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## MEASURE APPLICATIONS PARTNERSHIP

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## HOSPITAL WORKGROUP IN-PERSON MEETING

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FRIDAY

DECEMBER 9, 2016

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The Workgroup met at the National Quality Forum, 9th Floor Conference Room, 1030 15th Street, N.W., Washington, D.C., at 9:00 a.m., Cristie Upshaw Travis and Ronald S. Walters, Co-Chairs, presiding.

Washington DC

**PRESENT:** 

CRISTIE UPSHAW TRAVIS, MSHHA, Co-Chair RONALD S. WALTERS, MD, MBA, MHA, MS, Co-Chair GREGORY ALEXANDER, PhD, RN, FAAN ANDREA BENIN, MD, Children's Hospital Association AKIN DEMEHIN, American Hospital Association WOODY EISENBERG, MD, Pharmacy Quality Alliance DAVID ENGLER, PhD, America's Essential Hospitals ELIZABETH EVANS, DNP\* LEE FLEISHER, MD FRANK GHINASSI, PhD, ABPP KIMBERLY GLASSMAN, PhD, RN, NEA-BC, FAAN, Nursing Alliance for Quality Care MARTIN HATLIE, JD, Project Patient Care JENNIFER EAMES HUFF, Mothers Against Medical Error MIMI HUIZINGA, MD, Premier, Inc. JEFF JACOBS, MD, The Society of Thoracic Surgeons\* JACK JORDAN HEATHER LEWIS, MS, MBA, Geisinger Health System MARSHA MANNING, University of Michigan R. SEAN MORRISON, MD ALLEN NISSENSON, MD, Kidney Care Partners SARAH NOLAN, Service Employees International Union ANEEB SHARIF, Service Employees International Union KAREN SHEHADE, MBA, Medtronic-Minimally Invasive Therapy Group BROCK SLABACH, MPH, FACHE, National Rural Health Association ANN MARIE SULLIVAN, MD\* MARISA VALDES, RN, MSN, Baylor Scott & White Health\* LINDSEY WISHAM, BA, MPA WEI YING, MD, MS, MBA, Blue Cross Blue Shield of Massachusetts

NQF STAFF:

HELEN BURSTIN, MD, MPH, Chief Scientific Officer ANN HAMMERSMITH, JD, General Counsel MELISSA MARINELARENA, Senior Director KATHERINE MCQUESTON, Project Manager, Quality Measurement ELISA MUNTHALI, Vice President, Quality Management ERIN O'ROURKE, Senior Director DESMIRRA QUINNONEZ, Project Analyst ALSO PRESENT: HEIDI BOSSLEY, MSN, MBA REENA DUSEJA, CMS JOANN FITZELL MARLIS GONZALEZ-FERNANDEZ, MD, AAPM&R\* ROXANNE JENSEN, Georgetown University JOSHUA LAPIN WILLIAM LEHRMAN, CMS TARA LEMONS, CMS TIFFANY MCNAIR, CMS PAM OWENS, PhD, AHRQ\* DANIEL POLLOCK, CDC ALVERA RYAN BOB SHANER, American Academy of Pain Medicine DONNA SLOSBURG, ASC Quality Collaboration\* ASHLEY WILDER SMITH, PhD, MPH, NCI LISA SUTER, MD ANGEL VALLADARES, Avalere Health PIERRE YONG, MD, CMS

\* present by teleconference

## C-O-N-T-E-N-T-S

Welcome and Review of Day 1 6
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Opportunity for Public Comment
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(MUC16-178)
(MUC16-180)
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Measure of Quality of Informed Consent Documents
for Hospital-Performed, Elective Procedures
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and Medicaid EHR Incentive Program for Hospitals
and Critical Access Hospitals (CAHs) (Meaningful
Nutrition Care Plan for Patients Identified as
Malnourished after a Completed Nutrition
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Completion of a Malnutrition Screening within 24
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Patients Identified as At-Risk for Malnutrition
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1	P-R-O-C-E-E-D-I-N-G-S
2	9:02 a.m.
3	CO-CHAIR TRAVIS: Well, this is
4	Cristie Travis, for those on the phone. I want
5	to welcome everybody back today to Day 2. If
6	you're like me and it's your first time, it was
7	like drinking from a fire hose yesterday.
8	(Laughter.)
9	CO-CHAIR TRAVIS: We did cover a
10	number of different federal programs, so we got
11	to have a variety of issues that we were able to
12	discuss.
13	I also want to thank everybody for
14	working through the decision matrix,
15	understanding what we needed to do to give the
16	proper recommendations and guidance, both to the
17	Coordinating Committee for MAP and ultimately to
18	CMS. And I think we got into a really good
19	rhythm about understanding our four decision
20	categories and really working hard to be
21	consistent and to give the level of detail that
22	we needed to. So thank all of you for kind of

working through that with us.

2	It's the first time we've had this
3	particular decision category, and we have found
4	it does take just kind of actually doing it,
5	because things can look great on paper, but when
6	you have to make decisions, you realize there are
7	some nuances that you need to take into account.
8	So thank you very much for that.
9	We are excited about the programs
10	we're going to be covering today, which are
11	primarily IQR and value-based purchasing. And
12	then at the end of the day we will do like we did
13	yesterday and go through the current measure sets
14	for those two programs as well as the other two
15	that we haven't covered yet in terms of new
16	measures, because there weren't any new measures
17	coming forward.
18	So with all of that, I'm going to turn
19	it over to Ron.
20	CO-CHAIR WALTERS: Thanks again for
21	everybody's work yesterday. We really do
22	appreciate it. You make our job as chairs very

2	First thing is people that were not
3	here yesterday that are new today filling in for
4	someone, et cetera, et cetera, please introduce
5	yourself and disclose any conflicts that you
6	have. And I'm looking at Allen first.
7	MEMBER DEMEHIN: Good morning. I'm
8	Akin Demehin. I'm the Director of Policy at the
9	American Hospital Association sitting in for
10	Nancy Foster. Glad to be with you. No conflicts
11	to disclose.
12	CO-CHAIR WALTERS: Sorry. I said
13	Allen.
14	Is there anybody else? Going around
15	the table I don't see anybody.
16	CO-CHAIR TRAVIS: There was somebody.
17	CO-CHAIR WALTERS: Oh, yes.
18	CO-CHAIR TRAVIS: When he comes back.
19	CO-CHAIR WALTERS: Okay. We'll get
20	him when he comes back.
21	The second thing, you got a new
22	agenda, and that agenda is just about two minutes

1 old already. As you note on the agenda, on your 2 prior spreadsheet there was one measure for value-based purchasing, and then it was not on 3 4 the agenda you got yesterday. It is back on the 5 agenda now, the Communication About Pain. So we'll deal with that later on after IQR. 6 Just 7 wanted to get you thinking about that early in 8 the day. We also literally just found out about 9 it. The only other change I know about is 10 11 that we're going to -- yesterday Nancy asked a 12 question about the rationale of some of the 13 design of the IQR Program. So after PROMIS and 14 after the overview, before the public comment, 15 Pierre is going to give a high-level response to Nancy's question. We'll still go through the 16 17 measures measure by measure and not at the 18 measure level, but kind of what they were 19 thinking as far as IQR. 20 Okay. Not back yet. 21 All right. Well, then let's --Melissa, do you have anything you want to say? 22

1	MS. MARINELARENA: (No audible
2	response.)
3	CO-CHAIR WALTERS: Okay. We'll have
4	to catch up with the disclosure, I guess.
5	CO-CHAIR TRAVIS: We have a little bit
6	of time because we go into the PROMIS discussion.
7	We'll do it after PROMIS.
8	CO-CHAIR WALTERS: Yes, we'll do it
9	after PROMIS. Always grab time when you find it.
10	(Laughter.)
11	CO-CHAIR WALTERS: Always take those
12	So, Pierre, you ready to start the PROMIS
13	discussion?
14	DR. YONG: Absolutely.
15	CO-CHAIR WALTERS: Good. Thank you.
16	DR. DUSEJA: Okay. Good morning,
17	everyone. So we wanted to use the opportunity
18	today to talk about PROMIS. I think yesterday
19	there was a lot of discussion about patient-
20	reported outcomes, and our agency has been trying
21	to think about this. And we're really early on
22	in the process of how to think about PROs as it

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relates to quality measurement. So we wanted to 1 2 use the opportunity with this group to get your feedback on what we've been doing and to get your 3 4 input. 5 I'm going to hand off to our colleagues here from Georgetown and NCI. 6 And so, 7 this is Roxanne. And I'll ask you to take the 8 floor next. 9 DR. JENSEN: Hi, everyone. Thank you. 10 I'm -- my name is Roxanne Jensen. I'm an 11 assistant professor at Georgetown. And so, 12 Ashley Wilder Smith from the Outcomes Research 13 Branch at NCI was supposed to give these first 14 slides, but I'm going to wing it and we'll see how I do, hopefully. 15 16 All right. So to tell you a bit about 17 what PROMIS is, the acronym is Patient Reported 18 Outcomes Measurement Information System. And 19 what it is, it's a system of patient-reported 20 outcome selection and its way of administering 21 PROs in a brief way that's precise, valid and 22 reliable. And there's a lot of different ways

you can administer it. And the advantages are 1 2 that it goes -- not my slides. So some of the advantages of 3 Okay. 4 this type of administration of patient-reported 5 outcomes is that PROMIS is -- it goes across diseases, it's not disease-specific and yet it's 6 7 flexible and it has a lower patient burden and 8 has electronic and paper options. 9 And so how it was developed, it was 10 using a thing called Item Response Theory, which 11 is taken from educational testing and applied 12 into the health realm. And one of the benefits 13 of this is that you can have a lot of different 14 items in one item bank and you can build a survey 15 that best meets the population you're trying to 16 assess. 17 Okay. So I guess one of the main 18 concepts of PROMIS is that it is not disease-19 specific, it's not setting-specific, and so what 20 these questions are is that you develop a bank of 21 questions that measure a construct of health. And so it's a continuum. 22

1	So for example, fatigue. You have
2	items that measure fatigue and then from there
3	you select the items that you go into your
4	questionnaire or your survey.
5	All right. So IRT methodology is used
6	to develop something called an item bank, which
7	I've mentioned previously. And basically what
8	happens is that you take a number of candidate
9	items for a construct and then these are
10	evaluated and retained as long as they can
11	measure across continuums. So for something like
12	physical function, you're going to have a wide
13	range of content that goes from people who are
14	have difficulty getting out of bed, for example,
15	to people that are able to run a marathon. And
16	all of these items can be used interchangeably
17	within the short forms that are administered.
18	Okay. So PROMIS is a system, and
19	there are a lot of different topics that are
20	measured using it in physical health, mental
21	health and social health. And so, you can see
22	the wide range of content that is available. So

for example, you can get a short form in physical
 function, pain intensity, pain interference,
 fatigue, mental health. Same idea.

And you can see the ones kind of in 4 5 dark are the ones that are more commonly used as part of a profile. And they're used to kind of 6 7 map common symptoms and functional issues that 8 patients with chronic conditions may experience 9 to get kind of a full flavor of what's going on. And then the ones that are in the light shading 10 are more recent additions to the PROMIS kind of 11 12 library of options.

13 Okay. All right. So to reiterate -so I think one of the real benefits of PROMIS and 14 administering it is that there are really as many 15 16 options as you can imagine to administer. If you 17 have electronic capabilities, you're able to do 18 it electronically or using paper forms. You can use stuff that's available or you can create your 19 20 own short forms that are tailored to, say, a 21 specific population.

22

And then there's a lot of platforms

that are currently available. So REDCap for 1 2 example has kind of the common standard off-theshelf short forms that are available to 3 administer. And then also what's being developed 4 5 as part of the health measures. There's the API interface which allows for administration, say, 6 within hospital systems 7 8 My God, I --9 DR. SMITH: Should I just do it? 10 DR. DUSEJA: Well, okay. 11 DR. SMITH: Can I say one other thing 12 about that? 13 DR. DUSEJA: Yes, please do. 14 DR. SMITH: First of all --15 CO-CHAIR TRAVIS: Introduce yourself. 16 DR. SMITH: Yes, absolutely. 17 Apologies. Metro, unfortunately. 18 So just one thing to say relative to 19 availability, and this is going to come up at the First of all, there are links at the bottom 20 end. of this which we can of course distribute. 21 And 22 just so you know, this is being updated all of

the time because our availability just increases. And the main thing for your purposes that would be useful for you to know is that we are actually embedding these instruments in two different EHR vendors.

And specifically, Epic is the roll-out 6 7 for the 2016 version. It's getting updated 8 actually spring of 2017. So anyone who had an 9 update in 2016 will actually have both short And so, the PDFs that are listed there 10 forms. 11 and also will have computer adaptive testing. 12 And I'm not sure, Roxanne, if you 13 explained what that was, but I'll say a word or 14 two about it. So, sorry if this is duplicative. 15 16 What's really unique about this measurement set 17 is that it allows for the ability to assess from 18 a patient's perspective their health status in 19 ways that are very low-burden. And the computer 20 adaptive testing is something to think about

purposes in a variety of clinical settings

moving toward in the future for assessment

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because as it is being rolled out again in medical record through MyChart, et cetera, and Epic -- and then also we're in conversation with Cerner, and that should happen later this year as well, too. So again, you can see that this is sort of a -- we're really in a sea change in terms of availability.

8 But computer adaptive testing allows 9 you to ask a question based on the response to the prior question. So all of you who have 10 children who have recently taken standardized 11 12 tests or for whom you have gone back to school 13 and taken your own standardized test recently, 14 you've done it on the computer or they've done it 15 on the computer. And when they get a question 16 wrong, they get an easier question. When they 17 get a question right, they get a harder question. 18 And you hone in very quickly on a skill level. We've adapted the same kind of 19 20 methodology to health. So for example when 21 you're talking about physical function, if you ask somebody can you walk around the block and 22

they say no, you don't ask them, can you walk a 1 2 mile. You ask -- the next question is can you get out of bed? So you hone in very quickly to 3 4 the person's ability level based on the responses 5 that they had to the prior item. That's an important methodology for 6 7 you to know about because burden is a real issue, especially when one is thinking about rolling out 8 9 questions to patients across the country. So, and then the other thing I just 10 11 wanted to mention is that there is the ability to 12 -- and we can talk about this a little bit later 13 in the last couple of slides, but the metric that 14 I'm assuming that Roxanne covered a little bit, which is -- and she'll cover it a little bit more 15 16 in some detail about some data -- is it's a scale 17 between 0 and 100 and it has applicability across 18 health domains so you can get scores on each of 19 the different health domains. Regardless of the 20 number of questions that you ask you can get a 21 score. 22 So that computer adaptive test -- for

example, you could ask different questions to 1 2 different people, but still get that same score because you may not want to waste their effort on 3 4 questions that don't apply to them. 5 We also have the ability to actually 6 compare those scores to other kinds of patient-7 reported outcome measures that have been used 8 quite widely in the field. So those include 9 things like the SF-36, for anybody who is familiar with patient-reported outcomes, and many 10 11 The CESD for depression. others. There are a 12 number of other instruments. 13 So what happens is even when people 14 have been assessing using a different kind of assessment tool, they can compare it to the 15 16 metric and you can actually have scores that 17 apply to everyone regardless of what instrument 18 they've taken. So this is another piece I just 19 thought would be useful for you. 20 You want to go next? 21 DR. JENSEN: All right. Great. Now onto my slides, which -- thank God. 22

1	(Laughter.)
2	DR. JENSEN: Oh my gosh. All right.
3	Now, I'm a psychometrician, or at least a
4	practicing one, and so basically a lot of people
5	come to me and they say, oh, Roxanne, I want to
6	measure physical function. So now this is how I
7	approached these questions before when someone
8	would come to me. I would say, okay, so you want
9	to measure physical function. That's great.
10	All right. How detailed do you want
11	to get into it? I mean, is this just an overview
12	or you want to get really into like the
13	functional ability that people have? How much
14	space do you have on your survey? We all know
15	that's very precious and patient burden is
16	important. Who do you want to compare it to? I
17	work in cancer, so do you want to compare to
18	cancer patients? Do you want to compare to the
19	general population? Those are different surveys
20	and they're different items.
21	So for example, if it's a general
22	population and it's just a wide overview, the SF-

12 has six items for physical function. 1 That 2 will do the job just for like real bare-bones If you want to get into it, the HAQ, I 3 stuff. mean, that's 34 questions about physical function 4 5 and that will really get some detailed information. 6 7 For cancer patients, we have some 8 broad quality of life surveys that are disease-9 specific, but you can see the number of questions goes up based on kind of how people respond to 10 11 these questions. 12 All right. So now here are some of 13 the problems with using your standard paper 14 survey, is the response burden. As mentioned before, people have to fill these out. It takes 15 16 time, especially for sick people, right? 17 Comparability beyond the study sample. 18 So I have a FACT-E score of 113. What does that 19 Well, I can compare to other studies and mean? 20 you can get a flavor of how my patient population 21 compares to others, but -- there might be 22 reference values that people have created, but

these don't do a great job of painting the big picture.

Also sensitivity. If you administer five items of physical function on an SF-12, it's not going to be very sensitive to change or kind of the individual things that are going on for people.

8 So moving forward, this is what Ashley 9 was alluding to. There are these new methods that came about, and I think I mentioned this 10 11 earlier, too, item response theory, educational 12 testing, these computer adaptive tests, and kind 13 of what you need to know. Also, just as an add 14 on, when you're taking say the GRE and the vocab is getting easier, not harder, or the math 15 16 questions are getting easier, not harder, you're 17 in trouble. Your score is going down. Okay? 18 (Laughter.) 19 DR. JENSEN: And so, yes, I even 20 remember living in fear. It was like oh, no, 21 CATs, like I'm in trouble. 22 (Laughter.)

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1	DR. JENSEN: Fortunately, I guess it
2	worked out.
3	(Laughter.)
4	DR. JENSEN: All right. So let's move
5	on. So this is what happens now when people come
6	to me to talk about PROMIS and they want to ask
7	about physical function.
8	Well, the first thing I ask them is
9	are you using a computer or do you need paper?
10	This is a really big concern for people. And so,
11	they tell me, oh, I need a paper. Oh, okay. If
12	you have a computer, are you going to be able to
13	actually run a computer adaptive test? Do you
14	have programming capability, or do you just need
15	the items to just show up, be answered? How much
16	wiggle room? How fancy are we going to get? All
17	right. Do you want to use something that's
18	established?
19	Now, researchers, especially quality
20	of life researchers, they get a little oh, I
21	want to use something that's been used and
22	validated and tested. I don't want to create my

I want something that's available and 1 own form. 2 I know is going to work because -- I just want something that's out there. So, all right. 3 So 4 there is a 4, a 6, an 8, a 10 and a 20-item short 5 form for physical function that you can select. And what people generally do is they take a look 6 7 at the content and they say, okay, this covers 8 the range of my patient group. That makes me 9 happy. 10 You can create your own and you can 11 create -- so you can look through the item bank 12 of 124 questions and pick any items you want and 13 it -- you can create a score from it. And so 14 some people do that. Some people will -- I would -- and so 15 how many items you actually put on. People say, 16 17 well, how few can I get away with? That's like 18 the number one question. And to be honest, you 19 don't need that many. I mean, but it depends, 20 right? But don't give someone 124 questions 21 about physical function. That's just -- ah man, that's not very nice. So there you go. 22

1	And then this is a visual
2	representation more about physical function and
3	how this works on the continuum of 0 to 100. So
4	people that are not able to get out of bed are
5	going to be more towards the zero and people who
6	run ultra-marathons, Ironmen, they're going to be
7	the other side. And so, you can see these are
8	some of the questions that fall across continuum.
9	And then they're in order from highest
10	functioning to lowest functioning.
11	So you can see that on the top, are
12	you able to run five miles? Then are you able to
13	jog two miles? And bear in mind, people are
14	responding, they have five response options. And
15	so, the item response theory is taking the
16	probability of a response and the response
17	pattern together to give you a response. And so,
18	it's kind of taking the lid off of how we used to
19	do questionnaires.
20	All right. So here's another visual
21	representation. I'm going to talk to you today
22	about some findings from physical function,

because quite honestly when we talk about PROMIS, 1 2 we say these great things that it does. We say you can ask all the questions you want or just a 3 4 few and you're going to get the same score, but, 5 okay, in theory this is what happens, but let's 6 take a look at what's really going on, right. Ι 7 mean, let's see if it actually can do what it says it's going to do. 8

9 So let's go ahead and hit the next 10 slide here. Interpretability. So something that we hit on a little bit. And just look at the 11 12 colors, really. So this is a T score metric. Ι think what to take from this 10 points is a 13 14 standard deviation, but it's also -- I think if you think about this in percentiles, because I 15 16 think sometimes people think that way, too, this 17 is -- also can be gridded that way.

And so, when you're up at something like 40, that's -- let's say 64 or 84, 80. And then 30 is going to be at 98th percentile. So you can see that people are really at the ends kind where as -- as these colors get more towards

So, and we're able to kind of mark out 1 red. 2 where clinically relevant differences are. So a mild issue in physical function, 3 4 for example, is going to be someone between 45 5 and 40. That's half a standard deviation below the U.S. population, right? And so, we actually 6 know where someone falls relative to the average 7 8 person in the United States, and that's really 9 cool. Then moderate change is from 40 and 10 11 So you see it's kind of in that orange zone. 30. 12 And that's above a standard deviation lower. So 13 these are people that are kind of approaching 14 that 98th percentile, or 2 percentile of physical 15 function. 16 And then below that you have your 17 severe functioning issues between 30 and 20. 18 Yes? 19 DR. SMITH: Just to that slide, 20 actually. Can you go back? So actually, just so you know, the 21 bottom of the scale is for functioning. 22 So

physical function, you see a higher-functioning person has a higher score. So the 80 is on the left. And essentially PROMIS scores are more of whatever it is that you're measuring, so a higher anxiety score means more anxiety. A higher physical function score means you are doing better.

8 But in terms of the interpretation for 9 clinical purposes and other application purposes, 10 this slide is a generic that shows you across 11 That could be physical function, health domains. 12 cognitive function. Symptoms are at the top; 13 functioning at the bottom. But essentially there 14 are fairly robust ranges for severity, meaning somebody is doing worse. And there are some 15 individual differences for domain. And we can 16 17 talk about that as well, but this is a general 18 sort of framework for interpretation. 19 DR. JENSEN: Higher is more of. Just 20 remember that.

21 All right. So let's take a look at 22 what scores actually mean because we have some

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information about that.

2	So this is from a study that we're
3	doing validating PROMIS domains in a very broad
4	community-based cancer sample. Seven different
5	cancers, 5,000 people. And we asked questions
6	about exercise and needing help with mobility.
7	And so, you can see that if someone's
8	in a wheelchair they reported having a PROMIS
9	physical function score of 28. Okay? With a
10	cane it's 34. No help is 47. And these are
11	so these are cancer patients, so you would expect
12	it to be close to 50, but perhaps maybe a little
13	under. And then people who are reporting five to
14	seven times a week of exercise is above 50. So
15	you can see they're doing better, meaningfully
16	better than the general U.S. population.
17	All right. Next slide. Okay. We
18	also oh, can you go back one? We can keep
19	that, I guess. There's a lot of colors.
20	Hopefully we can see it all here.
21	On the bottom though and so you can
22	see this is how these scores can work. So we

1 have an overall lung cancer physical function 2 score. We have a colorectal cancer score. We have a prostate cancer score. And again, I don't 3 4 know what you guys' background is, but prostate 5 cancer patients on all they probably are doing pretty average, right, generally speaking. 6 This 7 is after treatment. Colorectal cancer patients, there's a 8 9 bit more of a range. And so they're at 44. 10 Lung cancer patients typically are not 11 doing well. And you can see they're about a 12 standard deviation lower than the U.S. population with their scores. 13 14 And now if you can click the slide I color coded, so you can see the 15 forward. 16 pretty colors, and this maps into the severity 17 level. So people that are in a wheelchair are in 18 the red, right? Cane, you can see -- and you can 19 see this all goes up. So green is better. And 20 then we have some problems. 21 All right. And then I included this, too, so you can see the range. We also are able 22

to do -- and these are U.S. reference values that 1 2 we've created for cancer and by stage. And so you can see the range by stage. And this is just 3 4 the level of detail we can really give. So oftentimes when people don't know how to 5 interpret a score, I mean, the thing about PROMIS 6 7 is you really can because we could create scores 8 for different diseases. You name it and there --9 it -- this provides a really nice comparison that 10 really puts things in context. 11 All right. Okay. All right. Just to 12 look at this another way. So this is a self-13 report item, physical functional status. And 14 people said they're normal. They said they had some symptoms. They were less than half the day 15 16 on bed rest or more than 50 percent of the day on 17 bed rest. And so you can see these are people 18 that are about nine months post-diagnosis of 19 cancer, seven different cancers. This is a 20 really broad community-based sample that we collected at four sites in the U.S. 21

22

So you can see most people are feeling

They don't have symptoms. 1 good or normal. And 2 you'll see these bars. All of these colors are the different physical function surveys. 3 And so 4 you can see across the board these are doing 5 exactly what we said they're going to do. They're measuring exactly the same way. 6 They're 7 within a point, which is minuscule. And you can 8 ask 4 items, you can ask 16 items, you could ask 9 more than that, and you're going to get the same And that's what this is suggesting. 10 scores. 11 And if you click it one more time, 12 there are my colors again. And look, this is --13 quite frankly, you're not going to get a better 14 slide than this one when it comes to physical It just makes me feel good as someone 15 function. 16 who does measurement, because it just goes down 17 the continuum there. So you're able to really 18 discriminate against -- for groups. 19 All right. And they left -- we left 20 this one slide in. So part of the validation 21 work I've done -- and we did this for eight 22 different domains; this is physical function --

is we asked compared to six months ago how is your physical function. This is a follow-up survey. And then we measured the actual change and what people said. The effect sizes there are next to the response that people gave.

And this is quite frankly probably one 6 7 of the better response graphs you're going to get 8 when you ask this type of question. You'll see 9 that above three is kind of what we hope -- 0.3 is what we hope for for a clinically relevant 10 difference for an effect size. And you see that 11 12 when people said they were a lot better, six --13 between that six-month period, they improved in 14 physical function about three points, or one-15 third of a standard deviation.

And then when you see it declines, you'll see it's much more sensitive to declines, where it's three points for a little worse and then five points for a lot worse. And this is very standard what you see for these type of metrics, and this performs absolutely like the best we could hope for.

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1	DR. SMITH: So there's just two slides
2	left. So this is some oh, and I guess we
3	didn't incorporate the
4	DR. JENSEN: No.
5	DR. SMITH: Okay. This was not the
6	most up to date, but essentially what I had
7	mentioned earlier first of all, there's
8	increasing adoption for clinical care and
9	treatment decision-making. And originally so
10	these were developed from the NIH, which is a
11	research organization. So we're really
12	developing them for clinical research purposes.
13	However, in the process of this it
14	became very clear that they were useful in
15	clinical settings. And there have been a number
16	of early adopters who have really, I would say,
17	drunk the Kool-Aid themselves, and are rolling
18	out PROMIS in fairly substantial ways.
19	The biggest early adopters are
20	orthopedists, which is not entirely surprising,
21	right? I mean, if you have a surgical outcome
22	and someone either has knee pain or can't

function well, you want to know that from the 1 2 patient. So this is the reason that you're seeing that in orthopedics. But we have it 3 4 applied in a lot of other settings. Oncology 5 Roxanne's just been discussing. And also we have in -- we've had even ICU -- surprise, surprise --6 the ability to ask some questions. We've seen it 7 8 being used in a lot of different ways, and in 9 some places pretty ubiquitously in health 10 systems.

11 So the availability in -- through the 12 EHR is obviously a huge impact in terms of the 13 roll-out and ability to use these more across the 14 board. And there are a lot of other ways that people can access it. And frankly, you could go 15 16 to the Health Measures web site now and download 17 any PDF you want. So that's always a 18 possibility. And as I mentioned, the 19 availability in Cerner in something that we have 20 negotiated, but the roll-out and the particulars 21 are happening in calendar year 2017.

If you want to go to the next slide.

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So we've been in consideration of where this 1 2 might be. This is really the last slide. It's just an example to say that, what are some of the 3 4 potential uses in settings? And keep in mind 5 that these instruments were not originally developed for setting-specific comparisons or 6 7 uses, but across and within specific diseases. Those diseases are treated or 8 9 functional pieces are -- of health are treated in settings. One of the things that we've been 10 considering is are there data that we still need 11 12 to understand used in particular settings? We 13 actually have quite a lot of data that we've 14 collected across many different investigators 15 over many, many years, so we're pooling them a 16 little bit differently, is part of what's 17 happening. 18 But the other thing is that some of

19 the earliest potential uses would be -- have 20 potentially been in post-acute care. And some of 21 the topics associated with the IMPACT Act could 22 be addressed fairly well and quite reasonably now
with many of the different PROMIS domains. So some of the ones that could be considered are cognitive function, anxiety, physical function and mobility, fatigue, sleep disturbance, social 4 role functioning, depression and pain. So those are the different areas that we've just been in conversation about thinking through.

And there's the ability to determine 8 9 domain-specific scores for each of those health domains that I've just mentioned. But the other 10 piece is that -- and I don't know much Roxanne 11 12 covered this -- we have profile scores available, 13 and profile scores are basically across domains. 14 So it might be some mental health, some physical 15 health, and you get summaries of a person's 16 health status.

