -- so the reason -- and this 8 is Tulika. So the reason in the denial, what we get is an 9 Excel file with just one line for each patient, not much 10 information. But when we send that information back to the hospital, they provide us the background why they said they 11 were at capacity. Was it because truly all beds, 100 12 13 percent of the beds, were full or there was a staffing issue or male/female issue or equity level issue therefore it is 14 "quasi full" but not really full. So can we do something to 15 16 kind of, like, an automatic expansion of the unit so, on 17 that day, I have 25 licensed beds, 23 of them are full, but 18 those two beds are in a room where there is an issue. Can I 19 take that bed out and put it in another room without going through a lengthy CON or licensing process? I don't know. 20 So we are getting those responses back and analyzing what is 21 22 the reason behind that broad category of being at capacity.

23 MS. BROOKS-WILLIAMS: This is Commissioner Brooks-24 Williams. And not to derail the conversation or the data, 25 but we've experienced days where I've rounded -- and I'm not

a physician. I am a CEO. But when I round in the Emergency 1 2 Department because I see length of stay of patients and I'll have an adolescent patient that is 17 years and 9 months, 3 4 let's just say. And I've asked the question so we would, of course, say we can't take that patient because they're not 5 an adult and we only have adult beds, but by definition they 6 7 would be -- I literally had a person whose birthday was 8 within a week of this like

9 multi-day stay in the Emergency Department because we 10 couldn't place them. So there probably is in this letter some guidance needed. And I think that would help myself 11 and my colleagues around how do we become more flexible with 12 13 putting the patient first. And really they are at risk if they sit in our Emergency Department for three or four days 14 without placement and they're so close to being considered 15 16 an adult. So I've said the same thing, couldn't I put them 17 in a private room where they could at least begin their 18 treatment and their care versus remaining in the ED where they're getting, you know, supervision but probably not 19 actual care, because the beds are so limited. So there 20 every day I think are variances around when we will say we 21 22 can't or can accept someone, and it's not doing a service to the patients whatsoever. So any flexibility that might be 23 able to be negotiated or discussed I think would actually 24 25 help tremendously.

MS. BHATTACHARYA: And thank you for that comment, 1 2 Commissioner. So as you think about the last major case that we made into the standards, which was never thought of 3 before, the flex beds. So you can flex some of your adults 4 beds as child, and you don't have to tell the Department on 5 6 which days you are using them as adult and child. It's 7 totally up to you and depending on the peaks and valleys. 8 You just need to set it up in a way that, when it is being 9 used for child/adolescent, they are secured from the adult population and properly segregated. So that was -- I think, 10 was a very -- what should I say? -- useful policy change. 11 And we have seen lots of use of those flex beds. We 12 13 collected data for calendar year 2015 for the first time.

DR. KESHISHIAN: Any other comments or questions? 14 I think there are three decisions that I perceive that we 15 16 need to make. The first is, do we accept the changes that the Department has made and then we do proposed action to 17 18 send it back to public hearing and then final action in 19 September, or do we do final action now on what we approved at the last CON meeting? The second issue is, do we want to 20 write a letter to the state Legislature regarding a registry 21 22 and the subsets of that is that then now is that done in our annual report? And then the third issue is, do we want to 23 say anything about loan forgiveness for psychiatrists? I 24 mean, and that one -- well, both the registry and loan 25

forgiveness the state would have to find money in the budget to do that, so easier said than done, but at least we'd go on record that this would be an important issue. So let's deal with -- if it's okay with the Commissioners, let's deal with the three issues separately. So first, do I hear a motion on the first issue?

7 MR. FALAHEE: This is Falahee. I'll make a motion 8 to support and accept the proposed language as written and 9 then to schedule then a public hearing on that proposed 10 language and that the proposed language will also go to the 11 joint Legislative Committee for review.

12DR. KESHISHIAN: You did that very well. Thank13you. Is there a second?

14DR. COWLING: Second; Commissioner Cowling second.15DR. KESHISHIAN: Okay. Any discussion? All in16favor say aye.

17

25

(All in favor)

DR. KESHISHIAN: Opposed? Okay. Second issue, do we want to send a letter to the state Legislature on behalf of the CON Commission with the idea that we would ask the Department and Commissioner Cowling if she accepts the responsibility to discuss that a registry is needed because, while the information provided today is very, very valuable, it is just one small segment of the population.

MS. NAGEL: Could I -- just one quick comment. If

-- because of the timing of the 2017 report, you usually 1 2 approve that in your December meeting, but you see a preview 3 of it at your September meeting. 4 DR. KESHISHIAN: Okay. 5 MS. NAGEL: So it may be good timing process-wise to combine it into the annual report. 6 7 DR. KESHISHIAN: Okay. Thank you. 8 MR. FALAHEE: Falahee with a question. Perhaps 9 one other option would be to instruct Commissioner Cowling, 10 if she volunteers yet again -- I know I owe you for that -and to work with the Department to develop, let's call it, a 11 all inclusive letter whether it includes a registry, loan 12 13 forgiveness, whatever, that we think as a Commission whether it's inside or outside our purview would be something the 14 Legislature should consider. Personally, for example, loan 15 16 forgiveness, I think that's up to the individual hospitals. 17 That's where loan forgiveness occurs now; it's within the 18 hospitals. It's not a state Legislative action. But it'd 19 be at least good in this Commissioner's opinion to -- the Legislature to see --20 okay -- here's the whole range of ideas we've got. Take 21

one, take two, take none. Leave it up to them. That'sanother option.

24 DR. KESHISHIAN: Absolutely. Do I hear a motion 25 of any kind on this?

MR. FALAHEE: I'll take what I just said and make it a motion, to put together a letter with Commissioner Cowling's help and the Department's help and include within that letter whatever we as a Commission or as a Department think would be appropriate to the Legislature and submit that either as a separate letter or as part of our annual report.

9 DR. KESHISHIAN: Thank you. Any more discussion? 10 I perceive that next meeting we will go through that letter 11 and there might be some parts of that letter that we would 12 not want to accept. Okay. Is there any other motion -- I

MS. KOCHIN: Commissioner Kochin, second.

mean motion -- discussion? All in favor say aye.

14

8

13

(All in favor)

DR. KESHISHIAN: Opposed? Okay. Thank you. CT
 Scanner Services - Workgroup Final Report. Commissioner
 Mukherji?

DR. MUKHERJI: So once again I was the chair of the CT CON workgroup. So this was a bit of an unusual workgroup. In fact, just to come full circle, the first time I ever got involved in CON was I was in the audience and the specific topic was dental CT, believe it or not, and that was about ten years ago.

24 So there was only a single charge given to this 25 workgroup, and maybe the reasons will come out later. But the specific charge was should, quote/unquote, "dental CT be deregulated."

1

2

3 Just to give you a little bit of background, because unfortunately not everyone in the audience is a 4 5 radiologist like myself. So the point is, is that many of 6 you all may not be familiar with CT scanners, I assume. 7 It's probably not in your regular purview. But on the 8 left-hand side is, if you will, a hospital-based CT scanner. 9 So you have a large bore like this, the patient lays here 10 (indicating) and you enter the bore with the magnet. And the terminology that we typically use is this is what's 11 referred to as a fixed unit. On the right-hand side is what 12 13 we call a dental CT scanner. And so when we go back to the charge before "Should dental CT scanners be deregulated," 14 15 this is the type of unit that we're referring to. So this 16 clearly does not take up as much room. It has a work station where you can see the images, but you can clearly 17 18 see a distinct difference.

19 The other terminology for dental CTs is that the 20 actual real term is something called a "Cone Beam CT." And 21 a Cone Beam CT can be used by various physicians. The way 22 our regulations are written, a dental CT scanner is a Cone 23 Beam CT used in the practice of dentistry. However, just 24 realize that Cone Beam CTs can be used by other physicians 25 as well that treat various maxillofacial disorders.

So just to give a little bit of a difference, this 1 2 (indicating) is a typical radiation thickness when you look at a fixed CT scanner. So when you look at this type of 3 fixed CT scanner, this is the type of radiation that's 4 delivered. So it's very, very thin. It's almost like 5 6 slicing -- if you go to Great Harvest and you order a loaf 7 of bread and they slice it for you, you have very, very thin 8 slices. So you take individual thin slices, and then you 9 can put the slices together and do whatever you wish. The Cone Beam CT is -- think of going to Great Harvest and just 10 getting the loaf. So the fan of the beam or the beam of the 11 CT is literally in a conical shape as opposed to a slice 12 13 shape and, as a result, you can now take this data and, if you will, reconstruct it in any way you wish. But I think 14 it's important to note that the thickness of the cone beam 15 16 is just not limited to the teeth itself, but it includes all 17 of the face. So that's why the Cone Beam CT is used around the country not only by dentists, but by other providers as 18 well including ENT surgeons, plastic surgeons and anybody 19 else taking care of patients with various disorders. 20

21 So what happens to that patient, you sit here and 22 this thing literally rotates around your head. And you end 23 up having the images that we'll see. So on the left-hand 24 side when you look at dental or Cone Beam CT, this is 25 typically what you see. So in the scope of dentistry, you

get very elegant images of the teeth and the sockets, the 1 2 thickness of the tooth and a very elegant assessment of various periodontal diseases. And there are various 3 clinical applications that this can be used for in the field 4 5 of dentistry. One thing to note is that, when you do a cone Beam CT, you only look at, if you will, the bone and air, 6 7 nothing else. You don't get very good discrimination of the 8 tissue. Whereas in a fixed unit CT, if you will, a medical 9 CT, not only do you get the bone, but you can also see the 10 soft tissues. So these are the eyeballs right here (indicating), and this just happened to be a lesion right 11 here that's very difficult to see on the brain. So if 12 13 you're ever wondering why medically you're referred to a hospital to get a CT scan, that's one of the reasons, 14 because the level of detail and the information is much 15 16 greater with a fixed unit versus a dental CT. So from a bird's eye view, that's the difference, if you will, between 17 18 a Dental/Cone Beam CT and a fixed unit CT.

19This slide, I think, pretty much encapsulates the20discussion. On the right-hand side this is the cost21associated with medical care, and this is the total cost22associated with dental care, and this is the total spent.23So in 2014 the total amount of costs associated with just24medical care itself was three trillion dollars whereas25dental imaging -- or excuse me -- just dental care itself

was about -- this is in the billions -- about 135 billion.
 So you can see there's a huge discrepancy versus medical
 versus dental.

4 So with that as the background, these were the attendees of the CON, Certificate of Need, workgroup 5 6 meeting. And using the principles of Certificate of Need 7 which is cost, quality and access, what we ended up doing 8 was looking at the pros and cons of the dental CT units 9 about potential deregulation. So if we just look at a cost standpoint, the pros of deregulation is that, if we 10 deregulated the dental CT, these machines have progressively 11 decreased in cost. So before they were about a quarter 12 13 million dollars; now they can run anywhere from 75,000 to \$100,000. But the cons of this is that, although the cost 14 15 of the equipment is going down, it's unclear whether or not 16 the cost -- this reduced cost is actually transferred to the patient. 17

18 From a cost standpoint, this is an uncovered 19 benefit. So if you do go to see your dentist, these are typically out-of-pocket payments, because the Blues don't 20 cover this or the payers don't cover it, nor CMS, whereas 21 22 the costs are borne by the patient if you -- if you will, deregulate this. The patient cost of these are determined 23 by each provider. It could be higher or lower. But unlike 24 25 the Blues or CMS, this is a standardized fee that's paid for

by medical CT.

1

2 As I mentioned before, the thing about dental CT is that because -- if you look at that big bar curve, 3 there's very little overall health care costs associated 4 5 with dental imaging, so there's really no substantial 6 increase in the overall health care costs for the hospital 7 payers if we deregulate it because it's such a small amount. 8 But it's unclear what the individual costs would be and how 9 this would be transferred to the various patients.

10 From an access standpoint, one of the pros of deregulation of dental CT is that it is a cumbersome 11 application process, and there's no doubt it's a hassle. 12 13 But having said that, no applications have been denied by the Department. The pros again for deregulation that this 14 would eliminate restrictions to the access to the 15 16 technology, but in the state of Michigan the access has increased by 300 percent over the last three years. And it 17 was stated in the workgroup that about 20 to 30 percent of 18 19 dentists have these in other states; in Michigan only 2 percent. So if we did deregulate it, this would provide 20 greater access of this technology to the dentists in our 21 22 state. And this would eventually translate into improved access for all citizens of the state. However having said 23 24 that, one of the nuances about our regulation is that this 25 would eliminate the CON provisions for requiring dentists to

treat Medicaid patients. So if you actually look at our 1 2 regulations, this is one of the stipulations in the 3 regulations. It's clearly more convenient for patients to have the scanners in the dentist office. It just provides 4 better continuity of care. But understand that this does 5 heighten the potential of self-referral. And unlike medical 6 7 CT which requires preauthorization before we can do a 8 patient, there's no preauthorization if this is deregulated 9 for these patients. This does improve the access of Cone Beam CT for dentists, but it does prevent access for Cone 10 Beam CT for other providers that manage patients with 11 maxillofacial disorders. So one of the issues about 12 13 deregulation is that we really have selected out a certain 14 provider base, which typically has not been the case for Certificate of Need, especially for the imaging service 15 16 line.

From a quality standpoint, the majority of the 17 18 scanners and utilizations are provided by subspecialists in 19 dentistry right now. This was discussed in the workgroup is that, if we deregulate it, this would permit some dentists 20 currently not performing the procedures to perform these 21 22 procedures. Now, I can't comment as a radiologist on this. 23 This really is an MDA decision whether or not this is good for quality. I'll just -- we can have comment on that 24 25 later. The pros are that it clearly provides better

visualization of bone thickness prior to implants but, you know, what about these other areas? Remember when I showed that thing of the cone? It's not just the teeth, but it's other areas of the face. Just realize that sinuses, TMJ and tumors can be seen, and these units clearly are not optimized for evaluating tumors of the maxillofacial area.

7 One of the things that came out in the workgroup 8 is that there was a claim that there was better outcome for 9 orthodontics. But this is debatable, I think, as I've gone around and, you know, talked to my colleagues and even, you 10 know, my kids. They didn't have Cone Beam CT for 11 orthodontics, but some people claim that for orthodontia the 12 13 Cone Beam CTs will provide better outcomes. This could have 14 more availability for dental students. That again was 15 raised at the CON workgroup meeting. But this is currently 16 available at schools such as U of M. We do have these -- or I should say I did have these when I worked at U of M, at 17 18 that institution. And one of the key things is is dental CT 19 considered a CT or is it an upgraded panorex. That was one of the things that came out. And historically our CON 20 Commission has considered this a CT as opposed to an 21 22 upgraded panorex.

23 So when we did the workgroup -- now, again this 24 is, I think, my sixth workgroup I've been involved in over 25 the last eight years. Typically there's a uniform consensus

and, in this one, the vote was 12 to 9. So by the letter of 1 2 the law, the workgroup did vote to deregulate dental CT. But I just wanted to point out that this was not a 3 4 consensus, and I think part of it was basically who just happened to show up in the room, because the -- the 5 attendance is not dictated by state statutes as it is in 6 7 SAC. It's any interested parties that happen to be there. 8 But technically the workgroup did recommend deregulation of 9 dental CT.

10 So with that, I'll go ahead and open it up to 11 questions. And that's all I have.

12DR. KESHISHIAN: Thank you very much. Great13report as always. Any questions from the Commission?14MR. MITTELBRUN: Tom Mittelbrun. Could you15possibly go back to the slide before the "quality" slide?16DR. MUKHERJI: Yeah; sure.

MR. MITTELBRUN: The bottom item -- I'm at a bad angle, but it kind of confused me. The very bottom one "Improves access to CBCT for Dentists" and under Cons "Prevents access to CBCT for other providers who manage and treat patients." Why would it prevent access?

22 DR. MUKHERJI: Right. So what the -- the 23 stipulation was -- is that this Legislation we're 24 specifically voting on is a relative regulation, if you 25 will. So we're looking at deregulation of dental CTs specifically for the care -- for the treatment of dentists.
So therefore it's axiomatic that this would improve better
access to Cone Beam CT for the dentists, but it retains the
current regulation for Cone Beam CTs for other physicians
that manage patients with maxillofacial disorders.

6 MR. MITTELBRUN: Can I ask a follow-up7 question? Tom Mittelbrun.

8

DR. MUKHERJI: Sure; yeah.

9 MR. MITTELBRUN: It was 12 to 9 in your workgroup 10 for the vote. And as I understand it, we're only one of two 11 states that regulate this. I'm just curious why -- why we 12 stand out compared to the rest of the country and why the --13 you know, why the 9 who did not want to regulate but believe 14 that we still should have regulation?

DR. MUKHERJI: Right. So I'll put it this way. 15 16 The 36 -- when CON were first started, there were 36 states that have CON. And there's been a modification of CON in 17 18 different states. And there are certain services that we 19 regulate here that are not regulated in any other states. And I think, in part, it's just due to the choice of the 20 state of Michigan. So I think the reason we have CON is 21 22 because that's our policy within the state.

I think one of the things that we can discuss as a group is historically, from an imaging standpoint, we've regulated the technology. So we have decided to regulate

Cone Beam CT, but we've never really regulated individual 1 2 providers or physicians that have access to that specific 3 technology. So moving forward when we actually took the workgroup vote, the initial proposal was maybe we can have 4 5 three things to vote on. Number one, should we regulate 6 dental CT? Should we potentially deregulate Cone Beam CTs 7 as a whole, so therefore as a public policy measure we're 8 deregulating the whole technology as opposed to just carving 9 out a certain provider that has access? And the third option would be continue the status quo? It was the will of 10 the workgroup that we just have two choices, either 11 deregulation of dental CT or just maintain regulations as a 12 13 whole. So that's a long answer to a short question, but I 14 hope it summarizes and gives you a comprehensive answer.

MR. MITTELBRUN: Yes. Thank you. And it just made me -- Tom Mittelbrun again. But what made me think of that was that you also said no applications had been denied. So evidently, you know, it's a good technology for the use, you know, being asked for.

20 DR. KESHISHIAN: This is Commissioner Keshishian. 21 I just want to comment on no applications being denied. The 22 application basically -- the only requirement is that you 23 are a dentist and you certify that you're going to do 200 24 dental CTs in the next year. There are some other ones, but 25 there's certification that you -- or attestation that you're

going to do 200. In fact, many people aren't doing 200, but 1 2 it is -- you know, if you attest to it, you receive it. And the other thing is it costs money. And if people are going 3 to put money down on the table to get it, they're going to 4 5 be pretty sure that they're going to receive CON approval. 6 I think our overall denial rate on all CON issues is 7 probably 98 percent plus, because no one's going to put 8 money down to get denied.

9 MS. NAGEL: If I could just add another really important reason that we -- that zero have been denied is 10 because our CON staff works tirelessly with each dentist. 11 They go above and beyond to make sure that their application 12 13 is complete. So it's a little bit of a misnomer to say 14 that, you know, every application that comes in we either 15 just stamp it approved or not approved. We look at it, we 16 see the deficiencies, and we go back and forth, back and forth, back and forth with the dentist to get it right until 17 18 we get it right. So there's a little -- you know, there's a 19 little more to the story with that statistic.

20DR. KESHISHIAN: Thank you. Commissioner Tomatis?21DR. TOMATIS: Commissioner Tomatis. Do you think22that deregulating will result in better patient care?

23 DR. MUKHERJI: Well, it depends on how we define 24 "patient care," how we define "quality" and how we define 25 "value." And I think a lot of it depends on the perspective

and what type of stakeholder you are in our healthcare 1 2 system. I think, from a patient access standpoint, you know, when you go to a physician's office, you want 3 everything to be here. That can be the ultimate definition 4 of patient centeredness. But on the other hand, you know, 5 6 we just want to make sure that whatever services are 7 provided to the patient, they're appropriately done so and 8 to make sure it's done in the best interest of those 9 patients. So it's hard for me to say, because I don't want 10 to speak for -- this was a very -- it was a very good -- I think this was a great workgroup, because it really got to 11 the core of cost, quality and access albeit for a very small 12 13 component of our healthcare system. And I'm sure you're going to hear different opinions to your question in the 14 15 public comments.

MS. GUIDO-ALLEN: This is Guido-Allen. Oh, I'm sorry. Question, what's the likelihood if we do deregulate for the dentists that the oral maxillofacial surgeons come and ask to be deregulated?

20DR. MUKHERJI: I think you can answer that21already.

22 MR. FALAHEE: This is Commissioner Falahee. I've 23 already had that discussion. I've had that discussion two 24 months ago. I had it again one month ago, and there are 25 others as well. So the likelihood is very high.

DR. KESHISHIAN: Yeah. And this is Commissioner Keshishian. I agree with Commissioner Falahee. But then we'll have to deal with that issue at that time. Certainly one of the differences is that the employer community is not paying for dental CT scanners. Once you get into medical, the employer community might have a different voice at that point in time.

8 DR. MUKHERJI: This is Mukherji. I think that's 9 an important issue about the role of a CON Commission. You know, the CON Commission, in my opinion, should set policy 10 consistent across the board. And who pays for a study, I 11 personally don't think it's relevant. And we really haven't 12 13 gotten in the realm, at least from the imaging services, trying to find which providers have targeted access to 14 certain technologies that are currently covered. 15

16 MR. FALAHEE: This is Falahee. I think that's 17 why, to answer your question again, one of the options that 18 the workgroup looked at was that -- I think it was the 19 second one -- instead of deregulating by profession, we deregulate by technology. So Cone Beam CT, deregulate it 20 whether you're a dentist, ENT -- I don't know -- plastic 21 22 surgeon. I don't know who else might use it. So that's --23 that was why that option, I'm sure, was on the table.

24 MS. BROOKS-WILLIAMS: This is Commissioner Brooks-25 Williams. Can -- Dr. Mukherji, can you discuss a little bit more why the global deregulation? I understand you all didn't bring that forward as a recommendation, but it was an option. Why was it and what was the discussion behind not wanting to do that?

DR. MUKHERJI: Well, that's a great question. 5 Ιt was brought up, but there -- and again when you have a 6 7 workgroup it's an ambiguous group, but it's a very learned 8 group and I think, in a word, to ensure that everyone's 9 voice was heard, because there are really no set rules. 10 That was raised, and there were several individuals that had opposition. I think we actually took a vote as a group 11 12 whether we should have two options or three options, and the 13 majority of the group was to have two options. And that's why we decided to go that way. So just trying to consensus 14 build. 15

MS. BROOKS-WILLIAMS: Okay. Thank you.

17DR. KESHISHIAN: Any other questions? Okay. One18public comment card unless anyone else -- Dr. Mark Johnston19from the Michigan Dental Association.

16

20 DR. MARK JOHNSTON: Good morning, everyone. Those 21 of you who play golf, you know that this week is the U.S. 22 Open. And I feel like, you know, when I'm watching golf on 23 television, they've got these pros that can hit a shot and 24 you've got all these people standing around. And for me as 25 an amateur golfer, I don't think I could pull off that shot. But today I'm representing the dentists of the state of
 Michigan, and I hope I can pull this off in front of such a
 distinguished crowd today. So keep your head down when I
 hit the shot. Okay?

5 Last year I was president of the Michigan Dental 6 Association, and I now have the distinct honor of being the 7 past president, a very envious position. But I am 8 representing 5500 dentists across the state, and I really 9 appreciate this honor and privilege to speak for them.

I do want to make a couple of disclosures right off the bat. I am not interested in purchasing a dental CT unit now or in the future. And my brother is a radiologist, so I feel like my mother is being honored here today when they're speaking about two of her five sons.

15 One of the issues that came up -- and I was able 16 to attend some of the workgroup meetings, and I've spoken to some of you in conference calls on the phone -- is safety. 17 Dental CT is currently and will continue to be regulated by 18 19 the Radiation Safety people within the state of Michigan. So every piece of dental x-ray equipment that is in my 20 office, someone from the state of Michigan comes in and 21 22 checks on it every year, and then I get a certificate to 23 display on the wall. That continues whether you deregulate 24 or not.

25

The other thing I wanted to mention about dental

1 CT is that the Radiation Safety people, the people who are 2 medical physicists, the experts have determined that it's 3 not appropriate to regulate dental CT like the medical CT as 4 been illustrated here earlier. That's because the emissions 5 coming from these machines are so small in comparison to the 6 medical units that they feel that it really belongs in an 7 area where panoramic x-rays which

we -- a lot of dentists have in their offices currently.

8

9 The second point I'd like to make is on the current regulations of CON. This is a system where dentists 10 are being dictated to some extent on how they practice their 11 profession. This does not allow the dentist to use their 12 13 expertise in determining when a Cone Beam is necessary for the patient. And I'd like to specifically talk about the 14 orthodontic case that was brought up earlier, because I've 15 16 talked to many orthodontists, some of them who have the 17 dental CT. Dental CT is not the standard of care for treating orthodontic patients. Where it comes into play is 18 19 when you have a surgical case in an orthodontic case. So that every orthodontic program across the United States 20 teaches their orthodontic residents the use of Cone Beam in 21 22 determining the best treatment plans for those very complicated surgical cases where the jaws have to be 23 24 repositioned in order to get the outcome that they'd like to 25 see.

In dental school, dentists undergo significant 1 2 training in radiology. We have always performed our own imaging and interpretation. This is not new to us. Because 3 I am not interested in buying one, I don't know exactly, but 4 5 I do know that the focal point and the area of concern that 6 a dentist has is a very small area. As the machines 7 increase in their technology, we are just looking at teeth 8 and jaws, something that we are actually good at. I do not 9 believe that the Dental Association nor the dentists of the state of Michigan want to become radiologists and take away 10 the expertise in treatment or diagnosing head and neck 11 12 cancers.

I understand my time is done. I apologize for going over slightly. Thank you very much for your time and your consideration.

16DR. KESHISHIAN: Thank you for the testimony. Any17questions for Dr. Johnston? Commissioner Falahee?

18 MR. FALAHEE: Please get back on the tee. Thank 19 you. A couple questions. Medicaid patients, if we choose 20 to deregulate, how do we as a Commission or how do we as the 21 Department know that Medicaid patients will continue to have 22 access to care?

23 DR. MARK JOHNSTON: So as you know, the governor 24 just passed their budget, and one of the things that has 25 been fully approved is Healthy Kids Dental. So we are

answering that question outside the realm of Medicaid 1 2 especially in the area of children such to the point that 3 there are mobile dental hygiene units that go around the state in order to go to schools, and they perform under the 4 5 Public Act 161. They are running out of students that need care in that type of venue, because Healthy Kids Dental is 6 7 working. Because I can see a child, an adolescent up to age 8 20, in my office where all my equipment is right there, my 9 dental assistant is there, all my supplies are right there. And we're treating the kids at a high level of care at a 10 reimbursement rate that I can basically break even at. 11 The adult Medicaid population is maybe another story, but there 12 13 is a Healthy Michigan Plan which is also addressing those patients with dental needs in my office which we see. So I 14 am not a Medicaid provider, but I do treat those people that 15 16 fall into those two categories, Healthy Michigan Plan, Healthy Kids Dental. 17 18 MR. FALAHEE: Thank you. 19 DR. MARK JOHNSTON: You're welcome. MR. FALAHEE: Next question, radiation levels. 20 When you and I chatted and others have contacted me about 21 22 radiation levels, do the dentists that have this

23 procedure -- do they inform the patients of the radiation 24 level so the patient or the patient's mom or dad knows 25 what's going on?

DR. MARK JOHNSTON: In my office -- as I said 1 2 before, I don't have one. But what I do have on the wall is a radiation diagram, how much radiation you receive when you 3 sit in front of a television, how much radiation you receive 4 5 when you fly across the country in an airplane. And that's in an office that doesn't have it. What I didn't get to 6 7 mention in my three minutes of time that I'm going to steal 8 from you now and mention it is that, as the radiography --

9

MR. FALAHEE: This is called a mulligan.

10 DR. MARK JOHNSTON: Thank god I've got one golfer in this room that understands. As my equipment -- I go back 11 15 years to my first digital piece of equipment. And I'll 12 13 be honest with you. One of the main reasons why I switched to digital so I can get rid of that damn processor and all 14 the chemicals that were involved and we had to deal with 15 16 disposing of that stuff. So now I'm on my second dental 17 digital piece of equipment in my office. The radiation has 18 gone down from my first unit to my second unit so much that 19 the little unit that hangs on the wall I had to set at the lowest setting in order to get it in. I can't -- if I got 20 another new piece of equipment, I'd have to get a different 21 22 wall unit, because the unit that I have right now is set at the very lowest setting. As our equipment ages in the 23 office, that's when the dentist is going to take a look at a 24 25 new panoramic digital machine. Then they have to decide

whether they want to add on this dental CT Cone Beam. 1 But 2 the radiation is so low that it is lower with the new 3 equipment than the current equipment that they have in their office. Absolutely we would love to discuss the amount of 4 5 radiation. What's so great is that the new equipment is 6 less than the equipment that they had when -- you know, in 7 their old system. So again we're advancing the type of 8 equipment used in medicine. And what I'm asking this 9 Commission to do is to deregulate the dental CT, move Michigan forward and the citizens of the state of Michigan. 10 Because there are accurate diagnoses made when you just 11 scratch your head and then from a plain film when you go to 12 13 a dental CT, the accuracy increases up to 60 percent so that you have the correct diagnosis, and now you have the correct 14 15 treatment for that case. And then the person, the 16 individual, the citizen of Michigan gets the correct treatment and gets out of pain or whatever the situation is. 17 18 MR. FALAHEE: Thank you. 19 DR. MARK JOHNSTON: You're welcome. DR. KESHISHIAN: Any other questions? 20 MR. HUGHES: I just think maybe the question on 21 22 that is with the radiation is not -- obviously the equipment is made a lot better, the radiation is less. But are you 23 confident that the additional radiation that patients would 24 25 experience through this because of the more access to them

is going to be explained to the patient at the time of service? Because people just do what dentists tell them what to do because they're the professionals, and now they're going to be getting more radiation potentially than they have in the past, and they may or may not elect to do that if they're aware of the risks.

7 DR. MARK JOHNSTON: So I'm going to answer your 8 question in slightly -- as mentioned before, is that 9 dentists who have these are not fulfilling the 200 scans per 10 year that they technically should have in order to be under the qualifications of the CON permit that they have in their 11 office. Why is that? Because if a patient doesn't need it, 12 13 they don't expose them to that radiation. Dentistry is prevention, the all star prevention. We are trying to work 14 ourselves out of a job of fluoride and other preventive 15 16 services, and we do a pretty damn good job at it. The one 17 thing that I don't see with people who have the dental CT 18 unit is them looking at it as a profit center and exposing 19 radiation unnecessarily just because they have a machine. Now, that comes down to the individual and the ethics of 20 that individual, and there are always bad seeds in every 21 22 profession. I'm not saying that dentists are exempt from having bad seeds. We do, and we try to take care of them in 23 the peer review system. I may not be the answer you're 24 25 looking for, but I don't think that the patient is going to

be exposed unless there's a real need for it. And that's 1 2 why I don't think that -- you know, I don't have a problem with the dentist explaining to them, and they should, that 3 we're going to take another study, it's a different study 4 5 than what you had previously because the plain film or the 6 two-dimensional picture doesn't show what a three-7 dimensional picture would show. And that's where the Cone 8 Beam brings in that third dimension of depth to the picture. 9 DR. KESHISHIAN: Commissioner Tomatis? DR. TOMATIS: Commissioner Tomatis. Just 10 (inaudible). What is the difference in the amount of 11 radiation between the more typical x-rays for all the teeth 12 13 and the CT? DR. MARK JOHNSTON: Brent, I'm going to defer to 14 15 you on that question. He wants to know the difference

between a full mouth -- are you talking about the individual films?

DR. TOMATIS: Yeah, the full amount of I go thereand they get it all over.

20 DR. KESHISHIAN: Please identify yourself and sign 21 in.

22 MR. BRENT GARVIN: Brent Garvin, Planmeca Imaging. 23 To give us a benchmark in dental, we use the dose 24 measurement in microsieverts versus medical uses 25 millisieverts. When it comes to the average daily

background dose, the average adult receives approximately 10 1 2 microsieverts of radiation a day just living their lives. When we look at a comparison of a single x-ray, which is 3 called a periapical x-ray, you're looking at about 5 to 10 4 5 microsieverts of radiation. A single tooth 6 three-dimensional image on a CT scanner is only 5. It can 7 be as low as 5. A bite wing series which is done every 12 8 months is 20 to 40 conventionally from film digital, and we 9 can do upper and lower arches as low as 12, full head scans 10 as low as 18 microsieverts. DR. COWLING: Traditional panoramics or 11 (inaudible) scanners? 12 13 MR. BRENT GARVIN: Twenty. So we can go full midcranial to back of head images is low -- is less than a 14 15 panoramic. 16 DR. KESHISHIAN: Any other questions? 17 DR. MARK JOHNSTON: Did I an- -- was your question 18 geared towards informed consent? Is that --19 MR. HUGHES: I mean, my question was kind of non-definable and, like you said, there's good and bad in 20 everything. There's really good hospital guides and there's 21 22 really bad hospital -- exactly. DR. MARK JOHNSTON: And he probably takes a lot of 23 24 mulligans on the golf course, too. 25 MR. HUGHES: I just think most people, like I,

1 trust their dentist and, if they say do this, do this and if 2 they're being exposed to unnecessary radiation that was my 3 concern.

DR. MARK JOHNSTON: And I think the new patients that I gain in my office who have come from another office, they didn't feel comfortable or that trust factor, and that's why they -- sometimes that's why they change dentists. Thank you for your time.

9 DR. KESHISHIAN: Okay. Thank you. Commission 10 discussion?

11

UNIDENTIFIED SPEAKER: There's one more.

DR. KESHISHIAN: Oh, I don't have a card. Pleaseidentify yourself.

DR. MICHAEL KASOTAKIS: Dr. Michael Kasotakis,
 radiologist.

16 DR. KESHISHIAN: Are there any other blue cards or 17 anybody else wants to speak on this topic?

18 DR. MICHAEL KASOTAKIS: So thank you, Commission, 19 for your time. I also want to introduce in the audience Dr. Brian Smiley, one my colleagues from the Detroit Medical 20 Center, and Dr. Gaurang Shah from the University of 21 Michigan. And unlike the dentist who came before me, 22 unfortunately I don't have a fun golfing analogy to use. 23 The reason is I'm too busy flossing my teeth every day and, 24 25 for the record, I've never had a cavity, but I think that's

genetics.

1

2 But seriously so I'm a practicing radiology in Ann 3 Arbor, Michigan, but I'm here representing the Michigan Radiology Society. I'm the president currently. We 4 5 represent around 1500 membership consisting of radiologists, 6 radiation oncologists and medical physicists and trainees. 7 As a society, we're acutely aware of the challenges based in 8 our healthcare system. We should always make our best 9 attempts to achieve the goals of high quality, affordable 10 healthcare. And although we as a society prefer to keep dental CT regulated as per the current protocol, we 11 understand that the Commission may choose to do otherwise. 12 13 As president and representative of the Michigan Radiology Society, we believe in a strong CON that would serve the 14 interests of cost containment, radiation exposure and safety 15 16 and quality of care and access. We urge the Commission to consider the potentially slippery slope of deregulation and 17 to consider, if they choose to deregulate, to carve out 18 19 modality specific Cone Beam CT and professional specific for dentistry. We, as a medical society, are concerned with 20 deregulation opening the potential floodgates for other 21 22 subspecialists such as the ENT surgeons and orthopedics, for example. Deregulating these low cost, in-office CAT 23 24 scanners could lead to increased healthcare costs, 25 overutilization, compromised patient safety, increased

radiation exposure to the population and perhaps lower of
 quality of care. Thank you for allowing me to express my
 concerns and for your considerations in your deliberations.
 Do you have any questions?

5 DR. KESHISHIAN: Any questions? Commissioner 6 Falahee?

7 MR. FALAHEE: This is Falahee. So let's say we 8 deregulate dental and then, at our September of December 9 meeting, in walks -- pick one -- say ENT and says, "Me, 10 too." I'm not fa- -- I've been working on CON for a few 11 decades. I'm never familiar that we've ever regulated based 12 on a profession versus technology. So what's the answer to 13 the ENT as to why -- why not you but the dentists yes?