17 One of the things that is possible to 18 do is to calculate some profile scores on these 19 different domain areas that have a fewer number 20 of questions for the specific purposes, again, of 21 evaluating, for example, the IMPACT Act or anything else related to quality programs. 22

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1	And the other thing is that there's
2	the ability to when I was talking before about
3	the ability to compare the metric to other
4	measures that have been used, PRO measures that
5	have been used, one can also use CMS items that
6	have already been fielded and compare them to
7	PROMIS scores so that there's continuity even
8	over time, or for those folks who've been using
9	other items to do that kind of comparison.
10	So that's just sort of an early
11	example of one application, but there are many.
12	And the beauty of this is just how flexible it
13	is. And what it just means is that we need to be
14	in conversation with the people who want to use
15	it.
16	So the last slide just has my contact
17	information if you'd like.
18	DR. YONG: So one, thank you, Roxanne
19	and Ashley, for that sort of background about
20	PROMIS. And so I just wanted to frame it a bit
21	before we go into discussions, so why did we ask
22	Ashley and Roxanne to come down and why did we

1 stress Roxanne out to cover --2 (Laughter.) DR. YONG: -- those initial slides, 3 4 which she did a great job on. So I think as Reena mentioned, we've 5 -- and yesterday, right, we heard lots of talk on 6 7 the gaps in all of these programs is patient-8 reported outcomes. So we've been thinking 9 internally, not just at CMS, but in collaboration with our colleagues at NIH, all the way up to 10 11 Francis Collins and Patrick Conway, how can we 12 leverage some of the resources we have within the 13 agency at HHS? And so, there's just tremendous 14 work, as we just heard about, with PROMIS in research settings, but also have clinical 15 application. 16 17 And so, some of the things that really 18 attracted us to PROMIS, as Ashley and Roxanne 19 covered, right, it's not disease-specific, it's 20 not setting-specific; it's really adaptable. It

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both comes in paper and e-form, just the number

of questions validated and tested. But are there

ways to think about using PROMIS and use that as 1 2 a basis to turn it into a PRO, be a performance measure that then could be incorporated into one 3 or across programs, right, that addresses some of 4 5 these issues that we talked about yesterday in terms of thinking across programs and how we sort 6 7 of -- how patients move across these different providers and care settings. 8

9 So what we'd love to get back from you today is really your feedback and thoughts about 10 11 is there an idea here? Are there -- these aren't 12 measure concepts per se that we've brought to you, right? 13 There would need to be additional 14 work to bring back an actual measure for consideration by the MAP. But are we down the 15 16 right path? Are there applications that we can 17 -- you can start envisioning?

I will also say that we are -- Ashley mentioned at the end how there are some ideas that we have around the PAC setting. We are having the discussion across all the workgroups because we are trying to think about this

1	broadly, so not just in the Hospital Workgroup,
2	but also in the PAC Long-Term Care Workgroup, as
3	well as in the Commission Workgroup.
4	So happy to answer any questions, but
5	really do want your feedback.
6	CO-CHAIR WALTERS: Well, thank you
7	very much. Just a second. I'll get to Allen.
8	Yes, this is thank you very much
9	for the presentation.
10	One I really happen to be a fan of
11	the OCM, the oncology care model. That was a
12	good move forward. One of the things I was
13	disappointed about was in some of the original
14	proposals it included use of a tool such as
15	PROMIS as one of the measures. And then that
16	fell out somewhere along the way.
17	But pertinent to our discussion
18	yesterday that's where I think certainly
19	oncology world, but in general we have to start
20	out offering these sorts of tools, educating
21	people, because I've got a whole bunch of health
22	services researchers who have their own REDCap

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databases about tool X. Ah, this is not -- you hear all of their arguments.

It's going to take a lot of education 3 4 and discussion to get this going and support that 5 with things like a structural measure in various programs heading towards actually the outcomes 6 7 measurement, which is of course what we care 8 about more. But to get people to use tools such 9 as PROMIS adapted to their particular circumstance and using measure development to 10 11 support that so that people can start realizing, oh, my goodness, this really does have a lot of 12 value after all. 13

14 And so, we're still very early in that, I know. And I worked at MD Anderson. 15 And 16 so, I really support the work that you're doing 17 and we need to continue to move forward with 18 exactly this kind of effort, because there's a 19 lot of inertia and I'm glad to hear that it's 20 being built into EHRs. I think it's a little 21 more feasible. Thank you very much though.

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Allen?

1	MEMBER NISSENSON: So this an area
2	that I have spent a lot of my career working in,
3	so I have particular interest in it. And I love
4	the PROMIS promise
5	(Laughter.)
6	MEMBER NISSENSON: and think our
7	population I know there's been a little
8	dabbling in the kidney disease population, but
9	there in my view there needs to be a lot more
10	than dabbling. I think it's the perfect
11	population to apply this approach to.
12	But I have a question. Maybe this is
13	more for Pierre. So as we think about using this
14	and possibly somehow incorporating it into
15	accountability metrics and I'll use our ESRD
16	example, but it may be applicable to some of the
17	other folks.
18	So we currently have for ESRD in
19	the conditions for coverage for certifications of
20	a dialysis facility we have to administer the
21	KDQOL at least once a year. So KDQOL, it's an
22	SF-36+. So we have to do that. We now have the

CAP survey.

2	So my question to Pierre; and it's
3	sort of the measure bloat issue, how kind of are
4	you thinking about when you look at individual
5	programs and the applicability of a tool like
6	PROMIS in terms of PROs, not just here's another
7	thing to add on to the other stuff we're already
8	doing, and how we can impress this, because
9	and I'll use the term "burden" on patients is
10	really substantial, having to administer and
11	CAPS, as you know, we're actually doing CAPS
12	twice a year. And we're doing KDQOL once a year.
13	And my final question is this sort of
14	self-reporting, which I think is really great for
15	patients, we have on the CAPS side a requirement
16	that CAPS can only be administered by an external
17	third party. So kind of how do you think about
18	tools like PROMIS and patients just kind of doing
19	this, or will there be requirements that we have
20	to hire outside consulting companies to
21	administer this, or what are you thinking from
22	the agency point of view?

1	DR. SMITH: So the beauty is in part
2	the metric that I was talking about relative to
3	PROMIS. So for example, all those SF-36 items,
4	you would not have to administer them because we
5	would have the ability to get similar information
6	using many fewer questions using PROMIS. The
7	other thing is that it's self-administered. So
8	you can hand someone an iPad and they fill it
9	out. And you saw that that was one of the
10	availability pieces.
11	So actually the idea behind trying to
12	get a standard set using a measurement system
13	that's applicable across both disease setting,
14	etcetera, etcetera is that you have the ability
15	to have scores that are that again can be
16	interpreted across those different places and
17	people.
18	Just to mention your comment about the
19	need for education or training or a better
20	understanding of interpretability, the more that
21	you continue to use that 0 to 100 scale and
22	people get a sense of what those scores and the

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cutoffs mean across different areas, the easier 1 2 it is to facilitate their interpretation and use. So I think that -- and I'm very 3 4 familiar with CAPS. We do a cancer CAPS, a 5 linkage with our cancer registries that we provide, so I'm quite familiar with CAPS and how 6 many questions it is. And that is not designed 7 8 in the same way, so I can't really speak to that 9 because CAPS is really more of a process measure 10 as opposed to an outcome measure. 11 But I think that the idea of using 12 this as a framework would actually substantially 13 reduce the burden that you're thinking about. Ι don't think it would add. 14 15 CO-CHAIR WALTERS: I know we've got a 16 lot of people lined up here about this, so, 17 Karen, you're first. 18 MEMBER SHEHADE: I just wanted to 19 mention yesterday we talked about the importance 20 of looking at measures that are important to 21 patients. And when you were speaking it made me think about the Stanford Chronic Disease Self-22

Management Program, and in my past work with 1 2 chronic disease management looking across chronic conditions and what are the common themes that 3 resonate with all chronic disease? And Stanford 4 5 did some of this. And I just wanted to ask you 6 to think about how that -- the PROMIS approach 7 could even tie into something like this, looking 8 at things that cut across a variety of 9 conditions. So just wanted to put that out 10 there. 11 So just again to reiterate DR. SMITH: 12 that the design of PROMIS was to be cross-13 disease. 14 MEMBER SHEHADE: Yes. 15 DR. SMITH: That as -- and actually 16 that was part of the foundational reason for 17 developing it. It was part of the NIH Common 18 Fund or Road Map Initiative. That's by 19 definition across disease for exactly that 20 And for patients frankly with multiple reason. 21 morbidities and diseases. 22 CO-CHAIR WALTERS: Okay. I got the

1	list going here. Don't worry. Everybody will
2	get their chance. Helen gets priority though.
3	(Off microphone comment.)
4	CO-CHAIR WALTERS: Okay.
5	(Off microphone comment.)
6	CO-CHAIR WALTERS: Okay. Good.
7	Andrea?
8	MEMBER BENIN: This seems really
9	fascinating to me and definitely right in line
10	with what we've been talking about as needing to
11	understand where patients stand and how they
12	feel. It does seem to me that at this moment
13	really far from an accountability metric,
14	substantially far from an accountability metric,
15	and even thinking about what that would look like
16	is complex, I think. I think I can go if you
17	think about how it is a one patient, one cancer
18	look and how do you hold a hospital accountable
19	for how that person's dealing and while risk-
20	adjusting or whatever else needs to happen. I
21	don't even know. So I think that it's far from
22	an accountability metric right now.

1	I could imagine a world where there
2	was a structural metric around using a tool like
3	this or another kind of tool that I could
4	imagine, but I think that is a way that if CMS
5	felt it was wanting to support the HHS effort, I
6	suppose. But to me this feels like a very
7	clinical tool that should be propagated
8	extensively in the clinical areas and but the
9	payment methodology may not really be the right
10	one for that. I'm not sure that that's this
11	is the right place to put this tool right now.
12	It doesn't feel that way to me yet.
13	It feels really valuable. It feels
14	like it move things forward. I'm curious to fill
15	it out myself, but yes, just the anxiety part,
16	right? So anyway, thanks.
17	CO-CHAIR WALTERS: David?
18	MEMBER ENGLER: Thank you. So I'm a
19	big supporter of PROs. I think it really goes to
20	the point of patients and making it patient-
21	centered. So congratulations on the work being
22	done. And by the way, I'm not going to take it

today because I'm depressed as hell, so --1 2 (Laughter.) 3 MEMBER ENGLER: -- as are many people 4 around the table. 5 But so I support it. I wonder if there's an opportunity here to place this in a 6 category since it's not yet ready for 7 8 accountability. But I wonder if there's an 9 opportunity for you to think about placing this in the category of emerging population health 10 11 Many of our member hospitals are moving metrics. 12 towards more and more population health, given 13 both our mission and where they're going in terms 14 of their steering organizations. And it seems to me that if you 15 16 broadened this just a bit and looked at the 17 notion behind reported, self-reported measures in 18 a population that you would be metricating and 19 measuring something that we're not currently 20 picking up on the clinical side. 21 So I offer that as both a comment about the excitement and the forward thinking 22

1	that you're bringing to the table, but also as
2	the opportunity to look forward in terms of this
3	being a population health metric or consideration
4	for population health. So thanks.
5	CO-CHAIR WALTERS: Lindsey?
6	MEMBER WISHAM: So thank you for your
7	presentation. It was interesting and exciting
8	all at the same time.
9	I think though when we talk about the
10	scores and how comparable they can be, whether
11	it's across care settings or disease-specific
12	conditions is that ultimately that's
13	beneficial perhaps to a researcher or even a
14	provider that's giving the care. But if this is
15	truly meant to engage the patient, the patient's
16	going to say so what? So what I'm a 93? What
17	does that mean? Or how does that change the care
18	that I'm going to receive? How does that change
19	maybe how my providers interact with each other?
20	And so I think that ultimately if this
21	is the a goal is getting us started down a
22	really good path of truly making patients engaged

1	in their care is that we have to be able to
2	communicate what that means back to them.
3	DR. SMITH: So that is something that
4	we are already taking up, absolutely. And in
5	fact there are a number of there have been a
6	number of studies that are about both patient
7	communication and thinking about integrating
8	information for decision making, dose
9	modification or whatever it is. There are
10	definitely both the interpretation by the patient
11	and the clinician, and getting them in a
12	synergistic place has been a part of using these.
13	And I would say that patients actually have been
14	fairly enthusiastic.
15	Do you want to
16	DR. JENSEN: So my other hat is that
17	I actually have been developing patient-focused
18	symptom reports. So say a breast cancer patient
19	who's done with treatment, 35, stage whatever.
20	They're able to look at the scores and see how
21	they compare to someone just like them. And
22	people not only really wanted this information,

but they see like direct application, because 1 2 it's very difficult in this -- my narrow setting to understand what fatigue means to them now that 3 4 they're done with treatment. And just even 5 though maybe there isn't direct applications immediately, this is something, this is 6 information that patients seem to really want and 7 are enthusiastic about. 8 9 CO-CHAIR WALTERS: The feedback's very good. 10 Keep it up. I've got everybody on. 11 Jack? 12 MEMBER JORDAN: I completely welcome 13 this, and it's really nice when what we're trying 14 to do in our health system is actually aligning with where CMS is going. 15 Our associate chief medical officer of 16 17 our main hospital has essentially told people 18 that if you're doing a research study, you will 19 use PROMIS unless you have a compelling reason 20 not to. We're trying to really work through in 21 our own system thinking through -- we've had this 22 problem in the past. They have a research study;

and their ERB captures it there and it's lost, it just passed through there, to really try to unify this so that we're actually tracking it with one data monitor. We can reuse this for different things and not have a patient take it twice. We are an early adopter. We do have

it built into our patient portal in Epic prior to it being released as a complete thing. So it exists.

10 I want to agree with the population 11 health portion, too. I think looking at 12 populations over time -- they see a model. This is a great way to have that be kind of common and 13 14 thought of. And I think we're also trying to think about is -- this is a way to look at 15 16 primary care panels and kind of look at kind of 17 the risk scoring kind of a tool for looking at 18 panels as well. So I think there's a ton of uses 19 for this.

20 And I think that the standardizing on 21 something this on a large scale so we can get 22 things marched across the country and doing that.

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So I'm completely all for this and I think there's a lot of benefits in a lot of places if we try to commonize on this where we can. And I think what we'll lose in the specific disease things are pretty small in comparison to what we gained by being able to have comparability across.

8 One thing I did hear that I want to 9 make sure of is that we don't build something like this where we're officially sending it to 10 11 CMS, that we don't get to keep our own data, 12 because I think we want to use it for other 13 purposes. If you're wanting to measure what 14 we're doing, I would really encourage you to not set up a model where the official blessed one you 15 16 trust is data then that's blinded to us and we 17 don't get to keep. I think it's important that 18 we get to keep and use it. 19 CO-CHAIR WALTERS: Thank you. Frank? 20 MEMBER GHINASSI: Okay. I'm going to

try not to repeat anything anybody said.

Just first of all, this is -- I'm very

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fond of this and I was actually part of the group that did the winnowing and thinning way back. And so it's exciting to see this one come to -so the real PROMIS is the IRT-CAT combination, so I want to really stress if you can make that a priority, because I think that's where the magic is in this.

8 The second thing; it's just a concern, 9 is are you thinking of this -- and you don't have to answer this. I'm just putting it out there 10 for you to think about. Are you thinking about 11 12 this as a graphic tool or a nomothetic tool? So 13 is this a one patient kind of issue or are you 14 really looking at this to measure large populations? Because I think it has implications 15 16 both ways.

17 The third thing is, at least in my 18 experience, within populations there are patients 19 who consistently underreport or endorse and over 20 report and endorse. And so, change among those 21 populations is not the same. And when you're 22 measuring a population, begin to think if you can

about ways to include individuals who restrict 1 2 the range of their own self-report versus those who exaggerate the range, because it's a real 3 4 phenomenon and it will affect this. 5 The next one is are you thinking about this as a treatment planning tool or are you 6 7 thinking about this as a quality outcome tool in 8 a pay-for-performance environment? Because those 9 are two very different agencies. And then the other question is are you 10 11 thinking about a delta in these scores as the 12 measure? And if so, is that a withinorganization delta or some kind of national 13 14 delta? Because there are problems on both sides Organizations that are in different 15 of that. 16 environments maybe work with different 17 populations. Their deltas may look very good 18 within their organization structures, but not so 19 good across a larger one. 20 And the last point simply is I'd 21 recommend that if you're going to do this, numbers are going to help. Millions of people 22

are going to be better. Hundreds of thousands. 1 2 There may be 15,000. So for -- if you're going to do an accountability measure, it's probably 3 4 going to be better if you do it at the payer or state level than at the provider level. 5 Just thoughts. 6 7 CO-CHAIR TRAVIS: All feedback, aren't 8 you? 9 Brock? 10 MEMBER SLABACH: I think prefacing my 11 comments, I'm a hospital administrator, so I 12 always think about things kind of operationally. 13 First of all, is Epic and Cerner going 14 to be charging for this package to their offering to its hospitals and clinics? 15 16 DR. SMITH: I'm fairly certain that 17 anyone who has the ability to -- so Cerner I 18 don't know yet, because that's like too early for 19 me to actually -- so the Epic piece, I'm fairly 20 certain if you have the ability and have already 21 selected patient reported outcomes it's part of 22 that package. And so for those who already had

1	it, it's available.
2	And just I wanted to mention that
3	these are also available in English and Spanish.
4	MEMBER SLABACH: It's available where?
5	DR. SMITH: In English and Spanish.
6	MEMBER SLABACH: Oh.
7	DR. SMITH: Through Epic.
8	MEMBER SLABACH: The other question I
9	have is and maybe I missed it in part of the
10	presentation, but is this administered to all
11	patients? So upon admission to either a hospital
12	or a clinic setting are they asked to interface
13	with tool in all cases or just in certain
14	disease-specific conditions of cases?
15	DR. SMITH: So you mean how is it
16	currently being used in clinical settings?
17	MEMBER SLABACH: Yes, I mean
18	DR. SMITH: Specifically
19	MEMBER SLABACH: what do you
20	perceive is the best way to do this
21	DR. SMITH: Well, I
22	MEMBER SLABACH: going forward and

how do we I guess respond to that in terms of 1 2 implementation of process, because in the hospital context and the clinic context you've 3 4 got to make -- you got to translate this into --5 we're required to have patient portal -- a certain percentage of patients accessing our 6 7 portal, for example. 8 DR. SMITH: Right. 9 MEMBER SLABACH: So is this going to be a requirement that we're going to have to have 10 11 so many of these forms filled out for so many of 12 our patients in terms of population? So it's a little bit of a 13 DR. SMITH: 14 complicated question. I can tell you what's 15 being done now and I will also defer to Pierre 16 and also the thinking with guidance from you all 17 and of CMS relative to developing a performance 18 measure, because some of the questions and 19 comments just made were incredibly poignant and important to consider in terms of how this 20 21 interpretation will happen and what kind of 22 change in one's reported abilities or symptoms

for tests, whatever it is, is going to be --1 2 matter based on what the ultimate measure is. But in terms of current use -- and I 3 4 would say; as I mentioned, that orthopedics is 5 the biggest starter, there are -- so for example, University of Rochester, every single orthopedic 6 7 patient gets it the minute they walk in. Every 8 time. 9 MEMBER SLABACH: Every visit? 10 DR. SMITH: Every visit. And they actually have iPads set up. And initially they 11 12 thought they needed a nurse consultant or 13 somebody to explain it, and they very quickly 14 recognized that they did not actually need that. So they reduced that FTE burden, etcetera. 15 The 16 administration fees is actually pretty great. 17 So, yes, they use it. And they track 18 patients over time and they make decision related 19 to physical therapy, surgery, I mean, etcetera. 20 So they're -- and now they are moving it into 21 their oncology setting. Again, the second sort of high user group. But there are lots of 22

1	examples. And GI distress, for example, was one
2	of the domain areas. That tends to be used in
3	particular populations more. But and is being
4	used in clinical settings. So there are examples
5	all around.
6	Some I think for the most part in
7	clinical practice the idea is to be tracking
8	people either for flagging them for a particular
9	the patient population in general for problems
10	or for if there are decision points that are
11	being made. And that depends on what the
12	condition is and who the patient population is.
13	Yes.
14	And the other thing is that the
15	earliest adopters had to do a lot of their own
16	IT-related pieces, but moving into these
17	electronic health records, that changes that ball
18	game completely.
19	MEMBER SLABACH: And I think that the
20	key will be is to make sure; and I think I've
21	heard it said, but just stating it another way,
22	the benefits to the clinician and to the patients

have to be clearly outlined so that it will be 1 2 saturated and the use of this will proliferate. Because otherwise if it's just seen as a 3 4 requirement that CMS or Joint Commission or whoever requires fill this out. So that -- and I 5 see the benefits and I see the direct outcome of 6 7 the benefit, but if it's not translated in a 8 really positive way, I think it could be seen 9 negative.

Finally, the question I have is 10 11 predictive ability. So I know in dealing with 12 patients you get a certain condition at this 13 moment in time. In terms of decision support, 14 looking ahead in terms of the progress given the 15 reality of where a patient is now, can you 16 project certain characteristics or where this 17 patient's path will go and will be planning for 18 that in terms of reality of the situation? 19 That's probably not a very well-asked question, 20 but --21 DR. SMITH: No, no, no. That's a good question. 22

1	To some extent, yes, I would say that;
2	keeping in mind that these have been tested in so
3	many different studies, like hundreds of studies
4	actually, the looking at predictive ability
5	for every patient type in every single situation,
6	we're not going to have that kind of information
7	available at this point. But there are certainly
8	indicators for that have been that have
9	gotten more attention or more study that we do
10	have the ability to have a general sense of
11	someone's trajectory and that sort of thing. I
12	wouldn't say it would we could assume, oh, in
13	three months someone's going to have a three-
14	point change. That's not going to happen.
15	MEMBER SLABACH: Right.
16	DR. SMITH: But a general trend is
17	potentially possible, yes.
18	MEMBER SLABACH: Yes, I think it could
19	provide a real reality moment for people. And
20	then I just think about myself and the question
21	about filling out a form and such. It helps the
22	feedback. Instead of denial and

1	DR. SMITH: Right.
2	MEMBER SLABACH: avoidance, it
3	maybe helps to craft the conversation. I think
4	it's a really good communication tool to set up a
5	plan of treatment that's realistic and
6	appropriate.
7	DR. SMITH: And there are research
8	studies on how to best provide the information to
9	clinicians and helping clinicians action back
10	what they are doing, and again in different
11	settings.
12	But your comment earlier about how
13	this gets incorporated and the sort of way in
14	which to make it ubiquitous or such that it's
15	easily interpreted and integrated is that if you
16	start with; I guess the comment earlier was about
17	structural measures, just the assessment of these
18	and people get used to having the information and
19	there is guidance provided just cause, here's how
20	you can use it, and there's these are
21	here's some information, but that isn't actually
22	evaluating the outcome piece yet. But getting

people used to it is sort of a stepped approach. 1 2 And then the potential to look at indicators either at the population level or -- depending on 3 4 what you want at the individual level, too. 5 CO-CHAIR WALTERS: Pierre's been taking copious notes. We'll get back to him 6 7 after Helen. 8 But, Jennifer? 9 MEMBER EAMES HUFF: So first of all, just congratulations on all the work. 10 It's pretty amazing. And I think we would all agree, 11 12 I think we have all agreed on the importance of 13 patient reported outcomes and can see how it's a 14 place where many users can come together and get benefits for a variety of reasons and leads 15 16 towards a more patient-centered healthcare 17 environment. 18 I want to underscore a couple of 19 things, one around engaging the patients in using 20 the info and the importance that has. And care 21 delivery, and care management, and care 22 engagement. And I think there's also a piece of

1	I know so I've filled out surveys, too, and
2	I get really pissed if I don't know what happens
3	with the results or don't see that. It just
4	so if we're talking about doing even more
5	surveys, we need a way to actually get the
6	patients to buy in to doing that.
7	And I think one of the ways so I
8	don't know if you're doing research on
9	smartphones and apps and how those can play a
10	role. And I'm thinking more of it's not the
11	solution for everybody. And we know there are
12	population differences, but there was a time when
13	there was like a standard model of you mail out
14	the survey once, twice and then you do a phone.
15	Is there a way that we can move to apps being a
16	part of the multi-modal way in which you reach
17	patients? And it's not the be-all-end-all, but
18	it serves as a really important point for a
19	variety of reasons.
20	And then the other thing I want to say
21	to CMS is I think you've done a great job already
22	starting to create momentum in terms of using

PROs in healthcare, the voluntary option in the 1 2 CJR Program. And I actually even like CPC+ because it becomes a part of the package. 3 You get to choose the track, you choose the PROs. 4 So 5 I think that's really important to getting engagement and comfort with using that as 6 7 starting to have it.

8 And I do think I find one of the 9 challenges -- particularly as we're talking about different disease states, and if you're looking 10 11 at doing aggregate comparisons across organizations, is the numbers challenge, right? 12 13 Some of these places it's just small numbers to 14 even get to the point of creating reliable and It's kind of challenging. 15 valid. So I'd 16 strongly encourage you to engage with the private 17 sector in doing this towards the beginning. Is 18 there a way in which the private sector can also 19 be in alignment? One, for a variety of reasons 20 it just creates having multiple signals of what's 21 important; but two, in working together on the 22 measure development so you're creating the

volume.

2	And I know that requires a lot more
3	front-end work, but I think this is one of those
4	places in measurement we have a key opportunity
5	to get people on board and sort of driving in the
6	same direction instead of having lots of
7	different measures about the same thing. I think
8	that's something we'd really want to avoid. So
9	there really needs to be a lot of care from the
10	get go in terms of having very early
11	conversations about what people can and cannot
12	do. From the registries to healthcare systems to
13	the payers there's a variety of opportunities
14	around that.
15	DR. SMITH: Just one quick
16	clarification. The app is already available. So
17	one of the things in the early slides was about
18	that there's a PROMIS app and but it's
19	available for iPad. It has not been developed
20	for smartphone use yet. And that's where again
21	the University of Rochester, everybody's using an
22	iPad, distributing it, and that's how it's

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specifically done.

2	I think one of the things I don't
3	know if the iPad if it's in sort of an office
4	space use, but I think as we're seeing some of
5	the things that you're doing, we wouldn't want it
6	tied to an office visit. It does not have to be.
7	It can be done remotely. It can be done
8	anywhere. I just more mean that if a hospital
9	is, for example, doing it for every patient that
10	walks in the door, you can do it on buy five
11	iPads and you're and, but, yes, it can be done
12	remotely, and that is used and can be integrated
13	directly.
14	CO-CHAIR WALTERS: Wei?
15	MEMBER YING: Actually this year will
16	be the third year our organization will be
17	receiving the patient reported outcome data from
18	our physician organization, so I can share some
19	of the experience and the lessons learned from
20	this exercise.
21	It's very exciting to hear that
22	they're now PROMIS has kind of integration

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with other two, but one question that we 1 2 encountered when we tried to negotiate this contract is physicians are receptive to using the 3 PROMIS tool, especially the physical function and 4 the global tool, but they're hesitant on the 5 mental health side. The main issue there is PHQ-6 9 has been out there for such a long time and 7 8 they're so familiar with it. So they'll usually 9 shy away from the mental health part. And also another thing is a lot of 10 11 times these things are -- specialist societies didn't want to use it, and we developed their own 12 13 specialist-driven app. So usually, while we 14 engage with orthopedists or oncologists, it's always PROMIS -- we offer PROMIS as one of the 15 16 options, but they always want to couple it with 17 another tool that they're more familiar.

So my question is, in terms of collaboration do you mean the collaboration was a more general standardized health status tool, SF-36, or do you mean the collaboration with some kind of the specialty society development tool?

1	DR. SMITH: So I should have had a
2	slide on this. And there's actually web site
3	about it. It's called PROsetta Stone. Very
4	cute. It was
5	(Laughter.)
6	DR. SMITH: It was a grant that was
7	funded by the NCI, the National Cancer Institute,
8	and it was specifically to develop these
9	crosswalks between what we call legacy measures
10	so SF-36 is one, PHQ-9 is also one, the CSD,
11	etcetera, etcetera. And there's actually a list
12	there. And we are planning additional ones in
13	the current grant that NIH is funding now for
14	use.
15	In terms of any and an oncology
16	fact, for example, Roxanne had is used
17	extensively. Many fact items are actually the
18	same in PROMIS because the development of PROMIS
19	actually came from both the identification of
20	specific legacy measures that could be items
21	could be pulled in directly from them. Then we
22	have agreements with the authors of those
instruments to do that. And then we added 1 2 additional items where there were gaps. So some of that crosswalking is fairly direct, actually. 3 And if there are little-used -- so the 4 5 other thing I always tell the patient we understand there are many assessment tools that 6 7 are -- people are very comfortable and familiar. 8 Go ahead and use it. We can compare it to the 9 PROMIS metric and get you a PROMIS score. If you 10 want to change over, it's seamless. And if you 11 want to stick with the PHQ-9 because you know it, 12 that's fine, too. 13 So if there are specialty society-14 driven assessment tools that are more -- narrower 15 use, I don't know that we would have crosswalking 16 available now. It sort of depends on what it is. 17 We've been trying to go with the most used ones 18 first, obviously. Yes, but the methodology is 19 there. 20 MEMBER YING: Oh, great. And another 21 lesson learned we -- that we learned from this 22 exercise is the actionability. So PHQ-9, the

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reason we ran out with PHQ-9 the first two. 1 The 2 reason for that is there is -- I want to call it clinical guideline, but physicians sort of know 3 4 if a patient gets scored within this score range, 5 it means this. We think that's working. They know how -- what to do about it. 6 For the other two their argument is, 7 8 yes, it's nice. I know it's 80. But what does 9 that mean? What's the difference between 80 and So they're -- if they don't know what to do 10 85? about it, it's very hard to persuade physicians 11 12 to actually adopt a tool into their work flow. 13 And another thing about PHQ-9 is there

14 are two PHO-9 measures that's out there. I've Maybe both of them 15 seen at least one of them. 16 are endorsed by NQF. Again, when we go out with 17 these measurements, we still get a lot of 18 pushback. So we don't use it for payment 19 We use it sort of as a monitoring purpose. 20 But again, there is something there purpose. 21 that we can monitor what's going on and we can look to claims data to see what is the treatment 22

1	has that leads to different kind of improvement
2	pre and post the survey.
3	So for these other choose if there is
4	no actionability so the physician doesn't know
5	what to do about it, it's very hard to push
6	forward.
7	CO-CHAIR WALTERS: Take home
8	assignment, everybody should visit PROsetta just
9	to look through it.
10	(Laughter.)
11	CO-CHAIR TRAVIS: Sean?
12	MEMBER MORRISON: So, Ashley, you've
13	heard this from everybody, but just to
14	reemphasize what an extraordinary body of work
15	the PROMIS people have done over the years. And
16	the amount of psychometric work to get a measure
17	set like this is extraordinary, so thank you for
18	that. I think it's probably one of the most
19	pragmatic things that NIH has ever done.
20	(Off microphone comment.)
21	(Laughter.)
22	MEMBER MORRISON: Please do not. I

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1 still rely on you for funding.