DR. MICHAEL KASOTAKIS: That's why we're 14 15 opposed -- we promote -- we propose not deregulating, 16 period. All right? The rest is up to the Commission. So 17 that's our first stance is do not deregulate because of this potential slippery slope. From there, it's up to the 18 19 Commission. But if we were to deregulate, we would carve out -- we would suggest carving out for dentistry only. 20 21 MR. FALAHEE: Thank you. DR. KESHISHIAN: Commissioner Mittelbrun? 22 MR. MITTELBRUN: Unless I misunderstood the slide 23

24 presentation, it seems like the equipment and the technology 25 is different for the medical application than for the dental

application; am I correct?

2 DR. MUKHERJI: Yes; that's correct. 3 MR. MITTELBRUN: Okay. So there's a -- there's a -- it seems like -- I know we're talking about the 4 5 technology as a whole and we're talking about an individual 6 profession, but it seems like the technologies are different 7 between the two applications. So I'm not quite sure from my 8 -- you know, I'm trying to wrap my head around it. I'm not 9 quite sure it's the same discussion. That was my only --10 just wanted to make sure I was -- I was clear. Thank you. 11 DR. MUKHERJI: There's a difference -- this (indicating) is what's in the hospital. This is what would 12 13 be that is in the dentist office and in the ENT's office and in the plastic surgeon's office. 14 15 MR. MITTELBRUN: Okay. 16 DR. MUKHERJI: So this (indicating) is the 17 technology that we're referring to, and it's transportable 18 and can be used by the various providers. So now we're 19 talking deregulating this just for the dentists, and this is just for comparison's sake so you understand --20 MR. MITTELBRUN: Okay. But both technologies can 21 be used for medical and dental? 22 DR. MUKHERJI: Right. 23 MR. MITTELBRUN: Gotcha. I got it. 24 25 DR. MUKHERJI: Correct; right.

DR. KESHISHIAN: Any other questions? Okay.
 Thank you. Michael Kas- -- oh, sorry. Thank you. Robert
 Langlais?

DR. ROBERT LANGLAIS: So I'm a dentist, but many years ago I became a dental radiologist, oral maxillofacial radiologist. And we have a board that certifies people, so I'm Board Certified in what we call oral and maxillofacial radiology. And I'm licensed in Texas.

9 So what -- what I -- my title here is CBCT 10 applications and how CBCT enhances treatment outcomes. And 11 in your handout, there's going to be a couple of pictures of 12 cases.

13 Anyway just really quickly before these cases, one of the things we have trouble measuring with standard 14 15 radiology is measurements, because there's magnification, 16 sometimes unequal magnification. So whenever's there's resonance, there's problems. And sometimes, for example, in 17 18 orthodontics you're trying to figure out how much space is 19 available for all those teeth that aren't growing in. Well, Cone Beam CT gives us accurate measurements, also curved 20 measurements in root canal -- in root canal treatment. It's 21 22 very hard to measure curved accurately -- although you can 23 with software, but you're using a standard image. So you're measuring something that's magnified or actually smaller in 24 25 size. Both things occur. And also the angles are hard,

because it's -- the relationships of structures to each 1 2 other can be not accurate. And those are accurate in Cone 3 And this is very important for malaligned teeth, for Beam. orthodontists and people that do that. And then volume. 4 5 You want to put in a bone graft at a site where bone's been 6 lost. You don't want to order three times as much as you 7 So you can measure the volume of that bone graft, the need. 8 material. Also people lose bone from chronic periodontal 9 disease or a localized infection and order the amount of bone that'll fit to put the graft in there using CBCT 10 measurement. 11

Treatment tools as developed from the CBCT volume 12 13 is the second one. So implant specifications, I was talking about measurements. Well, the size and shape you can figure 14 15 out what's going to fit in there from the CBCT, and then the 16 software usually contains a library of all implants available, all brands, and so you can pick the best one to 17 fit in there with that CBCT software. Also the surgical 18 guides, you know, that help you -- like even if you just go 19 and say -- look at the jaw and say "Well, I think I should 20 just drill a hole in there and I should be able to get an 21 22 implant to fit, " well, with surgical guides you accurately 23 prepare the site according to what Cone Beam CT told us where we could go, how far we could go, how wide we could 24 25 got to get an implant that'll fit in there and not crack the

jaw in the process.

1

2 And then third, molars, wisdom teeth is lots of trouble getting those out, and a lot of times they can come 3 in if there's space for them. And so once again you can 4 5 measure, you can plan those kinds of things. Even orthodontic treatment without braces now is possible. 6 You 7 get a series of things -- plastic things you put in the 8 mouth, and sequentially those plastic things apply pressure 9 here and there, it's invisible, and the teeth get 10 straightened without braces. Those are made from measurements based on Cone Beam CT or physical models, 11 impressions of the teeth. 12

13 Also the extent -- so that was my last thing is 14 that disease not always visible how far it goes. So if you look on these four cases -- and look for yourselves. 15 16 There's little notations, there's pictures there. And in 17 each of these four cases, you can see how the Cone Beam CT 18 showed us exactly what was going on. And pretty dire 19 circumstances might have happened if only the 2D images had been used to handle these cases. And all of us who work on 20 this, we have dozens, hundreds of cases --21

22DR. KESHISHIAN: If you could wrap it up quick?23DR. ROBERT LANGLAIS: I'm done.

24DR. KESHISHIAN: Okay. Thank you. Okay. Any25questions? Okay. Thank you very much. Okay. I think

that's it. The Department has a position.

MS. NAGEL: For the record, for your discussion, the Department does support deregulation of dental CT or Cone Beam CT. We have historically supported deregulation the last several times, at least three times, that the CT standards have come to you, so we certainly support it this time as well.

8 A couple of things I wanted to point out for your 9 conversation is first in regards to Medicaid. The standard actually reads -- or the statute actually reads "participate 10 in Medicaid." It doesn't actually say "treat patients." 11 And so though that seems like a interesting or a kind of 12 13 nit-picky distinction, it is very important, because what we heard from the dentists is that participating in Medicaid, 14 this piece of technology is not a impetus to do that, that 15 16 there are other business reasons why they would participate and treat patients in Medicaid, not necessarily to comply 17 18 with this regulation.

19The second is, right now we are actually concerned20about a workforce issue with dental CT. The dentistry21schools -- and I believe there was a letter in your22packet -- teach new dentists how to diagnose and treat with23this technology. And we've had many studies that show our24dentistry workforce is aging. We want to encourage new25dentists to practice, to stay and practice in Michigan so

that dental access can remain.

2 And thirdly, so there's concern about deregulating 3 -- for your concerns about deregulating based on a specific profession. It's regulated right now in the CT standards 4 5 based on a specific profession. So it's -- yes, it would be 6 a new thing to deregulate for a specific profession, but you 7 already regulate specific to dentistry right now. 8 DR. KESHISHIAN: Okay. Thank you. Are there any 9 questions for Beth? MR. FALAHEE: Commissioner Falahee. So if we 10 regulate -- or the Department regulates based on dentistry? 11 MS. NAGEL: That's what the standards say, yes. 12 13 MS. ROGERS: Right. The standards that are --14 MS. NAGEL: Yes; yeah. MR. FALAHEE: Okay. But if we took those 15 16 standards away and deregulated, there's still Radiation 17 Safety protection for those units? 18 MS. NAGEL: Yes. 19 MR. FALAHEE: Regardless of profession? MS. NAGEL: Yes. We made contact with our 20 Radiation Safety to make sure that that was, in fact, the 21 22 case. 23 MR. FALAHEE: Okay. MS. NAGEL: And interestingly enough, I think it's 24 25 worth discussion, our Radiation Safety does not consider

2

this technology to be a CT machine.

MR. FALAHEE: Right; right.

MS. NAGEL: They consider it to be part of dental -- dental imaging. And so -- and that's because of the low -- what is it? -- wattage. I'm not a -- I don't know "words," but the low amount of power that it emits. Yes, kilowatts.

8 DR. MUKHERJI: You know, I think -- Mukherji. 9 When I first started, I think the reason why there was a --10 quote, unquote, a regulation for dental CT was to actually make it easier for the dentists to obtain this. Because 11 when it was first introduced, CT was attached to Cone Beam 12 13 CT, and therefore it defaulted to the regulations for the fixed CT units which I showed. So places like U of M that 14 have the Cone Beam CTs that are in oral maxillofacial clinic 15 16 that are billing Medicaid, they're actually burning up a 17 full CT for those, but the dental schools are now being --18 because the CON lowered the threshold regulations, it's now 19 easier for them to have it. So, yes, they are regulated, but the carve-out was actually initially created in order to 20 make it easier for certain professions to get the CT and 21 22 actually not to make it harder for them to get it.

23DR. KESHISHIAN: Any other questions for Beth?24Comments? Okay.

25

MR. FALAHEE: One -- Falahee with a follow-up,

We talked about the regulation not within CON but 1 Beth. 2 within the Department for dental CT. If we chose to deregulate Cone Beam, is there still regulation that would 3 apply in the Department? Not the CON, but --4 MS. NAGEL: Oh, in Radiation Safety? 5 MR. FALAHEE: Yes; right. 6 7 MS. NAGEL: Yes. MR. FALAHEE: Okay. Thank you. 8 9 DR. KESHISHIAN: All right. Any other questions for Beth? Okay. Commission discussion? 10 DR. MUKHERJI: I'll just start off, because I 11 chaired the workgroup. I think -- and this -- it was a good 12 13 discussion, because a lot of the opinions that you heard 14 today, I think, nicely encapsulated the workgroup discussions. I don't think there's any question that Cone 15 16 Beam CT is beneficial. And oftentimes we need to make sure that we're not debating the benefits of Cone Beam CT. 17 Because it does -- it does work, and everyone knows that. 18 19 It's beneficial in selected cases. In fact, you know, I wrote a two-part article ten years ago on this, and I think 20 the last Commission group we actually shared that. So 21 there's no doubt it adds value. I think for the discussion 22 moving forward, the specific question is -- is, what's the 23 value of deregulation of specific dental CT and how does the 24 25 Commission -- how does the Commission feel about a public

policy decision that is going to deregulate it for a certain
 group of providers? I think that's the thing that we need
 to focus on in the upcoming discussion.

4 DR. KESHISHIAN: Any comments? Commission 5 Falahee?

MR. FALAHEE: This is Commissioner Falahee. 6 Т 7 share those -- those comments. I think the key is -- isn't 8 so much the profession of the person that's handling the 9 piece of equipment as much as it is the piece of equipment 10 itself. So I think from a CON perspective, at least my opinion is we should look at deregulation if we choose to 11 vote for deregulation of Cone Beam CT. And -- and Brenda 12 13 will correct me if I get this wrong. What we have in front 14 of us is proposed language that would go out to public comment anyway if we approved it this way or -- and, Brenda, 15 16 tell me if I get it wrong -- if we instead voted to 17 deregulate Cone Beam, period, then I'm guessing we could 18 instruct the Department to come up with proposed language to 19 do that. That proposed language would also go to public comment and then back to us at our next meeting for 20 potential final action; is that correct? 21

22 MS. ROGERS: This is Brenda. That is correct. 23 And I -- as you've had the discussion just so kind of in the 24 back of my mind, if the Commission would decide to go that 25 route, I think it's going to be a simple fix. And I think

Tulika's -- or, yeah -- Tania's going to bring up the 1 2 language -- is under the definition of CT scanner. So basically what we're going to -- what we would do if the 3 Commission decided to do that is, under the definition of CT 4 5 scanner, where we added the language "and dental CT scanners 6 that generate peak power of five kilowatts or less as 7 certified by the manufacturer," we would end it there and 8 take out the rest of that sentence. That would be the 9 change. And then we would just double-check just to make 10 sure that there is no other area in the language that we would have to correct. So you are correct. So depending on 11 how the Commission passes today, you have the option to --12 13 because it has not gone for public hearing yet, so you have the option to take proposed action as it is or take proposed 14 action with whatever modifications you see fit. 15 16 DR. KESHISHIAN: Commissioner Tomatis? 17 DR. TOMATIS: Commissioner Tomatis. You know, 18 changes in technology can change every day. If we are going

19 to deregulate the dental CT because in three months a new 20 technology come, we would put Cone and they use something 21 else, we would have to address it. I would be in favor to 22 just deregulate dental CT.

DR. KESHISHIAN: Commissioner Cowling?
 DR. COWLING: Commissioner Cowling. I actually
 would be in support of what Commissioner Falahee said, which

is actually just go ahead and do away with the whole Cone
 Beam CT, period.

3 DR. KESHISHIAN: Any other comment? Commission
4 Brooks-Williams?

5 MS. BROOKS-WILLIAMS: Yes, Commissioner 6 Brooks-Williams. Can you -- does the Department know the 7 broader use of the Cone Beam CT? I know we've talked 8 speculatively about ENT and plastics. Do you have that in 9 the Department of Radiology or your Department of Radiation 10 Safety? Is that what you were --

MS. NAGEL: Radiation Safety is actually in the Licensing and Regulatory part of state government. And because it's not allowed today, no, I don't think that they have that. They would probably need to develop a specific program to that because, as the standards are written, there's no --MS. BROOKS-WILLIAMS: It's excluded?

18 MS. NAGEL: Yeah.

19 MS. BROOKS-WILLIAMS: Okay.

20 MS. NAGEL: So, no, there's no one using it for 21 anything else today in Michigan.

22 MS. BROOKS-WILLIAMS: So can I have another 23 question? Brooks-Williams again. So, Commissioner Falahee, 24 your recommendation to broadly deregulate is just heading 25 off what we perceive will be multiple people coming forward and requesting it? I'm just trying to understand how it
 helps us in the short term.

MR. FALAHEE: This is Falahee. It's not so much 3 others that may come forward. It's more -- and this is just 4 5 my opinion -- do we regulate based on profession or based on the widget itself, the technology itself? And again to 6 7 me -- and others may disagree, and that's fine -- we 8 regulate based on the technology and not the person 9 operating the technology. I don't care whether we -- if we 10 deregulate on dental and ENT shows up three months, six months from now, fine. We'll deal with it then. But to me 11 it'd be the same argument, and I just think the better 12 13 option -- again others may disagree and that's fine -- is to just deregulate regardless of who's using the machine. 14

15

DR. KESHISHIAN: Go ahead.

MS. BROOKS-WILLIAMS: Okay. Another question. So we deregulate it, and some -- then anyone can have it and the standards are just applied through Radiation Safety? Different department; right? So they're getting the licensure to have it?

21

MS. NAGEL: Yes.

22 MS. BROOKS-WILLIAMS: And so they would develop 23 that. Is there a way for us then, if we were to suggest 24 deregulation of the equipment versus the specifying it for 25 the dentists which I understand how we got there, why we had

to carve out for dentistry, that we would understand what 1 2 access looked like? I guess my discomfort is not knowing. I understand the evolution of why we had the exception for 3 dentistry because it's well known and not we literally -- we 4 weren't sitting here probably -- but that whoever decided to 5 6 create the carve-out understood the efficacy and value for 7 that patient population. I would hate to have the 8 unintended consequence of saying now it's open to everyone, 9 but I honestly don't really know who everyone is and how it would be used going forward. And we would then lose, it 10 sounds like, our ability to have a voice in that. And so 11 that would be my only concern is how would we know how new 12 13 entrants would be covered.

MS. NAGEL: That's a great concern, and it would require us to sit down with the Radiation Safety folks and talk about their ability. Because now it is regulated under their dental imagery. So if we're expanding the scope of what they do, they would need to create a new program, ENT and imagery or whatever, to make sure that those are covered.

21 MS. BROOKS-WILLIAMS: Last question. Is it 22 possible then, if we took action today, whatever that action 23 was, to revisit broader deregulation? So, say, we did 24 deregulate today for dentistry specifically. Could we come 25 back maybe through a request of understanding how others

4

might be able to access the technology going forward?

2 MS. NAGEL: Absolutely. The Commission can come 3 back to these standards at any time.

MS. BROOKS-WILLIAMS: Okay. Thank you.

5 DR. KESHISHIAN: I have a question for Commissioner Mukherji. This is doctor -- excuse me. 6 This 7 is Commissioner Keshishian. My sense is the dental CTs will 8 take the place of a lot of panoramics that are being done 9 right now. If we deregulate it for others, certainly I 10 think the sense I have is there are too many sinus CTs being done already. You know, choosing wisely is one of their 11 criteria. It states, "Do not routinely do CT scans of the 12 13 sinus for sinusitis." My question is, do we have any concern about -- for me for dental, it's sort of a 14 substitution; for others, it might be an addition. Do you 15 16 have any thoughts on that?

17 DR. MUKHERJI: I think the premise of your 18 question is a great question is, is it really a substitution 19 for dentistry? And that's -- again I've talked to -- I haven't talked to every single dentist in the state, but the 20 people that I trust and a lot of people don't want to get --21 22 they have really no interest in this. But when you do look at utilization, the places that do have it tend to use it 23 more when they obtain it. So is it truly a substitution? I 24 25 don't know. You hope it is. But how can you be sure of

I think you just have to look at utilization data. 1 that? 2 Certainly if you deregulated Cone Beam CTs, then you run 3 into tangible issues about steerage away from hospitals. Because if you did deregulate the service as a whole, right 4 5 now a lot of these sinus CTs are being done on the fixed units that I illustrated, and those would then be steered 6 7 away from the hospital-based systems, because most ENT 8 surgeons don't have a CT unit in their office. So there are 9 steerage issues. There's are also preauthorization issues. Because, in general, I know the Blues and Aetna and United, 10 they do have preauthorizations for CTs where Medicare 11 doesn't right now. So -- and they would be billed under a 12 13 separate code. So all of these issues right now that are below the surface to the payers and the hospital system 14 15 would all of a sudden come into play.

16 DR. KESHISHIAN: Okay. Thank you. Any other? 17 Beth?

18 MS. NAGEL: There was just one issue that was 19 brought up in the workgroup that I don't know that we ever got firm-firm, but perhaps someone in the audience may 20 know -- is whether or not the FDA regulates this piece of 21 22 technology for ENT. That was a question that was widely talked about and debated. And some of the folks in the 23 workgroup that are part of manufacturers of Cone Beam 24 25 technology said that there is no market for ENT because of

FDA regulations.