2	I wanted to make really three
3	comments. The first is that what we've seen is
4	CMS evolve from really essentially a big
5	insurance company to an organization that has
6	really focused on the health and quality of life
7	of people in this country. And that is a very,
8	very important change. And all of the work that
9	we have done around this table has really focused
10	on the goal of how do we improve health and
11	quality of life for people who sit under CMS, and
12	all the measures that we have done are really
13	surrogates in that.
14	But as healthcare has moved forward
15	and becomes more fragmented and more personalized

and becomes more fragmented and more personalized and we get individual treatment options, all of these multiple measures that we have are going to become obsolete because either we're going to be spending all of our time measuring every single specific small outcome or process that goes with every single individualized treatment, or we're going to have to rethink how we're doing that.

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And I think what this does is really focus on -this set of measures as what are -- what is important for the nation's health? It is the patient reported outcomes. It is what's important to know.

They don't -- my 90-year-old doesn't 6 7 care what his or her glycosylated hemoglobin is. 8 She really doesn't. What she cares about is how 9 she's feeling. And I think that we really need 10 to think very, very hard about how we push this 11 forward extremely quickly, that the opportunity 12 is here to have a set of measures that goes 13 across diseases. It goes across settings, it 14 goes across plans and it goes across providers in 15 a way that's very meaningful to the people we're 16 taking care of.

And I would love in five years to be sitting here and thinking about what are the PROMIS measure sets or what are the measure sets rather than when I'm going to be looking at is 25 different items such as alcohol use and brief -if you provided or offered an alcohol use brief,

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and multiple measures like that.

2	So thank you for doing that. And,
3	Pierre, thank you for the opportunity for us to
4	hear about it. And thank you for CMS considering
5	this as a move forward. I think it is the right
6	direction.
7	CO-CHAIR WALTERS: Okay. We're
8	drawing near, but we'll get to Lee, then Dan and
9	then Lindsey and then Helen and then Pierre.
10	Lee?
11	MEMBER FLEISHER: Yes, another kudos.
12	We actually do use it on every visit for our pain
13	practice. And one of the key questions is
14	particularly we don't know in pain what works at
15	all for many of our treatments. In fact, I would
16	question a lot of what we do, as do my own
17	people, which is why they've done it in 3,000
18	patients longitudinally with other scores. It
19	would be great to somehow use this to actually do
20	a comparative effectiveness trial within certain
21	areas, because I think; Sean, I think would
22	agree, some way to marry up payment with research

to find --1 2 DR. SMITH: We at NIH welcome applications all the time. There are multiple 3 receipt dates for January --4 5 (Simultaneous speaking.) Yes, between you and 6 MEMBER FLEISHER: 7 PCORI, right. 8 DR. SMITH: Right, yes. 9 MEMBER FLEISHER: So I think --DR. SMITH: No, but really actually we 10 do support a grant portfolio that would be very 11 12 enthusiastic. I'm in a healthcare delivery research program. We're very much focused on how 13 can we use tools like this. So additional 14 15 studies, NIH funds, yes. 16 CO-CHAIR WALTERS: Dan? 17 MEMBER POLLOCK: And to that end and 18 thinking in terms of moving this from where it is 19 now to the measurement world for quality 20 improvement, one of the most important dimensions 21 of quality measures is to establish that there's 22 a performance gap and to establish how the metric

can be used to close that gap. So I would just 1 2 encourage keeping those very important parameters in mind as you move forward. Where is the 3 4 performance gap? This is a vital sign. What you 5 are developing is another vital sign. So how does that vital sign get used to actually improve 6 patient care and where are the gaps? 7 8 CO-CHAIR WALTERS: Lindsey? 9 MEMBER WISHAM: So kind of having grown up through electronic clinical quality 10 measures, I tend to look back at what are the 11 12 lessons learned, what maybe we could have done 13 differently to make that a smoother process. And 14 I think that this is a new frontier, just as ECOMs have been as well. 15 16 I think one thing to consider from an 17 implementation perspective is though while it

17 Implementation perspective is though while it 18 seems it's very positive that it's configurable 19 and there are so many questions that you could 20 put together to hopefully achieve a very light 21 score, depending on the questions you ask of 22 course, but is it -- how do we get this data back

1	out of the systems? So I'd be very interested to
2	talk with and Epic or a Cerner to see how they
3	would potentially get the data back out in some
4	sort of meaningful way for reporting so that
5	initial benchmarking could be done, so that
6	performance metrics could be developed, that it
7	could begin to look at what these benchmarks may
8	drive.
9	CO-CHAIR TRAVIS: Thank you, all. And
10	before I turn it to Helen, there are just kind of
11	three observations I've made about things that
12	were interesting to me about this.
13	One was the whole discussion about is
14	this for individual treatment decision making and
15	how that may not align really very well
16	necessarily with looking at performance measures.
17	I was in a conversation earlier this
18	year around oncology actually, and the whole
19	concept that this type of information could be
20	used as part of the work flow and to the point
21	about making it important to patients. I mean,
22	if they see that what they're giving you actually

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changes the treatment decisions that are being made, I think that's a significant piece. So whatever -- I would hate to think it only becomes a performance measure and is still not there for individuals treatment decisions along the way that need to be made.

7 Another thing I kind of picked up on -- and I'm -- I work with employers on their 8 9 health, I don't work out in the industry per se, 10 just as background -- is that there may be in other regulations, in other pieces of licensure 11 12 or other regulatory processes for people who are 13 required to do other types of patient reported 14 outcomes. So I think being sure that as CMS looks at how do we use this that it's not just 15 16 CMS programs that you're looking at, but that you 17 understand what are the other pieces? And I 18 think to Jennifer's point, working with others 19 now to figure that out, whether it's an 20 accreditation requirement, whether it's a 21 regulatory requirement, whether it's a state 22 requirement, so that there can be some kind of

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consensus on how we move forward.

2	But the whole idea that we could
3	actually have performance measurement be part of
4	work flow versus this added thing that happens
5	over on the side I think would be exciting, and I
6	can kind of see how this could do that as long as
7	it still continues to meet both needs.
8	And with that, I think I'll turn it to
9	Helen.
10	DR. BURSTIN: Great. Thanks so much.
11	I want to thank both of you. It was great. And
12	Ashley and I have talked about this in the past.
13	Just so you know, PROPMs has been a major purpose
14	of NQF for the last several years, since very
15	generous funding from HHS that allowed us to
16	actually create a pathway for how do you go from
17	the tool and this was a brilliant tool we
18	talked about this morning where a series of item
19	banks were essentially a PRO. How does that make
20	the transition to a PRO-based performance measure
21	is where I think a lot of our emphasis has been
22	and I think a lot of the work is going to need to

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2	For those of you who haven't done it,
3	I would really recommend going onto PROMIS and
4	doing a couple of the item banks. There's
5	nothing more instructive than actually doing
6	itself, and we'd be happy to send those links
7	out. And since Ashley mentioned the University
8	of Rochester, I actually have the video from Judy
9	Blumenauer that she shared and she allowed me to
10	share with anyone of the work they've done of
11	literally a patient sitting with their clinician
12	looking at their PROMIS results and seeing how
13	well they did compared to where they could be.
14	And what's really extraordinary is
15	they're also using it to get at appropriateness.
16	So they can figure out based on somebody's pre-op
17	score how far they would actually have had to
18	move to make sufficient improvement that surgery
19	is every worth doing. And they can actually tell
20	people based on what your PROMIS physical
21	functioning score is you're actually too well
22	off. Surgery wouldn't get you enough benefit to

take the risk on. So this is really clinically
 transformative in a way we're just beginning to
 scratch the surface of.

4 So as part of our PROPM work funded by 5 HHS there was a monograph developed, which is on Amazon; I think we shared the link with you, or 6 7 free paper versions of it, that explain that 8 The lead author is David Sella, who pathway. 9 works very, very closely with Ashley and her team at PROMIS. And again, this pathway is where I 10 11 think we really need to think about how do we 12 move from having a structural measure -- and we 13 talked about this yesterday. Is that really 14 satisfying enough just that you checked that to 15 the other extreme of did you demonstrate 16 sufficient improvement like we have with our 17 depression measures?

And I think part of what we have to figure out is there something in between those two poles that in the interim we could move towards -- is that you used it in a clinically meaningful way might be another way to help us

get closer to actually your point about being 1 2 able to use it in practice, with being able to use it for measurement and what that looks like 3 4 and the promise of -- it's very easy to do that, 5 isn't it? 6 (Laughter.) The promise of 7 DR. BURSTIN: Redact. 8 putting it in the HR means, with all the caveats 9 we heard from Lindsey -- it's actually in there 10 and I hope that it actually gets used clinically 11 beyond a check box measure. Yes, I checked that 12 somebody has an annual KDQOL, to Allen's earlier 13 point. 14 We also have some incubator work we're 15 doing as part of the NQF incubator, developing 16 some new PROPMs. And David Sella is working very 17 closely with is on those as well. And there is 18 an interesting model to Wei's earlier comment 19 about using a generic tool like physical 20 functioning as we're doing for a multiple 21 sclerosis project, but then adding on a series of 22 more disease-specific kind of items to get sort

of the best of both worlds, but not get just the
 addition of multiple and multiple tools. And
 we'd be happy to share that as well.

4 Since Lindsey also -- I'm sorry, since 5 Ashley also mentioned the PROsetta Stone work, we actually have been working closely with both 6 developers, Minnesota Community Measurement and 7 8 NCQA, to actually consider moving away from the 9 measure requiring a PHQ-9, but to allow the full range of tolls that have been covered by the 10 11 PROsetta Stone analysis to show that you can do 12 that equivalence.

13 There's still some work ongoing, but 14 from our vantage point the idea of being able to 15 have a set of tools that you don't have to force 16 hospitals to say I've been using this for years. 17 Well, sorry, you now going to have to switch to 18 this. That's not what we want to do. So we're 19 actually very excited about what could be done 20 here.

21 And just lastly -- there's one other 22 thing I wanted to say. Now I can't remember what

Oh, the last thing just in terms of the 1 it was. 2 private sector, since both Jennifer and Cristie brought it up, we're actually doing a joint 3 convening in -- I think it's now scheduled for 4 5 February or March with ICHOM, the International Consortium for Health Outcomes Measurement; 6 7 PROMIS is part of those discussions, being co-8 convened by NQF and the Healthcare Transformation 9 So David Lansky and I are leading Task Force. those efforts with the folks at ICHOM. 10 11 So again, very much trying to see 12 whatever we can to bring all of these different 13 forces together. This is such a remarkable 14 There's just -- we spent so much time approach. 15 trying to harmonize at the back end and banging 16 our head against the well and it's just very

exciting to see opportunities to very highly
upstream harmonize before these measures even
kind of hiccup. So thanks.

20 CO-CHAIR WALTERS: And a sincere thank 21 you for everybody's thoughts and comments. You 22 can tell people are quite energized about this.

1	Pierre, did you get enough feedback?
2	(Laughter.)
3	DR. YONG: We could spend the rest of
4	the day. We can just skip the measures, right?
5	(Laughter.)
6	DR. YONG: No, I this has been
7	I mean, wow, right? I mean, I think I loved the
8	engagement and didn't expect anything less, but
9	really the discussion here in the past hour I
10	think has been tremendously valuable, not just
11	for us, but also for our NIH colleagues as we
12	continue to sort of think and think about the
13	potential next steps in this. So really do
14	appreciate that and so want to thank Ashley and
15	Roxanne for coming and providing their expertise,
16	and also their additional CMS staff in the room,
17	but also back at CMS who've been working with
18	Roxanne and Ashley closely on this.
19	DR. SMITH: One thing just for synergy
20	purposes, we are also working with the FDA and
21	they are currently evaluating PROMIS as a for
22	use as a PRO in drug development trials, and

specifically they're looking at physical 1 2 function. And at their request they were interested in physical function in oncology. 3 But 4 that's an earliest place where; speaking of 5 industry, other side of industry, will be using these as part of their comparisons in their arms 6 7 to better understand the effects of the drugs 8 that they're testing. 9 CO-CHAIR WALTERS: Thank you. This is 10 what MAP and NQF is about right here. You just 11 saw a great example. 12 We have one thing to take care of 13 first. Aneeb, would you introduce yourself and 14 disclose any conflicts you have? MEMBER SHARIF: Aneeb Sharif with SEIU 15 16 and there are no conflicts. 17 CO-CHAIR TRAVIS: Okay. Well, thank 18 you all for a warm-up. It obviously was a very 19 engaging conversation, and I think for me is very 20 optimistic and very hopeful for where we can go. 21 And I do want to echo Sean's opening comments 22 about the role that CMS is playing and really

thinking about the health of our nation and not just being a payer and how you've aligned those two things together, which brings us to our next set of federal programs that we're going to talk about today.

The first program that we're going to 6 7 address today is the Hospital Inpatient Quality 8 Program, one of the ones that is nearest and 9 dearest to all of our hearts. It also includes the Medicare and Medicaid EHR Incentive Program 10 11 for Eligible Hospitals and Critical Access 12 Hospitals. And I am going to turn it over to Melissa. 13 who? 14 (Laughter.) 15 CO-CHAIR TRAVIS: I can't read and 16 talk at the same time. It's like chewing gum and 17 walking. 18 So, Melissa, thank you for kicking us 19 off. 20 MS. MARINELARENA: Thank you, Cristie. 21 Okay. Let's keep that positive attitude that we just had while we go through these last programs. 22

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1	(Laughter.)
2	MS. MARINELARENA: So as we all know,
3	IQR, this is a pay-for-reporting and public
4	reporting program. Hospitals that do not
5	participate or do not meet the program
6	requirements are can receive up to a quarter
7	reduction of the annual payment update and the
8	program rules are to progress towards paying
9	providers based on the quality rather than the
10	quantity of care that they give patients. And
11	there's also a goal of interoperability between
12	EHRs and CMS data collection, which is where you
13	see the integration of IQR and the EHR Incentive
14	Programs, which are separate and; I think I got
15	the EHR Incentive Programs right, to provide of
16	course consumers information about hospital
17	quality so that they can make informed decisions.
18	And I'll look to my CMS colleagues to see if I
19	got this right.
20	So the Medicare and Medicaid EHR
21	Incentive Program for eligible hospitals and
22	critical access hospitals, which is was

meaningful use -- it was three different
 programs. So the Medicare EHR Incentive Program,
 that is for eligible hospitals and critical
 access hospitals that do not successfully
 demonstrate meaningful use. They receive reduced
 Medicare payments.

For the Medicaid EHR Incentive Program those eligible hospitals and critical access hospitals that only participate in the Medicaid EHR Incentive Program, which is state-based, and do not bill for Medicare are not subject to any kind of payment adjustments.

Then there's the Medicare and Medicaid 13 14 EHR Incentive Program. I think I got this right. So hospitals, eligible hospitals and critical 15 16 access hospitals that participate in both and do 17 not meet meaningful use, they are subject to 18 payment adjustments, is that correct? I think 19 so, yes. 20 Okav. And of course the goal is to

21 promote the adoption and meaningful use of 22 interoperable information, technology and

qualified EHRs and to accelerate the adoption of HIT and utilization of qualified EHRs. So we have measures that were -- are introduced into the program for both IQR and the EHR Incentive Program, and then some are just for IQR. We have separated them out.

7 Here's a slide provided to us by our 8 colleagues from CMS. And we have again the NQF's 9 priorities on the left. And you have -- all 10 these measures on the right that were introduced 11 in the MUC. The ones in the parentheses are the 12 ones that are just the EHR Incentive Program, but 13 we will -- those are the ones that we're voting 14 on last, so we'll make that every clear when we 15 go through them.

16 This is the current state of the IQR 17 EHR Incentive Program, and we have it lined out 18 where there's the ECQM only measures. And you 19 can see the progress of the IQR Program over There used to be -- like when I started 20 time. 21 all of this there was a lot of chart-abstracted 22 measures. There's very few left.

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The slide that you have now, I did 1 2 update it with the measures that are slated to be removed within in the next couple of years, but 3 we start off with your COTIs, COPSIs, your 4 5 claims-based measures. If we go to the next slide, these are 6 7 more the claims-based measures, and I tried to 8 like lay them out my mortality or the 9 readmissions measure, excess days in acute care So these again are all based on sort 10 measures. 11 of themes. 12 Keep going. We have a whole lot. So 13 here's your ECQMs. Those are the ones that are 14 -- can qualify either in the EHS Incentive Program or some of the ones that the IHR IQR 15 16 Program can use as part of meaningful use. 17 Now the ones that are highlighted in 18 purple; and I have it, those are finalized for 19 removal. So the original slides that you saw 20 back during the web meeting, I did include those, 21 but now I've put those back in so you could see what CMS has scheduled to move out. So those are 22

scheduled to move out, so we don't look at those 1 2 They've been taken out. And you have as gaps. it in your handout as well. 3 So these are the only chart-abstracted 4 5 measures that are left. So CMS is really moving towards either the ECOMs or claims-based 6 measures. And we have your patient surveys and 7 8 some structural measures. And then there's two 9 that are scheduled to be removed as well. And there's a guiz afterwards --10 11 (Laughter.) 12 MS. MARINELARENA: -- to name all the 13 measures. 14 CO-CHAIR TRAVIS: Thank you. That 15 will take a while. 16 (Laughter.) 17 CO-CHAIR TRAVIS: Before we go to 18 public comment, Pierre, I know you wanted to make 19 some comments based on some feedback you got 20 yesterday. So if you would like to make some 21 comments, or to -- whatever you're prepared 22 comments are, those are the right ones.

1	DR. YONG: Thanks, Cristie.
2	So just wanted to offer just some
3	general context for the measures we're about to
4	discuss for IQR, so hopefully that will be
5	helpful for you all as you're thinking about why
6	we put these measures on the MUC list for IQR.
7	And I'm just going to cover this at a very high
8	level. Obviously if you have specific questions
9	during individual measure discussions, we can
10	certainly cover that.
11	But, so one of the things that folks
12	have been I know many folks around the room do
13	follow closely our regulations, but in last
14	year's IPPS rule for the Inpatient Quality
15	Reporting Program one of the questions we did ask
16	for feedback on was generally we noted that
17	based on some MedPAC analyses about a third of
18	psychiatric hospitalizations for Medicare
19	beneficiaries actually occur not in inpatient
20	psychiatric facilities specifically, but in acute
21	care general hospitals. So there's a substantial
22	amount of psychiatric-related conditions that are

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taken care of in general hospitals.

2	And so one of the questions we asked
3	for feedback in last year's rule was or
4	earlier this year was should we consider more
5	behavioral health-specific measures in the IQR
6	Program? And we did get a variety of responses
7	that were quite supportive of that concept, but
8	then also got some comments just cautioning again
9	you needed us to consider general implications
10	for work flow and effort, if you will.
11	But so what we did in this year's
12	when putting together this year's MUC list is we
13	looked at as you know, yesterday we discussed
14	the measures for the IPF Program, the Inpatient
15	Psychiatric Facility Program. So we looked at
16	the measures there that may be applicable to the
17	Inpatient Quality Reporting Program. So for
18	example, acute care hospitals.
19	And so you'll see a number of those
20	measures on the MUC list, and they are all
21	implemented into the IPF Program. So that's what
22	was generating that and driving those decisions

to put those on the MUC list. And so we want your feedback on those. And are those the right measures? And so that's what we're here to discuss.

5 I think yesterday we also had a robust 6 discussion and expect that we will have another robust discussion, as I'm sure Sean will lead the 7 way on -- in certain terms of pain and opioid 8 9 questions, but as we all know the opioid epidemic in this country is something that's garnered a 10 11 huge amount of attention. And so we do have a 12 couple of questions relating to pain management 13 and opioid use. And so that's what's driving 14 those particular questions being -- or measures, excuse me, being on the MUC list, and we'll have 15 16 a discussion around that.

And then we also look generally across general gaps, so nutrition for example, there's a collection of four -- a set of four questions relating to patient nutrition and malnutrition status that are on there. There are some questions around tobacco use and other sort of

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questions along those lines to fill those kind of 1 2 So hopefully that will provide some gaps. general high level context for the decision 3 4 making that went around measures that went onto 5 the MUC list. So thank you. CO-CHAIR TRAVIS: Well, thank you. 6 7 That's very helpful for us to really think about 8 how we go through these measures when we do. 9 So before we get started with the 10 measures I'm going to open it up for public 11 comment. 12 Operator, will you see if there's any 13 public comment on the phone? 14 Thank you. At this time if **OPERATOR:** you would like to make a comment, please press 15 16 star then the number one on your telephone 17 keypad. We'll pause for just a moment. 18 (Pause.) 19 OPERATOR: And there are no public 20 comments at this time. 21 CO-CHAIR TRAVIS: Public comment in the room? 22 You may go ahead.

1	DR. SUTER: Can you hear me? Okay.
2	Hi, my name is Lisa Suter. I'm the oversaw
3	director I was directed measure development
4	for the informed consent measure that you're
5	actually going to be hearing about later, but the
6	NQF staff indicated that we had new information
7	relevant to today's discussion. They had new
8	information relevant to the MUC 16-262 measure,
9	the informed consent measure, and the NQF staff
10	asked me as the developer to present during
11	public comment.
12	So we have information relevant to the
13	hospital level measure result reliability
14	testing. We performed split sample test/retest.
15	I'm happy to share documents if people want to
16	see this in front of them. But this is where we
17	took hospital level data for the informed consent
18	measure, which we'll discuss later. We split the
19	patients at each hospital randomly into two 50
20	percent samples. We ran the measure results in
21	both 50 percent samples and then calculated
22	interclass coalition coefficients to determine

measure result at the hospital level reliability. 1 2 If you're looking just at the mean score, the ICC is 0.94. If you're looking at the 3 4 proportion of informed consent quality scores at 5 that hospital that were over a quality threshold of 5, a score of 5, the ICC was 0.73. 6 And if you're looking at the proportion of informed 7 8 consent quality scores over a threshold of 10, 9 the ICC was 0.95. So I'll be happy to discuss 10 this later, but the staff asked me to present this early during public comment. Thank you. 11 12 CO-CHAIR TRAVIS: Thank you. 13 MS. BOSSLEY: Hi, Heidi Bossley. I'm 14 speaking on behalf of AMA. Their staff unfortunately couldn't make it today; asked me to 15 16 read a couple comments for them. 17 Specifically, I believe the two HCAHPS 18 pain measures are for discussion, not for votes. 19 Or is one for vote and one's -- okay. Either way 20 we're going to provide some comments on both. 21 (Laughter.) MS. BOSSLEY: Pain is a high priority 22

when treating a patient and should be assessed 1 2 frequently, but the measures and questions as drafted imply that it is the first and foremost 3 topic of conversation. The questions still only 4 5 highlight prescription medications as a sole option for managing pain when alternatives may 6 also be effective such as physical therapy, non-7 prescription medications and so forth. 8 9 The questions associated with specifically the 263, the Assessing Pain During 10 the Actual Stay, seemed very open-ended. 11 And the 12 second and third questions that are associated 13 with that same MUC number, the ones dealing with 14 has the hospital talked to you about how much pain you've had and then have they actually 15 16 talked to you about how to treat that pain are 17 not realistic since the scoring aspect is -- be 18 always by patients? 19 We also suggest that instead of asking 20 whether hospital staff explained side effects of 21 any prescribed pain medications the question

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should ask if the hospital staff explained how to

safely use the medications. Therefore, there is
 a need for CMS to complete testing and bring the
 measures back to the MAP for careful review after
 the testing results and revised measures are
 developed to ensure the measures are valid and
 they do not lead to unintended consequences.

7 Second measure, the Safe Use on 8 They just wanted to briefly comment as Opioids. 9 well that they support the intent of the measure, but are very concerned that it will lead to 10 11 unintended consequences that patients that 12 legitimately need concurrent opioids prescribed 13 will have an access issue primarily due to the 14 fact that physicians might be penalized for 15 prescribing those. Thank you.

16 CO-CHAIR TRAVIS: Thank you both very
17 much. Oh, we have another one.

MR. SHANER: One more. Thank you.
Hi, I'm Bob Shaner. I'm here on behalf of the
American Academy of Pain Medicine, which is the
AMA-recognized specialty society in pain
medicine. And we want to say us, too.

I think we endorse the comments that were 1 2 just made on behalf of the AMA. We think it would be a terrible mistake to change the 3 existing measures and adopt a new set of measures 4 5 that simply puts more focus on medication. Quality pain control in the inpatient setting is 6 7 a lot more complicated than a yes/no choice on 8 opioids. 9 And in fact, there's been tremendous 10 progress in the last 20 years on inpatient pain control, and much of it has very little to do 11 12 with opioids. Sometimes it's opioids in 13 conjunction with other therapies. Sometimes it's 14 other therapies instead of opioids. But to come back with five questions, two of which now 15 16 basically focus on did you get medication or 17 didn't you get medication, and did they talk to 18 you about side effects or didn't they talk to you about side effects? Just vastly oversimplifies a 19 20 complicated part of quality inpatient care. 21 So we would urge you as the AMA has to 22 hold off on the five that you have proposed, do

more work, gather more input, and our academy 1 2 would be more than happy to participate in that. We submitted a very lengthy statement to CMS in 3 4 connection with the de-linkage of the quality 5 measures for pain for payment purposes, and I'd like to make that available to you and hope 6 you'll have a chance to share that among your 7 8 colleagues. So thank you very much for the 9 opportunity to weigh in on this. 10 CO-CHAIR TRAVIS: Well, thank you. 11 Are there any other comments in the 12 room? 13 DR. GONZALEZ-FERNANDEZ: Hi, yes. Ι 14 am Marlis Gonzalez-Fernandez. I'm a physiatrist, Johns Hopkins School of Medicine, and I'm here 15 16 today to give comments representing the American 17 Academy of Physical Medicine and Rehabilitation. 18 CO-CHAIR TRAVIS: Okay. 19 DR. GONZALEZ-FERNANDEZ: We also --20 CO-CHAIR TRAVIS: Yes, I'm sorry. Go 21 on. DR. GONZALEZ-FERNANDEZ: 22 We also agree

1	with the comments that AMA and AAPM just put
2	forward. We further suggest that expanding the
3	scope of the options for managing pain is
4	incredibly important, especially, as we mentioned
5	before, the opioid epidemic is upon us.
6	So those things that are beyond
7	medications include activity, behavioral
8	modifications, mindfulness, medication
9	counseling, psychological support, physical
10	occupational therapy. So and the measures are
11	not addressing any of those interventions.
12	Further, we would suggest that MUC 16
13	the 263 and 264 should better represent the
14	intent of testing the communication of pain,
15	rather the treatment of pain. So we would
16	suggest that changing the how often questions in
17	HP-2 and HP-3 to, for example, quote, "During the
18	hospital stay did the hospital staff discuss ways
19	to treat your pain with treatments other than
20	medication," and perhaps saying, for example,
21	"During this hospital stay did the hospital staff
22	ask about the effectiveness of your pain

1	treatment" would be a little bit more open and
2	help patients tell us if pain has been in the
3	forefront, not just in the medicational realm,
4	but overall.
5	So thank you for your consideration.
6	CO-CHAIR TRAVIS: Thank you. Are
7	there any other comments on the phone, operator?
8	OPERATOR: There are no comments at
9	this time.
10	CO-CHAIR TRAVIS: Okay.
11	MR. LAPIN: I believe I have a
12	comment, if I'm able to right now.
13	CO-CHAIR TRAVIS: Sure.
14	MR. LAPIN: So, I'm Joshua Lapin. I'm
15	at the Society of Hospital Medicine and I just
16	wanted to I guess forward the comments from the
17	AMA on the 263 and 264, the HCAHPS measures.
18	Hospitalists are frequently in the position of
19	treating pain for hospitalized patients, and we
20	strongly appreciate that CMS has been working to
21	address some of the unintended consequences and
22	pressures around the HCAHPS questions.
1	And similarly, to the AMA's comments,
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2	we think that there's an opportunity to continue
3	working on the measures to be able to focus more
4	on the communication of pain and the wide range
5	of non-opioid options available for pain
6	management for hospitalized patients and for pain
7	management post-discharge.
8	CO-CHAIR TRAVIS: Okay. Thank you
9	very much.
10	I'm going to pause one moment to see
11	if there's anybody else out there before we close
12	public comment. Any other comments?
13	OPERATOR: And there are no further
14	comments.
15	CO-CHAIR TRAVIS: Thank you, operator.
16	All right. Well, thank you to all of
17	those who made comments and we really appreciate
18	your perspectives as we begin to look at these
19	particular measures.
20	The first set of measures that we're
21	going to be looking at address alcohol use and
22	drug use as well as one smoking prevalence

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1	measure. I didn't get any notification ahead of
2	time as to whether anyone wanted to pull these
3	measures, but we will go measure by measure to
4	see if anybody would like to pull them.
5	The first one is Alcohol Use
6	Screening, which is MUC 16-179. It was
7	originally and is being recommended to support a
8	rulemaking. Is there anyone that would like to
9	pull that measure? Okay. Akin says yes. Okay.
10	That's great. So that measure's pulled.
11	The second one is Alcohol Use Brief
12	Intervention Provided or Offered and Alcohol Use
13	Brief Intervention. The recommendation on the
14	consent calendar is support. Would anybody like
15	to pull that? Mimi. Okay.
16	The third one is Alcohol and Other
17	Drug Use Disorder Treatment Provided or Offered
18	at Discharge and Alcohol and Other Drug Use
19	Disorder Treatment at Discharge. And the
20	recommendation is do not support. Would anybody
21	like to pull that measure for discussion?
22	(No audible response.)

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1	CO-CHAIR TRAVIS: Okay. Seeing none,
2	it stays on the consent calendar.
3	And the final one is Patient Panel
4	Smoking Prevalence IQR, which is MUC 16-68.
5	Recommendation of do not support on the consent
6	calendar. Anyone want to pull it?
7	(No audible response.)
8	CO-CHAIR TRAVIS: Okay. So we have
9	two measures that are remaining on the consent
10	calendar. They are MUC 16-180 and MUC 16-68.
11	Are there any general comments that
12	anyone would like to make about these measures
13	before we see if we can just accept the consent
14	calendar? Akin?
15	MEMBER DEMEHIN: Since we pulled this
16	I did want to give a
17	CO-CHAIR TRAVIS: Oh, no, we're not
18	there yet.
19	MEMBER DEMEHIN: Oh, okay.
20	CO-CHAIR TRAVIS: Sorry about that.
21	We're just considering we'd like to offer an
22	opportunity for people to say something about the

consent calendar measures in case there's a 1 2 burning desire to do so. So that's where we still are. 3 4 Okav. I don't see anybody based on 5 their card to do that. So are there any objections to accepting the consent calendar with 6 those two measures on there? 7 8 (No audible response.) I don't see any 9 CO-CHAIR TRAVIS: objections. So now we will move to looking at 10 11 the particular measures that have been pulled for 12 discussion. And the first one is Alcohol Use Screening, MUC 16-179. 13 14 And, Akin, if you'd like to open us up with your rationale for why you had it pulled. 15 16 MEMBER DEMEHIN: Thanks, Cristie. So 17 it was helpful to hear from Pierre some of the 18 rationale for putting measures on the IQR list, 19 one of which was looking at the IPF measure set 20 and seeing if there was an opportunity to 21 incorporate measures from that. 22 I'll be pretty blunt and say that we

aren't a fan of this measure in the IPF measure
set and we're not particularly big fans of it in
the IQR measure set either.