1

2 DR. MUKHERJI: I don't think that -- I mean, if 3 you're asking is there a market for Cone Beam CTs in the ENT 4 community? Is that what you're suggesting?

5 MS. NAGEL: No. I'm asking if the FDA regulations 6 prevent this piece of tech- -- specific uses of this 7 technology already.

B DR. MUKHERJI: No. Because outside the state --9 if you do look at the various vendors that provide this, I 10 know the vendor that showed up to our workgroup does not 11 market to ENTS. But certainly at U of M because I actually 12 helped get one of these into our system -- a couple of them 13 in our system, they were used by ENT surgeons. So there is 14 no FDA prevention of allowing these units to be used by ENT.

15MS. NAGEL: So you are using a Cone Beam, a dental16CT, Cone Beam CT for sinus or ENT?

17DR. MUKHERJI: Sure; sure. I'm not, but they18are -- I used to be.

19 MR. FALAHEE: U of M. You can't go after --

20 DR. MUKHERJI: Yeah. The people -- you go out 21 shaking his head, yeah; absolutely.

DR. KESHISHIAN: But I think it's -- they use it
as a CT scanner.
MS. NAGEL: Okay.

25 DR. KESHISHIAN: They use it as a CT scanner.

1

MS. NAGEL: Okay.

2 MS. NAGEL: She was going to get into violation of CON against the University of Michigan. I just saved --3 4 DR. MUKHERJI: No. We burned -- you know, we burned a full scale for a dental CT that's being used 5 clearly not as much, but --6 7 MR. GAURANG SHAH: Am I allowed to share my 8 experience with the University of Michigan ENT Cone Beam? 9 DR. KESHISHIAN: Can you come up to the microphone and make a statement and identify yourself, please? 10 11 MR. GAURANG SHAH: My name is Gaurang Shah. I'm professor of radiology at University of Michigan, and I am 12 13 the professor of Michigan State Radiology Society. So as Dr. Mukherji just said, we do have Cone Beam CT at the 14 University of Michigan for the ENT surgeons. And that 15 16 program started about four, five years back, and it was for 17 the express purpose that it could be used only -- the only 18 indication there would be for sinusitis. So we have like a 19 eight-page disclaimer in every report that radiologist makes that this can be used only for sinusitis. It is not used 20 for anything else. Now, fast forward five years. and even 21 22 yesterday when I was actually on CT rotation, only 20 percent of the CT scan that I did from that Cone Beam were 23 meant for sinusitis. The rest of them were for bone cysts, 24 25 the other was for sleep apnea. And then every time in my

report I have to write down that you will have to repeat 1 2 this study in the Department of Radiology. So the patient got double exposure, the cost was increased. And you have 3 to realize that, with ENT, the imaging is covered by 4 5 Medicaid and Medicare. So if you open the floodgates here, 6 what will happen is that there will be increased utilization 7 and over utilization is not a possibility, it's a certainty, 8 I mean, looking at the human behavior. And at the same 9 time, there will be increased radiation, and there will be increased costs. So I believe that, if you open up Cone 10 Beam CT completely, it will go against the grain of CON. 11 Because the regulatory process is here for a purpose, and 12 13 that will go against the purpose.

14DR. KESHISHIAN: Any questions? Commissioner15Cowling?

16 DR. COWLING: Commissioner Cowling. Then I think 17 we've got a disconnect, because what I'm hearing is that 18 you're allowing them to go ahead and do the Cone Beam CT for 19 other reasons besides sinus and then, after they're done, you're saying that this needs to be repeated in another 20 official CAT scan machine. Why aren't you stopping them in 21 22 the first place from doing the first study and make them do the other study? I mean, at some point, who's -- who is 23 holding the choosing wisely campaign? I mean, we've got to 24 25 realize it's not the patient's fault that they're going

to -- and plus this is a safety issue. They're getting
double dinged with radiation. So the onus, I think, falls
on us as professionals to stop this process then. And I
don't think the CON deregulation of the Cone Beam CT is
going to fix that.

MR. GAURANG SHAH: So what I understand is that 6 7 the Cone Beam CT at the University of Michigan is owned by 8 ENT. It is supposed to be one of those office accessories 9 which does not go through the Department of Radiology. They 10 actually order it just outside their own office. And the whole purpose was to avoid a second visit for the patient to 11 come in for a CT scan that they might need. So the whole 12 13 argument for a Cone Beam CT is that it's easy access for the 14 patient. What ends up happening is that, in a way, it's a 15 self-referral, because you are actually using a equipment 16 which you own yourself. So what happens is that you're more 17 likely to use it, at least the ordering physician. And when 18 you order a patient to undergo a study in your own office, 19 there is no regulatory mechanism in between. But when it comes to radiology for reading -- because they don't read 20 their own Cone Beam CTs. They still give it to 21 22 radiologists, because they realize that there's a lot to a radiological image. The radiation is not a part that 23 everyone can play. You need to be trained very well into 24 25 interpreting the images. So when they come to us, you let

them know that, you know, this is not good for the question 1 2 that you asked. I cannot answer it based on this particular study and you will repeat it -- repeat the study at the 3 4 Department of Radiology. So that's where it comes in, and that's where I feel that, when you allow every dentist who 5 wants a Cone Beam CT in his office, it will lead to a 6 7 certain behavioral change which may not be good for the 8 society at large.

9 DR. COWLING: But the dentists aren't submitting 10 their films to the radiologists for second opinion.

MR. GAURANG SHAH: No. They read their own films.
DR. COWLING: Right. So they're not going to get
the -- which is what you're saying --

MR. GAURANG SHAH: They're not going to get thatright also.

16 DR. COWLING: -- repeat it otherwise. So I think
17 it's still --

MR. GAURANG SHAH: And the last actually new 18 19 thing, Dr. Kasotakis has mentioned a pretty good case where an ENT person actually repeated a study on a single patient 20 so many times that he had bone necrosis. Because the fact 21 22 is that they think it's very innocuous, it can -- it's just a photograph, and they keep on using it. I don't -- there 23 are many red flags here. That's what I believe. And if you 24 25 deregulate Cone Beam CT, it will open the floodgates to

other physicians, increase patient costs and increase
 radiation exposure. That's what we believe. And that's why
 as a society we oppose this move.

4 DR. KESHISHIAN: Thank you. Do you have a 5 question for him or a comment?

6 MS. BROOKS-WILLIAMS: No. I was going to make a 7 motion.

DR. KESHISHIAN: Okay.

8

9 MS. BROOKS-WILLIAMS: Okay. This is Commissioner 10 Brooks-Williams, and I am going to ask Brenda to help me, 11 but I think I'll get this right. So I move that we move 12 forward with the proposed language as written, which is to 13 deregulate dental Cone Beam CT, and then move it for public 14 hearing and for the proposed language to go to the JLC for 15 review.

16 DR. KESHISHIAN: Thank you. Do I hear a second? 17 DR. COWLING: Commissioner Cowling, second. 18 DR. KESHISHIAN: Okay. Any more discussion? On this one I'm going to ask for a show of hands. All in favor 19 of the motion on the floor, please raise your right hand. 20 (Nine in favor) 21 22 DR. KESHISHIAN: All opposed? 23 (Dr. Mukherji opposes) DR. KESHISHIAN: One. Nine to one, motion 24 25 carries. I'm going to make -- because we have a number of

items still on the agenda, we've been at this for a couple
 hours, I'm going to ask for ten-minute break and then to
 return in ten minutes. Thank you.

(Off the record at 11:32 a.m.)

(Reconvene at 11:44 a.m.)

6 DR. KESHISHIAN: We're going to start the meeting 7 again. Neonatal Intensive Care Services/Beds and Special 8 Newborn Nursing Services. Brenda?

MS. ROGERS: This is Brenda. And you do have 9 language in front of you today for NICU services. And at 10 your January Commission meeting, if you'll recall, you 11 12 accepted the Department's recommendation to draft a language 13 regarding technical edits, and so that's what you have in front of you today. Contained within that language is a 14 15 definition for special care nursery services. We've 16 modified it to make it clearer for what types of services are provided in special care nurseries. And this is a 17 technical edit, so even though it looks like it's a lot of 18 19 changes, it really isn't. It's more kind of organizational for the applicants. It was an issue that was run into when 20 these standards first took effect, has actually since then 21 22 been worked out, but again for any new applicants this will 23 be clearer. So it makes no changes as far as how it's being 24 administered today.

25

4

5

And then the second piece under the definition is

there is a new definition for well born nursery services. 1 2 And again it's to clarify what a well newborn nursery is and to specifically state that it does not require a Certificate 3 of Need. So again doesn't change anything in regards to how 4 5 the standards that are being administered today but to just 6 to help clarify for the applicant. So if you take action 7 today -- oh, the other piece before that is we also talked 8 about eliminating the language that limits expansion to no 9 more than five beds. So the methodology that's currently in there has been maintained. But if you read through that, 10 whatever that methodology came up with for a number to 11 expand, if it came up with seven, you were capped at 12 13 expanding to five. We just removed that cap. So if the methodology calculates seven, you get seven. So that's --14 so that's the change for that. And then I think the only 15 16 other technical edits were like updating the Department name 17 and some of those things. So if you take action today on 18 the language as written, this is proposed action. A public 19 hearing would be scheduled. It would be sent to the Joint Legislative Committee, and then it would be brought back to 20 you later for final action. Thank you. 21

22 DR. KESHISHIAN: Okay. Any questions for Brenda? 23 Okay. I do not have any blue cards. Does anyone have any 24 comments? Nope. Commission discussion. Any discussion? 25 MR. HUGHES: No.

DR. KESHISHIAN: Okay. Commission proposed 1 2 action? 3 DR. TOMATIS: Do you want a motion? 4 DR. KESHISHIAN: Yes. 5 DR. TOMATIS: Okay. 6 DR. KESHISHIAN: Thank you. 7 DR. TOMATIS: Commissioner Tomatis, so move. 8 MR. HUGHES: Second, Mr. Hughes. 9 DR. KESHISHIAN: Okay. And the motion is to -- as 10 you state it, to put it public hearing and Joint Legislative Committee. Any more discussion on that? All in favor say 11 12 aye. 13 (All in favor) DR. KESHISHIAN: Opposed? Okay. Thank you. Next 14 item, Bone Marrow Transplant Standard Advisory Committee 15 16 (SAC) Final Report. Dr. Bruce Carl? DR. BRUCE CARL: Good morning, Commissioners. 17 I'm 18 Dr. Bruce Carl, and I did chair the 2015 Bone Marrow 19 Transplantation and Services Standards Advisory Committee. I'm a family practitioner, but I would like to recognize --20 and they are in the report -- the hard work and dedication 21 22 of both the experts and the non-experts on the panel. I'm 23 proud to present this report. It was a pleasure to meet colleagues who I had not before and work with them. As a 24 25 group, we were all serious about what we were doing,

engaged, and throughout we maintained a cordial spirit. 1 We 2 met six times in the course of our work. We had two subcommittees, which I'll describe their work. 3 We considered six charges that were given to us by the CON, and 4 5 I'll summarize our findings. I hope everyone in the packet 6 has the five or six appendices and you've had a chance to 7 review them.

8 So at our introductory meeting, we talked about 9 the CON process and our role in it. And over the course of the first couple meetings, we looked into the reality of 10 bone marrow transplant patients in the state and in the 11 country. Basically there's about 600 bone marrow 12 13 transplants per year in Michigan; sometimes it's lower than that, sometimes it's higher. There are five institutions 14 15 that are performing the bone marrow transplants; Karmanos, 16 Henry Ford, Childrens', University of Michigan and Spectrum 17 Health. The bone marrow transplant surgeons who were present said they had no -- they were working under 18 19 capacity, typically reported 50 percent of capacity. Thev had adequate time frames for seeing patients in terms of 20 consultation and bone marrow typing. Many, but not all, of 21 22 the surgeons felt that the need for bone marrow transplants 23 may decrease in the future. This is because there are ever 24 more drugs to treat many of the conditions and even some 25 newer therapies that will obviate the bone marrow process

1 itself, but we can't foretell the future.

2 We looked at a study from Dr. Delamater, whom I'm sure you're all familiar with. Basically 84 percent of 3 Michigan residents who need a transplant are within 90 4 5 minutes drive times of going to one of the current centers. 6 There was a lot of discussion throughout the meetings about 7 unmet need and what that meant. It was thought by many that 8 really socioeconomic disparities were more of a factor in 9 Michigan members not getting transplants and not necessarily 10 geographic or driving time issues.

11 There was a lot of comment that more education 12 needs to happen not only to the public but to the oncology 13 community and when to transfer patients -- transplant 14 patients. But this was not a problem that the CON process 15 was going to solve but was for the health system itself.

16 So we looked at transplants across the nation. We 17 have a population approaching 320 million. There's about 18 20,000 transplants done nationally per year. There are 200 19 transplant centers. Looking at some of the statistics, you see some of our comparator states. While we have 5, New 20 York has 13 transplant centers and they have a population of 21 22 20 million. Maryland, which is kind of a research center centered around Washington, D.C. has 5 transplant centers, 23 and they have a population of 5.5. Ohio has 6 with a 24 25 population of 11 million. And Indiana has 3 with a

population of 6 million. Now, Dr. Delamater in his 2010 study had said there's about one transplant center for two million population, and roughly that's what I found from this 2014 data.

So we looked at the five or six states that 5 6 continue to regulate bone marrow transplants, and there's no 7 consistent methodology that any of them are using. In my 8 mind -- and I'll call this -- they use a soft cap. What 9 they do on a periodic basis is they assemble a commission of multi-stake holders, they consider a lot of things that we 10 were asked to consider; quality, access, cost, socioeconomic 11 disparities. And they come to a conclusion whether the 12 13 existing centers they have are adequate or inadequate. And if you look at the time series of data, there's not much 14 15 change in the number of transplant centers in those other 16 CON regulated states.

17 So then we turned our attention to look at cost, 18 quality and access, which is part of charge five. And most 19 of the committee members thought that both autologous and allogeneic had the same concerns, same pros and cons. 20 And those are listed in appendix two. And we had a subcommittee 21 22 look at these. What we actually did at our committee level 23 was every committee member was offered the opportunity to 24 make as many comments or no comments on cost, quality and 25 access as they affect the bone marrow transplantation

process. These were then put together by the State in order 1 2 of their presumed placement, and then we looked at them 3 There was some disagreement amongst the full again. committee about whether something was properly allocated, 4 5 then we had a subcommittee look at them and put them in the 6 priority that they thought was important in terms of judging 7 cost, quality and access. And that's how you should see 8 that appendix. That is the subcommittees, and this was 9 blessed by the full group as being appropriate.

So just to summarize, in terms of cost, we thought 10 the continued regulation of BMT allows lower costs due to 11 economies of scale and more patient volumes to defray large 12 13 fixed costs. Also there was the issue of physician, allied 14 staff and facility costs could be kept lower if there was 15 less competition between the centers for these highly 16 skilled workers. Again it was brought about innovative therapies and drugs and through clinical trials may lead to 17 18 alternative treatments which may be to lower transplant 19 demand. We thought that discontinuing CON regulation would probably lead to decreased volumes at existing centers 20 possibly leading to poorer outcomes. As to access, there 21 22 was general agreement that it was determined by issues other 23 than geographic considerations. Again socioeconomic disparities, finding suitable donors, lack of caregivers, 24 25 timely referral and evaluation of bone marrow transplant

services were thought to be as important as geographic and
 driving times. And adding programs again will not improve
 these access barriers and their solution is outside of the
 scope of the SAC, which just concluded.

5 So we did take formal votes on Charges 1 and 2, 6 and both of them received a 10 to 2 vote to continue to 7 regulate autologous and allogeneic bone marrow transplants.

8 Now, the most difficult but probably the most 9 important work the SAC accomplished was in developing and debating alternative methodologies for CON regulation. As 10 mentioned, the majority of the committee did not feel that 11 12 these services should be regulated by a cap and that another 13 methodology should be presented to the CON Commission that was rationale. It was obvious that geographic distance, 14 geographic considerations and driving distances would 15 16 preclude new interest facilities, but it was also felt that existing providers should be held accountable. And I really 17 do want to commend the work of two physicians on the panel, 18 19 Doctors Akhtar and Yanik, for working hard to develop objective alternatives from different perspectives for your 20 consideration. 21

22 One I would -- I look at as from a provider-based 23 approach; the other is from a State-need approach. And both 24 of these are in your packet. Appendix C is Dr. Akhtar and 25 Dr. Yanik is appendix 4A and 4B.

But basically Dr. Akhtar has four steps to his 1 2 methodology, and the detail is in his PowerPoint. Step one 3 is to review the state tumor registry cases, and then step two is to calculate the percentage of those likely to need 4 5 to be transplanted. In other words, everyone with multiple 6 myeloma, which is probably the most common indication for 7 a -- will not need a transplant. But for each of the 8 diseases, each of the cancers, there's a percentage. Then 9 the third step is the applicant institution could look at their tumor registry using that State derived percentage, 10 calculate how much volume they have at their institution, 11 and importantly they could also use other hospitals that 12 13 commit their volume to their institution. And if this volume was greater than 30 cases per year, then the 14 applicant could be designated as a bone marrow transplant 15 16 center. Now, all of the requirements the State has right now in terms of accreditation would still apply if they were 17 given the opportunity to be a new center. And Dr. Akhtar --18 19 and I think correctly noted -- his methodology is more consistent with other CON regulated services and that it 20 moves from a cap to an institution specific cases. And 21 22 there are other examples of those he gave in his 23 presentation.

24Then we looked at Dr. Yanik's proposal. I'll call25it a needs based methodology. And again that's appendix 4A

and B. And there are four steps and three tiers which he 1 2 has. One was to assess the performance of existing 3 transplant centers versus national standards. So basically what we're doing is comparing Michigan percentages to the US 4 5 percentages. And then a very low threshold, if the State is 6 less than five percent lower than the national average, in 7 other words, the unmet need, then we would go to step 8 tier -- tier two. We would assess availability of 9 transplant services at existing bone marrow transplant centers using two objective criteria; time to referral to 10 consult, which I believe was less than 28 days, and time to 11 referral to receipt of sample for HLA typing, which is 14 12 13 days. And if the centers are unable to meet both metrics, then you flow to the third criteria, which is similar to Dr. 14 Akhtar's fourth criteria. But we demanded a -- he suggested 15 16 using a three-year average volumes of more than 50 bone 17 marrow transplant cases per year.

18 So Dr. Yanik believes this forces existing 19 institutions to show superior to national performance in both volumes and availability and that a new applicant 20 institution could support the volumes making it cost 21 22 effective. Now, the State pointed out that we don't currently measure tier two measures. All institutions don't 23 currently have them, but they could all go -- they all could 24 25 provide that on a going forward basis. And it was thought

we shouldn't make judgments on a year-to-year basis but
 should use a three-year time frame.

3 A subcommittee looked at some data from transplants in Michigan about what happened once Spectrum 4 5 opened a hospital, a bone marrow transplant facility in 6 2013, and there was a suggestion that this didn't affect 7 volume on the east side of the state but volume on the west 8 side of the state increased. And there are numbers in your 9 packet showing this. However, another institution 10 volunteered at our final meeting that they were losing volume to both the west side and to the east side 11 institutions. And I think Dr. Yanik will want to talk about 12 13 that.

So again many of the observations that we made are 14 15 similar to ones we already had on Charges 1 and 2, and most 16 believe that, irrespective whether an institution or a needs 17 based approach was adopted, that costs would not go down as 18 we'd have another institution that would need to pay for 19 fixed overhead, compete for more highly trained personnel, accreditation costs. A minority felt a competition would 20 ensue, but most felt this was unlikely. And is not 21 22 supported by what we see in our paid claims data, and this 23 is coming from the trust. It was mentioned that maybe we could jumpstart quality by having a mentor from one of the 24 25 existing institutions go to the new institution, should that

be approved, but that would only approve the access for those patients going to the new facility. And again even for patients transferring from committed sister or system hospitals, the same socioeconomic factors would not be addressed.

6 And so the full committee considered both 7 proposals. And Dr. Akhtar's proposal was defeated by an 8 8 to 3 vote, and Dr. Yanik's proposal was approved by a 9 to 2 9 vote. And the State didn't think we needed to comment on 10 Charge 6. So that is basically a summary of what we 11 completed.

DR. KESHISHIAN: Thank you, Bruce. First I want to thank you for chairing this SAC. It was a lot of work, so thank you very much. Questions from the Commissioners? Commissioner Mukherji?

16 DR. MUKHERJI: Thanks. Very nice report. How 17 many states currently have BMT regulated?

18DR. BRUCE CARL: Five; sometimes I see six.19DR. MUKHERJI: Five to six? And you mentioned20four states; New York, Indiana, Maryland, Ohio. Were those21regulated or unregulated states?

22 DR. BRUCE CARL: Two were regulated, two were 23 unregulated.

24DR. MUKHERJI: Okay. So whether or not things25were regulated or not, you did hit the sweet spot, if you

will, of one site per two million? 1 2 DR. BRUCE CARL: Seemed to be the math. 3 DR. KESHISHIAN: Any other questions? 4 MR. FALAHEE: Commissioner Falahee. Again thank 5 you for all the time for you and all the members of the SAC. 6 It's not easy. The formulas or the methodologies that were 7 presented, were they reviewed by, let's call it, an 8 independent body for their rationale, holes in the argument, 9 pluses or minuses? I know there's some report in here 10 about -- and I'll get them mixed up -- the first methodology, I think there was an MSU report about that. 11 But what about the second one? 12 13 DR. BRUCE CARL: Well, the only one that we had time to look at was Dr. Akhtar's methodology. I did not 14 15 include it in your packet because we didn't have the chance 16 to look at Dr. Yanik's, so I didn't think that was 17 appropriate but it is available. 18 MR. FALAHEE: Okay. Thank you. 19 DR. BRUCE CARL: And maybe you have it. I don't 20 know. MR. FALAHEE: We do not have. 21 22 DR. BRUCE CARL: I'm glad to give it to you. MS. GUIDO-ALLEN: Guido-Allen. I have just a 23 couple of questions. Did the SAC take into account what the 24 25 national trends are and how many of the states that are

unregulated with -- or are regulated have a cap? What's the 1 2 level of regulation? 3 DR. BRUCE CARL: None of the states that have a 4 cap -- none of the states that have a CON regulation use a 5 cap. 6 MS. GUIDO-ALLEN: Okay. None? 7 DR. BRUCE CARL: None. 8 MS. GUIDO-ALLEN: Okay. And then when 9 Spectrum -- there was a question about quality decreasing or diminishing the new programs open. Did we as a state see a 10 diminished quality in the patients receiving bone marrow 11 transplant when Spectrum opened? 12 13 DR. BRUCE CARL: No. MS. GUIDO-ALLEN: Okay. 14 DR. KESHISHIAN: Okay. Commissioner Falahee? 15 16 MR. FALAHEE: James Falahee again. I forgot to I see where back in 1986 we said there will be three. 17 ask. 18 Now you said there are five. How did we get from a max of 19 three to allow five, if you know? 20 DR. BRUCE CARL: I believe Spectrum was given 21 approval somehow in 2012. I'm not exactly sure how. DR. KESHISHIAN: This is Commissioner Keshishian. 22 And my understanding is that in 2012 the CON Commission made 23 a decision to divide the state in half to allow one on the 24 west side of the state and to continue with three on the 25

east side of the state. I think the five is because of
 Children's versus Karmanos and DMC and all that relationship
 it was my --

That's correct.

UNIDENTIFIED SPEAKER:

5 DR. MUKHERJI: This is Mukherji. In the states 6 that are regulated versus unregulated, you say only five 7 states or six states are regulated and the majority of the 8 states are not regulated. And I'm sure -- and I don't know 9 the bone marrow quality metrics as well as others on the SAC 10 would. Is there any perceived difference in the quality in 11 states that are regulated versus unregulated?

DR. BRUCE CARL: Not as far as I know. I know we 12 13 have many experts here that will be glad to voice their opinion about that. I know -- I just know everyone from my 14 15 understanding has to have FACT accreditation every three 16 years or five years, whatever it is. So as far as I know, 17 there's no difference that I know about whether they 18 maintain their FACT accreditation, therefore have a minimum 19 level of quality, if that's the correct way of saying it.

20 DR. KESHISHIAN: Commissioner Brooks-Williams? 21 MS. BROOKS-WILLIAMS: Yes. I just want to clarify 22 with the Department or maybe with our chair. What exactly 23 are we being asked to take action on today? We don't have 24 the language right?

25

4

DR. KESHISHIAN: This is Commissioner Keshishian.

We do not have language today. The understanding that we have is that we will direct the Department what we want them to draft language over the summer and to present to us at September's meeting.

5 MS. ROGERS: And this is Brenda. Just to clarify, 6 the reason you don't have language today is because the 7 methodology that was voted on and approved by the SAC was 8 presented at their very last meeting. So it did not give 9 us -- and due to the timing of this Commission meeting, 10 there was not enough time to draft and thoroughly vet 11 language to be able to give to you today.

MS. BROOKS-WILLIAMS: Thank you.

12

DR. MUKHERJI: So this is Mukherji. Can I just follow up on that? You're saying that the -- how much time -- when these two methodologies were presented and eventually voted on, how much time was given actual for deliberation at that SAC?

18 MS. ROGERS: Do you want to answer that, Dr. Carl,19 or do you want me?

20 DR. BRUCE CARL: Yeah. I think we knew the more 21 certain outlines of Dr. Akhtar for three, four months. And 22 Dr. Yanik had presented a preliminary version also around 23 the same time. And we saw the final versions before the 24 last SAC meeting in May. But I think the details were 25 circulated well in advance. Everyone had time on the 1

15

20

committee to look at them and make their own judgment.

2 DR. KESHISHIAN: Any other questions? MS. GUIDO-ALLEN: Guido-Allen. I have one more 3 question. The data on the volume that since Spectrum opened 4 5 their volumes have increased, Henry Ford has seen an 6 increase, I believe U of M has seen a slight decrease. Did 7 the SAC discuss -- what was happening with the patients who 8 were seeing more of an increase than a decrease at the 9 sites, but where were those patients going for a bone marrow transplant prior to having another center available to them 10 or were they not? Was there any discussion about that? 11

DR. BRUCE CARL: Yeah. You know, probably a majority of them were going to the planning area one or the eastern sites, some of them were going outside the state.

MS. GUIDO-ALLEN: Out of state?

DR. BRUCE CARL: Down to Chicago, maybe down to Indiana. We do learn -- we do know that a majority of our UP residents don't go to Michigan centers. Most go over to Wisconsin.

DR. KESHISHIAN: Any other questions?

21 MS. KOCHIN: This is Commissioner Kochin, and I do 22 have one more question. And I appreciate the thought that 23 went into the report. And thank you again for leading this 24 SAC and all the experts and other participants in the SAC 25 for helping us sort out the options that are presented to us

today. My question is about the question of access. 1 And I 2 understand access is not an easy question as outlined in 3 this summary report, because there's so many factors when thinking about access. But can you tell us a little bit 4 5 more about why the two options, as I understand them, on the table do not include a geographical component in the 6 7 proposed methodology? Or correct me if I'm wrong. But I 8 didn't see that in either of the proposed methodologies.

9 DR. BRUCE CARL: Yeah. Well, we had looked at Dr. Delamater's study early, which was a study from 2010. And 10 since the volumes hadn't increased a lot by now, we relied 11 on the results of the study. And we were, not unanimously, 12 13 but pretty much convinced that driving time was not a burden for most of the citizens in the state outside the UP. 14 We 15 even had letters from oncologists from Up North, Traverse 16 City I believe, saying that access was not a problem for 17 their patients. But when you hear the stories from the oncologists about why their patients aren't getting bone 18 19 marrow transplant and probably could benefit from one, a lot of this flows to the status of the individual. And so --20 but we made a judgment. If we were to use drive times, 21 22 geographic, then that would automatically preclude some of the centers we heard that wanted to have transplant centers 23 from being considered. So we chose -- we obviously were 24 25 aware of the driving distance and geography, but we tried to

1 find methodologies that would let new entrants come about if 2 there was a real need.

3 MS. KOCHIN: Based on needs today? This is4 Commissioner Kochin.

5

6

DR. BRUCE CARL: Yes, based on need today.

MS. KOCHIN: Okay.

7 DR. KESHISHIAN: Any other questions? Thank you. 8 I have five cards. I think I heard we're out of cards. So 9 if you want to make a public statement, either let Beth know 10 or give a sheet of paper to somebody to add in. So I will 11 take them in alphabetical order now. Brett Jackson from the 12 Economic Alliance.

13 MR. BRETT JACKSON: Well, good afternoon. My name is Brett Jackson, president of the Economic Alliance for 14 15 Michigan. I came up here to support the SAC's 16 recommendation to continue regulating bone marrow transplant 17 services. We believe the services that we have here in Michigan here today do offer very high quality services 18 19 compared to national benchmarks and relatively low cost according to the same national benchmarks. We think that 20 any of the methodologies would still need some work, not 21 22 just some language drawn up but some probably fine tuning, some work with the Department to see what and if -- if all 23 of the parts of the methodologies could be enforced by the 24 25 Department or are fair to the Department to be considered in

their enforcement processes. We also want to make sure that 1 2 any methodologies don't put a future entrant at the mercy of the current providers. So we think that there's still more 3 4 work to be done. We think the SAC did an excellent job, and 5 probably the experts on the SAC are fantastic physicians. 6 But in terms of crafting the methodologies, you know, 7 probably could use some more time and some assistance to 8 have something that is a little more workable through the 9 CON process.

DR. KESHISHIAN: Are there any questions? I have a basic question. These last comments, what do you perceive to be happening? Do you perceive that the couple commissioners would get together with the Department? Do you perceive that we would ask Dr. Carl to get together with the Department? What are you talking about there?

16 MR. BRETT JACKSON: Well, I'm never one to tell17 the Commission what to do.

DR. KESHISHIAN: Well, I'm just asking you youropinion.

20 MR. BRETT JACKSON: Right. You know, I think 21 there are a number of people in the audience even searching 22 out some third party help like Dr. Delamater or folks from 23 MSU School of Geography to -- you know, who helped craft the 24 hospital bed methodology to figure out how best to move 25 forward. You know, I think that there is a philosophical

choice to be made by the Commission. Does the Commission 1 2 feel that a statewide needs based methodology like the 3 hospital bed methodology where you're assigning need, you know, based on where patients are coming from is right for 4 5 bone marrow transplant or a facility based methodology, 6 which you see in a host of other services? And I think 7 that's really the decision that the Commission needs to 8 wrestle with first and then figure out a process, whether 9 it's a work or process, whether it's going to outside consultants, to figure out how to then implement that type 10 of methodology with the guidance that the SAC put forth, 11 what kind of -- you know, here's some of the variables to 12 13 take into account. 14 DR. KESHISHIAN: Okay. Thank you.

MS. GUIDO-ALLEN: I have a question. This is Guido-Allen. But you said that the Michigan's quality data is above national benchmark. Can you share some of that data with me?

19MR. BRETT JACKSON: I think you'll find that in a20future presentation.

21 MS. GUIDO-ALLEN: Okay. Not doubting that the 22 citizens are receiving quality data, but I'd like to see 23 that we exceed national benchmarks.

24DR. KESHISHIAN: And follow up on that. We also25have heard that it's lower cost. Do you have data on that?

MR. BRETT JACKSON: I think that's also coming in
 a future here.

3 DR. KESHISHIAN: Okay. All right. Thank you.
4 Any other questions for Brett?

5 MR. BRETT JACKSON: But it was sure -- it --6 those -- that information was shared with the SAC broadly 7 and then through the SAC to the public.

B DR. KESHISHIAN: Okay. Great. Dr. Peres from
Henry Ford Health System.

10DR. EDWARD PERES: Good afternoon Committee11members. Thank you for giving -- letting me serve on the12SAC Committee. And again I want to commemorate Dr. Yanik13and Dr. Akhtar for putting together their methodologies.

There was a review in regards to Dr. Akhtar's 14 15 methodology that Dr. Delamater had sent to us in regards to 16 that review. Dr. Yanik's methodology was -- because of the 17 time frame to put it together and the hard work he did was 18 not reviewed, but the methodology that was reviewed again 19 did not -- again as one of the Committee members had discussed, based on a geographical access. But really the 20 BMT access in regards to infrastructure cost within the 21 22 state is really not very highly received. There's really been no significant increase in center specific numbers. 23 24 And with the formation of the Spectrum system, there's 25 actually been a decrease in the Ann Arbor Health System's

numbers. We continue to educate physicians in regards to 1 2 referrals, and it's really based on the socioeconomic status of the patient, the ability to find donors and center 3 specific outcomes in the ability to do transplantation. I 4 think the Committee has to understand this is a very 5 6 specialized service in regards to outcomes and morbidity and 7 mortality our patients undergo unfortunately. But again the 8 ability to do -- continue to do clinical trials improve the 9 outcomes in regards to the complications our patients undergo is what I strive to do and continue to do that. And 10 allowing deregulation, I think, would dilute not only center 11 specific numbers, but dilute the quality that each center in 12 13 the state of Michigan continues to strive for.

DR. KESHISHIAN: Any questions?

14

MR. FALAHEE: This is Falahee. Doctor, help me understand the socioeconomic issues that were discussed within the SAC. I've read it, and I under- -- I read what was said in the report, but I need to understand the issue better.

20 DR. EDWARD PERES: So the socioeconomic status in 21 regards to a patient who undergoes especially allogeneic 22 transplant, they rely on a caregiver, they rely on 23 transportation, they rely on the ability to obtain very 24 costly medications for immune suppression. So the ability 25 to do transplantation in a given patient, one has to have

those services available. So a caregiver to provide 24/7 1 2 care within the first 100 days of transplantation, the 3 ability to get the coverage of their medications, the medication in regards to an agent like -- such as Prograf 4 5 which is one of the immune suppressions which is about 6 3,000, \$4,000 a month, the ability for transplantation. So 7 we see our patients post-transplantation three to four times 8 a week; the ability to get visiting nurses to their home, 9 cleanliness of their home, other services that the patient requires once they've undergone the transplantation. So 10 there's a lot of caveats in regards to getting our patients 11 to transplant. We have a whole team in regards to social 12 13 workers, nurse practitioners, pharmacists who work very diligently to provide these services. But again the ability 14 15 of a patient to get to transplant really relies on their 16 socioeconomic status and the ability to have those services provided to them. 17

18

MR. FALAHEE: Thank you.

19DR. KESHISHIAN: Thank you. Any other questions?20Joe Uberti from Karmanos Cancer Center.

21 DR. JOSEPH UBERTI: Well, I'd like to first thank 22 the Commission to allow me to comment on the SAC I was part 23 of. You know, we were charged with developing a needs based 24 methodology for stem cell transplantation, which is actually 25 very difficult. If you look at the article that Dr.

Delamater wrote even just talking about that, he said "maybe 1 2 transplant isn't the ideal situation to develop a needs based methodology." It's a very complex procedure. 3 There's very few transplants done in the state of Michigan. 4 And 5 with the mortality as high as 50 percent in the first year 6 of a transplant, it's a difficult thing to think about how 7 to expand safely.