4 In raising concerns about this I 5 certainly don't want to convey the impression that we don't believe alcohol abuse is an 6 7 important public health topic, because it most 8 certainly is. I just think we question the 9 extent to which a measure like this, which is really offering a brief intervention during a 10 11 hospitalization, during a time when a lot is 12 happening for a patient -- just how much of a 13 downstream impact this has on overall rates of 14 alcohol abuse.

It seems to us that this is kind of a 15 16 process measure. It's more of a check-the-box 17 thing that something that has a strong linkage to 18 So from our perspective the effort to outcomes. 19 collect the measure doesn't seem to pay off 20 downstream. So our recommendation on this would 21 be do not support.

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CO-CHAIR TRAVIS: Thank you, Akin.

1	And just as a clarification we do have several
2	alcohol measures here. This particular one is a
3	screening measure, but we will get to the brief
4	intervention measure in a moment. So thank you
5	for that.
6	And so his thoughts are do not
7	support. Are there other comments on this
8	measure? Mimi?
9	MEMBER HUIZINGA: We agree with the
10	AHA that the effort required to submit and
11	collect the information for this particular
12	measure doesn't seem to be paying off, I guess,
13	in actionable and proven evidence.
14	Again, like the AHA, we don't like
15	this measure in the current program that it's
16	being used in and think that better understanding
17	of the impact across a broad range of different
18	types of acute care settings is needed before
19	going forward.
20	CO-CHAIR TRAVIS: Thank you.
21	Sean?
22	MEMBER MORRISON: Oh, I just want to

1	offer a counter-argument. Alcohol screening is
2	something that is not done well in hospitals.
3	The risk of not identifying it is acute alcohol
4	withdrawal syndrome, which is often missed and
5	can be deadly. And one of the reasons actually
6	to keep this is in is to ensure that people with
7	a history of heavy alcohol use are screened and
8	appropriately targeted, not to develop a brief
9	alcohol intervention while they're in the
10	hospital. I would just urge consideration to
11	keep it for that reason, not for a brief alcohol
12	intervention.
13	CO-CHAIR TRAVIS: Thank you, Sean.
14	Marty?
15	MEMBER HATLIE: Just to reinforce
16	that, there were comments made by the Joint
17	Commission and public comments about how
18	important this is because the problem is very
19	real. So I'm just supporting Sean's analysis.
20	MEMBER SULLIVAN: This is Ann on the
21	phone. I just want to echo what the last two
22	individuals have said. There's a high use of

alcohol in the elderly especially and often not 1 2 noticed, not asked, not pursued, and I think causes lots of trouble actually in their ongoing 3 medical care, and even as was mentioned the 4 5 possibility of missing it and having a severe outcome. 6 7 But I really do think you need to be 8 screening for this like you would for anything 9 else that you're concerned about the elderly, especially since it's so unidentified. 10 So I 11 would support particularly the screening measure. 12 CO-CHAIR TRAVIS: Thank you, Ann. 13 Nice to hear your voice this morning. 14 Are there other comments? Ron? 15 CO-CHAIR WALTERS: I agree with Sean 16 and Ann, and I do distinguish between the 17 screening measure and the intervention measure. 18 There obviously are a subset of people who come 19 into the hospital, either their first time or 20 without direct connection to other outpatient 21 programs. I believe this is -- this underlies 22

the Joint Commission's stewardship of the measure 1 2 that it's an important place of capture. The attribution in that sense can only be to the 3 facility for doing it. The Joint Commission is 4 obviously going to keep this as a belief that 5 they have that it is a responsibility; I'm not 6 7 speaking for them, by the way, of hospitals to do 8 as a potential point of marking people for 9 intervention, I would say. And I would urge that 10 we support this, the preliminary analysis of supporting for rulemaking. 11 12 CO-CHAIR TRAVIS: Thank you, Ron. 13 Yes, David? 14 MEMBER ENGLER: Can you hear me now? Sounds like a commercial. 15 Great. Thanks. 16 So with respect to Ron's comment, I'd 17 like to support that, on 178 in particular. Α 18 number of hospitals have a significant burden of 19 drug and alcohol abuse, a disease burden in our 20 particular populations. I'll give you a number. 21 It's over 30 percent of patients that we're 22 serving that have underlying drug and alcohol

issues affecting their conditions, and chronic
conditions at that.

I did have a question on -- and I'm 3 4 glad the developer is on the line today. I did 5 have a question because I'm pretty much encouraged by what I see in terms of the ability 6 7 of brief interventions to have some sort of 8 impact on alcohol use in the long term. And if 9 in fact that is the case and if in fact we can do brief interventions and have these opportunities 10 11 to reduce the burden of disease in the 12 population, which by the way is a horrible 13 disease, then I think it's up to us to support 14 178 as we go forward. So those are my comments. 15 Thank you very much.

16 CO-CHAIR TRAVIS: Well, thank you. 17 And let's please keep David's thoughts in mind 18 when we do address 178. It's a little confusing 19 here I know because we're kind of doing both of 20 these, but they've both been pulled. So we will 21 have the opportunity. So if we can, let's think 22 about the screening component so that our vote is

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1	clean at the end of this conversation.
2	So, Mimi?
3	MEMBER HUIZINGA: Thank you. I forgot
4	to add that we would be much more interested in
5	this measure if it was eSpecified. So we feel
6	that if right now this is a manual extraction
7	measure and the effort required to manually
8	extract this is what we're concerned about from
9	the screening perspective. However, if it was
10	eSpecified, that would alleviate some of those
11	concerns.
12	CO-CHAIR TRAVIS: Well, thank you for
13	that. Just as a question I had had in my own
14	mind was where's the burden? Is it on finding
15	out whether you did the screening or is it on the
16	screening, because there appears, at least from
17	my perspective, to be support for doing the
18	screening from a clinical standpoint. So, Mimi,
19	am I interpreting you correctly that it's maybe
20	more burdensome from the data collection
21	standpoint?
22	MEMBER HUIZINGA: It's burdensome on

So in this standpoint -- but particularly 1 both. 2 on the data collection. So in this case it required it to be an approved measure, so you 3 need to ensure that from a work flow standpoint 4 5 that you built out the process to collect that information and to prompt that. 6 7 But when -- then when you're going 8 back through as an abstractor and trying to --9 you have to find what note it was performed in. 10 It could be a nursing note or a physician note. So it's in multiple places in the EHR, because 11 12 it's not especified. Then the reviewer must know whether or 13 14 not the tool that was used is a validated tool. And you could use different tools for different 15 16 age groups and what qualifies as validated versus 17 not validated could be debated. 18 And then lastly, what happens if the 19 tool is not completed? Maybe the patient 20 answered or the person recorded only a few parts 21 of the question. So these are some of the very really 22

challenges that we have with abstraction of the 1 2 screening tool in the current program. And we don't feel that those have been adequately 3 4 resolved to move this to a broader program. Even 5 though we totally understand and agree with what 6 everybody said that alcohol screening is 7 critically important, we would be more in favor 8 of this if this were especified and maybe further 9 delineated. 10 CO-CHAIR TRAVIS: Thank you. That's 11 helpful. 12 Any other comments before we go Okay. 13 to a vote? Yes? 14 MEMBER JORDAN: Well, I would like to propose then for No. 2 that we have the ability 15 16 to vote to say -- the clarification would be to 17 develop a new measure as the -- what we're voting 18 for with conditional support, the condition of an 19 eMeasure be developed and --20 CO-CHAIR TRAVIS: Okay. And I'm going 21 I thank you for that, Jack. I'm going to look to staff around that as to whether that would be a 22

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1	refine and resubmit or whether that would be a
2	conditional support.
3	MS. MARINELARENA: That would be a
4	different measure. So you have to vote on the
5	measure.
6	CO-CHAIR TRAVIS: We're going to vote
7	on the measure. We're trying to decide if we
8	vote one, two, three or four.
9	MS. MARINELARENA: Right.
10	CO-CHAIR TRAVIS: So the question is
11	would refine and resubmit if we wanted it to
12	be an eMeasure would it fall under refine and
13	resubmit? So it doesn't even fall under that?
14	MS. MARINELARENA: Well, that's
15	DR. FITZELL: Hi, I'm Joann Fitzell.
16	I'm one of the nurses that works at CMS. I'm one
17	of the measure leads on this. So this is
18	currently being eSpecified by SAMHSA, and TJC is
19	consulting with them.
20	(Off microphone comment.)
21	DR. FITZELL: Well, for right, for
22	one of the measures we actually have quite a bit
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1	of data. The two sub two and sub three, the
2	time frame is not well, not yet. We're
3	CO-CHAIR TRAVIS: We're early use. I
4	mean, the screen.
5	DR. FITZELL: Right. So pardon?
6	(Off microphone comment.)
7	DR. FITZELL: Yes. Yes, it is.
8	CO-CHAIR TRAVIS: I'm sorry. I
9	couldn't hear Helen's question. So I
10	(Off microphone comment.)
11	DR. FITZELL: On, not it's not. It is
12	not complete yet, no.
13	CO-CHAIR TRAVIS: And when we says is
14	it done yet, meaning toward eSpecification, is
15	that
16	DR. FITZELL: Right.
17	CO-CHAIR TRAVIS: the content? I
18	wanted to be sure. There are all these sub-
19	conversations going on so it's difficult for us
20	to all year.
21	So I'm going to go back to the same
22	question: The fact that there may be an interest

in an especified measure would not therefore be 1 2 anything that could get you into two or three? It can capture that 3 MS. MARINELARENA: 4 you -- if you support this measure now and then 5 make -- and capture the report that you strongly support the especification of this measure that 6 is in process. 7 8 DR. BURSTIN: So that would be yes. 9 MS. MARINELARENA: Right. So the recommendation for this one now is support for 10 rulemaking, this measure now. And then know that 11 12 the workgroup really wants the eMeasure, which is 13 in process. 14 CO-CHAIR TRAVIS: That's great. Ι can't read the whole room, but what if the answer 15 16 is -- I guess we could make that comment no matter what we voted on. So if we voted -- it 17 18 can't be a condition or a refine and resubmit is 19 what you're telling us? Okay. That's what I 20 wanted to give clearly since that was the 21 question Jack brought up. 22 Okay. We've still got some cards

1	going up. So I know this has been a little
2	confusing and I want to be sure we get there.
3	Marty?
4	MEMBER HATLIE: Just given the
5	magnitude of the problem that several of us have
6	spoken to today, I would urge us to support this
7	measure and not wait for the eMeasure with the
8	strong comments that we've talked about, the
9	importance of how an eMeasure would reduce
10	burden, but I think this is one of those areas
11	where we really have the opportunity to make a
12	difference by using that hospitalization
13	opportunity to address this national problem. So
14	please let's support this one.
15	CO-CHAIR TRAVIS: Thank you, Marty.
16	Brock?
17	MEMBER SLABACH: I would probably say
18	it the other way, that we need to not support but
19	strongly recommend that this be eSpecified and
20	brought back for inclusion in the program.
21	CO-CHAIR TRAVIS: Right, I mean, I
22	think we've got that. I think that whatever we

say people are going to -- might to put a strong urging that an eMeasure be associated with this. So that can be kind of a side comment. It won't come into the voting, but it'll come in as a side comment.

## Mimi?

MEMBER HUIZINGA: Well, thank you, and 7 8 I agree with Brock. Of course, I mean, I want 9 people to understand that if you put this measure in now, and even if we get conditional support, 10 11 there is a history that CMS would take that 12 forward and put that into a payment program. And 13 so hospitals would build an entire abstracting 14 team and program, train people, invest lots of 15 money in making this happen. And then maybe it 16 sounds like next year we would be talking about 17 an eMeasure. So I would strongly support people 18 not to support this and just do it right the 19 first time and not have a runabout process. 20 MEMBER SULLIVAN: This is Ann. 21 CO-CHAIR TRAVIS: Yes, Ann? Could I just get 22 MEMBER SULLIVAN:

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some clarification here? They said the eMeasure 1 2 is in process. I mean, does that mean that it's going to be done very, very soon, or not? 3 4 And the second thing is I don't know 5 the -- I would still vote for approving this and then saying that we strongly support getting the 6 eMeasure. Because again, putting it off is 7 8 something -- it interferes with the -- now you 9 can be a long time before you do alcohol 10 screening. 11 And I would just like to echo what 12 other people have said. We have used taught 13 processes. I know they can be difficult. I know 14 they're a little burdensome, but this is a big issue. And I don't think it's very wise of us to 15 16 not approve it now, but maybe with a very, very 17 strong recommendation that the eMeasure move 18 And I'm not so sure that CMS would put along. 19 this out as an eMeasure. We're almost ready, I 20 would assume, although maybe I shouldn't, that 21 they would then do it as an eMeasure. 22 CO-CHAIR TRAVIS: Thank you. We'll

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1	get clarification again. Can you all speak to
2	the eMeasure?
3	DR. YONG: I mean, the eMeasures we're
4	working with SAMHSA on this and eSpecifying it.
5	That's I don't have a specific timeline.
6	CO-CHAIR TRAVIS: Oh, so there's no
7	specific timeline on when the eMeasure would be
8	available.
9	So unless it's something different
10	than has already been said, Akin because I
11	think we're being a little repetitive. So I want
12	to be sure it's additive.
13	MEMBER DEMEHIN: This is a slightly
14	this is more a question especially for the
15	clinicians in the room. So this particular
16	measure has as time window of three days within
17	admission to screen for problem alcohol use.
18	Does it make it and I know one of the points
19	that was made was around this could be helpful in
20	terms of identifying alcohol toxicity and its
21	downstream impacts on patients, but does that
22	three-day window make it any more or less useful

for that purpose?

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2	CO-CHAIR TRAVIS: Sean?
3	MEMBER MORRISON: Yes, speaking as a
4	clinician, the if you're looking at alcohol
5	withdrawal syndrome, the window is 48 to 72
6	hours. And unlike opioid withdrawal syndrome,
7	alcohol withdrawal syndrome kills. Opioids,
8	typically withdrawal doesn't kill. Alcohol does.
9	CO-CHAIR TRAVIS: Okay. Well, I think
10	that we have kind of addressed and we see the
11	two issues that are before us. So I think it's
12	time to move to a vote. As a realistic issue,
13	our vote really is support and do not support at
14	this point because the eMeasure development is
15	not suitable for conditional or refine and
16	resubmit.
17	Just to I guess I'm looking at
18	whether we should just vote on those two, or
19	should we include okay.
20	So we're going to just give you the
21	option, unless I hear differently from you all,
22	because I want to give you a chance to vote in

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any category. But it looks like it's going to be 1 2 support or do not support. And unless there's an objection, those are going to be the two options. 3 4 MS. MARINELARENA: Before you vote I 5 just want you to take a look at the measures that 6 are in the current set now. There's only six 7 chart-abstracted measures, so I don't know if 8 that makes a difference. I remember the days 9 when there was a whole lot. So if CMS is moving towards -- there's less chart-abstracted 10 11 So I don't know if that makes a measures. 12 difference in decreasing the burden, but I was 13 there when you were doing --14 (Simultaneous speaking.) Well, thank you. 15 CO-CHAIR TRAVIS: 16 No, I think that is helpful. So thank you very 17 much for adding that. 18 (Laughter.) 19 CO-CHAIR TRAVIS: Okay. I think we'll 20 go on and move -- and we're only going to vote 21 one and four. 22 MS. QUINNONEZ: Yes, before you cast

your votes I just want to do a quick reminder for 1 2 the sake of those who may not have been with us yesterday. When you cast your vote, everyone, I 3 4 want to make sure everyone who is voting has 5 their voting clicker, yes, in the room? Okay. If you -- when you are ready to vote, when we 6 7 open the vote, if you could just point your 8 clicker towards me. 9 And also to remind you that your last 10 click that you do make will be your vote. Okay? 11 So you can click as many times as you want, but 12 the very last click that you do make will be your 13 final vote. 14 And we may have to do this more than 15 once. Hopefully not. But thank you for your 16 patience. Okay? 17 So we are now voting on Hospital 18 Inpatient Quality Reporting for Consent Calendar 19 This is Measure -- the Alcohol Use No. 6. 20 Screening measure, and that's MUC 16-179. 21 You have two options. For those who are on the phone, you can cast your ballots 22

1 through our chat system. Option No. 1 is 2 support. Option No. 4, do not support. So you have two options for MUC 16-179, the Alcohol Use 3 4 Screening measure. And Option No. 1 is support; 5 Option 4, do not support. (Voting.) 6 MS. QUINNONEZ: Thank you, Marisa and 7 8 Ann. 9 Okay. Voting is now closed. Okay. 10 WOW. 11 (Laughter.) 12 MS. QUINNONEZ: For the results of 13 Alcohol Use Screening measure, MUC 16-179, the 14 results are 61 percent voted for support, 39 15 percent voted do not support. This moves forward 16 with support. 17 CO-CHAIR TRAVIS: Well, the only thing 18 I can say from a project -- I mean, a meeting 19 management standpoint, I'm relieved that we at 20 least came down one way or the other on this 21 measure --22 (Laughter.)

1	CO-CHAIR TRAVIS: because we were
2	going to have to go back and talk about this even
3	more. So, but thank you. And I do hope that
4	those who voted do not support understand that
5	your thoughts were heard and they will be they
6	are being communicated directly, but also will be
7	considered as we move forward. So thank you all
8	for that.
9	The next measure that's been pulled is
10	the Alcohol Use Brief Intervention Provided or
11	Offered and Alcohol Use Brief Intervention. I
12	think it means happening. But anyway, and this
13	is MUC 16-178. We've had a little bit of
14	discussion because these things are so close
15	already, but I know that Mimi pulled this.
16	So if you would like to talk with us
17	about the rationale behind pulling it.
18	MEMBER HUIZINGA: I think that the
19	rationale has already been well-stated, so I'll
20	just review at a high level. Offering a brief
21	intervention during the hospital stay is already
22	a measure in another program and we haven't

necessarily seen the payoff from having that 1 measure as we would like to see. 2 There is a tremendous amount of effort 3 that goes both into implementing this 4 5 intervention, tracking it, even determining if it's been offered. The amount of training, which 6 7 I feel like maybe I didn't spend enough time speaking on, and the cost to a hospital of 8 9 training abstractor -- first developing the 10 process, defining the protocol, developing the 11 abstraction tools, training all the abstractors, 12 having to fill in the abstractors when somebody can't be there is a tremendous amount of time and 13 14 effort and money. And so every time we put in a chart-abstracted measure, even if there's only 15 16 six, is still -- just maintaining them on an 17 annual basis is a phenomenal amount of time and 18 effort. 19 This not only -- even if this was 20 eSpecified, we would still have concerns about it 21 due to several of the comments that David and Akin both made earlier about just the overall 22

benefit of having the brief intervention compared to the effort that is required to capture this particular measure.

4 CO-CHAIR TRAVIS: Okav. And I 5 apologize for this. I did not do this earlier. 6 It gets confusing up here, believe it or not. But we do have some lead discussants that were 7 8 engaged with this set of measures. David is one 9 of them and has raised his card, so I'll probably start with you. But either Marsha or Jennifer 10 11 want to add any comments, we would like to hear 12 from you, if you can, regarding what your 13 thoughts were. 14 So, David? 15 Thank you. MEMBER ENGLER: Thank you. 16 And thank you, Mimi, for your comments 17 as well. 18 My -- I had as a lead discussion I had 19 -- hopefully the developer is on the line today. 20 Am I thinking correctly? Are they --21 CO-CHAIR TRAVIS: I don't --22 MEMBER ENGLER: Are they not with us

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today?

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2 CO-CHAIR TRAVIS: No, they're not with 3 us today.

4 MEMBER ENGLER: Oh, okay. Because I 5 was hopeful for a little bit more conversation about whether or not the interventions in 6 7 hospitals, these brief interventions have been 8 proven to impact alcohol abuse in patients that 9 are being served. And it's a question that I have that was raised by some of my staff and some 10 11 of my members, whether or not that has been 12 tested on the inpatient side. My notes suggest 13 that it has been effective in primary care 14 settings, but I do not know. And this is a 15 question that I'd be interested -- and perhaps 16 Mimi can chime in on this. I'd be interested in 17 knowing it hasn't had any impact on the use in 18 inpatients; that is, does brief interventions 19 have any impact on long-term use of alcohol? Thanks. 20

21 CO-CHAIR TRAVIS: Well, why don't we, 22 if that's okay, go on and try to see if we can

get some additional information on that, and then 1 2 we'll go to the other lead discussants if they have any additional comments. 3 I'm looking at CMS. Do you all know 4 5 what the evidence is related to the brief intervention in an inpatient setting in terms of 6 the effectiveness? 7 8 (Off microphone comment.) 9 CO-CHAIR TRAVIS: Okay. I don't know 10 if any of the Committee members on the phone have 11 any comments. Ann, I don't know if you have any 12 work in this area or know of any that might be 13 helpful. 14 MEMBER SULLIVAN: I think the major 15 studies have been done in primary care. To tell 16 you the truth, I'm not sure if they've looked at absolute outcomes from individuals who are 17 18 actually in the hospital and get brief 19 interventions. So I'm sorry I can't really help with that issue. 20 21 CO-CHAIR TRAVIS: No, that's fine. 22 Thank you.

1	It's my understanding there may be
2	some additional information in our detailed
3	summaries of this measure, but I don't have that
4	in front of me. So would somebody who's looking
5	at it like to read what it says? I don't know if
6	that's Helen, Melissa, Ron.
7	CO-CHAIR WALTERS: So, yes, I'm
8	reading in the measure description itself and
9	down in the it's actually called the
10	Endorsement and Public Comments. And what it
11	says is, "The Committee noted that the majority
12	of the evidence generally is related to the
13	outpatient setting, however, following
14	substantial discussion Committee members agreed
15	that certain evidence could be generalizable from
16	the primary care setting to the inpatient setting
17	and that sufficient evidence was presented
18	related to the inpatient setting based on the
19	USPSTF and Cochrane Review evidence to support
20	the measure."
21	We don't have the actual data, but
22	that's the statement that's made.

Okay. I think 1 CO-CHAIR TRAVIS: 2 that's helpful. Is that helpful to you, David? (Off microphone comment.) 3 4 CO-CHAIR TRAVIS: Yes. Is that related to this, Sean? Okay. 5 MEMBER MORRISON: So a brief PubMed 6 7 search found two RCTs in the inpatient setting of 8 the effectiveness of a brief alcohol intervention 9 in the hospital with highly statistically significant results. 10 11 CO-CHAIR TRAVIS: So to us non-12 researchers does that mean it is working? 13 MEMBER MORRISON: I'm sorry. What it 14 means is, yes, there are two randomized control trials that have shown that a brief alcohol --15 16 oh, man. 17 (Laughter.) 18 (Simultaneous speaking.) 19 MEMBER MORRISON: A hundred and 20 twenty-four large confidence intervals, but 21 statistically significant. 22 CO-CHAIR TRAVIS: Okay. So I guess

1	one thing I mean, there's two things that I'm
2	taking away from that: There are some PubMed
3	results that show that it was effective, albeit
4	people may be looking at the numbers, but that in
5	the standing committee they did feel that the
6	evidence from primary care they felt after
7	looking at it would also apply in this setting.
8	So I think we've given you the answers that we
9	can give you relative to David's concerns.
10	I do want to give a moment, if any of
11	the other lead discussants had any comments that
12	they wanted to make relative to this particular
13	measure, MUC 16-178. And it's okay to say no.
14	Okay. I just didn't want to not honor the work
15	that may have been done in advance.
16	Okay. So because I have been thinking
17	and not looking, I'm just going to start down at
18	the end of the table with Marty and work my way
19	up on this side. And then those of you over
20	there can start thinking about whether you want
21	to have any comments.
22	So, Marty?

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1	MEMBER HATLIE: Okay. Since we don't
2	have the Joint Commission with us on the phone,
3	they did file a very significant and strongly-
4	worded comment. Clinical trials have
5	demonstrated that brief interventions, especially
6	prior to the onset of addiction, improved health,
7	but also reduced cost. So there's a cost element
8	here that I wanted to highlight that we haven't
9	really talked about except for the effort side of
10	the equation. Thank you.
11	CO-CHAIR TRAVIS: Thank you, Marty.
12	We're glad you're looking at those comments, so
13	thank you very much.
14	Brock?
15	MEMBER SLABACH: This measure I think
16	illustrates, and Mimi talked about the very
17	important parts of data collection, but I'm going
18	to move upstream now and suggest to you that
19	there's about 1,500, 1,800 small and rural
20	hospitals that have a very difficult time in
21	terms of staffing to be able to provide this
22	intervention. So the first question I ask is

who would do this in a particular facility? 1 2 And usually, like in the tobacco cessation requirements, it's respiratory therapy. 3 4 We say you go up to talk to the patient. This is 5 even more difficult I think in terms of a conversation, especially if family is involved 6 7 and they're in the room and you're in a two, 8 three, four-day acute care stay dealing with 9 important acute care issues that are going all on at the same time. And now you're trying to talk 10 11 with them about some systemic issue that is going 12 to go on well beyond that short stay. And it needs to be done well, I guess is my point. 13 And then this becomes a check-the-box 14 And then the value of it I think 15 program. 16 diminishes despite some of the evidence to the 17 contrary. I just know how this is 18 operationalized in a facility. 19 CO-CHAIR TRAVIS: Thank you. Mimi? 20 21 MEMBER HUIZINGA: Thank you. So I 22 wanted to clarify the points about the data that

we were looking for, and then also because I'm an epidemiologist and I can't -- I feel like I can't let Sean's comments go unspoken to.

The first piece of it, what we were 4 5 specifically talking about was evidence of the use of this measure. So not a randomized control 6 7 trial. But this measure has been in use and we're very interested how this measure has 8 9 impacted long-term alcohol use, and we don't feel that that has been publicized. And if it has, 10 11 CMS, we would love to see that information and 12 data and I would love to be corrected.

13 Second, when we look at this measure 14 and how it aligns to just the Cochrane study, the Cochrane Review was a 14 randomized control 15 16 trial. Cochrane does a great job. It only shows 17 a benefit for heavy alcohol users, which is not 18 what this measure is. This measure is anyone 19 with unhealthy alcohol use. There are multiple studies that show -- randomized control trials 20 21 that show that use and light drinkers or at-risk drinkers does not show benefit. 22

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1	And so we've taken a population where	
2	there is evidence for we've expanded in this	
3	measure creating additional work and effort that	
4	again doesn't have the support. I know this	
5	isn't our place to debate the scientific merits	
6	of the study; and Helen's shaking her head at me,	
7	but it was opened up and there was a question	
8	that was asked, so I felt that it's worthwhile to	
9	respond then to you.	
10	CO-CHAIR TRAVIS: Thank you, Mimi.	
11	Brock, anymore comments or	
12	MEMBER SLABACH: No.	
13	DR. BURSTIN: Operator, could you	
14	please open the line for Ann Watt from the Joint	
15	Commission?	
16	(Pause.)	
17	DR. BURSTIN: Ann, are you with us?	
18	(Pause.)	
19	DR. BURSTIN: Operator, are you with	
20	us?	
21	OPERATOR: Ann has not dialed in. We	
22	do have Alvera Ryan on with the Joint Commission.	
1	DR. BURSTIN: Okay. Maybe they	
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2	switched. Go ahead.	
3	(Pause.)	
4	DR. BURSTIN: Good morning.	
5	MS. RYAN: Hi, this is Alvera Ryan.	
6	DR. BURSTIN: Wonderful. Are you able	
7	to speak to the questions that have been raised	
8	about the alcohol intervention measure?	
9	MS. RYAN: I can't really speak in	
10	terms of studies about how the measure has	
11	impacted long-term alcohol use.	
12	With the work that we have done we	
13	have looked at studies that have spoken to brief	
14	interventions being done in the hospital and	
15	during hospitalization being a prime time to	
16	approach the patients, and that at that point in	
17	time they are more amenable to interventions, and	
18	that the impetus is to get that process started	
19	during the hospitalization. And studies have	
20	shown that patients who have that initiated while	
21	they're inpatients have a greater tendency to	
22	follow through with treatment in the outpatient	

1 setting. 2 CO-CHAIR TRAVIS: Thank you very much for that information. 3 I'm going to go back to Mimi, and then 4 5 I'm hoping that we'll be ready for a vote. MEMBER HUIZINGA: 6 Okay. I promise this is the last thing I'm going to say. 7 So the Cochrane Review actually showed 8 9 that there was a difference in alcohol use at three and six -- I'm sorry six and nine months, 10 but not at one year. So clearly this -- even --11 and that was only in the population of heavy 12 alcohol drinkers. 13 14 So I appreciate everyone's comments that this has an impact, but we should understand 15 16 what the impact is. We're asking for a lot of 17 effort to have some improvement in a small piece 18 of denominator population that's currently 19 defined in the measure. It is not a long-term 20 life changing intervention. According to the 21 evidence it does have impact in a period after the hospitalization for a subset of the 22

denominator.