8 You know, the SAC did look at several issues 9 pertaining to transplant. First we looked at the geographic 10 distribution of transplant centers throughout Michigan, and we found out and we wrote an article on this that was 11 12 actually better than most states in the country right now. 13 Currently 71 percent of patients in the state of Michigan 14 live within a one-hour drive to transplant centers. And a one-hour drive is a benchmark of how well patients can get 15 16 through the transplant with all the issues that occur with the transplant, and we're really better than most states 17 around the country right now in terms of our geographic 18 19 distribution of transplant centers. But I do agree geographic -- geography is an important role in how patients 20 get to transplant. 21

22 Secondly, the SAC looked at transplant volumes 23 specifically looking at southeastern Michigan. Five years 24 ago in 2011, there are 548 transplants done in southeastern 25 Michigan at the three transplant sites. In 2015 there are

555, so we increased by seven transplants over the last five 1 2 years. We projected out this year based on the first five months of this year, and we're going to go down to 550 3 transplants. So really over the last six years, there's 4 5 been no increase in transplants in southeastern Michigan. 6 Each center indicated they had excess capacity. Each center 7 wasn't full. Each center indicated they have no waiting 8 list to get patients to transplant. We currently have hepa-9 filtered beds in our transplant unit, very expensive beds that have been re-purposed not for transplant patients but 10 for patients with lung cancer, breast cancer, colon cancer, 11 which is good for those patients but was a high cost output 12 13 of beds for patients that we can't fill with the type of patients that should be in those beds. 14

You know, in the previous SACs, we did look at 15 16 geographic distribution of transplant centers, and we looked to identify a needs based methodology. And certainly the 17 18 Grand Rapids area needed a transplant center, and it really 19 was an ideal place to put a transplant center because they had an up and running transplant center for ten years in the 20 pediatric population. So the infrastructure was already 21 22 built up there. They had much of the outlay to build a transplant center, so it was an ideal place to put another 23 transplant center where there was a geographic need. You 24 25 know, we don't have waiting lists at our transplant center.

All centers expressed excess capacity in southeastern 1 Michigan, so it was difficult to say there was a unmet need in southeastern Michigan for additional transplant centers.

2

3

4 We did look at outcome analysis. And this is all 5 public knowledge, because this is all -- we're all graded yearly on our outcomes, and all of our centers do above 6 7 benchmarks of where we should be in terms of our transplant 8 outcomes. And that looks at allogeneic and unrelated 9 transplants. We've been above the benchmark at our center 10 now for the last eight years, I believe.

So just to summarize here, I think it's difficult 11 to develop a needs based methodology, and we did our best to 12 13 try to do that. And we tried to identify an unmet need for patients going to transplant, and we could not identify an 14 unmet need. I think for the patients in the upper part of 15 16 Michigan, they do have an unmet need of getting to 17 transplant centers. How do we work the SAC group in such a 18 difficult procedure where there's not many experts around, 19 where there's a shortage of BMT physicians? How do we get transplant services up to the upper part of Michigan? I 20 think that's the real issue here. 21

22 DR. KESHISHIAN: Thank you. Any questions? MS. GUIDO-ALLEN: This is Guido-Allen. 23 I have a 24 question. Based on the experience from Spectrum, my 25 question is, is there any research studies or any evidence

to show how many patients in Michigan opt not to proceed with bone marrow transplant because they're leaving their physician group, their homesteading for oncology care?

1

2

3

4 DR. JOSEPH UBERTI: That's a good question. We 5 tried to look at ways to try to get at that, and there's 6 really no easy way to get at that. And part of, I think, 7 Dr. Yanik's proposal will start looking at that. How do we 8 identify patients who will not come to a transplant center 9 for referral because of just what you said? You know, actually the transplant -- you know, and that could be more 10 important if somebody lives in Midland or Saginaw or 11 someplace further away. You know, it's hard to believe 12 13 somebody won't drive ten miles to come to a transplant center if that's what the distance is between where they are 14 15 and another transplant center.

MS. GUIDO-ALLEN: I'm just saying it may not be about distance.

DR. JOSEPH UBERTI: Absolutely; absolutely.
MS. GUIDO-ALLEN: It's the relationship with their
care teams.
DR. JOSEPH UBERTI: Yeah. There's many -- yeah.

22DR. KESHISHIAN: Okay. Any other questions?23Okay.24DR. JOSEPH UBERTI: Thank you.

25 DR. KESHISHIAN: Thank you. David Walker,

Spectrum Health?

1

2 MR. DAVID WALKER: Hello, again. Thank you again for the opportunity to speak. On behalf of Spectrum Health, 3 4 I wanted to lend our support to the BMT staff transplantations. You should have all received an e-mail 5 from Dr. Abidi, our medical director of our BMT program. As 6 7 a member of the BMT staff, he wanted to attend today's 8 meeting but was unable to due to responsibilities at the 9 hospital.

As he shared in his e-mail, Spectrum Health 10 11 supports the work of the SAC and methodology recommended. We do recognize that some work is needed to flush out the 12 13 details and have it ready for Commission action. And we would support having the Department work with the MSU 14 Department of Geography to do so, and we'd also support the 15 16 addition of a geographic component to the methodology, which 17 the MSU Department of Geography would be a perfect candidate 18 for creating that component. They have a tremendous amount 19 of experience in working on and improving methodologies in several sets of the CON standards and believe that they 20 would be helpful for this as well. Thank you very much. 21 22 DR. KESHISHIAN: Any questions? Thank you. 23 MR. DAVID WALKER: Thank you. DR. KESHISHIAN: Dr. Yanik, University of 24

25 Michigan.

DR. GREGORY YANIK: I'm Greg Yanik. I'm one of the bone marrow transplant physicians at the University of Michigan. And it's truly a pleasure to be here. I want to thank Bruce also for a great job.

5 I just want to start by saying that, in February 6 of this year, I drafted a needs based methodology that I 7 threw out. I found it too favorable to University of 8 Michigan. In March I drafted a needs based methodology that 9 I threw out because it was based on geographic distance and it was too favorable to the existing centers. I then 10 proceeded to talk to referring physicians around the state, 11 physicians around the country to ask what would be the 12 13 outcome of a needs based methodology, and they all came back with one comment: Start by asking are the existing centers 14 15 currently meeting the needs of the state and meeting 16 national standards? Are the existing centers providing high quality care that's cost efficient without any delays in the 17 service? Actually just for time, scroll down to the bottom 18 of this (indicating). By the way, do you see our transplant 19 numbers there? You can see at the University of Michigan 20 over the last five years our numbers have gone down by 50, 21 22 and that reflects an increase in 50 patients at Spectrum. 23 In essence, as Spectrum has ramped up by roughly 50 patients, we've lost 50 patients. The West Michigan area --24 25 Holland, Muskegon, Grand Rapids -- have accounted for 31

percent of our transplant referrals up until the Spectrum
 program opened. Now it's less than 10 percent of our
 referrals. In other words, our transplant population base
 just got shifted from Ann Arbor to Spectrum.

5 You can actually see the quality of care for services in the state. At the University of Michigan --6 7 that's the only data I'll present here -- you can see the 8 national averages for a one year survival for related donor 9 transplants is 73 percent, unrelated donor transplant 65 10 percent. You can see at the University of Michigan one year survival for related donors and unrelated donors. 11 Especially the unrelated donors, the toughest transplants, 12 13 we exceed the national averages.

And by the way, the next line underneath it, "How long are patients waiting to be seen?" At U of M, the median time from referral to appointment is 12 days. That's all comers from all ends of the state. The median time from referral to receipt of HLA typing is nine days. Again that's from all parts of the state.

20 Scroll back up for a second because Debra asked 21 this question:

"Will building another program in southeast
Michigan lead to duplicity in resources? Conversely,
how cost efficient are current transplant centers?"
So it's kind of split in half this table, but

you'll see our transplant billable charges and national 1 2 median average in the Milliman database in 2014 was 212,000 3 for autologous transplants at the University of Michigan was 185,000. Go to the next line if you can, Tania. So what 4 5 you can see there for allogeneic transplant services, median cost nationally of 479,000, we split it at U of M to sibling 6 7 donor/related donors and unrelated donors. You can see that 8 we're very cost efficient compared to national averages.

9 What I can tell you is this. Currently in the 10 state the existing centers are offering high quality care 11 that's cost efficient without any delays in services. I 12 worked hard to develop this needs based methodology. I 13 believe that it's at least reasonable. It's based on, A, 14 performance of the existing centers, are we meeting national 15 standards --

16 DR. KESHISHIAN: If you can start wrapping up, I'd 17 appreciate it.

DR. GREGORY YANIK: This is my last line. Are we 18 19 meeting national standards? The second tier of the methodology was to hold our centers accountable. How long 20 is it taking to get patients in to transplant and get that 21 22 HLA typing done? And then the third part of the tier based methodology I built is based on is there another center that 23 24 has the volume to support the services? And I think all 25 three of these are important. Are the existing centers

meeting national standards, can we hold ourselves accountable and is there centers that also have that (inaudible)?

By the way, I'd just like to end by one question 4 5 that was asked about the CON versus non-CON states and 6 comparing the quality of care, outcome data and charges. Ι 7 actually asked this. I went to the CIBMTR economic task 8 force and asked for that data. It's never been given. It's 9 never been done. I actually talked to several CIBMTR members and asked how come. They actually are going to it 10 sounds like appoint me to lead a task force to look for 11 outcome data and costs in CON regulated states versus 12 13 non-CON regulated states. You can ask the question of us --Bruce didn't know the answer, nobody knows the answer 14 15 because it hasn't been looked at. By the way, I'd like to 16 look and thank Bruce. Bruce did a fantastic job running this SAC, and I can't thank him enough. 17

18 DR. KESHISHIAN: Okay. Thank you. Any questions? 19 MR. FALAHEE: This is Falahee. I appreciate you throwing out programs that were either too favorable to 20 column A or column B. When I first read this, I was 21 22 thinking of the classic Calvin & Hobbes cartoons where 23 Calvin would always come up with different rules depending on the game so that he would win. So I appreciate that. 24 25 The last one you came up with, the one that we have in the

1

2

SAC report and that you discussed in the appendix, that went to the last SAC Committee meeting; is that correct?

DR. GREGORY YANIK: You know, it took me -- it 3 took me, Chip -- literally in February I spent a good deal 4 5 of time developing a needs based methodology and, in the 6 end, I just said, "You know what? This is going to be seen 7 as so favorable to U of M. People will see right through 8 it." And then in March I looked at one that was really 9 based on geographic distance, and that's when I started talking to people and realized that, you know, the 10 availability access for transplant services should be built 11 on a lot more than just geographic distance. You know, as 12 Joe Uberti has commented several times, is eight -- is ten 13 14 miles really a barrier? No. The barriers to transplant are 15 a lot more than just geographic distance. And I think Dr. 16 Peres said a lot of that. You know, it's the actual ability of a patient to physically drive to get there. One of the 17 interesting things that -- and have the resources to come 18 19 back and forth.

20 One of the interesting things that happened as a 21 result of the SAC has not been commented on yet, and that's 22 the fact that Jennifer Barish and myself -- Jennifer Barish 23 is an MBMT link -- we actually came up with a plan. In 24 fact, I just want to read you one thing here. This is from 25 the Delamater article that hit -- Paul actually reviewed the 1

2

Beaumont methodology. And I don't know if you have this document from March? He actually stated the following:

"From our understanding of the scientific 3 literature, the unmet need for BMT services is not (and 4 5 will not be in the future) driven simply by a lack of 6 facilities providing BMT but by the lack of appropriate 7 human resources and infrastructure necessary to provide 8 BMT services. BMT provision may be considered a zero-9 sum game such that an increase in capacity in one place 10 can only be gained via a decrease in capacity in another place." 11

So what Jennifer Barish and myself did, we 12 13 actually came up with the idea for a web-based portal that 14 would actually use -- that would actually link all the 15 existing transplant centers -- using her group also, the 16 NMBT (sic) link -- with non-transplant centers so that you have easy access to just say, "I'm going to click on the 17 University of Michigan." Here's who to call, here's who to 18 send the HLA typing to so that now you don't have to look 19 "You know what? I'm going to send this patient to 20 around. Karmanos." Here's who to call exactly. You know, here's 21 22 their coordinator. Here's how you get the HLA typing in. We'd also build in that portal an edu- -- we'd also build in 23 an education site for patients, for referring physicians. I 24 25 actually think the lack of access is not based on geographic

It's a lack of awareness by referring physicians for 1 need. 2 who should go to transplant and when. The delays in coming 3 to transplant are based oftentimes on the delay in the referring physician even realizing that that patient should 4 5 go to transplant. The ability to develop this web-based 6 portal may actually be a very good education tool for 7 referring physicians. I would ask you this: I don't think 8 that we should put emphasis on building another program in 9 the state. We should put emphasis on increasing physician awareness and building something creative like a web-based 10 portal. 11

12 DR. KESHISHIAN: Any other questions? 13 MS. GUIDO-ALLEN: One statement. Deb did 14 submit -- Jennifer Barrett submitted a letter saying, quote: 15 "Sometimes we must look beyond quality, cost and 16 access to determine how we can save more lives. 17 Whatever the right answer or answers might be, I know that we must continue to put the patient first." 18 And speaking on behalf of nursing as a patient advocate, how 19 many patients -- again my question -- how many patients, not 20 referring physicians, but patients, will not leave their 21 22 care team that they have spent their entire oncology journey with to go -- whether you can click on a site or not, they 23 don't want to leave that fold, that trust that they've 24 25 developed, those relationships and connections that they've

made?

1

2 DR. GREGORY YANIK: So, Brenda, I --3 MS. GUIDO-ALLEN: No, I'm Debbie. 4 DR. GREGORY YANIK: Oh, Debbie. Sorry. That's 5 right. Debbie, Beth, Brenda. Debbie, I appreciate that. I 6 met with two families from Beaumont in the last two months, 7 and both had the same comments to me not about services that 8 we provided. We obviously transplanted both families, and I 9 was taking them to lunch because it was their one-year patient anniversary. By the way, just the fact that we do 10 things like that, take patients to lunch or dinner, says a 11 lot, I think, for how we care about our patients. But what 12 13 both families actually said was the following in terms of this issue. They said we don't want to go where care is 14 convenient. We want to go where care is optimized. A 15 16 center that has transplant services has not only the transplant trained physicians, but they have transplant 17 18 trained pharmacists, infectious disease specialists, 19 surgeons, physical therapists, nutrionists, everybody who's trained on taking care of those patients. And I -- and to 20 quote -- I mean, I could give you a name, but I won't for 21 22 this HIPAA violation. This gentleman was very in -- this gentleman -- they live in Royal Oak -- were very exact about 23 the fact that we will not go where transplant is convenient; 24 25 we will go where transplant can be optimized at all levels.

1 They will do anything it takes.

2 I actually thank the gal from Midland that was on the committee. She talked to her referring physicians in 3 the Midland area to see if they felt there was an access 4 barrier for their patients in the Mid-Michigan region, and 5 she said no. As Bruce said, a physician in Traverse 6 7 City -- a physician group in Traverse City sent a letter 8 stating just that fact. They did not feel there was a 9 barrier for physician ac- -- for transplant services or access for their patients. That's two groups, the group in 10 Midland and the group in Traverse City both stating the same 11 thing. I talked to Ed Smith up in St. Ignace/Petoskey who 12 13 said the exact same thing, that he did not feel that their patients had a barrier on access issues. 14

DR. KESHISHIAN: Any other questions? I have a few questions. You have data here for the University of Michigan, both cost and survival. Do we have data from the other transplant units in the state and --

DR. GREGORY YANIK: Well, Joe actually -- Joe Uberti actually showed data on -- specifically on survival outcome. I think we are the ones that have the most data on the cost because I actually took the time to get it, Marc.

DR. KESHISHIAN: Okay.

23

24 DR. GREGORY YANIK: It took a fair amount of work 25 as you can see just to generate this paper. And Joe

1

2

3

4

5

actually did provide all of his cost data (inaudible) from -- Spectrum talked about their cost analysis as did Ed Peres. I did not feel that I had the purview to put all of their cost data on there, for example, or --

DR. KESHISHIAN: How about quality?

6 DR. GREGORY YANIK: You know, again Ed share -- or 7 Joe, for example, showed slides that had their outcome data. 8 And I guess you could bring Joe up. If he had his slide, he 9 could actually say here was our outcome data. In fact, 10 their outcome data was actually incredible. I'm not going 11 to quote the numbers. You can turn and ask Joe the numbers.

12DR. KESHISHIAN: Yeah, I will. And -- well, let13me refer to Joe and then Dr. --

DR. JOSEPH UBERTI: And I realize I forgot to introduce myself. I'm Joe Uberti with Karmanos. I run the BMT and key malignancy program there. And I also -- I'm also president of the Michigan Society of Hematology/Oncology which represents about 95 percent of the physicians in hemonc in the state.

20 So, you know, we get -- we get -- when I look at 21 quality and I think when most people look at quality is 22 outcomes analysis. I'm sorry. I think when we look at 23 quality, we look at quality in terms of outcomes analysis. 24 How many people are alive? How many people are dead? So 25 every year we get a report from the CIBMTR which tracks us

amongst all of the other transplant centers in the country, 1 2 and they give you a risk adapted outcomes analysis; that is, 3 you bring a bunch of sick patients and the transplants are good patients and the transplants. When we looked at our 4 5 data, we were one of only six centers who had above the 6 percentage of what we'd expected to create two standard 7 deviations over our survival compared to what we should 8 have. So we were only one of six centers in the country 9 when we looked at this.

10DR. KESHISHIAN: What year was that and was that11for both related and unrelated?

DR. JOSEPH UBERTI: The first was just for 12 13 unrelated, which is the most difficult transplant, and more 14 recently they've included the related and unrelated. These 15 are on the web sites, so every -- you know, it's kind of 16 hard to see, but it's all there on the web sites from the CIBMTR. So there's a lot of ways to look at quality. You 17 know, we talked about the FACT accreditation a lot as a way 18 19 of looking at quality. But one thing FACT does not look at are outcomes. So FACT looks kind of at the paperwork you 20 The CIBMTR actually looks at outcomes. So you can be 21 have. 22 a great FACT program on paper and have lousy outcomes. So 23 we go by outcomes more so than FACT accreditation, because we're all FACT accredited. And I think Dr. Carl may have 24 25 mentioned that all centers are FACT accredited. Actually

all centers aren't FACT accredited. So some centers do
 continue to survive without being FACT accredited; not many,
 but some do.