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2 CO-CHAIR TRAVIS: Okay. Thank you. And just because we can go through rebuttal and 3 4 everything back and forth every time, if the 5 Joint Commission person would like to make any statements; and it's okay not to --6 7 (Laughter.) 8 CO-CHAIR TRAVIS: -- I do want to give 9 you an opportunity to. But if I don't hear, I'll assume you would not like to make a follow-up 10 11 comment. 12 While you're thinking, Frank? MEMBER GHINASSI: This is more of a 13 14 question. I don't know if I'm looking at the same 127-person study you are. Was it South 15 16 Africa? No, it wasn't? 17 So it's a similar thing. It was a 18 randomized trial, three-month follow-up. About 19 30 of the 127 they looked at showed improvement 20 at 3 months. It was self-report, not -- there's no concurrent evidence on it. And of the 60 21 22 people that referred to treatment, only 30 of

1	them actually went. So it was a positive study
2	and significant, but if you read it a little more
3	closely, the significance is not how it would
4	initially sound.
5	My second question is a technical one.
6	This is NQF-endorsed, so I have to assume that it
7	met a standard for scientific acceptability.
8	PARTICIPANT: Yes.
9	MEMBER GHINASSI: And that
10	acceptability was based on primary care
11	effectiveness or inpatient effectiveness?
12	Because that would be my question. That's all.
13	MEMBER ENGLER: That was my question,
14	too.
15	CO-CHAIR TRAVIS: We're looking it up
16	so we can read it to you.
17	DR. BURSTIN: I recall it was a very,
18	very lengthy discussion about what would be
19	translatable and what was uniquely inpatient-
20	based. We're just looking at the submission
21	again. I don't know if the person; sorry I
22	missed your name, on the phone has any

1 information to shed while we look this up, 2 specifically on the evidence for the inpatient brief intervention. 3 4 (Simultaneous speaking.) CO-CHAIR TRAVIS: Yes, and she did 5 mention some of that. 6 DR. BURSTIN: They did actually cite; 7 8 let's see, three different studies, the first of 9 which had 12 trials, the second of which had 11 trials. And there's also a DoD guideline review 10 11 that had 1,177 studies. So they did have a 12 pretty significant number. Each of the studies was rated in terms of the quality of the evidence 13 14 as well. And ultimately we felt this was 15 evidence-based. We're happy to share the 16 specific submission form if you'd like to see it. 17 CO-CHAIR TRAVIS: Okay. This is going 18 to hopefully be our last comment. Well, we've 19 got -- Mimi, is your card still up? 20 (No audible response.) 21 CO-CHAIR TRAVIS: Okay. So, Brock, 22 you get to bring it home.

1	MEMBER SLABACH: Well, I just wanted
2	to quickly follow up on the data that was
3	suggested on the effectiveness.
4	How was the structure of the
5	interventions made in those studies? And is it
6	done under such a fashion that it could be
7	replicable in terms of the content of those
8	interventions across 4,000-plus acute care
9	hospitals in the United States? And is each of
10	those going to be the same in terms of the
11	quality? And that's the real question I think
12	that I have a concern about in terms of being
13	able to meet this, the intent of what this is
14	trying to achieve versus what the reality will
15	be.
16	CO-CHAIR TRAVIS: So I'm going to
17	probably take that as a rhetorical question since
18	I don't think we have anybody here who can answer
19	that, but I really failed to see that Marty's
20	card was up before Brock's, so now, Marty.
21	MEMBER HATLIE: So the evidence gap
22	for me here is really the cost of the burden that

we hear about from hospitals for investing and addressing this real issue, and I don't have that I come from a rural part of the country data. where I know this is a real issue where families 4 who need an intervention, if they're going to get it anywhere, that they can't do themselves, it's going to be at the hospital.

I think it is a huge issue, and I just 8 9 want to see hospitals stepping up and doing this. If it's a huge or prohibitive cost burden, I 10 guess that needs to be considered, but I don't 11 12 know that it is. We're talking about a brief 13 intervention for an important national problem. 14 CO-CHAIR TRAVIS: Okay. Well, thank 15 you so much, Marty. 16 I think that for the second time in a row we've kind of had a broad discussion and 17 18 gotten rather deep into some of this, which I think it's worth. So I thank you all for your 19 20 thoughtful comments. 21 I think we will go to the vote and I think we'll just go with the vote that's on the 22

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1	screen. I have not heard any conditions or
2	refine and resubmit, but we will like we did
3	yesterday, we'll just kind of go through all
4	those options.
5	MS. QUINNONEZ: Okay. We are now
6	voting on the IQR Program measure, Alcohol Use
7	Brief Intervention Provided or Offered and
8	Alcohol Use Brief Intervention. And this is MUC
9	16-178. Option No. 1, support; Option No. 2,
10	conditional support; Option No. 3, refine and
11	resubmit; and Option No. 4, do not support.
12	I'll go over those options one more
13	time for those on the phone. Option No. 1,
14	support; Option No. 2, conditional support;
15	Option No. 3, refine and resubmit; and Option No.
16	4, do not support.
17	(Voting.)
18	MS. QUINNONEZ: Thank you, Ann.
19	(Voting.)
20	MS. QUINNONEZ: Okay. All votes are
21	in and voting is now closed. For MUC 16-178
22	Alcohol Use Brief Intervention Provided or

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Offered and Alcohol Use Brief Intervention the 1 2 results read 48 percent voted for support; 0 percent for conditional support; 4 percent voted 3 4 for refine and resubmit; and 48 percent voted do 5 not support. CO-CHAIR TRAVIS: 6 Okay. So I'm going 7 to huddle over here --8 (Laughter.) 9 CO-CHAIR TRAVIS: -- and see what we need to do. I'll be back with you in a moment. 10 11 (Pause.) 12 MS. QUINNONEZ: The verdict for MUC 13 16-178 is do not support. 14 CO-CHAIR TRAVIS: And the rationale is 15 we didn't have 60 percent or above to go, so it 16 fails. So see, we've now had an experience with 17 that and we know what to do on the next time, if 18 and when that ever happens. But thank you all 19 very much. 20 Before we leave this consent calendar, 21 it has been brought to my attention that although 22 it was part of the consent calendar that we

accepted, the recommendation for do not support 1 2 for the Patient Panel Smoking Prevalence, there is a desire that we hear some discussion around 3 4 that so that there can be an understanding for 5 why we as a group decided to accept the do not That would be helpful to CMS for us to 6 support. 7 -- for them to understand our rationale. 8 So I can maybe start to see if any of 9 the lead discussants have anything they would like to bring up relative to this particular 10 11 measure. Oh, yes. Sorry. Thank you, Pierre. 12 MEMBER YONG: So thank you. I know it 13 wasn't proper. We just wanted to get some 14 feedback about this. This folks who are on the MAP Committee last year may remember we had a 15 16 similar type measure. There was a very robust 17 discussion about the Tobacco Prevalence measure, 18 which I think got 61 percent also. I think it 19 was last year. It got support and continue 20 development. 21 And so we wanted to bring back -- this

was brought back and to adjust some of the

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concerns that were raised and some discussion 1 that was raised last year in that. And so 2 Tiffany McNair from the Innovation Center at CMI 3 is going to talk a little bit about this. 4 But 5 the feedback would be helpful to us. Thanks so much, Pierre. 6 DR. MCNAIR: And thank you all. 7 Thank you to NQF and thank you to the MAP for this opportunity to present 8 9 today. We really appreciate it. 10 I just want to start off by saying as 11 a practicing OB/GYN and preventive medicine 12 physician myself I'm especially enthused about 13 the opportunity the outcomes-based measures 14 present, especially the one that we're presenting 15 and proposing to you, to the IQR today really to 16 achieve shared accountability across our 17 healthcare system. This opportunity represents a 18 future state I think in which the people that I 19 and all you in this room serve are able to receive the most effective evidence-based care, 20 21 one in which disease is not only prevented, but 22 really help us promote it, and that's the framing

that we are trying to achieve.

2	It's in that vein that we are
3	proposing MUC 16-68, which is the Patient Panel
4	Smoking Prevalence measure to the Hospital IQR.
5	You can go to the next slide. Thank
6	you. This measure is collected to be a hospital
7	records and captures the percentage of adult
8	hospital patients who are current smokers. And
9	as Pierre said, we at CMS did submit a related
10	geographically defined measure to the IQR last
11	year during the 2015 MUC cycle. That measure was
12	assessing smoking prevalence at the county level
13	among household dwelling adults in the U.S.
14	After robust discussion, as you said,
15	the measure was supported for continued
16	development. And one key reaction that we did
17	received concerned this issue around
18	accountability in the hospital for the smoking
19	behavior of individuals not directly served in
20	the inpatient setting.
21	And so we took this feedback to heart
22	in response to that and several other responses

that you all provided to us. We did refine the 1 2 measure, still with an eye towards outcomes, as you'll see, that's really within the boundaries 3 of the hospital, so the patient panel. 4 I just -- I know that all Next slide. 5 of you know this already, but at HHS and CMS we 6 7 really are committed to realizing this healthcare system that delivers better care, practices 8 9 smarter spending and at least to help their people. And so we are trying to focus more and 10 11 more on quality as opposed to quantity and value 12 over volume. And do as this framework 13 Next slide. 14 depicts, which some of you may be familiar with, our reform efforts really are shifting toward 15 16 altering the payment models and population-based 17 payments. And it's in light of this movement 18 towards a value-oriented outcomes-based system 19 that we believe this is the right opportunity for 20 the measure we're presenting to you today. 21 Next slide. You may also be asking 22 why smoking? Well, number one, we all know this

is expensive. Smoking is the leading cause of
preventable death and disease in the U.S. and
costs nearly \$170 billion annually in direct
medical costs. So tackling this particular
problem we believe is ideal in terms of improving
health and reducing the cost to the system.

7 But number two, we know that hospitals 8 can do something about it. There's a really 9 strong evidence base that shows that a coordinated multi-modal community-wide and 10 patient-centered approach improves the success of 11 12 smoking reduction efforts. And I might add that 13 with eight percent of the population being 14 hospitalized each year, there really are repeat opportunities for hospitals to have an impact 15 16 beginning with the inpatient stay.

17 In fact, there's already a growing 18 number of hospitals that are already engaged in 19 the types of efforts that we think that our 20 measure incentivizes. This is everything from 21 using EHR prompts to prompt physicians to ask 22 about smoking; improving combined approaches to

treatment like behavioral and pharmacotherapy 1 2 therapy interventions, which is consistent with the Joint Commission recommendations; referring 3 patients upon discharge to outpatient smoking 4 cessation treatment, right, and quit lines. 5 And then of course strengthening those 6 linkages with local primary care providers and 7 other community partners in order to improve 8 9 coordination of care and care management. This in the end not only helps people to guit, but 10 11 helps to sustain guitting. 12 We also know of a number of hospitals 13 across the U.S. that are using community-wide 14 policies like smoke-free campuses, which have all 15 been shown to be effective approaches to 16 promoting and sustaining smoking cessation. 17 So these approaches we believe not 18 only fall within the scope of the hospitals' 19 sphere of influence, but also ultimately move the 20 needle on the outcome that we care most about, 21 which is reduced smoking. 22 Next slide. Finally, we would add

that we can actually measure the fruits of our labor in this space, the outcome. Until now really smoking and other tobacco use measures utilized in CMS quality programs have focused 4 primarily on process as opposed to outcomes and often without an orientation towards primary prevention, which is perhaps the biggest cost saver.

9 And so we recognize that this kind of broader outcomes measure used in conjunction with 10 11 clinical process measures actually could do two 12 things: One is expand the reach of the process measure, right? So incentivize folks to do even 13 14 more of that, as well as improve our understanding of the magnitude of the impact of 15 our clinical care services such as cessation 16 17 counseling on the specific health behavior like 18 smoking.

19 So just taking together those three 20 elements that I described: cost, the evidence 21 base and the opportunities for measuring our 22 success, we believe that this smoking prevalence

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measure, as refined since last year, offers the logical next step in terms of assessing the quality of the care furnished in hospitals.

So last slide. Just want to -- a 4 5 point of clarification based on the analyses that we received from NQF. Please note that we did 6 7 perform internal reliability and validity testing 8 on this measure utilizing eligible provider data 9 from the PORS electronic health record. It was shown to have higher liability and moderate 10 validity including demonstrating an association 11 12 between provider screening practices and smoking 13 prevalence in the subsequent reporting year.

14 So we actually found that with an absolute 10 percent increase in screening 15 16 practices in one reporting year we saw a two 17 percent absolute decrease in smoking prevalence 18 in the subsequent reporting year. And this 19 finding was significant and it's critical. 20 As previously described, there is a 21 strong evidence base showing that hospitals,

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similar to individual clinicians, can really

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influence the smoking behavior of their patients. So while our initial testing was not performed realizing hospital-based data, we expect comparable results among hospitals given the availability of the similar prevention tools and the repeated opportunities for impact.

7 The last point that I'll make is that 8 CMS has also proposed a tobacco process measure 9 which is on the slate for later on today, MUC 16-10 60, to this year's MUC list. And although useful, we believe standing alone it captures 11 12 just a clinical process rather than an outcome. 13 We would propose that using these two measures in 14 tandem would actually achieve the most 15 comprehensive end. It would encourage hospitals 16 to advance best practices to reduce smoking, but 17 it would also promote the formation of critical 18 partnerships that embrace a more coordinated 19 multi-modal and patient-centered approach to 20 care. 21 So it's in that spirit of shared 22 accountability and coordination across the system

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1 that we're exploring the potential for smoking 2 prevalence measures, not only in the hospital IQR, but also across several other quality 3 4 programs including the Medicare Shared Savings 5 Program and MIPS. And we think this is a great opportunity for us to think more about this 6 7 shared purpose and to encourage accountability 8 across our entire healthcare system. 9 So I'll stop there. I know that I speak very quickly, but I knew that I didn't have 10 11 a ton of time. If you have any feedback, we look 12 forward to the discussion. And again, I really 13 do thank you for this opportunity today. 14 CO-CHAIR TRAVIS: Well, you may be quick, but you're very organized --15 16 (Laughter.) 17 CO-CHAIR TRAVIS: -- and logical. So 18 thank you for that. We do appreciate the 19 overview. 20 I am, as I indicated, going to kind of 21 go to our lead discussants to see if they have 22 any comments.

1	Marsha?
2	MEMBER MANNING: My comment and I
3	didn't have the benefit obviously of last year's
4	discussion. I knew to this workgroup. I am just
5	very focused on data that's very actionable at
6	the patient level, and so I have concerns about a
7	population health metric. While I totally
8	support the need for us to develop interventions
9	at the population level for smoking interventions
10	or smoking cessation interventions, a population
11	level doesn't feel actionable to me at the
12	patient level when somebody's there in the
13	hospital. And so that is why I'm supporting
14	NQF's recommendation.
15	CO-CHAIR TRAVIS: Thank you, Marsha.
16	David or Jennifer, any comments?
17	(No audible response.)
18	CO-CHAIR TRAVIS: Okay. All right.
19	So I think Jack might have done his card first,
20	so we'll start with Jack.
21	MEMBER JORDAN: Okay. I actually
22	think this is a measure that is a dangerous

mistake for CMS to make, and that is that I think 1 2 it carries a very real risk of kind of undermining their credibility. This is something 3 that I can see the cynical physician in the 4 health system just puking on with the how can we 5 be responsible, the fact that our hospital sits 6 7 in a place where lots of people smoke? The community around us choosing to 8 9 smoke or not, the best lever for that is not really a hospital. And I think it almost gives a 10 11 sense of learned helplessness to the people that 12 are trying to do the right things in hospitals because it's -- the connection between the 13 14 smoking in your community and what you're doing in the hospital seem so disconnected, or at least 15 16 so indirect, even if you do have some evidence of 17 this. The perception of it alone I think really 18 will hurt your credibility. So I think that it's 19 very problematic for this kind of a measure to go

20 forward.

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I know my own health system did send in comments on this, that it just seems like

something that you have very little control over 1 2 when you list the hospitals of who's good and If your hospital's in Kentucky, you're 3 bad. 4 going to look bad because lots of people smoke in 5 Kentucky versus Vermont. But then that isn't something you should interpret as a good or bad 6 7 hospital, though maybe over time that might have 8 But I think that it really would carry a sense. 9 huge burden to the hospitals of feeling a learned helplessness kind of a thing, that they have no 10 11 control over this. Mimi? 12 CO-CHAIR TRAVIS: 13 MEMBER HUIZINGA: I echo Jack's 14 comments, although I probably wouldn't have been quite as colorful. 15 16 (Laughter.) 17 MEMBER HUIZINGA: We are extremely 18 supportive of actionable measures. And you 19 listed a slew of potential actionable measures. 20 And so I guess I don't understand why you would 21 go for a measure that hospitals and the providers 22 within the hospitals have no control over versus

all of the different options that you guys did, that they can do and that do have impact. So we would encourage you to rethink your entire approach to this and move away from a populationbased measure.

In addition, there are issues that we 6 7 would have with this measure. So this is --8 shows the value of going through the NQF 9 endorsement process. What is a hospital panel? What if somebody visits from -- is visiting from 10 11 Kentucky in Florida? Are they part of that 12 Is there going to be a Kentucky panel? panel? There's just a lack of definition and 13 14 understanding about what you mean here that would benefit through the resolution of the NQF 15 16 process.

17 In addition, you have an exclusion 18 criteria for an EP, which is an eligible 19 professional. It looks like you took this 20 measure from PQRS and moved it over. I would not 21 say that you should make that assumption that you 22 could do that. There's a lot of things that go

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into attribution and thinking through those. 1 All 2 of these highlight the importance of going through the NOF process, which again you 3 4 shouldn't do this measure, but if you develop 5 actionable structure measures or clinical process measures, they would still need to go through the 6 7 NQF process. 8 Thank you, Mimi. CO-CHAIR TRAVIS: 9 MEMBER HUIZINGA: We would recommend 10 that. I shouldn't say they need to go. We would 11 recommend that they go through. 12 (Laughter.) 13 CO-CHAIR TRAVIS: Thank you. 14 Sean? 15 MEMBER MORRISON: I'll be brief and I 16 will say this again; and I was here for the 17 discussion last year, I -- it really distresses 18 me when CMS comes with a measure that has not 19 gone through the NQF endorsement process. I know 20 the law says that you guys can do that, but the 21 NQF endorsement process exists for a reason. Ι 22 don't represent any organization or stakeholder.

1	So send it back. That was the
2	recommendation last year. Do the right process
3	work and then bring it back to us, please.
4	CO-CHAIR TRAVIS: Akin?
5	MEMBER DEMEHIN: I really echo the
6	comments that have already been made about
7	actionability, about some of the technical
8	aspects of the measure.
9	I think there's kind of a broader
10	conceptual issue here, too. I think by boiling
11	what is a complex multi-faceted societal problem
12	into a single measure I think it almost has
13	the effect of trivializing what is a very
14	important effort, and that is the joint effort to
15	address smoking prevalence.
16	And hospitals recognize the need to
17	play a role in that activity. Part of what
18	hospitals do, using their community health needs
19	assessment process, is to identify things like
20	smoking rates in their community and develop some
21	interventions that they can work on jointly with
22	the community to affect it.

1	So I really agree with what's been
2	said. This doesn't seem like a very fruitful
3	path and it could actually end up being really
4	quite a dangerous path if it becomes something
5	that's the basis of public reporting, Star
6	ratings, pay-for-performance, and so forth.
7	CO-CHAIR TRAVIS: Okay. Any comments
8	from Committee members on the phone?
9	(No audible response.)
10	CO-CHAIR TRAVIS: Okay. Yes?
11	DR. McNAIR: Yes, quite briefly.
12	Thank you very much.
13	First I will say thank you all for
14	your comments and for your feedback. Definitely
15	appreciate it.
16	Number one, I will say that an NQF
17	submission package is currently underway, so we
18	appreciate that feedback, and we'll continue to
19	work on all of the suggestions that you've
20	provided.
21	The other piece I would say again is
22	this emphasis around shared accountability. For

that reason we certainly see hospitals as the only locus of that, and so we are looking for opportunities and ways that we can begin to push forward that type of an agenda, which is I think a very important one to all of our quality programs.

7 But I would actually argue against the 8 response that said that this is not actionable. 9 At the end of the day you're correct that all of these different best practices are available, but 10 11 as opposed to having this kind of disparate 12 approach where we focus on the individual 13 screening processes or a specific intervention 14 we're basically saying you have all -- you have this menu, this potpourri of opportunity in order 15 16 to move the needle on the specific outcome, and 17 they're all available to you. And we are 18 beginning to demonstrate at least that there is a 19 correlation between including all of that in your 20 practice and seeing an effect on the outcome. 21 The other piece that I would just say 22 is that we have more work to do. We want to

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continue to hear your perspectives and we will
continue to move forward in this space. We
definitely appreciate it.

4 CO-CHAIR TRAVIS: Well, thank you very 5 much. And I always feel a huge sense of 6 responsibility when we said support continued 7 development and then to be where you are today. 8 So I do appreciate you giving us the opportunity 9 to kind of share with you what people's current 10 thinking is.

11 And I think we're sitting right now in 12 a place of tension. We know that we need to do 13 population health management, but our structures 14 are not quite there yet and that you don't necessarily -- the whole panel description, you 15 16 don't necessarily have an assigned group of 17 people that you're responsible for, and it could 18 be randomly different every year. And so to a 19 certain extent I think that -- at least my 20 concern around the accountability issue is that I 21 don't have a defined group of people that I'm 22 accountable for. It changes in the way we're

currently situated. And I think if the delivery system structure changes over time, then I think we could see maybe more comfort with that type of a measure.

5 So I hope you won't give up on 6 thinking about it because it's a critical issue 7 for us. I just think we're in kind of a -- in 8 that in between stage in some of the tensions 9 But I thank you for your continued work, here. and we will look forward to seeing it through the 10 11 endorsement process as well. So thank you very 12 much.

13 You know, guys, we're running about 45 14 minutes behind, and one of the concerns I have 15 today is that I am sure we all have flights out 16 this afternoon. So as much as I hate to say 17 this, we are not going to take a formal break 18 right now. If you do need to take a personal 19 break, please do so, but make it as quickly as 20 possible. But we're going to move ahead so that 21 we can make up for some of the time. It's been 22 all well worth it, but we do want to be sure that

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In fact, I know you'll 1 people get out of here. 2 get out of here. I just hope we're through with our work by the time you get out of here. 3 So I'm going to turn it over to Ron. 4 CO-CHAIR WALTERS: 5 Thank you. So we're on Consent Calendar 7 now, which has three 6 I'm going to go through them briefly. 7 measures. 8 MUC 16-165 is the Follow-Up After Hospitalization 9 for Mental Illness. The preliminary analysis was refine and resubmit because the NOF measure 576 10 11 was specified and tested at a health plan level, 12 and therefore it required more study about 13 attribution to a facility. Also there were some 14 problems noted with the results in the IPFQR Program and should be resolved prior to 15 16 implementing the measure in an additional 17 program. So that was a refine and resubmit. 18 The next measure was 16-262, MUC 16-19 262, which was the Measurement of the Quality of 20 Informed Consent Documents for Hospital Performed 21 Elective Procedures. That was a refine and

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resubmit prior to rulemaking basically to see the

	-
1	reliability and validity. And you heard some
2	testimony about that during the public commenting
3	period. So we'll be interested to see what you
4	do with that.
5	And then the final one is MUC 16-263,
6	which is Communication about Pain During the
7	Hospital Stay. That was also a refine and
8	resubmit originally. It was pulled and then put
9	back on the agenda. And the discussion you
10	heard a lot of discussion about that earlier
11	during the public commenting.
12	So what I'm going to ask now is
13	specifically about 16-165, which is on the
14	consent calendar as refine and resubmit. Is
15	there anybody who wishes to pull that measure for
16	discussion? Okay. Frank.
17	And now for the next measure, 16-262,
18	which was the Measurement of the Quality of
19	Informed
20	(Off microphone comment.)
21	CO-CHAIR WALTERS: Yes, the team.
22	I'll put team again. Frank and team.

1	Two-sixty-two, which is the
2	Measurement of the Quality of Informed Consent.
3	Is there anybody that wishes to pull that from
4	the consent calendar?
5	(Simultaneous speaking.)
6	CO-CHAIR WALTERS: Oh, okay. Frank
7	and then team. Yes, okay. Got it.
8	And finally, 16-263, which is
9	Communication About Pain During the Hospital
10	Stay, which again was refine and resubmit. Who
11	would like to pull that? Okay. Good. Okay. So
12	all three are pulled from the informed consent
13	calendar. Got it.
14	So let's start at the beginning with
15	Frank's comments. Just a second. I got to make
16	sure I got that right now. One-sixty-five. Yes.
17	Frank's comments about MUC 16-165. Why did you
18	pull it?
19	MEMBER GHINASSI: I'll make this brief
20	because I know we're trying to move ahead.
21	So this is again one of these measures
22	where it is impossible to argue with the critical

1	importance of this. I agree with it completely.
2	I think it's a prime directive of the hospital to
3	try to deliver that person to the next level of
4	care. I'm on board completely.
5	The challenge is that the ability to
6	make that happen is impacted by a number of
7	variables: How important the hospital takes it,
8	the measures they take in place to do evidence-
9	based treatment to make it happen, how they
10	prioritize it, the people they assign to it to
11	deliver that treatment, all of which is within
12	their span of control. The other difficulty is
13	that although you can throw a perfect spiral, if
14	a person catching that ball doesn't have good
15	hands, then you have a problem.
16	Now the other piece of this is; and
17	not that I'm a football so the other piece of
18	this is that if you're going to move toward a
19	measure like this, we need to take into account
20	the prevalence and availability of access in the
21	individual community within which that hospital
22	is sending that individual.

1	So a frontier state who's held to a
2	30-day and 7-day follow-up period is going to be
3	in a very different place than somebody's who's
4	in an environment-rich resources. And even if
5	you call agencies and say do you have access, the
6	reality on the ground is if they say yes to you,
7	that they give an appointment on Tuesday at 3:00,
8	and that's their yes, and there's no flex in
9	that, for many people that's a no.
10	So I think the problem with this is
11	I'm totally in favor of the intent of the
12	message. I think the measure doesn't take into
13	account the full system within which that measure
14	exists. I'm done. Thank you.
15	CO-CHAIR WALTERS: What is your
16	recommendation?
17	MEMBER GHINASSI: That if at the
18	very least that the measure include and I
19	think CMS has the capacity to do this that it
20	includes an assessment of that region's access,
21	capacity and standards and that institutions are
22	judged based on that access, not solely on does

1 it happen? 2 CO-CHAIR WALTERS: And to pin you down just a little step further, is that a --3 MEMBER GHINASSI: Please. 4 CO-CHAIR WALTERS: -- conditional 5 support or is that a refine and resubmit, or is 6 it a do not support? 7 8 MEMBER GHINASSI: I would make it --CO-CHAIR WALTERS: Yes, I'm sorry. 9 It's already -- well --10 11 (Simultaneous speaking.) 12 CO-CHAIR WALTERS: Yes, that would be a refine and resubmit. 13 14 MEMBER GHINASSI: If it's --15 (Simultaneous speaking.) 16 CO-CHAIR WALTERS: Which way is the 17 recommendation? 18 MEMBER GHINASSI: Yes, if it added 19 that component, if they built into it the access capacity and they benchmark institutions on that 20 21 marriage, then I think this has more capacity. 22 CO-CHAIR WALTERS: So it's an

agreement with the initial assessment, but you'd 1 2 like to see some additional -- comments on it? MEMBER GHINASSI: 3 Yes. 4 CO-CHAIR WALTERS: You've given some comments on it? 5 6 Okay. Marty? 7 MEMBER HATLIE: Well, I am always 8 happy when I see measures like this because of 9 the prime importance that's been identified. Ι think this gets to one of the priorities that we 10 11 tailor service to every year, which is person and 12 family engagement, follow-up after hospital to 13 engage patients and families. And patients 14 getting the care they need is a really important 15 thing. 16 I know there's a philosophical divide 17 here, and I'm on the side that really sees 18 hospital accountability being to community as well, to work with the community to work after 19 20 someone leaves the hospital to really advance the 21 overall journey across transitions to a safe 22 result. So that's really where I'm coming from,
and for that reason I think this is the 1 2 appropriate place in the category that it's in. I like all of the suggested 3 considerations that were made about what CMS 4 5 should consider as they refine this and resubmit it. Thank you. 6 7 CO-CHAIR WALTERS: Do you have a recommendation? 8 9 MEMBER HATLIE: I have a 10 recommendation that it stay right where it is. CO-CHAIR TRAVIS: Which is refine and 11 12 resubmit? MEMBER HATLIE: 13 Yes. 14 CO-CHAIR WALTERS: Okay. Mimi was the 15 other lead discussant. Mimi? 16 MEMBER HUIZINGA: Sorry. So in this 17 measure we support the idea of having better 18 follow-up after mental health, but we actually 19 are a do not support for this particular measure. 20 I wouldn't say that we have a 21 difference in philosophy from Marty. We do think 22 that the hospital should be working with their

communities, but as Frank said, this is a matter 1 2 of access. I mean, yesterday we talked about how we have hospitals who have patients sitting in 3 their ER for days just because they can't find a 4 So those same places struggle with access. 5 bed. The other issue that we have with this 6 7 measure is that is difficult for the hospitals to 8 drive action on it. They don't receive this 9 So this measure was initially developed data. 10 for a health plan and makes sense for someone who 11 has that data and maybe can influence access more 12 than hospitals can. 13 So ACOs, health plans, this type of 14 measure that goes cross-continuum, those are the 15 payment models that are focused on that, and 16 those are the payment models that actually have 17 the tools and resources available to potentially 18 drive change on them. 19 I like the suggestion that Frank made, 20 and that would certainly make this measure more 21 palatable, but without having the data source to drive improvement efforts we would still be do 22

not submit.

2	CO-CHAIR WALTERS: Okay, so we have a
3	do not submit and a refine and resubmit. Akin?
4	MEMBER DEMEHIN: I echo the concerns
5	that both Frank and Mimi have articulated, and
6	this really is a measure where the the core
7	idea behind it is sound. You do want hospitals
8	to take action to connect patients with the next
9	level in the continuum of care. But as Frank
10	pointed out, that continuum of care is often a
11	patchwork in a lot of communities, and so we're
12	kind of on the fence between a refine and
13	resubmit and a do not support.
14	I just don't know if it is technically
15	feasible to do the kind of the kind of
16	adjustment that Frank is talking about around
17	looking at access within communities and trying
18	to account for that in comparing performance, so
19	just not sure if the frame of this of this
20	particular measure is quite right to achieve the
21	goal we want to achieve.
22	CO-CHAIR WALTERS: Before we get to

1	Brock, I'd like to hear some thoughts, or be
2	thinking about, so, it is a currently endorsed
3	measure in the Inpatient Psychiatric Program, and
4	this is for the Inpatient Hospital Inpatient
5	Quality Program. Is that two standards of care
6	or not? Yes, yes.
7	MEMBER SULLIVAN: This is Ann. Can I
8	just talk to this a bit?
9	CO-CHAIR WALTERS: Sure.
10	MEMBER SULLIVAN: I realize
11	CO-CHAIR WALTERS: Ann, go ahead.
12	MEMBER SULLIVAN: Now there are big
13	problems with access, I agree, but we've had this
14	one in the Psychiatric Hospitalization Program
15	for years, and when someone is psychiatrically
16	hospitalized, even in some of the most
17	disadvantaged communities, they are able to
18	arrange for some degree of follow-up, because you
19	have to understand, this is not just a regular
20	psychiatric appointment, this is someone who has
21	been in the hospital, who has been very very ill,
22	and usually I mean, maybe in some very poor

rural communities, you may have to defer to the primary care doctor.

But that has not been the experience 3 4 in the psychiatric hospital situation. We have 5 been able to do this for these seriously ill patients in terms of getting them care, and there 6 7 is usually some availability as an intensive 8 outpatient or partial because we're not totally 9 bereft of any psychiatric services in these communities, but often, these guys are 10 prioritized, and that's what hospitals kind of 11 12 have to work at.

The second thing is I think that you 13 should not have two standards of care. 14 These are 15 hospitalizations that happen to occur in a 16 general hospital versus a psychiatric hospital, 17 but if you're not going to get a follow-up within 18 seven -- within 30 days, you're going to get a 19 readmission, so I think it behooves the hospitals 20 to really recognize that most of them are pretty 21 close to getting this kind of already because how could you in good faith discharge people with no 22

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follow-up? I sincerely doubt that that is
 happening.

This is just a way of keeping track 3 and making sure that those connections are made. 4 5 You know, there is not always primary care Sometimes, there is no cardiology 6 capacity. 7 capacity. Sometimes, there's other problems with 8 That doesn't stop us from saying there capacity. 9 has to be good care after hospitalization, or having impacted on some of the readmission 10 11 indicators that have been there.

12 So I think it is a little bit 13 overstating the facts because these are such 14 high-priority patients, even in New York, which 15 has some of the most rural areas, equal to 16 anyplace else, we manage to find places for these 17 individuals because they're such high priorities.

So I think it is perfectly worth refining and resubmitting. I think that's a good idea just to kind of get it -- make sure that it can work within these facilities, but I do think -- I wouldn't overstate that with very high-

priority people, that there is no way to get
 access, and that it would be such a burden on the
 hospital to arrange it.

4 CO-CHAIR WALTERS: Thank you very
5 much, Ann. Brock, you took your card down?
6 MEMBER SLABACH: Well I was going to
7 put it back up as soon as she finished.

I -- I would like to reiterate that 8 9 one of the most difficult problems in rural areas around the country, maybe New York probably is an 10 exception, is referrals to mental health follow-11 12 up, and if this is going to be a measure, as 13 Frank said, that is going to point out the access 14 issues and not be a penalty for the hospital in terms of doing what it is supposed to do, then I 15 16 would be in favor of it. In other words, it is 17 indicating that we need to invest more resources 18 in mental health and we need to have better 19 networks of care, you know, in rural and more underserved communities. 20

21 But if this is going to be, say I'm 22 holding the hospital responsible for the fact

1	that the patient didn't follow up to a mental
2	health provider following the discharge, then I
3	find this to be somewhat offensive to 2,000
4	hospitals in the United States who are doing
5	their best to try to make this happen, so
6	CO-CHAIR WALTERS: You are which side
7	of the fence?
8	MEMBER SLABACH: Oh, I do not support
9	
10	CO-CHAIR WALTERS: Okay.
11	MEMBER SLABACH: unless unless
12	the things that Frank talked about earlier were
13	introduced into it.
14	CO-CHAIR TRAVIS: I just this is
15	Cristie. I have just a clarifying question, in
16	that this the way this measure looks is that
17	you were actually treated for selected mental
18	illness diagnoses, and then whether or not you
19	have the follow-up afterwards, so that your
20	hospitalization included, or was for, treatment
21	of mental illness.
22	And I think the other piece that I

1	wanted to be sure I was reading it right, but the
2	other piece I was trying to understand and I
3	really don't mean to introduce a competition
4	here, and I really apologize but the Inpatient
5	Psychiatric Facility Program, does it include
6	psychiatric units in general acute care
7	hospitals, or is it and it does, doesn't it?
8	Okay. So it's not just freestanding psychiatric
9	hospitals.
10	DR. YONG: No, the facilities included
11	in the program include both freestanding
12	psychiatric facilities as well as psychiatric
13	facilities embedded in general acute care
14	hospitals.
15	CO-CHAIR TRAVIS: Okay. So the reason
16	that I wanted to confirm my understanding is, you
17	know, I am trying I am not saying there
18	wouldn't be some people who were admitted to a
19	hospital for mental illness that didn't have a
20	psychiatric unit, because I assume that could
21	happen, but that is who this really ends up
22	applying to that it doesn't already apply to.

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1	In other words, if a general acute
2	care hospital has a designated psychiatric unit,
3	assume they're participating in your program
4	under that, so they're already reporting it for
5	that. So this would be patients outside of that
6	unit?
7	DR. YONG: Right.
8	CO-CHAIR TRAVIS: I mean, I am trying
9	to figure out how these two things work together.
10	Maybe I should just say it that way.
11	DR. YONG: So we do know that but
12	there are also patients who have are
13	hospitalized for mental illnesses that aren't
14	hospitalized for the psychiatric ones, and so
15	that I think would be the population that would
16	additionally be captured.
17	CO-CHAIR TRAVIS: That's that's
18	what I'm trying to so the only reason I bring
19	this up is that it it is not all I mean,
20	some people are already having to report on this,
21	even from general acute care hospitals if they
22	have a designated psychiatric, so we're talking

about expanding that in that those patients then 1 2 that fall outside that psychiatric unit, or are in a hospital that doesn't have a psychiatric 3 unit, are the ones we're talking about. 4 But the other piece is, I mean, these 5 people were in the hospital for mental health 6 7 issues, not that they were in for a cardiac issue and needed follow-up care. 8 9 CO-CHAIR WALTERS: Lee. So I am sort of torn 10 MEMBER FLEISHER: 11 because I actually -- at my own hospital, until 12 the measures existed for readmission and for 13 appointments, we didn't have people who were 14 actually dedicated and going out and asking the 15 patient, when can you actually get to an 16 appointment? So that having something like this 17 would drive the right thing. 18 It's NCQA, so it is not Yale CORE, and 19 I'm just thinking if you can't do what Frank 20 suggested, some sort of SES look in this 21 population would tell us a lot as a surrogate for -- because I don't know the data that would exist 22

1	to look do you have it, where, I mean, to
2	MEMBER GHINASSI: I mean, there's a
3	variety of studies on this, and I can send you
4	data. But the
5	MEMBER FLEISHER: No, I am talking
6	about I am not talking about the what
7	what exists in easily accessible data because it
8	is CSAC
9	MEMBER GHINASSI: Oh, that would be
10	that would be from my hope would have been
11	that there would be a way for them to assess the
12	availability and access within a community before
13	you judge one part of the system.
14	MEMBER FLEISHER: Right, but I am not
15	sure that that data exists in an easy way, so as
16	a first pass, if it would be great to see if
17	regions that had different SES sort of by had
18	different rates of this to start, and even
19	getting better some of those regions would be an
20	important different way of looking at it because
21	I think improvement might be a a different way
22	of scoring better over time than just rates

looking between individual hospitals. 1 2 CO-CHAIR WALTERS: Andrea? I just wanted to -- I 3 MEMBER BENIN: think Cristie your question was helpful to me for 4 5 understanding this because frankly, my understanding is that if you can't have a CON for 6 a psych bed, you cannot admit someone with a 7 principal diagnosis of a psych problem to -- to 8 9 anywhere. And so if you are being admitted to a 10 regular bed, that means you have to have some 11 other diagnosis, so it is overdose, whatever that 12 is, it's suicide attempt that has an injury 13 remaining, so that, your principal diagnosis 14 actually is a medical diagnosis. It has to be or 15 else you cannot go forward. I mean, you couldn't 16 have a patient there. 17 I mean, Pierre or Ann Marie might

17 I mean, Pierre of Ann Marie might 18 understand this better than I do, but so I am not 19 actually sure then if that is the group that 20 we're trying to capture who those patients are at 21 this point because you have to be in a psych --22 unless it is psych facilities with -- with sets

1	of CON you know, with beds within hospitals
2	that are not freestanding psych hospitals, but
3	not it can't it's not just like every
4	hospital admitting patients who have a mental
5	illness. That is there just is a principal
6	diagnosis, just
7	CO-CHAIR TRAVIS: Right.
8	MEMBER BENIN: I am trying to make
9	sure I am super clear on your
10	CO-CHAIR TRAVIS: And I don't know,
11	yes, I mean that was kind of my and that was
12	trying to be sure we were clear. Now I will say
13	that CON is not in every state, but I don't
14	understand the there could be licensure
15	requirements. You know, I but that is that
16	is kind of what I was trying to say.
17	These people are not in a psychiatric
18	unit, I mean, because if they were in a
19	psychiatric unit, they would already be reporting
20	this information through the other measure of
21	psychiatric hospitals that we talked about
22	earlier, because even units within general acute

care hospitals are covered under that other 1 2 program. CO-CHAIR WALTERS: 3 Let me not put 4 words in your mouth, but you're saying do not 5 support because it's not needed and not 6 necessary? 7 MEMBER BENIN: I mean, I was fine with 8 the revise and resubmit, let people think about 9 it some more. 10 CO-CHAIR WALTERS: Okay. MEMBER BENIN: I mean, if it needs 11 12 more --13 CO-CHAIR WALTERS: Okay. 14 MEMBER BENIN: -- thinking or figuring 15 out, I am not --16 CO-CHAIR WALTERS: I got you. 17 MEMBER BENIN: -- I don't have any 18 sort of stake in this. 19 CO-CHAIR WALTERS: Mimi? 20 MEMBER HUIZINGA: So I had a question 21 for clarification, and then a point to make, but 22 my question first: so if we look at QPS, the NQF

measure that is currently being used in the 1 2 inpatient psych program, it says the level of analysis is health plan or integrated delivery 3 4 system, so were there any modifications made? Ι 5 mean, it seems like it's kind of like an off-6 label use to use it just in a psychiatric 7 facility and not at the health plan level, where 8 it is endorsed, so did it go through a 9 modification process in order -- it didn't. But it says endorsed here. 10 I don't 11 know --12 MS. MARINELARENA: It's endorsed at 13 the health plan or IDS level. 14 MEMBER HUIZINGA: Okay. It is -- do you know if in their maintenance, they will --15 16 are there any plans to resubmit it to --MS. MARINELARENA: I do believe it is 17 18 going through maintenance now in our Behavioral 19 Health Project, I believe. I can check right 20 If you read the preliminary analysis, that now. was one of the -- that's the refine and resubmit 21 22 to specify it, test it at the inpatient hospital

1 level. 2 CO-CHAIR WALTERS: Wei? And then I think we'll try to see if everybody has enough 3 4 information --But let me -- let 5 MS. MARINELARENA: 6 me --7 CO-CHAIR WALTERS: -- to vote. MS. MARINELARENA: -- confirm that 8 9 it's going to be --CO-CHAIR WALTERS: For the inpatient 10 11 12 MS. MARINELARENA: That -- right, yes. 13 MEMBER HUIZINGA: And so then my point 14 was, you know, going along with kind of what 15 Frank says, how this might be modified to be more 16 appealing to hospitals or useable by hospitals, 17 so I as a primary care provider, I would spend many hours on the phone trying to get 18 19 appointments for patients. I would get them, and 20 then they wouldn't go for various reasons that 21 were all outside of my control, so could there be a way that in order, if you can't measure access 22

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or adjust for it, that this measure could try to 1 2 be more structural or process to assess intent to get scheduled or actually scheduling the measure, 3 4 not -- those are the things that the hospital can 5 gather data on and can develop programs for and act upon. Whether or not a patient actually goes 6 is a little bit separate. 7 8 CO-CHAIR WALTERS: So I have heard a 9 lot of discussion that basically is around refine and resubmit, or do not support, for the 10 Inpatient Quality Reporting Program. 11 I think 12 we're ready for a vote? 13 (Pause.) 14 CO-CHAIR WALTERS: So what we're talking about up here is from a practical 15 16 purpose, even though we can't stop you from 17 voting for option 2, the options we -- the 18 options in reality are number 1, number 3, and 19 number 4. That's what the discussion hung 20 around. 21 MS. QUINNONEZ: Okay. Voting is now open for Follow-up After Hospitalization for 22

1 Mental Illness. This is MUC16-165 of the IQR 2 program. Option number 1, support. Option number 2, conditional support. Option number 3, 3 4 refine and resubmit. And option number 4, do not 5 support. I will read those options one more 6 7 time. Option number 1, support. Option number 8 2, conditional support. Option number 3, refine 9 and resubmit. And option number 4, do not 10 support. 11 Thank you, Marisa. Thank you, Ann. 12 Okay. Voting is now closed. 13 (Pause.) 14 MS. QUINNONEZ: Okay. We're going to ask you to vote one more time. 15 16 (Laughter.) 17 MS. QUINNONEZ: Oh, here we are, okay. 18 We actually have our totals now. Thank you. 19 All right. For the -- I will read the 20 results for the IQR Measure 16-165. 0 percent 21 support, 0 percent conditional support, 72 22 percent for refine and resubmit, and 28 percent

for do not support. This stands at a refine and 1 2 resubmit.

CO-CHAIR WALTERS: And as we said 3 yesterday, even though that was the preliminary 4 analysis recommendation, I think input by the 5 comments given to CMS would be very helpful. 6 7 Now proceeding on with MUC16-262 -- I 8 am going according to the agenda list -- which is 9 the measure The Quality of Informed Consent Documents for Hospital-Performed Elective 10 Procedures, and again, the preliminary analysis 11 12 was refine and resubmit, and basically, the whole 13 right side of the room said they recommended 14 pulling it. So would you put your cards up? 15 Not 16 the whole side, just half of it or so. 17 (Laughter.) 18 CO-CHAIR WALTERS: Mimi? 19 MEMBER HUIZINGA: Thank you. So we 20 don't support this for several reasons. Informed 21 consent is a process covered in other mechanisms, 22

namely the Conditions of Participation, and the

Joint Commission of course has standards. There is a high level of effort required for this measure.

4 There is some ambiguity. I realize 5 that we heard a little bit about reliability and validity testing, but we would argue that there 6 7 is still a great deal of training and development 8 that would need to happen in order to achieve 9 those numbers, and further testing would be needed, but we don't recommend that either 10 11 because we think that CMS should just stop here 12 with this.

13 And if you were ever going to consider 14 a measure like this, it should definitely go through the NQF process so that it could be 15 16 assessed for the reliability and validity as 17 needed. And most importantly, we feel that 18 informed consent is not an outcome. It's a 19 structural measure, and the way that the points 20 are structured in this measure, if you read what 21 you get points for, it really is just a yes or 22 no, did they write a different language? It

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doesn't say anything about was the language used 1 2 actually understood by the patient in the intent that it needed to be so that the patient was 3 really receiving an informed consent process. 4 So informed consent can't be judged by 5 a chart review. It is really -- or the quality 6 of it, I would argue, is judged by what the 7 patient understands. So we think, just in 8 9 summary, CMS has other mechanisms in place to 10 check off structural measure yes or no for 11 informed consent. The measure doesn't really 12 address an outcome, nor does it do much to drive 13 the quality of informed consent, as there is some -- a lot of variation that could be allowed 14 15 within the language as it is structured, and we 16 think that if you wanted to understand this 17 better, it really should be based on both the 18 patient, their preferences, and what they 19 understand to be the procedure that they are 20 undergoing and the risks that are associated with 21 it. 22 CO-CHAIR WALTERS: Marty, you were

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1	there to lead discussion?
2	MEMBER HATLIE: So I was delighted to
3	see this on the MUC list
4	(Laughter.)
5	MEMBER HATLIE: because it really
6	does address a problem, and that is I see the
7	informed consent process as one of the main ways
8	in which we can reach shared decision-making, the
9	costs of shared decision-making, and it has
10	become a check-the-box kind of thing in
11	hospitals, or at best. At worst, a risk
12	management strategy that has almost no shared
13	decision-making content anymore.
14	It is a priority because shared
15	decision-making is a content. It is a priority
16	not only for NQF, but in the CMS quality strategy
17	now.
18	I do think also I was impressed by the
19	analysis and the way in which hospitals who used
20	this seemed to find to get information that
21	they would find useful in improving their
22	their informed consent processes. It just seemed

like the testing was surprisingly creative and 1 2 interesting in pointing out ways in which things can be done better, which I -- I do think 3 4 hospitals need. 5 I am sympathetic, I mean, to the burden issue here. I think this could be one 6 7 that does take additional training, but I think 8 it is needed because this is just such a broken 9 process throughout the healthcare system, so for 10 all those reasons, I -- I want to just support where it is, continue to look at it in the 11 12 refinement and resubmit category, but I also want 13 to compliment CMS for actually taking this step, 14 CMS and NOF. It's kind of a next step. 15 It was 16 positioned nicely in the decision guide as a next 17 step in really looking at this key, key process 18 and taking it to the next level. Thank you. 19 CO-CHAIR WALTERS: Lee? 20 MEMBER FLEISHER: So I am -- I am glad 21 the lawyer was supportive because -- correct, it's the lawyer? -- because in fact the people 22

who have caused this to occur in my hospital are
 actually the lawyers all around malpractice
 suits.

To put this in perspective, the underlying issue is that is this a conceptual model according to which informed consent happens, or is this the legal document at the end of that conceptual model that leads to the support when you end up in court whether or not informed consent happened?

11 So my concern, and I did actually 12 comment privately, which they -- I didn't see 13 your responses, so I have to be accurate, that 14 were supposedly put up on the web, to some of these concerns that a lot of the elements --15 16 reliability is great, but if it doesn't -- if the 17 reliability is whether or not you time it and 18 date it, which are requirements by Joint 19 Commission, et cetera, and whether or not it is 20 legible, which are requirements by our lawyers, 21 that is different than whether or not the patient 22 actually understood everything.

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1	So while I commend them for taking a
2	first step, I think along the continuum of what
3	is shared decision-making and where we get to,
4	starting with a legal document is the wrong
5	place. And again, I would say what you have done
6	is created a great structure for every hospital
7	in this country to think about how to defend
8	their process because when you look at this, what
9	happens is patients do not read it. So while
10	highly educated patients read it, and while sort
11	of the people who need it potentially the least
12	read it, it it won't get to the achieved goal.
13	So getting back to I think it's Allen
14	who previously said utility of a measure, I think
15	this does not rise to a utility. Put in the
16	Joint Commission participation, let your legal
17	team say how great a job Yale did at defending
18	what the process occurred.
19	CO-CHAIR WALTERS: So I interpret that
20	as a do not support?
21	MEMBER FLEISHER: Do not support. And
22	lastly, I really do believe I agree with Mimi

entirely. This needs to go through the NQF 1 2 process where it is truly vetted and by the appropriate panel gets to CSAC, and then we'll 3 4 see what happens there too. 5 CO-CHAIR WALTERS: I -- I am just --I am just thinking a second. So with that last 6 7 sentence you made, which is what the initial 8 recommendation was, refine and resubmit, and 9 everybody agrees it should go through the 10 process, so is this measure as you read it 11 refinable --12 MEMBER FLEISHER: No, I --13 CO-CHAIR WALTERS: -- and ---- I actually -- I 14 MEMBER FLEISHER: would be -- I would be curious what happens in 15 16 the process, but I do not support this measure. 17 CO-CHAIR WALTERS: Got you. 18 MEMBER FLEISHER: I do not believe it 19 achieves the goals of improving the care of our 20 patients. 21 CO-CHAIR WALTERS: Okay. I just wanted to clarify that. Akin? 22

1	MEMBER DEMEHIN: We have a number of
2	significant concerns about this measure, many of
3	which both Mimi and Lee have articulated very
4	well, so I won't rehash them.
5	But I did want to underscore one
6	particular aspect of this that has us troubled.
7	There absolutely are standards from the Joint
8	Commission and under CMS Conditions of
9	Participation around informed consent, there are
10	often state-level laws that dictate what goes
11	into a an informed consent. This to me has a
12	very real risk of just adding to the confusion,
13	and it really is focused more on the piece of
14	paper than it is on sort of the real issue to
15	address here, and that is making the informed
16	consent process meaningful to patients. So we
17	absolutely do not support this measure.
18	CO-CHAIR WALTERS: Marty, did you have
19	another comment?
20	MEMBER HATLIE: Yes. I mean, informed
21	consent documents are unreadable because the
22	lawyers have put them together. I mean, we are

talking really about a paradigm here where no one could understand it, or else they are so meaningless. I mean, I have been asked to give informed consent now on a computer screen, you know, that makes me feel like I'm in a department store.

7 So -- so this is an opportunity actually to get out of that old paradigm that the 8 9 lawyers are defending because of defense worries. 10 Actually, there would be less litigation, in my belief, if we had better communication at this 11 12 stage in the process, where people really did 13 understand the risks they were undertaking, and 14 what -- and I totally agree with you though that this needs to go through a thorough vetting 15 16 process. The NQF process I think would be a 17 great, great step to really bring out all the 18 potential of -- of this opportunity to kind of 19 create a better practice here that might have 20 some influence on the bar, in saying, you know, 21 it's not just about defending the hospital, it's actually about communicating and choosing risks 22

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and making better decisions. So I love the idea
 of this actually going through the NQF process in
 a really thorough way.
 CO-CHAIR WALTERS: I am trying to
 avoid rebuttal, rebuttal, rebuttal number two,

rebuttal number three, rebuttal number four. Mimi, do you have anything else to add that is different from what has already been said?

9 MEMBER HUIZINGA: I do, and then this 10 will be the last time I speak on it.

The -- so the first thing is that 11 12 there is no evidence that implementing this would 13 in any way change what currently exists. It 14 would only -- it would likely, although I don't have evidence, but I feel that if we were to 15 16 gather a group of hospital lawyers, this would 17 add to what's in an informed consent document, 18 not take away, and it wouldn't do much to improve 19 the clarity or understandability by the patient. 20 However, if the CMS would like to 21 collect information on that or the measure

steward and bring that back for NQF through the

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process to evaluate, that would be the 1 2 appropriate place to handle that, and then we could have actual backing instead of conjecture. 3 I would say that I think that Lee 4 5 hinted at this earlier: we are strongly supportive of shared decision-making, but that 6 7 should happen well before you are ever into a 8 consent document. There should be a long, 9 thought-out process when an initial diagnosis is 10 made, and that conversation or guiding that shared decision-making process should not try to 11 12 be captured in a document that really exists for 13 more legal purposes than the actual conversation 14 and documentation of how the patient arrived at 15 the decision to proceed with the procedure. 16 CO-CHAIR WALTERS: Akin, incremental 17 information? 18 MEMBER DEMEHIN: More sort of on the 19 more constructive side. You know, we've talked 20 about this measure, we talked about the smoking 21 measure, to a certain extent the follow-up for mental illness measure, and I think part of the 22

struggle we have is we are talking about what can 1 2 be put into a quality measure versus what is an important improvement area that should be 3 4 addressed. 5 To me, something like informed consent 6 could be really, really nice to include in the efforts through the TYO. Maybe it is something 7 8 that the HIMSS take a look at downstream. 9 I also think that gives an opportunity 10 to see if there is anything in the context of 11 that improvement where it lends itself to a nice 12 measure that could be used in a national program, 13 but to me, this sort of feels like we're going to 14 boil it down to the measure to solve the overarching problem, and I think it has to be 15 16 looked at in a much more holistic way. 17 CO-CHAIR WALTERS: Okay. I am going 18 to open it up for voting. I did -- oh, sorry, 19 yes? 20 DR. SUTER: Hi, this is Lisa Suter. 21 I directed the measure development. I would like 22 to respond to some of the comments made. I very

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much appreciate this opportunity to speak.

2 The first thing I would like to just clarify is that this is -- definitely goes beyond 3 4 just having a document or dating a document. Ι 5 think it is important to recognize that this measure was developed in a very innovative way, 6 7 with patients involved from the very beginning. 8 They were brought in at every step. They were 9 involved in every step of testing. We have heard positive results from the hospitals that we're 10 working with to test, including premier hospitals 11 12 that have found it beneficial. 13 So I think important to recognize that 14 we've heard the hospital perspective. We've 15 heard a legal perspective. But we have not heard 16 the patients' perspective. The patients that 17 were involved in this measure feel it is very 18 valuable. They also, as well as the patient 19 20 advocates who commented during public comment and participated on our TEP, acknowledged that it 21

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does not go far enough, and we acknowledge that

1	as well. This is a first step, but it takes us a
2	very long way. Can we all imagine what it might
3	be like as a patient regardless of their
4	socioeconomic status to have a piece of paper
5	that actually describes the procedure that they
6	are having before an elective procedure well
7	before the actual procedure, before they are
8	under anesthesia?
9	This is the information that this
10	measure conveys. It is a potentially very
11	powerful document. Mimi is right. We do not
12	have data prospectively that indicates that this
13	has changed anyone's life at this point, but we
14	know from deep investment and collaboration with
15	patients organized through the National
16	Partnership for Women and Families working
17	collaboratively with us that this is a meaningful
18	measure to them. They see it as important even
19	in addition to a shared decision-making as a
20	first step, that this is critical information to
21	anyone going forward with an elective procedure.
22	It is low-burden. We anticipate it

would be a very minimal burden on hospitals. It takes only a few minutes to abstract. We are working -- as you heard earlier, our reliability estimates are exceptionally high. We ought to be able to drive the sample size per hospital down to minimize hospital burden.

7 So we think that there is a tremendous 8 amount of short-term benefit, right? This is 9 something we could get -- we could get every hospital in America to a point where they could 10 11 offer information to patients about elective procedures, or every physician, or every 12 13 outpatient surgical center, to get to a minimum 14 standard, and we hear again and again from patients that this is a minimum standard, but it 15 16 exceeds what is legally required.

17 The legal requirements are vague, and 18 they vary from state to state. We do not 19 envision any incompatibility with existing state 20 laws. For example, Louisiana has a lot of 21 requirements for their informed consent 22 documents. Hospitals we have tested from

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Louisiana actually rate very well, so they are working to improve, and what the states are doing is in complete alignment with what this measure shows.

5 I will also acknowledge that in terms of the NQF endorsement, there has not been an NQF 6 7 call for measures relevant to this measure. We are eager to have it in front of NQF. I think it 8 9 is important for the MAP to recognize that the 10 process of getting a measure out into use is a 11 several-year process, so when this meeting 12 decides in December of 2016 to revise and 13 resubmit a measure, that is probably a three- to 14 four-year delay for implementation in federal programs because of the -- if we move out next 15 16 year, putting it in rulemaking, it gets signaled in rulemaking in 2018, and it gets implemented in 17 18 2019, we'll for 2020 report it, so that -- I am 19 just recommending caution when you're on the 20 fence about measures to recognize that it is a 21 12-month delay when you guys make decisions that 22 may -- you may be on the fence about.

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1	So I don't know if I covered all of
2	the concerns, but I really appreciate the
3	opportunity to speak. Thank you.
4	CO-CHAIR WALTERS: Thank you, Lisa.
5	I am sorry I didn't see your card up before.
6	Okay. I'm going to call for a vote.
7	I think you've heard all the considerations. The
8	one you did not hear discussed by anybody was
9	option 2, conditional support. Any of the other
10	three options I think were brought up. So let's
11	vote.
12	MS. QUINNONEZ: Voting is now open for
13	IQR program measure Measure of Quality of
14	Informed Consent Documents for Hospital-Performed
15	Elective Procedures, and this is MUC16-262.
16	Option number 1, support. Option 2,
17	conditional support. Option 3, refine and
18	resubmit. Option 4, do not support.
19	I will repeat those one more time for
20	those on the phone. Option 1, support. Option
21	2, conditional support. Option 3, refine and
22	resubmit. And option 4, do not submit do not

support.

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2	(Pause.)
3	MS. QUINNONEZ: Okay. Thank you,
4	Marisa. Voting is now closed. The results of
5	IQR MUC16-262, 17 percent voted to support, 0
6	percent conditional support, 46 percent refine
7	and resubmit, and 38 percent do not support.
8	This yields a refine and resubmit.
9	CO-CHAIR WALTERS: It's refine and
10	resubmit.
11	Okay. The last measure in Consent
12	Calendar 7, which was pulled, is MUC16-263,
13	Communication About Pain During the Hospital
14	Stay. We will start with Kim, who asked that be
15	pulled.
16	MEMBER GLASSMAN: Thank you, Ron.
17	CO-CHAIR WALTERS: About I am
18	sorry, you want to do about the measure first?
19	Okay.
20	DR. YONG: Thanks Ron, I appreciate
21	it. Just wanted to give you some context for
22	this measure as we undertake this discussion. So

folks who have been following the program and the 1 2 regulations relating to the Hospital Value-Based Purchasing Program may have been aware that in 3 this past year's rule, we did propose and 4 5 finalize to move the domain relating to the pain component in HCAHPS given -- even though we do 6 7 acknowledge and do firmly believe that, you know, 8 the pain is a critical component of a patient 9 experience, it does need to be addressed that it may have -- we don't want to confuse the 10 11 situation given the concerns around opioid 12 overuse, and so that's why we finalized taking it out of the HVBP calculations for HCAHPS. 13 14 So as we have done that, we have continued to do work, and I wanted to give Bill 15 16 Lehrman, who has been working as a steward of 17 this measure, a chance to speak about our 18 continued thinking and evolution of thinking 19 around sort of how do we potentially address pain 20 as part of the HCAHPS survey? 21 MR. LEHRMAN: Thank you, Pierre. As Pierre mentioned, in the outpatient rule this 22

year, we propose removing the pain management
dimension from the VBP formula, beginning in the
fiscal year 2018 program.

This stems from concerns raised by 4 5 healthcare providers, physicians, et cetera that they believe the current pain management items in 6 the HCAHPS survey and especially their inclusion 7 8 in the VDP program was encouraging overuse of 9 This happened to coincide with the opioids. 10 opioid epidemic. CMS carefully considered the 11 comments and commentary and decided to remove 12 that measure from the -- the payment program. 13 However, it remained on the survey because we 14 believe that proper patient care should be a 15 routine part of good quality hospital care.