DR. KESHISHIAN: And a follow-up question. 4 Ι 5 mean, you're president or past president of the Michigan 6 Association of Hematologists and Oncologists. I am amazed 7 that oncologists are referring patients late in the disease 8 process for a transplant, but yet -- I mean, help me 9 understand that. Because it's life saving, but yet -and -- do you ever discuss this at the Michigan Society of 10 Hematologists and Oncologists? If they are late, why are 11 they being -- why are they late? 12

13 DR. JOSEPH UBERTI: Well, I think we as a group try to educate referring physicians about when should be --14 15 when patients should be referred to us. I think one of the 16 issues is the age issue, and I think people have some mind blocks saying anybody over the age of 60 can't be 17 transplanted. So now as we all get older, we're going to 18 19 say, yes, let's transplant us so we can be cured. So now we transplant patients up to 80. So one thing is the age. 20 They can't get over the stumbling block of age is an issue 21 22 of going to transplant. And the other thing is that -- you know, one of the things, there are more new medications out 23 there for all the diseases we transplant for. So although 24 25 these medications aren't curative, they do keep the disease

under control in our patients. So sometimes there's a delay because they're going through a list of medications which aren't curative. And we've argued that's probably not the way to do -- and to work in these patients if they do have curative therapy. So I think there's a lot of different issues that prevent them from coming on time.

7 DR. KESHISHIAN: Do you see the delay -- and this 8 is to both of you. Do you see the delay differently within 9 people within your own systems versus people from out of 10 your systems?

DR. JOSEPH UBERTI: You know, that's hard to say 11 because I don't know -- I don't know what the denominator 12 13 is. All I see are the patients who get referred to me. So I don't know if there's a million patients out there who are 14 15 not referred to me because they don't want to come to us. 16 All I see is the patients who are referred to me. I mean, quite frankly, in our own system I have arguments about 17 taking patients to transplant, too, with some of our 18 19 colleagues, so there's even delays within our own system. There is differences of opinion of where transplants should 20 be placed and some of the treatments of these patients. So 21 22 even within our own system, sometimes a big argument about 23 when to go to transplant in these patients.

24 DR. GREGORY YANIK: In our system, we're actually 25 surprised by the inter-physician variability and the time to

referral to transplant for leading diseases like AML in
 particular. And it does seem to be inter-physician
 variability. That's within our own system at the University
 of Michigan. Thus education even within our systems is
 needed.

6 DR. KESHISHIAN: Okay. Thank you. I don't know 7 if Mr. Walker or Dr. Peres can talk about Henry Ford's data 8 and/or Spectrum's data on quality?

9 DR. EDWARD PERES: Yes. So -- I'm Dr. Peres from 10 Henry Ford Hospital. So our -- the data that's published in 11 CIBMTR was presented to the SAC in regards to unrelated and 12 related donor transplantation, that our outcomes continued 13 to be above the national average with one standard 14 deviation.

15

DR. KESHISHIAN: Okay.

16 DR. EDWARD PERES: And the other thing that I 17 think I'd also like to mention in regards to careers as 18 transplanters, it's really changed in regards to the 19 patients we're taking to transplant. I mean, the age, in regards to the median age, I think on all centers now has 20 really increased. You know, it used to be around 55, 56; 21 22 now we're in the 66 median age range. In regards to the co-23 morbidities that these patients comes with, it makes it much 24 more difficult to manage the immune suppression in regards 25 to their co-morbidities and the transplant outcome. But with

the advent of reduced intensity, we are able to offer 1 2 transplantation to a patient population that was underserved previously. With that said, it doesn't mean that 3 transplantation of these elderly, more co-morbid patients is 4 5 any easier. So I think that speaks to every center since 6 the age has also increased and degree of -- or the 7 difficulty in doing these transplants to remain above 8 national averages at all centers is really a good thing. 9 DR. KESHISHIAN: Okay. Thank you. And, Mr. Walker, can you --10 MR. DAVID WALKER: Unfortunately I don't have that 11 data in front of me, but I'd have to look it up for you. 12 13 DR. KESHISHIAN: Okay. Thank you. MR. DAVID WALKER: Thank you. 14 15 DR. KESHISHIAN: Dr. Akhtar, Beaumont. 16 DR. ADIL AKHTAR: Thank you very much. I want to 17 thank all the SAC members and especially thank Dr. Carl. I 18 can tell you that he has a lot of patience. He had to 19 control a bunch of real passionate people and, I think, did 20 a great job. So all the scientific argument has been made. I 21 just wanted to review a few things which I think are 22 important before we make the final decision. And I would 23 like to focus here and Commission -- Commissioners and the 24

Department present to really pay attention to, you know,

25

1 what I'm going to say here.

2 So when the SAC was announced, it was my 3 understanding that the SAC was charged to look at the national trends for CON regulation for the BMT programs. 4 5 And we learned that only four to five states still regulate 6 the BMT services by CON. The other charge was looked at 7 other services within the state of Michigan and bring CON 8 regulation of the BMT to be in line with the methodologies 9 covering other services. And then the third one was to develop a methodology, which is evidence based, science 10 based and not cap based. 11

So based on that, we developed a methodology very early on in the process of the SAC discussion, and that was a institution and need based methodology which we think is in line with other CON covered services, and that methodology would not give any undue advantage to one or few institutions.

18 At the end of the SAC, it was voted that the three 19 tier methodology is more favored. And the three tiered methodology creates restrictions based on the performance of 20 the existing programs and not based on the patient's needs. 21 22 If you look at the three tiered methodology, the tier one 23 and two put in place after the permanent defacto cap on the 24 numbers of programs which will make sure that there will 25 never be another transplant program in the state of

Michigan. Tier one and two also put all the control in the 1 2 performance of existing programs to determine what is good for the citizens of the state of Michigan, which personally 3 I have never seen in any of the CON regulation. In my 4 5 opinion, if we adapt the three tiered methodology, this will 6 be the most restrictive and anti-competitive regulation in 7 the CON history. I think this is the responsibility of the 8 CON Commission and also the Department of Health and Human 9 Services to not adapt this methodology in its present form.

10 What I have proposed looking at the three tiered 11 methodology was to reverse the order of the tiers. I think 12 the tier one should be the methodology and then thus a 13 transplant program is approved or a new transplant program 14 is approved. Then tier one and two should be the quality 15 measure by which the state can measure a -- the progress of 16 the new transplant program.

17 I also wanted to clarify some numbers, which were 18 discussed in relation to the Spectrum Health bone marrow 19 transplant program. And we looked at the zip code discharge data. And in that data, all the transplant -- all the 20 patients who are transplanted were included both who are 21 22 referred inside the state or were referred outside of the state. And it was -- and since we have two service areas in 23 the CON Commission regulations, so we looked at east side 24 25 area where most of the transplant programs are and the west

side where we have the Spectrum Health program. And what we 1 2 saw is that there was a net increase in transplant -- in the 3 number of patients who are new to the transplant technology or treatment by a number of between 35 to 40 patients net on 4 the west side of the state and between 50 to 60 on the east 5 side of the state. And I see what Dr. Yanik had made a 6 7 point about that the University of Michigan lost 50 8 transplants and they were gained by Spectrum Health. But 9 what he did not say is that the additional net gain was present, and was present at the Henry Ford bone marrow 10 transplant program which was discussed in detail. The other 11 clarification that I would want to make is that, yes, our 12 13 methodology was reviewed by Dr. Delamater, but I would caution that Dr. Delamater has written papers with the 14 15 existing transplant program faculty members. So in my 16 opinion, when he reviewed the methodology, he was already 17 conflicted. If we have to have review done, the review should be done by a totally neutral third party and both 18 19 methodologies should be reviewed. Thank you very much.

20DR. KESHISHIAN: Thank you. Any questions?21Commissioner Tomatis?

DR. TOMATIS: Commissioner Tomatis. You mentioned the Spectrum numbers decreasing in Ann Arbor. Why won't it happen the same with a new center in Beaumont with the east transplant centers?

DR. ADIL AKHTAR: So my point is not that there 1 2 was a net transfer of patients from west side of the state to east side of the state. My point is that there was a net 3 gain of transplant patients both -- on both side of the 4 5 state. That means these patients were not being 6 transplanted before. These are not the patients who were 7 referred out of the state. These were present in the state 8 of Michigan and were not being transplanted. Now, this is 9 my third time here over the last ten years. You can tell 10 I'm very persevering. And every time we have brought the same discussion and every time the Commission has made the 11 same mistake -- or same -- apologies -- same decision. Now, 12 13 suppose we are varying towards the side that we should not let any other program open, and there are actually patients 14 15 who are then dying because they're not being transplanted in 16 the existing transplant centers. I would request that this 17 time we err on the side of the patients and see if, by 18 opening up another program, there will be another net gain 19 in the number of patients transplanted.

20 DR. TOMATIS: Excuse me. But you mentioned that 21 it was increase in the east -- in the west side but the 22 total in the state -- even with that case, it kept 23 decreasing. How do you intend to increase on the east now?

24DR. ADIL AKHTAR: So from our numbers, the total25numbers have not decreased actually. Total numbers continue

1

2

to increase in the state of Michigan. And we can supply that data. That data is public information.

MS. KOCHIN: This is Commissioner Kochin. 3 Can I ask a follow-up question to that? And I apologize putting 4 5 you on the spot. This is just a general question I've had 6 in reviewing all of these different data tables on the 7 number of cases in the history of the state of Michigan. We 8 seem to be a little bit, in my opinion, biased in terms of 9 how we're interpreting those results, because it's always what happened after the Spectrum facility gained the ability 10 to BMT transplants. But I'm wondering, have you been able 11 to isolate other factors that may have went into the 12 13 increases or decreases of numbers over that time period in 14 the state of Michigan such as general age of our population, 15 increases or decreases in the number of patient lives that 16 are here in the state of Michigan, et cetera? It seems as if we are making some conclusions without a lot of facts 17 18 behind those case numbers.

DR. ADIL AKHTAR: So we actually provided to the SAC a lot of data. So in 2010-2011, national marrow donor program started a program called BMT 2020. And their main premise is that nationwide there is an unmet need for BMT services, meaning that there is a gap between patients who should be transplanted and patients who are actually being transplanted. And they have done this work nationwide but

also statewide. And in the state of Michigan, this is the 1 2 national marrow donor program. They have proposed that in the adult population there is an unmet need of between 2- to 3 300 transplants. So what are their reasons? They are still 4 5 studying the reasons. Some of the reasons which have been 6 discussed is leaving the primary team going to a strange 7 team. Number two, the socioeconomic situation. So in terms 8 of the socioeconomic situation, I have provided a paper 9 which have made a statement that it is not anything else, 10 but what it looks like is that in minority population there is a lack of referral for advanced technologies like bone 11 marrow transplant technology. So that is another factor. 12 I 13 think we provided another paper which looked at the data of 14 major health systems and then they open up a transplant 15 program, their referral increased and the timing of the 16 transplant, late versus early, also improved. So it's a 17 multifactorial thing, and it's all, you know, published 18 data.

19

MS. KOCHIN: Thank you.

20 DR. TOMATIS: We create the SAC to advise us. Why 21 didn't you make these arguments in the SAC and came back 22 with a conclusion that we could accept?

23 DR. ADIL AKHTAR: I did. But nobody wanted --24 DR. TOMATIS: And you talked to the SAC and the 25 SAC didn't change their mind. Either your argument was not 1

as strong as now or they had argument to prove the contrary.

2 DR. ADIL AKHTAR: I mean, you can look at it two 3 I mean, there is a deep divide in the SAC, because ways. there are two philosophies here as the gentleman from 4 5 Economic Alliance said very well. I think so the 6 philosophical divide is -- so I am -- I was a part of the 7 bone marrow transplant team at Karmanos for several years, 8 and now I'm a (inaudible) doctor. So I've been on both 9 sides of the equation. So when I was at Karmanos, it is --10 it's a different world that's not the, I would say, the real world. Now I'm on ground every day diagnosing leukemia 11 patients, myeloma patients and treating them and referring 12 13 them. So now I can tell you that my philosophy is that I'm 14 here representing my patients, because I see what my 15 patients go through every single day to get to a transplant 16 center. I am a bone marrow transplanter, so I early -- I start the process of bone marrow transplant very early on in 17 the process. But majority of the general medical 18 19 oncologists or hematologists are not subspecialized BMT trained, so that's why sometimes you have late referral and 20 sometimes no referral at all. So the divide is that, in my 21 22 opinion, there's an unmet need, and the best methodology 23 would be to adopt a institution based methodology, which is 24 nonrestrictive and which is fair to every place and to all 25 the patients. But again I was voted out because, you know,

- 1
- we did not have enough votes.

2 DR. KESHISHIAN: Commissioner Falahee? 3 MR. FALAHEE: A couple questions, Doctor. I'm not 4 a statistician or a mathematician. That's why I became a lawyer. But when I look at the formula that was put 5 6 together where it says: 7 "Applicant institution will then multiple its 8 tumor registry cases by the percentage derived above, 9 an applicant would also be able to use volume committed." 10 Doesn't that mean that the larger you are, that begets the 11 necessary number? So is that just size related? If you're 12 13 big enough, you get it? DR. ADIL AKHTAR: Yes and no. Yes in the sense 14 15 that, if you have higher volume, you will have more 16 potential transplants, and no in the sense that there are certain institutions who do more of the BMT indicated 17 disease treatments. So their overall volume may not be that 18 19 big. But since they see more leukemia patients, they may be able to qualify. 20 21 MR. FALAHEE: Another question. Somewhere in the report they talked about a program that used to be, I think,

22 report they talked about a program that used to be, I think
23 at Oakwood for BMT that closed down. You may not know,
24 but --

25

DR. ADIL AKHTAR: I know, because I was a part of

that program.

1

2 MR. FALAHEE: Okay. Why did it close down? How 3 did it start and what happened to make it close down? 4 DR. ADIL AKHTAR: So I don't know how it started, 5 but the leadership at Oakwood changed, and they basically decided that BMT is a low volume service and they didn't 6 7 want to stay in that -- in the BMT area. That was number 8 one. And number two, at the time there was a theory that 9 may be able to offer a part of this transplant for breast 10 cancer. So that would have increased the volume of BMTs tremendously. So one of the reasons could be that, once the 11 studies proved negative, that increased volume never 12 13 happened. But it wasn't due to the lack of quality or availability, though. 14 15 MR. FALAHEE: Thank you. 16 DR. MUKHERJI: This is Mukherji. How did it In other words --17 start? 18 DR. ADIL AKHTAR: The Oakwood program? 19 DR. MUKHERJI: Yeah. How did --20 DR. ADIL AKHTAR: I wasn't there. DR. JOSEPH UBERTI: I was part of it. So it 21 22 actually partnered with the University of Michigan at the 23 time, so University of Michigan had some administrative and 24 position roles over the transplant program at Oakwood. So 25 we were part of the -- part of that. And I think it went

before the CON Committee actually at the time that they 1 2 started. Now -- and I know -- and I know -- it brings up a 3 good point that Dr. Akhtar was talking about. This is the problem with a needs based methodology. That was built on a 4 5 needs based methodology that there will be a lot of 6 transplants for breast cancer. So any needs based 7 methodology is dependent upon the fact that nothing changes 8 in the treatment of these diseases, and that's the 9 difficulty. Our transplants actually at Karmanos for breast cancer went from 200 to zero in the course of two months --10 course of two years. So that's the difficulty in using a 11 needs based methodology to decide how many patients will go 12 13 to transplant. Not only do indications change, but new therapies change minimizing the effect of needs of 14 transplant for certain diseases. As an example, right now 15 16 if we look at multiple myeloma, it's the number one disease we can transplant for. So if tomorrow we find a new drug --17 and there's many new drugs for multiple myeloma -- we're 18 19 going to go from 110 transplants a year to zero. So that's the difficulty in using a needs based methodology. You 20 know, all the data that Akhtar is -- Dr. Akhtar is talking 21 22 about is really theoretical data. As an example, there's a theoretical unmet need by the National Marrow Donor Program 23 of patients who don't get to transplant, but that does not 24 25 take into account their underlying disease, what their

socioeconomic status is, what the co-morbid conditions are. 1 2 None of those are taken into account. It's just based on a 3 percentage of the patients with the disease. So it's really an over estimate of if there are patients out there who 4 5 don't need a transplant. So this is a very complicated 6 issue. And remember this is a procedure which can have a 50 7 percent mortality in the first year. I mean, when you 8 expand a procedure like that, you have to be sure that you 9 really have an unmet need. Are there really patients who aren't being transplanted because they don't want to come to 10 us? Because that's really out there. You know, we tried to 11 find a number of that, and it's very impossible to find that 12 13 there are patients who really won't travel 10 or 12 miles to 14 get a transplant for a curative procedure. You know, I'm 15 sure there are some out there. There's no doubt about it. 16 But how do you help that when it's a procedure -- number one, a very difficult procedure to go through; number two, 17 there's no transplant physicians available. If you look at 18 19 the system in Grand Rapids, it took them two years to hire a transplant physician. Are you going to ask you guys to do 20 the --21

DR. KESHISHIAN: Yeah. Let's -- we need to move
on.
DR. ADIL AKHTAR: Can I just make one point?

25 DR. KESHISHIAN: Yeah.

DR. ADIL AKHTAR: So both the methodologies which 1 2 were discussed in the fact, they are either need based or 3 institution based. So ours is actually both need based and institution based. And again I will respectfully request 4 5 the CON Commission to look at the restrictive nature of tier 6 one and tier two and make that as a quality accountability 7 measure for a new transplant program and pay more attention 8 to tier three.

9 MR. HUGHES: Commissioner Hughes. Would it not be 10 theoretical to assume that, if there was sufficient volume 11 at Oakwood, it wouldn't have closed?

DR. ADIL AKHTAR: So again it's tough for me to 12 13 say just because it's so many years, number one, and, number 14 two, the leadership had changed. And the hematological 15 volume was there. And to be very honest with you, the 16 hematological volume has been stable or increasing in not only in the state of Michigan but also nationwide, because 17 basically the breast cancer volume, which did not 18 19 materialize because of the negative (inaudible).

20 DR. GREGORY YANIK: I was at the University of 21 Michigan when Oakwood had their program, so I saw some of 22 the issues. One of the issues they faced -- this is, again 23 Greg Yanik. One of the issues that Oakwood faced was the 24 difficulty in having adequate support staff personnel at all 25 levels to be able to handle such patients. I mean, Oakwood

has excellent physicians. But in terms of transplant team
personnel, it's incredibly a specialty experience. And you
just have to think about this as you deliberate over things.
Not where is transplant in 2015, but where is transplant
going to be in 2025?

6 DR. KESHISHIAN: Excuse me. We're going to have 7 to stop this. I mean, I've allowed it a couple times. I'm 8 going to ask that only if somebody -- if a Commissioner asks 9 somebody to come up and provide an answer to a specific 10 question rather than another three-minute statement. Thank 11 you. Okay.

Patrick -- are there any other questions for Dr.
Akhtar, because he was still on the stand and we -- not the
stand but answering questions. Did you get your question
answered?

16MR. HUGHES: (Nodding head in affirmative)17DR. KESHISHIAN: Okay. Patrick O'Donovan.

MR. PATRICK O'DONOVAN: Good afternoon. I'll be very brief, because a lot -- I'm Patrick O'Donovan from Beaumont Health. And I'll be very brief, because a lot of the points or things that I was going to emphasize when I put in the card have been made by Dr. Akhtar and others. So I'm just going to summarize.

I really thank the Commission. I know this is the third time through this and really appreciate the 1 2 presence -- the patience and the willingness of all the Commissioners to carefully consider this.

Again just to -- you know, just to recap. You 3 know, very few states regulate. I think that there's -- in 4 5 the discussions we've had even among the SAC and others in 6 the Department that the current cap is not acceptable 7 approach going forward. We did propose a need methodology 8 that's been discussed. If there are any specific questions 9 about the need methodology itself that we've proposed, I'd 10 be happy to answer those. We do believe that, for the reasons Dr. Akhtar mentioned that -- you know, including 11 tier one and two is really an extension of the cap, and it's 12 13 a de facto cap. It replaces one cap with another kind of cap. You know, we would ask the Commission to ask the 14 15 Department to develop language based on the methodology we 16 proposed. It was similar in concept to the tier three that Dr. Yanik proposed. And if there are, you know, 17 recommendations the Department has with regard to technical 18 19 edits or any thresholds, I think it's important that we put the methodology forward. We did not suggest, when we 20 initially presented it back in February, a specific 21 22 threshold number. Our hope was that that would be a 23 discussion and consensus developed among the SAC, but that didn't -- you know, it didn't end up that way. So as I 24 25 said, I'd be happy to respond to any questions.

DR. KESHISHIAN: Are there any questions?
 DR. MUKHERJI: Just one question. How big is
 Beaumont now? Because I know they've had all the mergers.
 What's the state of the system?

5 MR. PATRICK O'DONOVAN: Beaumont is eight 6 hospitals and is now the largest health system in the state 7 and is, you know, based in south Michigan. All eight of our 8 hospitals are in southeast Michigan and, you know, have a 9 very, very large cancer program. And, you know, essentially, you know, the -- you know, Henry Ford 10 appropriately treats patients that are within their system 11 primarily, and we're looking to be able to do the same thing 12 13 using a needs based methodology that is really based on other CON standards that have been developed. It uses -- we 14 15 use the PET standards as a model.

DR. KESHISHIAN: Any other questions? Thank you.Okay.

18 MS. NAGEL: On behalf of the Department, I have 19 some comments for your consideration and discussion. First, the Department strongly supports a methodology in these 20 That was one of the things that we recommended a 21 standards. 22 year ago in January. Recent history, longer than that, we have always recommended deregulation of this service. 23 So 24 absent that, we believe that there should be a methodology 25 that can expand to meet the needs of Michigan citizens.

That said, we do have some significant administrative issues 1 2 with the methodology that was passed by the SAC with the three tiers, particularly the first two tiers. And I can go 3 into those issues if you'd like, but we believe that, not 4 5 only did we not have enough time to put this in language for the Commission to consider, there are so many unanswered 6 7 questions that we sought out the advice of the attorney 8 general who said we shouldn't put into language things that 9 we can't fully administer. So we have some significant problems with that. We would suggest that we work with our 10 contractor MSU Geography, which does contract with Dr. Paul 11 Delamater who's been to the Commission several times before 12 13 to develop something that would be in the spirit of what the SAC recommended but would also be something that is within 14 the spirit of CON and can be administered by the Department. 15 16 That said, I would like to mention that it is true Dr. Delamater has written papers on bone marrow transplant and 17 has used some of the experts in Michigan, because those are 18 19 the experts in Michigan, and made conclusions based on data. We do not believe he is conflicted in any way. 20 DR. MUKHERJI: This is Mukherji. Did I hear you 21 22 say correctly the Department favors deregulation? 23

MS. NAGEL: We have --

24 DR. MUKHERJI: For how long?

25 MS. NAGEL: At least the last three times that this has come up, so the last nine years we have asked for
 deregulation of this service.

3 DR. KESHISHIAN: This is Commissioner Keshishian. 4 After all this discussion, the Department still recommends 5 deregulation?

6 MS. NAGEL: In this case, I would say we are 7 recommending a methodology, however, our initial has always 8 been deregulation.

DR. KESHISHIAN: Okay.

9

10 MS. NAGEL: And this information is the same 11 information that you hear at -- have heard at every single 12 SAC for the last nine years. So it's not new information to 13 us to inform the stance of deregulation.

14DR. KESHISHIAN: Okay. Thank you. Discussion15among the Commissioners? Commissioner Hughes?

16 MR. HUGHES: Commissioner Hughes. I guess this is 17 kind of the classic why we're here CON case, and typically 18 you have the haves and the have nots, but our charge is to 19 look at access, quality and cost. And I have not been convinced that we have an access problem. I haven't been 20 convinced that our costs are too high, and I'm a free market 21 person and certainly this is not a free market treatment 22 because of the cost of it. People aren't paying for it with 23 24 their own money. And when you look at the quality, our 25 quality is good. So I don't understand what -- putting

another specific location in an area where that's already 1 2 well served. Yeah, I would love to go to my own doctor for 3 everything, but every health care system can't be the best in everything and sometimes you have to drive a little bit. 4 5 You talk about the people in the other areas of the state 6 having to make a trip to get some special care. Health 7 care -- now for a family costs over \$16,000 a year for 8 health insurance. Employers typically pay in 75 percent of 9 that, employees pay in 25. We can't continue to ignore the cost component of it. Here we have access, we have quality 10 and we have good costs. Adding another duplicate facility 11 on top of what's already there is not going to help all 12 13 three of those. So if this isn't what CON is all about, I don't understand why we would do something like this. I 14 15 vote to keep the standards as is, but -- oh, excuse me. No. 16 I do think just an arbitrary cap is wrong. I think a good methodology going forward that uses geographic components 17 18 makes a lot of sense.

19DR. KESHISHIAN: If you're making a motion, that's20fine. If not, we can continue to have discussion. Any21other discussion?

MS. GUIDO-ALLEN: Guido-Allen. So I'm on the flip side. So I look at it from the patient's perspective. I look at all the other states that don't regulate and then the five states that do regulate that do not have a cap.

The Department has over the past number of years said 1 2 deregulate. I'm not convinced about the quality, the cost 3 or the access, because I don't have any data. And apparently we don't collect very much data. So from the 4 5 patient's perspective, from the nursing being the patient's 6 advocate's perspective, I would suggest listening to the 7 Department with deregulation or coming up with a methodology 8 that is not based on current existing programs, quality 9 standards or performance and access, but truly a methodology 10 that addresses the citizens in Michigan and what access they have to a program that is high quality. 11

DR. KESHISHIAN: Any other comments?

12

13 MS. KOCHIN: This is Commissioner Kochin. I'd 14 just like to weigh in on this, because I think this is such 15 a weighty topic for us to consider. I land somewhere 16 between the two commissioners that just gave their 17 perspectives in that, from a Certificate of Need standpoint, 18 I do think that our primary charge is to consider the cost, quality and access of all of these different services in the 19 state of Michigan. And from what I've seen, it doesn't 20 appear as if we have an issue around cost and it doesn't 21 22 appear as if we have a issue around the quality of those services that are currently being delivered. There does 23 appear to be a little bit of difference of opinion in terms 24 25 of access. It really depends on how you define access. And

from a state of Michigan perspective, I would hope that, as 1 2 part of whatever the proposed methodology is, that it considers both a geographic factor as well as other 3 considerations. Some of that's a little bit harder for 4 5 method, good methodology and public policy to meet, I 6 understand. But thinking about not patients from a facility 7 standpoint but from a state of Michigan standpoint is 8 something that I would be in favor of, especially patients 9 who don't currently have easy access to the facilities that are currently able to perform these services. I know that 10 that's a small segment of our state, but it's something that 11 we shouldn't just overlook. If you're talking about 70 or 12 13 80 percent of the state, there still is a percentage of individuals who really don't have access nor is it likely 14 that there will be an institution who is able to perform 15 16 these services in a location that's convenient for them. But definitely from a state of Michigan approach, I favor a 17 needs based methodology of some sort rather than an 18 19 arbitrary cap. Now -- thank you. That's my opinion. DR. KESHISHIAN: Any other comments? 20 MS. BROOKS-WILLIAMS: This is Commissioner Brooks-21

Williams. I just would like to follow up on that to say then, as you look at the methodology from a geographical perspective if we're going to define access, that we are using some sort of distance or something that speaks to the

fact that it's not access in the sense of I have to be able 1 2 to go where my provider is, but it really is geographical 3 access. Because I would agree that we know we have gaps in the state as it relates to that. And we as a Commission 4 5 clearly may not be able to do anything about it, but it 6 would be nice for it to be at least stated as a goal as we 7 go forward and therefore, if we do have other coalitions, 8 institutions or ways that we might be able to fill that, 9 we'd have guidance around what that looks like.

DR. KESHISHIAN: Commissioner Falahee?

10

MR. FALAHEE: A comment, and then I know 11 12 Commissioner Mukherji wants to make a comment. Because then 13 I would get this moving with a motion on the floor. But CON 14 has always been a balancing act between, you know, what's 15 best for a patient. One could argue that what's best for a 16 patient is every hospital should offer every service so that every patient can never have to leave that hospital system. 17 On the flip side, you have CON that looks at quality, access 18 19 and cost and tries to balance that, because we know for a lot of reasons not every hospital can be everything to 20 everybody. And it's a tough tug of war sometimes. I think 21 22 on this one, I personally support the idea of taking the 23 methodologies that were here and sending them to an independent entity -- and if MSU is that entity and believes 24 25 it's independent, I'm perfectly fine with that -- to look at

these to see if one of these will work, will a combination work, will a totally different one work to enable the Department to come up with language that can be enforced and appropriately applied. I'm totally fine with that. I agree that we should not deregulate, that we do need something other than a pick a number and the number was three 30 years ago. I think we need to get beyond that.

8

DR. KESHISHIAN: Commissioner Mukherji?

9 DR. MUKHERJI: Yeah. Just to encapsulate 10 everything, my thoughts, which is consistent with everyone else, I just look at it from a historical perspective. You 11 know, 30 years ago when the three winners were identified as 12 13 BMT, we were hospitals. And over the last 30 years we've 14 consolidated and hospitals have turned into health systems. And now -- and I'm not looking at a specific system, per se. 15 16 But even though Beaumont is the largest health system in the state, and I don't think their quality can be denied. 17 I'm 18 actually -- I didn't realize that the Department was for 19 deregulation. So on the one hand, I have the Department for deregulation. We also see a system where only five states 20 continue to have regulation of Certificate of Need. I don't 21 22 think there's any doubt that Karmanos and Ford and U of M and Spectrum and -- are providing terrific -- and Children's 23 are providing terrific care. That's well known. But having 24 25 said that, at the very least, we should have some type of

transparent methodology to replace some type of cap that was
 created in a far bygone era.

3DR. KESHISHIAN: Any other comments?4MR. FALAHEE: Falahee. The chairman is looking at

me like you better say something, so --

5

6 DR. KESHISHIAN: No. You had mentioned that you 7 were going to put a motion. Are there any other comments or 8 does somebody want to make a motion?

9 MR. FALAHEE: Falahee. I'll make the following 10 motion. That the Commission instruct the Department to work with an independent entity to analyze the methodologies that 11 were presented to the SAC, to look at the strengths and 12 13 weaknesses of those or the administrative issues with those. And if there are issues that mean either one or both of them 14 15 aren't adequate or enforceable, that the Department work 16 with that independent entity to come up with a new 17 methodology that would be presented to us at our next 18 meeting in September.

19DR. KESHISHIAN: Okay. We have a motion. Do I20hear a second?21MR. HUGHES: Second; Commissioner Hughes.22DR. KESHISHIAN: Okay. Any discussion?

23 MS. KOCHIN: May I ask a question? May I ask a 24 question before voting?

25 DR. KESHISHIAN: Uh-huh (affirmative).

MS. KOCHIN: Is the September time frame realistic 1 2 considering everything else that we've been weighing in on? 3 MR. FALAHEE: I prefer that --4 MS. KOCHIN: Could I ask the Department to 5 comment? MS. NAGEL: You know, I think that we can 6 7 certainly come back with an update and something to discuss 8 in September. We could have some leeway to move it to 9 December, if necessary, that would be wonderful. 10 MR. FALAHEE: I will happily amend my motion; September, if possible. 11 DR. KESHISHIAN: Any other discussion? Do you 12 13 accept the friendly amendment? MR. HUGHES: Yes, sir. 14 DR. KESHISHIAN: Okay. Good. 15 16 MS. GUIDO-ALLEN: One more discussion. Sorry. 17 Guido-Allen. We already have a letter from -- I don't know 18 if it's Dr. Delamater or -- Dr. Delamater, and he already 19 weighed in on the methodologies. So is there a way to take it back to his group but also have another independent group 20 also look at it? Because he's already weighed in. 21 22 MS. NAGEL: He weighed in on one methodology but not the other. The other one was presented at the last 23 meeting, and the Department didn't have it before that last 24 25 meeting. So he only weighed on the one in February.

1	MS.	GUIDO-AI	LLEN:	So	just	one	methodology?
2	MS.	NAGEL:	Yes.				

3 DR. KESHISHIAN: Okay. Any other comments? 4 Questions? Okay. Let's take a vote. All in favor raise 5 your right hand.

~		
6		

(All in favor)

DR. KESHISHIAN: All opposed? Motion passes.
Thank you very much. Moving on to the next item. Elizabeth
is here. Legislative Update Report. Thank you.

10 MS. HERTEL: Elizabeth Hertel from the Department 11 of Health and Human Services. There isn't much to report except we will speak with the Legislature. They've 12 13 completed their business for the summer. The competence reports were signed by both chambers, which had no effects 14 financially on the allocations for the CON program or how 15 16 we're spending those. The only other action that we've seen 17 having -- pertinent to the Certificate of Need Commission is 18 that Rule 741, the statutory deregulation of the dentist CTs 19 which has passed (inaudible) Policy Committee and awaits action in the Senate Chamber dependent on the actions of the 20 CON Commission. Since they -- the Legislature won't be back 21 until -- for action until after Labor Day, we'll wait to see 22 based on their reactions to the actions of the Commission on 23 what happens to that bill. And that's all that we've seen 24 in the last few months. 25

DR. KESHISHIAN: Okay. Administrative Update,
 Beth?

3 MS. NAGEL: Yes. We -- if you recall that in your January planning meeting you asked for the -- a SAC for 4 5 nursing home and hospital long-term care units, and we tried -- gave a -- had a SAC nomination period which we did 6 7 not get enough nominations. And so we have formed a 8 workgroup, and the workgroup dates have been posted on the 9 CON web site starting in July. You also requested in 10 January a Lithotripsy Standard Advisory Committee, and we are still working to seat that SAC. 11

DR. KESHISHIAN: Okay. Thank you. Tulika, CONEvaluation Section Update?

MS. BHATTACHARYA: So there are two reports in your packet. In the Compliance Report, as you can see, we continue to monitor the approved projects and follow up with respect to the deadlines for completion and to make sure that the projects are being implemented within the appropriate time frame or allow them extended time if they justify those extension.

As far as the compliance activities, we have concluded the statewide review of all the open heart surgery services, and all of the settlement agreements have been completed. We have also closed out the air ambulance service reviews that we had started. There was one pending

appli- -- investigation that we were able to justify -- or 1 2 they were able to demonstrate that they do meet all the project delivery requirements, so we have closed out that 3 file. We are in the process of doing the investigation --4 the statewide review of the little on cardiac cath 5 6 facilities. I expect to provide you with an update at the 7 next meeting. There were two service specific compliance 8 actions. One was related to PCI service and the other one 9 was related to MRI.

And the next report are the activity reports where that gives you an idea about the volume of applications that we process, and again we continue to meet that statutory timelines for those processing. So if you have any questions, I'd be happy to answer.

DR. KESHISHIAN: Okay. Thank you. Legal Activity
Report, Joe's not here.

MS. ROGERS: This is Brenda. You do have awritten report in your material.

19DR. KESHISHIAN: The rest of 2016 meeting dates,20September 21st, December 7th. Any public comment at this21point? I don't have any cards. Review of Commission Work22Plan, Brenda?

23 MS. ROGERS: This is Brenda. You do have the job 24 work plan in your packet. So the only changes that we'll be 25 making based on today's decision making is, for BMT, we will

be working with other individuals to come up with a 1 2 methodology based on the two methodologies or a new methodology depending on the outcome of all of that with a 3 goal of providing language in September, if not September, 4 5 then December. And then for psychiatric beds and services, 6 since the amendments were accepted today, we will schedule 7 public hearing and then bring those comments and language 8 back to you in September for final action. Having said 9 that, those will be the only changes unless any other Commissioner changes. Thank you. 10 11 DR. KESHISHIAN: Any discussion? We need to take action on it. Do I hear a motion to approve the work plan? 12 13 MR. HUGHES: Motion to approve the work plan as submitted. 14 DR. KESHISHIAN: 15 Second? 16 DR. MUKHERJI: Mukherji, second. 17 DR. KESHISHIAN: Any discussion? All in favor say 18 aye. 19 (All in favor) DR. KESHISHIAN: Opposed? And then adjournment. 20 Do I hear a motion for adjournment? 21 22 MR. FALAHEE: So motioned. MS. BROOKS-WILLIAMS: Second. 23 DR. KESHISHIAN: All in favor? 24 25 (All in favor)

1	(Proceedings concluded at 1:37 p.m.)	
2	-0-0-0-	
3		
4		
5		
6		
7		
8		
9		
10		
11		
12		
13		
14		
15		
16		
17		
18		
19		
20		
21		
22		
23		
24		
25		