However, we had the opportunity to investigate alternative questions for the HCAHPS survey that tapped into the same dimension about pain. Given the concerns about the current questions, the new items that we tested focused on communication about pain rather than patients' need for pain medication or belief that their

pain was well-controlled or that hospital staff
did everything they could.

So the items that we tested and the items that we are putting forward today focus on communication about pain with the patient during the hospital stay. We have tested this earlier this year. We have good empirical support for the three items we would like to propose in the new composite measure, which is 263.

We also tested the cognitive testing 10 with patients, inpatients and emergency 11 department patients, about the new items. 12 We also had a number of interviews, informative 13 14 interviews with hospital administrators, 15 physicians, and nurses about the content and 16 direction of the current items and the proposed 17 new items.

We feel that these empirical and cognitive informative interviews support the items in the composite that we are -- we have proposed in the MUC list, and with that, I will close.

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1	CO-CHAIR WALTERS: Thank you. Okay,
2	Kim?
3	MEMBER GLASSMAN: Okay. And I can
4	kill two birds as both a puller and a discussant.
5	So we would commend CMS for being
6	directionally appropriate in the changes that you
7	are proposing to these questions, and
8	particularly, I am pleased to see more plain
9	language in the HCAHPS survey and would urge you
10	to consider that for other questions, but also
11	feel that this is very premature in testing. We
12	are not aware of any of these data and therefore
13	do not recommend including this at this time.
14	I would also add that I believe we're
15	discussing questions 1, 2, and 3, which are
16	directionally better than questions 4 and 5,
17	which I believe generated a lot of comment this
18	morning, so as these questions are being
19	considered, we would urge CMS to also not focus
20	so much on pharmacologic measures, but allow a
21	wider range of treatment for people for pain.
22	CO-CHAIR WALTERS: Pierre is going to

respond to the question about the questions. 1 DR. YONG: Yes, just to make sure 2 we're all on the same page, but yes. So for the 3 committee's considerations, just HP1, 2, and 3, 4 which are part of MUC16-263, so we're not talking 5 about the other measures. 6 7 CO-CHAIR WALTERS: Akin? MEMBER DEMEHIN: I think Kim covered 8 9 a lot of the salient points already, so first just want to commend CMS for your willingness to 10 take another look at these questions and really 11 12 try to improve them in such a way that we are 13 striking that right balance between treating 14 pain, which we absolutely have to do because of 15 the enormous negative consequences it can have, 16 along with the concerns around the spread of the 17 opioid abuse epidemic. 18 Definitely for us, this falls pretty 19 squarely into the refine and resubmit category. 20 We would strongly urge you to bring this through 21 the NQF endorsement process before it goes into

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the program to really make sure we get a deeper

look at how this was tested and how this was developed.

I -- I -- we do have some questions 3 4 too around making sure that there are some 5 questions that target not just use of pain -pain medications, which I think is fair game to 6 ask, but some of the non-pharmacological 7 8 interventions as well, so look forward to 9 continuing to work with you on the development of this measure. It is really important to get it 10 11 right, and we're -- we're glad that you are going 12 down this path. 13 CO-CHAIR WALTERS: I forgot to ask, 14 what was your recommendation? To leave it where it 15 MEMBER DEMEHIN: 16 is, refine and resubmit. 17 CO-CHAIR WALTERS: And Kim? 18 MEMBER GLASSMAN: I had indicated my 19 recommendation of do not support at this time. 20 CO-CHAIR WALTERS: Are there any other 21 people who wish to make a comment about this measure for the IQR? 22

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1	(No audible response.)
2	CO-CHAIR WALTERS: Okay. I did not
3	hear anything resembling a condition for
4	conditional support, so we'll open it for voting.
5	MS. QUINNONEZ: We are now voting
6	before we vote, we'll have one more response.
7	CO-CHAIR WALTERS: Yes.
8	MR. LEHRMAN: Okay. In response to a
9	couple of the comments, we did the testing of the
10	items earlier this year. We tested the new
11	survey items in 50 hospitals from around the
12	country. We had about 16,000 surveys. We have
13	we can reveal here a few items that we learned
14	from that testing.
15	We found that the new items in the
16	three-item composite that Pierre mentioned,
17	that's just the three items, HP1, 2, and 3, in
18	MUC-263, they weren't subject to floor or ceiling
19	effects. They have excellent reliability at the
20	hospital level at the recommended sample size,
21	which is 300 completes per hospital per year.
22	They are not redundant with any of the

current items in the survey. They were related 1 2 in a predictable manner with the standard patient mix characteristics that we use when we adjust 3 4 the HCAHPS scores with public reporting. Thev 5 are predictive of hospital rating and recommend. A lot of hospitals want to know that. 6 They do 7 not -- they do not vary systematically by survey 8 mode -- that is, telephone, mail, IBR, or mixed 9 mode -- or by patient race, ethnicity, or by hospital characteristics, after we adjust for 10 11 patient mix. And they have a higher internal 12 consistency as composite, a Kronbeck offer of 13 0.81.

So we were encouraged by the empirical results. That was part of our decision to put these three items in particular into the new composite to replace the current items. We probably will go through the NQF. Timing was such that the MUC list came first.

20 Oh, and of course, I should indicate 21 that quite deliberately, the new items do not 22 mention medication. They ask if the hospital

staff talked to the patient about treating their 1 2 We do not limit what "treat" might mean, pain. and we know from cognitive interviews that 3 4 patients interpret "treat" as medicines and other 5 therapies and methods for relieving pain. CO-CHAIR WALTERS: 6 Sean? MEMBER MORRISON: 7 I'm sorry, Ron, I 8 just can't let this one go by. I think you guys 9 really need to look not at the research in the 10 past five years but the research what was done 20 11 to 25 years ago that looked at these line of 12 questioning and demonstrated that there actually 13 wasn't a link between patient experience and 14 outcomes and all it did was generate nurses 15 talking to patients about their pain but there 16 was no change in the experience. There was no 17 change in outcome. And there actually wasn't a 18 change in practice. And I think that has been 19 forgotten because those data were done almost 20 three decades ago. 21 So, please take a look at that before 22 you -- I would strongly encourage you to look at

those data before you bring it through 1 2 endorsement. CO-CHAIR WALTERS: Kim. 3 4 MEMBER GLASSMAN: Just a clarifying 5 question, then. Because it is included in the materials, are HP-4 and HP-5 off the table? 6 7 Okay. 8 So, I know we are not MEMBER DEMEHIN: 9 discussing them here, but are they undergoing any further development or kind of where do you see 10 11 it going? 12 DR. YONG: So, I will say what the 13 committee will vote on is HP-1, 2, and 3. 14 CO-CHAIR WALTERS: Presumably, what the appropriate Steering Committee would hear 15 16 along with the data presented, if that is the 17 choice. 18 Okay, let's open it up for voting. 19 MS. QUINNONEZ: Voting is now open for 20 IQR Program, communication about pain during the 21 hospital stay. This is MUC16-263, the questions HP-1, HP-2, and HP-3. 22

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1	Option 1 is support; Option 2,
2	conditional support; Option 3, refine and
3	resubmit; and Option 4, do not support. You may
4	cast your vote.
5	I will read those one more time.
6	Option 1, support; Option 2,
7	conditional support; Option 3, refine and
8	resubmit; and Option 4, do not support.
9	Okay, voting is now closed. We will
10	give the software a second.
11	(Simultaneous speaking.)
12	CO-CHAIR WALTERS: While I have an
13	opportunity, let me kind of give a layout of what
14	we are thinking here, at least some people.
15	Since we just got done talking about
16	this measure, that is a preview of all previous
17	measures. We are going to have vote again,
18	aren't we? Oh, go ahead.
19	MS. QUINNONEZ: Yes, we are going to
20	have to vote again. One second.
21	CO-CHAIR WALTERS: Okay, let's do that
22	first.

	23
1	MS. QUINNONEZ: Give me one second and
2	I will queue.
3	CO-CHAIR WALTERS: Ready? One second.
4	MS. QUINNONEZ: Voting is now again
5	open for MUC16-263, questions 1, 2, and 3.
6	Option 1, support; Option 2,
7	conditional support; Option 3, refine and
8	resubmit; and Option 4, do not support.
9	Thank you. Voting is closed. It was
10	successful. The voting results read 17 percent
11	voted for support, zero percent voted for
12	conditional support, 67 percent voted for refine
13	and resubmit, and 17 percent voted for do not
14	support.
15	So, this will move forward with refine
16	and resubmit.
17	CO-CHAIR WALTERS: Okay, here is what
18	we were just talking about. And opportunity
19	opened up this morning because, against, we
20	didn't have anything in the Consent Calendar for
21	value-based purchasing but it cleared. And it is
22	exactly the same measure that we just got done

1 talking about. So, we are going to go over 2 briefly the rules of a value-based purchasing Probably there won't have to be a great 3 program. deal of discussion about the details of the 4 5 measures we just got done talking about. It will be mostly about whether it is appropriate for the 6 7 value-based purchasing program.

8 And then, for you hypoglycemic people, 9 we are going to take a little bit more than just 10 go get your food but a moderately brief break for 11 lunch and then head into Consent Calendar 8 and 12 9. So, that is kind of how things are laying out 13 for one o'clock on.

And we are going to go to the overview and then the opportunity for public comment and then talk about this measure.

17 MS. MCQUESTON: Thank you. So the 18 Value-Based Purchasing Program. Medicare bases a 19 portion of hospital reimbursements on performance 20 through this program. Medicare began withholding 21 one percent of its regular hospital

reimbursements from all hospitals paid under its

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1	Inpatient Prospective Payment System to fund a
2	pool of the value-based payment incentive
3	payments.
4	The amount withheld from
5	reimbursements increases over time. For 2016 it
6	was 1.75 percent and for 2017 and for future
7	fiscal years, it will be 2.0 percent.
8	Hospitals are scored based on their
9	performance on each measure within the program,
10	relative to other hospitals, as well as on how
11	their performance on each measure has improved
12	over time. The higher of these scores on each
13	measure is used in determining incentive
14	payments.
15	This is an overview of the current
16	measures in the program and those proposed for
17	rule. And we are currently considering one
18	measure on the MUC List.
19	Current measure needs include adverse
20	stroke events, cancer, behavioral health, care
21	transitions, palliative and end of life care, as
22	well as medication reconciliation.

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	2. 
1	This is an overview of the first part
2	of the current measures in the set. The program
3	includes seven safety measures, four measures
4	related to clinical care measures around
5	readmissions, and then there is the one measure
6	related to efficiency and cost reduction, as well
7	as the HCAHPS measure within the domain of person
8	and community engagement.
9	Value-Based Purchasing also has five
10	measures for mortality, soon to be six, as CABG
11	was more recently or actually now six. And then
12	two measures related to payment associated with
13	episodes of care.
14	And now we will move to public comment
15	on this measure.
16	CO-CHAIR WALTERS: Operator, can you
17	open up the lines for any public comment?
18	OPERATOR: Thank you. At this time,
19	if you have a comment, please press star then the
20	number 1 on your telephone keypad. We will pause
21	for just a moment.
22	And there are no public comments at

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2	CO-CHAIR WALTERS: Are there any
3	public comments in the room?
4	Okay, there weren't any lead
5	discussants assigned to this because it didn't
6	exist until this morning. Oh, okay, thank you.
7	I might also just add that as far as
8	I remember, a measure had to be on IQR for a year
9	before being placed into the Value-Based
10	Purchasing Program.
11	So, Lee well, he didn't know. Oh,
12	Kim. You probably just acquired this, then.
13	MEMBER GLASSMAN: No, we were prepared
14	and then it went away and it came back. So,
15	obviously, because this isn't leading the fit
16	test for what would be included in Value-Based
17	Purchasing, we would not recommend it for
18	inclusion.
19	CO-CHAIR WALTERS: Jack? Oh, I'm
20	looking at the wrong one. Sorry. Akin. I am
21	looking at my agenda. Akin.
22	MEMBER DEMEHIN: So, I think I am a

little confused about sort of how to address this 1 particular measure in the context of VBP. 2 Τ think it is way too early, frankly, to talk about 3 whether it is a fit for VBP. And even a 4 5 recommendation of refine and resubmit feels like well, if we don't even know if it is working in 6 7 the IQR yet, it is very hard for us to get a 8 sense of whether it is ready for VBP or not. So, 9 I think we would probably lean towards do not 10 support for now. 11 CO-CHAIR WALTERS: Could I ask the 12 measure steward what their thinking was of 13 putting this on VBP at this point in time? 14 DR. YONG: It is just for the committee's consideration as for potential 15 16 inclusion in HVBP, just like I mean in this 17 circle, we have done that. We put measures that 18 we have potentially put in for IQR and for HVBP, 19 either substantive changes or new measures for 20 the committee at the same time.

21 CO-CHAIR WALTERS: So, Akin, I think 22 I interpret yours as do not support. And Kim, I

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am moderately sure I interpret yours as do not 1 2 support. Is there any other discussion about 3 this measure for the Value-based Purchasing 4 5 Program? Ready for a vote. MS. QUINNONEZ: Voting is now open for 6 7 the Value-Based Purchasing Program. 8 Communication about pain during the hospital 9 This is MUC16-263, questions 1, 2, and 3. stav. Option 1 is support; Option 2, 10 conditional support; Option 3, refine and 11 12 resubmit; and Option 4, do not support. 13 Option 1, support; Option 2, 14 conditional support; Option 3, refine and resubmit; and Option 4, do not support. 15 16 Okay, voting is now closed. The 17 results read 5 percent voted support, zero 18 percent voted conditional support, 19 percent 19 voted refine and resubmit, and 76 percent voted 20 do not support. This is a do not support 21 recommendation. 22 CO-CHAIR WALTERS: Thank you very much

for your time. 1 2 Now, the race to the counter, right? How long? 3 CO-CHAIR TRAVIS: How far behind are 4 5 we? CO-CHAIR WALTERS: We probably have a 6 7 good hour and a half yet for Consent Calendar 8 8 and 9. 9 Fifteen minutes, 1:10-ish. Thank you. (Whereupon, the above-entitled matter 10 11 went off the record at 12:55 p.m. and resumed at 12 1:15 p.m.) 13 CO-CHAIR TRAVIS: Okay, I think it is 14 time for us to get started. Just as a reminder, we are still in the Hospital Inpatient Quality 15 16 Reporting Program but we are now on Consent 17 Calendar 8. 18 Okay, if we could ask the people in 19 the back of the room to recognize that we are 20 about ready to get started and need to hear each 21 other, I would appreciate that. Is that a polite 22 way of asking you all to -- thank you.

All right, I really appreciate it.
Now, we are in Consent Calendar 8 and you see the
measures that we are going to address in this
Consent Calendar. And several of them, in fact,
all four of them in this Consent Calendar, deal
with nutrition and malnutrition.
We do have an update that we want to
share with you before we get into whether or not
any of these get pulled. And so I am going to
turn it over to Melissa.
MS. MARINELARENA: Thank you, Cristie.
So, these nutrition measures were or
are in the health and well-being project that is
undergoing now. They were three of them being
the number one, the MUC16-372, MUC16-294, MUC16-
296 were all consensus not reached during the in-
person meeting. MUC16-344 was not recommended by
the Standing Committee during the in-person
meeting.
On Tuesday, during the post-comment
call, the Standing Committee met again to vote on
the consensus not reached, the I think it was

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validity and evidence on some of them.

2 We are in the process of finalizing those results and we do not have them yet. 3 It 4 should be finalized probably next week or so. 5 And that is an up or down. They will either pass -- if they do pass and they are recommended by 6 7 the standing committee, then they will go forward 8 to member vote. If they do not pass, then they 9 will not be recommended and they will not go on to member vote. 10 11 So, the way they stand right now, 12 three out of the four are still consensus not reached but one has not been recommended. 13 And 14 you see that in the preliminary analysis, based on what the recommendations are. So, the ones 15 16 that are with conditions is that they would be 17 NQF-endorsed. 18 CO-CHAIR TRAVIS: Okay, so we have one 19 update but still more news to come on these 20 measures because the results of the standing 21 committee and then the CSAC review, we don't know 22 that as of today. So, we won't have that much

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added information but it is helpful to know that 1 2 they are moving through the process. So, we have already had public comment 3 4 on our IQR program. So, we won't be doing that 5 at the moment. So, we can move right into these particular measures. And I will read for you 6 what the recommendation is for each measure and 7 8 then see if anybody wants to pull it off the 9 Consent Calendar or leave it on the Consent Calendar. 10 11 The first one is nutrition care plan 12 for patients identified as malnourished after a 13 completed nutritional assessment, which is MUC16-14 372. It is currently sitting with a recommendation for condition support or 15 16 rulemaking, which is based on it continuing to go 17 through the NQF process and to pass and be 18 endorsed. 19 So, is there anyone that wants to pull this measure for discussion and vote? 20 21 Okay, Karen. 22 The second measure is completion of a

malnutrition screening within 24 hours of 1 2 admission. It currently sits on the Consent Calendar as conditional support for rulemaking 3 or, essentially, the same condition, which is 4 5 that it goes through the NQF process all the way through and receives endorsement. 6 7 Would anyone like to pull this measure 8 for discussion? Okay, Karen and Lee. 9 The third measure is completion of a nutrition assessment for patients identified as 10 at-risk for malnutrition within 24 hours of a 11 12 malnutrition screening. This is conditional 13 support for rulemaking for the same reasons to 14 complete the NQF process and be endorsed. Pulling that one? Okay. 15 16 I feel like I am almost at an auction. 17 People are raising their hands back and forth. 18 And then the fourth one is appropriate 19 documentation of a malnutrition diagnosis. This 20 currently sits as a do not support. The rationale was that it did not meet the evidence 21 22 requirement for the NQF standing committee. Does

anyone wish to pull this measure for discussion? 1 So, we have a Consent Calendar 2 Okay. that includes in item. It is MUC16-344 3 4 appropriate documentation of a malnutrition 5 diagnosis. The recommendation moving forward would be to do not support. Are there any 6 7 comments that we would like to hear about this 8 measure? Lee. 9 MEMBER FLEISHER: More of a comment to 10 Pierre. I have been thinking a lot about this 11 measure because it may get to frailty and this 12 may be the missing measure that we need to help 13 risk-adjust, rather than SES. So, I don't know 14 where in the future you want to think about this. 15 This is actually the reason I pulled the other 16 measure but Yale Corp. keeps saying if we want to 17 do it clinically, I think this is -- could be the 18 missing clinical factor. 19 CO-CHAIR TRAVIS: Thank you for that 20 input, Lee. Anyone else? 21 Okay, are there any objections to the Consent Calendar which just has this one measure 22

Okay, seeing none, the Consent Calendar 1 on it? 2 moves forward. Okay, let's go to MUC16-372, nutrition 3 4 care plan for patients identified as 5 malnourished, after a completed nutrition 6 assessment. 7 Karen, you pulled the measure. If you 8 would to tell us your rationale for pulling it and then we will have a broader discussion. 9 10 MEMBER SHEHADE: Thanks. So, 11 initially, on 372 I wanted to get some 12 clarification around what had come from that 13 meeting. 14 So, initially, it was to really get a 15 sense of what had happened in the meeting on 16 December 6th, to get a sense of where the 17 Committee was headed, you know what kinds of -- I 18 think they were looking for evidence for that 19 So, what additional evidence were they one. 20 looking for? 21 CO-CHAIR TRAVIS: It's validity. This 22 one is validity.

1	MEMBER SHEHADE: Okay.
2	CO-CHAIR TRAVIS: So, there were some
3	testing questions.
4	MEMBER SHEHADE: And in looking at
5	some of these nutrition measures, and it is hard
6	to think about them all as single measures
7	because it is really about the patient, when they
8	come in, for doing an appropriate screening for
9	that patient, doing an appropriate assessment for
10	the patient and then doing something about it.
11	And as a clinician who, as I mentioned
12	yesterday, and who has cared for lots of Medicare
13	beneficiaries over the years, when they come in
14	to an inpatient setting, this was something that
15	was key to the initial admitting process, an
16	assessment for that patient.
17	And when I read that only 30-something
18	percent had actually been completed, there is
19	clearly a gap in the work that needs to take
20	place to help identify patients for the
21	appropriate care and especially in a frail
22	elderly population where wound care is critical,

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infections, good nutrition is just paramount. 1 2 And it became, from a clinical standpoint as a PA, I was the house officer that 3 never left for 11 years and admitted over 500 4 patients, this was something that we did 5 automatically. And calling nutrition in, you 6 7 know the dieticians in to come and help us come up with an appropriate plan was really just good, 8 9 clinical care and it shouldn't be variable across the country. It is something that should take 10 place and be really a standard. It should be an 11 12 expectation of any Medicare beneficiary that good 13 nutrition is just fundamental to what we are 14 doing. So, I am hopeful that whatever it is 15 that is needed from the committee to look at this -- and clearly, we want to go through the appropriate process and make sure that everything has good evidence behind it, but clearly, to make

16 17 18 19 20 sure that all those patients receive that same 21 level of good screening assessments and a care 22 plan identified for them.

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1	CO-CHAIR TRAVIS: Thank you, Karen.
2	We have some other lead discussants.
3	We have Brock, Andrea, and Wei. And feel free,
4	somewhat like Karen did, if you want to discuss
5	these measures, all of these measures at the same
6	time, I think that is fine. We will vote on them
7	separately but feel free, if your comments are
8	much like hers.
9	So, any comments from Brock? Anything
10	to add?
11	MEMBER SLABACH: And I'm not sure.
12	Were some pulled for further discussion?
13	CO-CHAIR TRAVIS: Yes, we have got the
14	completion of the screening, completion of the
15	assessment, and the care plan all pulled for
16	discussion.
17	MEMBER SLABACH: Okay. It is our
18	position that we are in agreement with the
19	recommendations from NQF on staff and the Consent
20	Calendar was appropriate.
21	CO-CHAIR TRAVIS: Thank you. Wei or
22	Andrea?

1	MEMBER YING: I just have so, it
2	would be great if physicians working in hospital
3	can comment so that completion of sorry.
4	I was just going to say it would be
5	great if the physicians working in hospital can
6	comment on it so completion of a screening within
7	24 hours of admission, I kind of feel like it is
8	a given, right, as part of, as Karen mentioned,
9	as part of the admission process. I don't mean
10	screening. I mean this is a more formal way of
11	documenting it but as part of the intake process,
12	the height and the weight and the routine blood
13	work that usually has been done in a timely
14	fashion, from that a pretty good sense of where a
15	patient is at in terms of nutrition status
16	already presents. So, this is more a formal way
17	of documenting it.
18	My question is adopting this measure
19	will change the clinical practice but does it add
20	any value to the existing process? So, that is a
21	comment on that.

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And then on nutrition plan for patient

identified as malnutrition, I looked at specs and 1 2 it actually has five or six pretty long lists of the elements that has to be hit in order to be 3 4 considered completed. We talked about the burden for the 5 hospitals. Is this an eMeasure so it can be 6 7 pulled automatically from the system? 8 Yes, it is an MS. MARINELARENA: 9 eMeasure and it is being proposed for IQR and the 10 11 MEMBER YING: Okay, so this eMeasure. 12 So, my question is more about the screening. Does it add value? 13 14 CO-CHAIR TRAVIS: Thank you, Wei. 15 Andrea? 16 MEMBER BENIN: You know I think that 17 obviously this is a critically important topic 18 and a really important topic to address. These 19 metrics make sense. I think the one concern that 20 I had was really around the idea of having three or four malnutrition metrics in sort of the 21 balance of the portfolio. And so if one were to 22

pair them down for this purpose, which one would 1 2 be to choose -- you know it just seemed like a disproportionate number of metrics on 3 malnutrition in the portfolio. And maybe it is 4 5 that important. You know I don't have a good sense of that. And certainly in pediatrics, it 6 is important to deal with this for everybody's 7 nutrition but it is different when you get into 8 9 geriatrics. So, I recognize that. The idea that the screenings seem to 10 me actually to be the most critical because I 11 12 think that starts to trigger things. And I think 13 that we do find that when these screenings, you 14 know, you deliberate and you do whatever it is, you start doing these screenings, it does start 15 16 the process going. So, that one seemed to me to 17 be the most critical but I think perhaps those 18 would be questions if this committee is going to meet again, the committee that is reviewing it is 19 20 going to meet again. 21 Maybe there would be a way for that committee to also sort of prioritize how to think 22

about these things and that may help some of us 1 2 decide. Because if we vote these all forward as conditional and then the committee approved, 3 4 there may be an option to have a little bit of 5 additional help with how to prioritize the So, I think having the experts weigh in 6 metrics. on what that looks like would be valuable because 7 8 this does seem to be critically important. And 9 the one, to me, that seemed probably starter important was the screening. 10 The other two 11 seemed to me not to stand alone however. So, I 12 think it did not seem to me that if you have 372 or 296 without 294, that that didn't actually 13 14 seem to make sense. So, if you were going to go with one, it seemed like 294 was the one that had 15 16 it. So, it just seemed like there could be 17 18 a little bit -- there needed a little more 19 thought in that. So, if we say conditional 20 support, I might add the condition of with other, 21 I don't know exactly how to frame it, but with a little bit more recommendation from the committee 22

that is working on this about how to think about 1 2 it. But it was a little bit concerning that the committee, themselves, initially didn't even 3 approve it. And that gave me a little pause, 4 without understanding the nuances there. 5 CO-CHAIR TRAVIS: Thank you. 6 Is there 7 any additional kind of information that you can 8 give us maybe from the meetings that have already 9 occurred? Because then you are still out kind of finalizing the committee recommendations. 10 11 MS. MUNTHALI: So, with regards to the 12 screening, the committee had a lot of concern 13 because the screening wasn't linked to evidence 14 and it was so hard to see the proximity was quite distal. 15 16 And then the other issue with 17 screening was that all patients 18 and over were 18 to be screened. So, patients at-risk was not 19 stratified or there was no risk adjustment. So, 20 the committee was really concerned about burden 21 for inpatients and hospitals. 22 Essentially, those are the largest

issues with the measure.

2	CO-CHAIR TRAVIS: That's helpful. And
3	is there anything to add about any of the other
4	two measures, too, at least from the MUC meeting?
5	MS. MUNTHALI: I have to pull it up.
6	With the care assessment, I think we the care
7	plan, the issue was around exclusions. They were
8	not specified and that was the validity issue.
9	And then if I can refresh my memory,
10	there is a third one.
11	CO-CHAIR TRAVIS: Issue of a nutrition
12	assessment for those at risk after screening.
13	MS. MUNTHALI: And that was also
14	evidence. And Angel, who is part of the
15	developer team is there as well. And correct me,
16	if I am wrong, but it was also around evidence
17	and just linking process to help him.
18	CO-CHAIR TRAVIS: Thank you. I think
19	that will help our thinking as we move forward.
20	Okay, I will start with Lindsey.
21	MEMBER WISHAM: Quick question in
22	regards to the 1:34:38 or eCQMs. It does seem
that the specifications, one leads into the 1 2 other. So, I didn't know if they were tested. When they were field tested, were they tested as 3 a package? So, in essence, one of the measures 4 will produce a data element that then feeds into 5 the denominator of the next measure. 6 7 So, I think the best thing to consider is that do they get approved as a package or not 8 9 So, if you move one from the continuum at all? 10 do you then not use the prior data elements? 11 MR. VALLADARES: Yes, so the four 12 measures were tested together. I'm sorry, Angel 13 Valladares. I am with Avalere Health, who worked 14 with the Academy of Nutrition and Dietetics who developed the four malnutrition eCOMs. 15 16 So, the four eCQMs were all tested in 17 a cohort together with the same hospitals. 18 However, as you indicated, yes, sort of if you 19 look at them in order, so they are technically 20 supposed to go along the nutrition care process, 21 which is screening, assessment, care plan, 22 recommended and documented, and then a diagnosis

by the provider. The data elements are generated from the predecessor measure.

So, for instance, if you really want 3 4 to accurately identify the denominator of 5 patients who should be assessed based on the risk level from the screening that was identified. 6 7 You need to really identify that patient 8 population in the first cohort, which is the 9 patients that were screened for malnutrition risk. 10 11 So, if you don't have that cohort 12 accurately identified, then what occurs is you 13 may have a misleading denominator population in 14 the assessment because the appropriate rates of documentation are not happening, which is what we 15 16 are finding in terms of the gap for this, which 17 is their measure set. 18 CO-CHAIR TRAVIS: Very good question. 19 I was wondering about that, myself. 20 Akin. So, this set of 21 MEMBER DEMEHIN: 22 measures definitely gives us a little bit of

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pause, especially since there are two of the three are ones where the evidence doesn't appear to be particularly strong and it sounds like that is why it is landing in the consensus not reached at this point.

And if there are questions about 6 7 validity in terms of whether it is actually 8 measuring what we think it is measuring, I don't 9 And I also have to say that the fact that know. it is an eMeasure, I do think that something like 10 11 this makes sense as an eMeasure but I don't 12 necessarily think that this being an eMeasure in 13 and of itself obviates the potential burden that 14 this could entail. And in particular, I am curious about whether this measure is supported 15 16 by all of the -- or would be supported by all of 17 the EHR vendors.

I think it would be hard to lend this too much support without an understanding of kind of where they are in that process. And some of the evidence and validity issues, that gives us some pause, too.

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CO-CHAIR TRAVIS: Is your card still
, Lindsey?
Andrea.
MEMBER BENIN: I would just say that
ring heard some of this other discussion a
tle bit more about what the committee was
inking, perhaps this needs to go into a refine
l resubmit category. Maybe it needs a little
t more work than I understood it to need for
three of them.
I mean if I had to choose one, I would
obably choose the screening one but maybe there
a little bit more work to go into those.
CO-CHAIR TRAVIS: Thank you, Andrea.
I guess my question is how did the
mmittee really look at these? Did they look at
em as related? Did they look at them as I
an they are not a composite. So, how did the
mmittee kind of look at the cascading effect,
you will, of this set of measures?
MS. MUNTHALI: It was a topic of
scussion and I think there were some

recommendations for the developer prior to 1 2 submitting to think about them as a composite because they did recognize that they were related 3 4 and that, as it was mentioned before, this 5 screening proceeds, particularly for the first I think the other measure on the 6 two measures. evaluation plan, the assessment plan, is not a 7 8 screening measure. And that is something the 9 developer wanted to point out. But for the 10 others, you have to set your base population and 11 then build on that. 12 So, that was a recommendation by 13 staff, prior to submission and then the 14 Committee, when they first looked at the 15 measures. 16 CO-CHAIR TRAVIS: Okay, Sean. 17 MEMBER MORRISON: Yes, quickly 18 Cristie. So, if that is the case, that there was 19 a recommendation on a composite measure, what I 20 would -- and it has not gone through endorsement 21 process, what I would like to recommend or 22 suggest is it goes back as a revise and resubmit

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with that comment.

2	Because if it goes through and is
3	endorsed by NQF I'm sorry and we put that
4	as a conditional support, then it goes through
5	four specific measures and we never see it again.
6	What I would like to see is it go through the
7	evidence process and then for us to evaluate as
8	whether those four items are appropriate for this
9	program.
10	CO-CHAIR TRAVIS: And so that is
11	refine and resubmit from your perspective. Okay.
12	Are there any other comments? Would
13	you like to make one? Sure.
14	MR. VALLADARES: So, I have a few
15	comments that I can make on some of the concerns
16	that were addressed by the committee members. I
17	think one of the important things I can start
18	with sort of high or low. We will talk about
19	sort of the feasibility of the measures and
20	validity to adjust Akin's question that was
21	around the EHR vendors.
22	So, we did conduct feasibility

assessments with three of the largest EHR vendors 1 2 in the country, Epic, Cerner, and Allscripts. We received very high scores on our feasibilities 3 assessments for all of the data elements on all 4 5 four of the eCOMs. They indicated to us, in general, that at this time most of their recent 6 7 platforms have the capabilities to capture these 8 data elements. However, it is up to the 9 discretion of the hospital implementing that particular platform to, obviously, decide if they 10 want to incorporate that data element in the 11 12 structured manner that is required for the collection of an electronic measure. So, I just 13 14 wanted to share that. Then with validity to be clear as 15

15 Then with validity to be clear as 16 well, we did test the measure. So, this is the 17 nutrition care plan measure. So, we did test 18 that measure with -- well, we tested all four 19 measures because they were tested together as a 20 package for specific exclusions. When we worked 21 with our technical expert panel, we were not able 22 to show with our data we were able to collect

that there was a valid reason to include the exclusions that we tested on, with the exception of the length of stay under 24 hours because don't want to, obviously, penalize a hospital for a process if there wasn't even enough time to complete that process or location.

7 However, there were three what we were 8 calling experimental exclusions which were 9 discharged to Hospice, discharged palliative care as well and then also, left against medical 10 11 advice, which those were the three major exclusions. So, that is something that we are 12 13 continuing to test as we move forward with these 14 measures. We are testing these in other 15 hospitals.

16 So, the other comment around the 17 evidence, that is something that I do want to 18 bring to the committee's attention because I 19 think this is helpful with the discussion and 20 will also help with your recommendations to us as 21 to how we can move forward with these measures. 22 So, the evidence really sits more on,

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of course, as we know whatever process is most 1 2 linked directly to patient outcomes and improvement in patient outcomes. And that is 3 really when the intervention, the nutrition 4 invention gets implemented. We know that when a 5 specific nutrition intervention, there are 6 There is different 7 several. ONS is one. parenteral enteral nutritions, supports as 8 9 dietary, supports and modifications to the diet. 10 Those, there is strong evidence to link that 11 patient impact. And that is why the third 12 measure of the nutrition and care plan did pass 13 evidence.

14 However, the first two measures, which 15 are further back in the process, as we know, they 16 are a little more distal to the process but the 17 guidelines internationally, there is 18 international consensus from the United States, 19 Europe, other countries, that before you can 20 reach intervention, you need to properly identify 21 and assess the patient for physical indicators 22 for malnutrition. So, a lot of these studies

that we cited in our evidence submission showcase 1 2 the use of the proper screening and assessment tools for studies that looked at really what type 3 of interventions were implemented for patients. 4 So, I think that is where a lot of our 5 -- the challenge for us has been is really being 6 7 able to hone in on the direct causal linkage of a screening to the outcome of the patient. We have 8 9 a lot of evidence to showcase that. If you 10 identify the patient and intervene on them early, 11 you can improve outcomes. And we also have a lot 12 of evidence to showcase that assessments are a 13 great tool to identify risk factors for patients 14 and there is independent associations with increased length of stay, increased readmission, 15 16 mortality, several other clinical indicators that 17 are very important, obviously, for Medicare 18 patients. So, those are a few of the items that 19 20 I wanted to mention. 21 And the last thing -- and I do 22 apologize for going I am sure overtime, is the

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1	composite. So, that is another discussion that
2	we did have, as Elisa mentioned, at NQF.
3	So, one of the challenges that, of
4	course, there is with the development of a
5	composite measure is that you need to test all of
6	the individual components in the field and
7	generate performance evidence for each of the
8	individual composite components.
9	PARTICIPANT: No, that is not NQF.
10	MR. VALLADARES: Okay, well,
11	originally, that was our perspective, was we
12	wanted to first implement each of the measures
13	and sort of allow the performance used to be
14	generated and then create the composite but it is
15	not anything that we were held to but that was
16	sort of the approach that we took. Before
17	actually submitting a composite measure, we
18	wanted the four measures to be considered as
19	such.
20	So, those are the comments. Thank
21	you.
22	CO-CHAIR TRAVIS: Thank you very much.

1	Mimi.
2	MEMBER HUIZINGA: I will be very
3	quick. So, in general, we support these
4	measures. We think that malnutrition has been
5	linked to many conditions and that it is
6	something that hospitals can have direct impact
7	on and make a difference here. And it aligns
8	with maybe the other initiatives that our
9	hospitals are working on to try to prevent
10	complications and reduce readmissions.
11	So, we are supportive of the three in
12	the conditional support that were recommended by
13	NQF. However, if we had to choose one, I would
14	likely recommend actually a little bit different
15	than what was mentioned before.
16	I would probably go with the full
17	assessment, instead of just a screening. Care
18	planning often happens with assessments but we
19	find that the breakdown often happens from the
20	screening to full assessment. So, we would, if
21	you are only going to go with one, that is the
22	one that we would like. And if there is going to

further information available from this, we would 1 2 like to see and provide more information about what validated tools we should use for specific 3 4 conditions. For example, what should be used in a patient with concerns much like that. 5 But in general, we think these 6 7 measures are a very good idea and we are very appreciative if they are e-specified. 8 9 CO-CHAIR TRAVIS: Jennifer. 10 MEMBER EAMES HUFF: I guess I have the question, and I am thinking again of the diagram, 11 12 Helen, that you showed yesterday about the 13 outcomes and the drivers. I forget the bottom 14 one. I am not clear what role malnutrition 15 16 plays against the other drivers we have been 17 talking about in terms of priority. I got this 18 great evidence management, the role it plays in 19 terms of better outcomes, and the patient safety, 20 and better costs but I just want to connect to 21 the conversation that we are trying to -- or not 22 have it so separately in terms of thinking

holistically of how you prioritize about what
 gets in this program.

3 So, I guess that is a question for me 4 because where does it stand in the priorities of 5 drivers in terms of whether or not just being 6 sure it be in the program.

7 And then looking at the specific 8 measures, themselves, it sounds like the if you 9 had to choose one, you would choose. So, I will 10 throw mine in of I would choose the 372, which is 11 the nutrition care plan for malnourished.

12 And as a part of that, as a part of 13 the dominant, it includes and assessment and it 14 feels a little bit more complete and actionable. 15 It means you know what actions are going to be 16 taking place based on that, their status of 17 malnutrition.

18 CO-CHAIR TRAVIS: Thank you, Jennifer.
19 Akin.
20 MEMBER DEMEHIN: All very helpful

22 in sort of this not necessarily a dichotomy but

I mean I am a little caught up

points to hear.

when we are talking about malnutrition screening, we are talking about what a patient comes into the hospital with. And then the plan portion of it, the 372 is what you do once you know someone is malnourished.

6 From what I am hearing, there may be 7 some pretty good evidence around there being 8 downstream impacts on outcomes as the result of 9 having that care plan in place but less certain 10 that there is good evidence around just the act 11 of screening and the act of documentation.

So, it still feels to me that there are enough questions about these measures and how they hang together and how they are packaged that a refine and resubmit sounds a little better to me.

I do think Jennifer raises a really
interesting question, too, about so where does
this fit in the overall constellation of issues
that you would look at. Is this one of the most
important things we can do to affect outcomes?
And based on that we see here, it is not quite as

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1 clear-cut as one might hope. 2 CO-CHAIR TRAVIS: Sean. MEMBER MORRISON: 3 Sorry. 4 CO-CHAIR TRAVIS: Dan is that you? Ι 5 can't tell whose card is up. Oh, Lindsey. And just in regards to 6 MEMBER WISHAM: the comment about if I had to pick one, just 7 8 based off of Angel's comment, I would strongly 9 suggest not just picking just one, simply because 10 if we pick one or we recommend one, there is 11 going to be a whole host of implementation 12 problems when it comes to actually identifying what data elements or codified data elements, 13 14 rather, are we able to pull in. I think there is somewhat of a cat and 15 16 mouse game already with eCQMs, which is we 17 specify the measure and then vendors and 18 clinicians then figure out how to put it in some 19 sort of a discrete field. So, it looks like --20 again, I have not reviewed the exact data 21 elements in this group of measures but it sounds 22 like from the description because they feed into

each other you are, in essence creating your 1 2 denominators for the next round of measures. CO-CHAIR TRAVIS: Well, I think we 3 4 have run the gamut. I think there is general 5 consensus that nutrition and malnutrition is an important topic. However if it is within the 6 whole measure set, I think is something else that 7 8 would be important for us to kind of feel and be 9 sure that it is one of the drivers. 10 And then it does appear to me that 11 there are a number of questions about the measures, themselves, and how they hang together. 12 13 And I'm still trying to get a better feel for 14 what the Standing Committee's recommendations 15 are. 16 It would seem to me we are going to vote but I have heard a lot about refine and 17 18 resubmit, some of which is defined by what 19 happens in the endorsement process but not all of 20 which is having to do with the endorsement process. And that is what makes refine and 21 resubmit different than conditional support. 22

Because if it went through and was endorsed, it 1 2 would automatically be eligible for the program. So, as you are thinking about the way 3 4 you want to vote, just keep that in mind in terms 5 of the difference between conditional support and refine and resubmit. Conditional support is if 6 7 it goes to the endorsement process. If each of 8 these goes through and they are endorsed, then 9 they would be eligible with our recommendation. Our recommendation would be they are eligible for 10 11 the program. 12 If we would like to see how they hang 13 together and see what the ultimate results were, then refine and resubmit what would be what we 14 15 would need to do. 16 So, we will go on with the vote. 17 Oh, I'm sorry. There is a question. 18 David. 19 And then I realized I was talking about all three measures. We are going to vote 20 21 on each of these measures separately, right? 22 Okay.

So, I just had one 1 MEMBER ENGLER: 2 comment and it goes to the question of food insecurity. And how close of these metrics point 3 to issue of food insecurity with patients that 4 are being treated? 5 There is a hunger crisis in America 6 7 that has wound up on the doorsteps of a number of 8 the hospitals, in particularly in California, who 9 are facing large amounts of food insecurity, especially when their supplies run out at the end 10 11 of the month. And we know that because we see major spikes, hypoglycemic spikes and ED returns 12 13 and high amounts of ED utilization at the end of 14 very predictable times. So, I am wondering, because I don't 15 16 know the literature on malnutrition in these 17 particular measures, whether or not they are 18 picking up or there are other metrics that they 19 can look at relative to issues of food 20 insecurity, which to your point, are real drivers 21 of negative outcomes, especially in the high rates of ED utilization. 22

	27.
1	CO-CHAIR TRAVIS: Thank you, a very
2	important thing for us to keep in mind.
3	We are going to vote on each measure
4	separately. So, the first one we are going to
5	look at it is nutrition care plan for patients
6	identified as malnourished after completed
7	nutrition assessment, which is MUC16-372.
8	MS. QUINNONEZ: Voting is now open for
9	IQR Program measure MUC16-372. Option 1,
10	support; Option 2, conditional support; Option 3,
11	refine and resubmit; Option 4, do not support.
12	Option 1, support; Option 2,
13	conditional support; Option 3, refine and
14	resubmit; and Option 4, do not support.
15	If we have anyone on the phone, if you
16	could submit our votes, please.
17	Okay, voting is now closed. For MUC
18	measure 16-372, 9 percent voted for support; 43
19	percent voted for conditional support; 39 percent
20	voted refine and submit; and 9 percent voted do
21	not support.
22	MS. MARINELARENA: So if it is refine

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1	and resubmit, we need a rationale of the
2	suggested modifications. This is a measure that
3	is fully developed and tested and going through
4	the NQF process.
5	DR. BURSTIN: One of the opportunities
6	here says opportunities for improvement. And I
7	suspect from the discussion, something along
8	those lines.
9	CO-CHAIR TRAVIS: Yes, I mean I think
10	that was the main thing was that the
11	opportunities to kind of think about how they
12	hang together and some of those issues that I am
13	sure you recorded well conversation.
14	Ready?
15	MS. QUINNONEZ: Voting is now open for
16	IQR measure completion of a malnutrition
17	screening within 24 hours of admission. And this
18	is MUC16-294. Option 1, support; Option 2,
19	conditional support; Option 3, refine and
20	resubmit; and Option 4, do not support.
21	Option 1, support; Option 2,
22	conditional support; Option 3, refine and

resubmit; and Option 4, do not support. 1 2 Okay, all votes are in and voting is now closed. For the recommendation of MUC16-294, 3 13 percent voted for support, 46 percent voted 4 conditional support, 39 percent voted refine and 5 resubmit, and 4 percent voted do not support. 6 7 So, this yields a refine and resubmit. Voting is now open for IQR program 8 9 completion of a nutrition assessment for patients identified as at-risk for malnutrition within 24 10 11 hours of a malnutrition screening. This is 12 MUC16-296. Option 1, support; Option 2, 13 conditional support; Option 3, refine and 14 resubmit; Option 4, do not support. Option 1, support; Option 2, 15 16 conditional support; Option 3, refine and 17 resubmit; and Option 4, do not support. 18 Voting is now closed. For the 19 recommendation of MUC16-296, 17 percent voted for 20 support, 43 percent voted conditional support, 39 21 percent voted refine and resubmit, and zero 22 percent voted do not support.

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1	This yields a conditional support
2	recommendation.
3	CO-CHAIR TRAVIS: Okay, thank you all
4	very much for going through all of that with us.
5	All right, now we are going to go to
6	Consent Calendar 9. Ron doesn't think I have
7	done enough today so I'm doing two in a row.
8	So, Consent Calendar 9 is the tobacco
9	use and antipsychotic and an influenza, and a
10	safe use of opioids. So, we will be walking
11	through those and if you will give me just one
12	moment, I'm trying to be sure that I give you all
13	the right information here.
14	Well, it was done but it was done for
15	a different program. Here I go. We will. We
16	will.
17	So, here we are. Okay, so the first
18	one is tobacco use screening, which is MUC16-050.
19	It comes to the Consent Calendar with a refine
20	and resubmit. It is currently undergoing field
21	testings. The field testing should demonstrate
22	reliability and validity in the acute care

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1	setting. The eMeasure needs to be submitted to
2	NQF for review and endorsement.
3	Is there anyone that would like to
4	pull this measure for discussion and vote? Okay.
5	The second one is use of
6	antipsychotics in older adults in inpatient
7	hospital setting, which is 16-041. It currently
8	sits with a refine and resubmit. This is a newly
9	developed eMeasure. It is fully developed and
10	specified but it is currently undergoing testing.
11	It is one of the reasons it sits here.
12	The testing results should demonstrate
13	reliability and validity and then the measure
14	should be submitted for NQF endorsement.
15	Anyone want to pull MUC16-041? Okay,
16	Akin.
17	The next one is influenza
18	immunization, MUC16-053. Oh, here it is. This
19	is coming with a recommendation of do not
20	support. I'm just going to read what is here but
21	the Health and Well-Being Standing Committee
22	acknowledged the importance of this hospital-

1	based measure but did not believe narrowing
2	performance gaps were clinically significant in
3	the chart abstracted version of this measure,
4	which is already NQF-endorsed at 16-059. There
5	was no data or evidence provided demonstrating
6	that this eMeasure addresses a performance gap,
7	essentially, in IQR. And Lindsey would like to
8	pull this measure.
9	And then we have the safe use of
10	opioids concurrent prescribing, which we did
11	look at yesterday for a different program. And
12	that is MUC16-167.
13	I have so many things I am keeping
14	notes on, it is hard for me to find it. But I
15	believe that this was seen in a hospital
16	outpatient quality reporting and I believe it was
17	a do no support in that program. And it comes
18	into this program with a refine and resubmit on
19	the Consent Calendar.
20	Anybody want to pull it? Lee and
21	Sean. Okay, great. Thank you.
22	All right. If you all could see my

1	2
1	books and how many different pieces of paper I am
2	trying to you would understand why I lose
3	track. Everything gets updated along the way,
4	too.
5	All right, let's go to our tobacco use
6	screening, which is MUC16-050. And who pulled
7	that one? Nobody. Sorry. Although, is there a
8	comment?
9	Now, I know where I am. Is there a
10	comment on that particular before we go with
11	the Consent Calendar, is there a comment? And I
12	think there is.
13	MEMBER DEMEHIN: Yes, just didn't pull
14	it but did want to make a comment that, as we
15	look at this kind of screening measure, we know
16	that this is designed as an eMeasure. It makes
17	sense to design it as an eMeasure. We know that
18	some of the requirements around modified Stage 2
19	and Stage 3 include a requirement around
20	documentation of smoking status. I think it is
21	more kind of the overarching conceptual question
22	of how much value we get from measuring this.

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1	Even if we are capturing in the EHRs and the EHRs
2	required to capture it, it is less clear exactly
3	how much value this will add to the program
4	measure set.
5	CO-CHAIR TRAVIS: Okay, thank you very
6	much. Are there any objections to the Consent
7	Calendar, which has that one item on it, which is
8	the tobacco use screening?
9	Okay, hearing none, we will accept the
10	consent calendar.
11	Now, we will move to those that have
12	been pulled, use of antipsychotics in older
13	adults in inpatient setting. And Akin, I think
14	you pulled this one. Can you give us your
15	rationale and then we will see if we have any
16	comments from our lead discussants?
17	MEMBER DEMEHIN: Yes, I mean this is
18	one where the staff recommendation around refine
19	and resubmit may actually be the right one here.
20	But as we looked at the denominator exclusions,
21	it made us wonder whether the right groups were
22	included. So, it basically is looking at giving

antipsychotics to anyone other than patients with 1 2 schizophrenia, Tourette's, bipolar, Huntington's disease at the time of admission. 3 4 So, just maybe this is more a question 5 for some of the clinicians in the room. Does that look like the right group? Are there any 6 7 others that we should include. And then some more practical questions 8 9 around where the data come from. It is an EHR measure or it is a claims-based measure? 10 It is 11 an EHR measure. Okay. 12 So, I mean I guess our overarching 13 question is are there any other diagnoses for 14 which you might be prescribed an antipsychotic for a clinically appropriate reason. 15 16 Otherwise, I think refine and resubmit 17 probably is the right category here. 18 CO-CHAIR TRAVIS: Yes?

MEMBER EISENBERG: PQA has developed
an almost identical measure for outpatients. And
we came up with exactly the same categories of
exclusion that appear in this measure.

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1	When we brought that measure before
2	NQF, the only objections that we received was
3	that there are some people that have seizures
4	that could be excluded but it was felt by the
5	endorsement panel, at that point, that those
6	represented such a small number of patients that
7	that exclusion should not be included.
8	CO-CHAIR TRAVIS: Thank you, Woody.
9	Frank.
10	MEMBER GHINASSI: Just a brief thing.
11	The other one to consider is augmentation with
12	depression and doses. So but many people looked
13	at that.
14	But I think it is a good measure. I
15	just wanted to make that comment. I think that
16	my biggest concern is that often subclinical
17	doses of antipsychotics in moderate and
18	sufficient dosage to address any of these
19	disorders are given for two things, agitation and
20	sleep. So, I think this is a good measure.
21	CO-CHAIR TRAVIS: Thank you, Frank.
22	Woody.

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1	MEMBER EISENBERG: Yes, I would just
2	add that I would support this measure
3	conditionally with an NQF endorsement. I am not
4	sure what needs to be refined.
5	MEMBER ENGLER: Can you repeat that?
6	MEMBER EISENBERG: Yes, I don't think
7	this measure needs refinement. I just think it
8	needs NQF endorsement. I would support it
9	conditionally.
10	MS. MARINELARENA: It's not tested.
11	That's why it ended up in this category.
12	CO-CHAIR TRAVIS: And it doesn't
13	let me be sure I am on the right measure. It has
14	not been submitted for review yet, right?
15	So, if you look at kind of the way
16	these decision categories cascade, it hasn't even
17	been submitted yet. So, that is why it is in
18	MEMBER EISENBERG: Good. I withdraw
19	my comment.
20	CO-CHAIR TRAVIS: Okay. But it is
21	good for them to know that that is how you feel.
22	Okay, thank you.

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1	Jack?
2	MEMBER JORDAN: Yes, I think one thing
3	in this, too, as I have been starting to play
4	with these, oftentimes with this, how they define
5	the drug list. That EQM measure is usually in
6	the RxNorm Codes, which aren't entirely stable
7	and they also cause work statements for the
8	people who are trying to maintain these
9	eMeasures. Then, if they can actually be defined
10	by a kind of pharmacy class methodology instead,
11	those are much more stable and easy to build.
12	So, I think that is just a generic
13	thing in how you are building these medication
14	lists, that they are harder to build and maintain
15	when the lists are defined by RxNorm Codes.
16	There might be five or six thousand codes that
17	you have.
18	CO-CHAIR TRAVIS: Thank you, Jack.
19	Lee.
20	MEMBER FLEISHER: More of a question
21	because there is a lot of concern, questions
22	about the right treatment with delirium

postoperatively. So the question is, there is 1 2 actually more and more talk about how there will be an ideal agent, certainly not Benadryl, which 3 4 is the opposite. So, that is my only concern. When it 5 goes to NQF endorsement, whether or not a 6 7 diagnosis of delirium during the hospitalization 8 should be considered potential exclusion. So, I 9 still would say refine and resubmit. 10 CO-CHAIR TRAVIS: Okay, I don't see 11 any more cards. So, I think we are ready to go 12 to a vote on this. 13 MS. QUINNONEZ: Voting is now open for 14 IQR program measures use of antipsychotic in older adults in inpatient hospital setting. 15 And 16 this is MUC16-041. Option 1, support; Option 2, 17 conditional support; Option 3, refine and 18 resubmit; and Option 4, do not support. 19 Option 1, support; Option 2, 20 conditional support; Option 3, refine and 21 resubmit; and Option 4, do not support. Okay, voting is now closed. 22 The

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results for measure -- for MUC16-041, 13 percent 1 2 voted for support, 9 percent voted for conditional support, 78 percent voted for refine 3 4 and resubmit, zero percent for do not support. So, this yields a refine and resubmit 5 recommendation. 6 7 CO-CHAIR TRAVIS: Thank you. The next 8 measure is MUC16-053, influenza immunization. 9 And Lindsey pulled it. 10 MEMBER WISHAM: Yes, thank you. So, 11 going back to one of the conversations we had 12 yesterday in regards in an outpatient measure, we 13 ran into the same scenario, where there was a chart-abstracted version of the measure and an 14 eCOM version that was aimed for this. And I know 15 16 we tried to keep ourselves in line by saying the 17 measure is the measure. That is what we are 18 looking at. 19 The rationale behind the do not 20 support list is two-fold and I don't disagree 21 with it, which is that the measure is nearing top value rate. It is an 84 percent and even so, 22

looking at if there was any data performance gap. 1 2 However, I would like the committee to consider that if this could be a conditional support, 3 based on the fact that if the chart abstracted 4 measure does remain in the program, that the eCQM 5 version of this measure would offer a potential 6 7 reduction in reporting burden for people that were reporting the measure. 8 9 So, just looking at the measure for 10 itself, aside that the performance rate is high right now, if this an option for providers or 11 hospitals to report, it is an option. So, I am 12 asking for folks to consider conditional support 13 based off of that the chart abstracted measure 14 15 also remains in the program. 16 CO-CHAIR TRAVIS: Thank you. 17 Any other thoughts or comments on this 18 influenza measure? Yes. 19 MEMBER DEMEHIN: So, I quess from our 20 perspective, one of the most important things to 21 consider with these reporting programs is whether

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we are identifying the right topics for measures

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and whether we are really focusing on the most 1 2 important opportunities to improve. I certainly appreciate the potential 3 benefits of an eCQM version of this but it seems 4 5 to me that in terms of looking at it in terms of whether we are going to advance all that much 6 7 here, it is hard to see. 8 I think we want to send the message 9 that we want to move quality forward and not just implement measures to demonstrate that EHRs are 10 able to report on measures. I think it needs to 11 12 be tied to something a little more than that. 13 So, I guess the thing that I am 14 personally struggling with, so I'm taking the chair hat off, is if the chart abstracted version 15 16 stays in, I mean this could replace the chart 17 abstraction version, at some point, I am assuming 18 but maybe I shouldn't assume that. Is that the intent that this would replace that, roughly? 19 Okay. 20 So, we get back into that same 21 dilemma we had yesterday with the measure. So, whether it is better to live with the chart-22

abstracted version of it or replace it with the 1 2 eMeasure, that is my major struggle with it. 3 Lindsey. MEMBER WISHAM: Just that I think for 4 5 consideration that as we look to give opportunity for successful eCQM reporting, this is an 6 opportunity to have a measure that is 7 8 straightforward and that has been well-tested and 9 well-received, transition over, I guess from the chart-abstracted world into the eCOM. 10 11 Again, I don't discount that the 12 performance rate is high. I am not disagreeing 13 with that at all. It is just that I think this 14 should be considered as an opportunity if this measure is meaningful to CMS and it is meaningful 15 16 to patients as recognizing quality in a facility. I think it should be further considered to remain 17 18 in the program and ask that it be replaced with 19 the eCOM. 20 CO-CHAIR TRAVIS: So, I do have a 21 question for the staff, perhaps. I mean this 22 looks like -- and I am just looking at this one
sheet of paper I have, which summarizes it pretty 1 2 briefly. It looks like it is done through the Health and Well-Being Standing Committee but they 3 4 didn't believe that narrowing the performance gap 5 was clinically significant. So, I guess did they not endorse? 6 I'm 7 trying to figure out what they did with it. 8 MS. MUNTHALI: It was recommended for 9 endorsement with reserved status because of the 10 performance gap. The gap was narrowing. I think 11 it was around 95 percent. 12 CO-CHAIR TRAVIS: So, I am sorry for 13 this technical question. Was MUC16-053 that 14 version, e-version, it was endorsed for reserved 15 status out the gate? No, we haven't seen 16 MS. MUNTHALI: 17 that one. We have seen the chart-abstracted one. 18 CO-CHAIR TRAVIS: Okay. All right, 19 I'm sorry. The way this read, it was difficult 20 for me to --21 MS. MARINELARENA: So, here is a little nuance, just to confuse everybody. 22 Okay?

So, the chart-abstracted version is one that has been recommended for reserve status because it is considered topped out by the Standing Committee. That has not been finalized. It still needs to go to member vote, CSAC, be ratified. So, it has to go through the entire process.

7 However, for the eMeasure, the eCQM 8 that is before us right now, would not qualify to 9 come before us because the chart-abstracted version that this is based on is topped out. 10 So, it would not meet the NQF requirements of there 11 12 is a quality issue. So, that would -- it would 13 not. It would get voted down. It would not. 14

14 So, it would not be -- if you wanted 15 to do a conditional support, it wouldn't be NQF 16 endorsement. I'm not saying you couldn't do it, 17 but that couldn't be a condition.

18 MEMBER WISHAM: I mean I guess what I 19 was proposing was that the conditional support --20 this should be considered if the chart-abstracted 21 measure is intended to remain in the program, 22 which, by looking at our spreadsheets, it is.

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1	So, that was just a suggestion, again,
2	to reduce reporting burden, just looking how
3	applicable it is to the programs.
4	CO-CHAIR TRAVIS: Ron.
5	CO-CHAIR WALTERS: That leads to an
6	interesting paradox. So, what I just heard,
7	which I am still trying to think through is that
8	there is no incentive for developing an eCQM
9	version of a measure that is already topped out,
10	regardless of how important it is.
11	So, the chart-abstracted version would
12	sit there forever in reserve status and we would
13	never have even an eCQM version in reserve
14	status, which you know
15	DR. BURSTIN: It's a fair paradox and
16	we have talked about this a lot. We love
17	paradoxes at NQF. It is our specialty.
18	But in this particular instance, if we
19	know, for example, that a clinical area is topped
20	out, we don't have any presuppositions that if
21	you made it an eMeasure it would be any less
22	topped out, do you? I guess that is one of the

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1 basic principles.

2	MEMBER WISHAM: We would hope not.		
3	DR. BURSTIN: You hope not but then it		
4	might but if you think, for now, we think		
5	truth for now is what you are abstracting, right?		
6	And the eMeasure shows a performance that is not		
7	topped out. Your first reaction is is because		
8	the eMeasure is not valid because, again, it is		
9	circuitous.		
10	MEMBER WISHAM: It does lead to		
11	questions about parallel reporting of the		
12	measures in chart-abstracted versus eCQM. If		
13	there are discrepancies between the two reporting		
14	rates, is it that there is incorrect with the		
15	eCQM? Maybe not. Is it that there is something		
16	in a configured EHR that is not being reported		
17	correctly? Could be. So, it raises questions as		
18	to it might not have the issue with the eCQM, per		
19	se, because this one is you would say relatively		
20	ingrained within a clinical process already.		
21	CO-CHAIR TRAVIS: And just because I		
22	have already admitted that I am challenged today		

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with all of the paper in front of me, is this
 measure in any other program? Okay. Okay, I
 didn't remember it being.

I guess the question from my perspective would be if it is in a quality reporting program, one of the things we would be looking for would be that it is still high enough up on the radar screen of the providers to want to look good and to do the right thing and to keep immunizations high.

11 The other piece is for consumer and 12 purchasers for transparency for us to be able to 13 use it. I guess that is the dilemma I come into, 14 and this is my personal opinion, is that if 15 everybody is at the same rates from a selection 16 standpoint, it is not helping me.

I guess I could feel good that my hospital is at that rate and they are not worse than every other hospital but there is, even in that arena, being topped out I think does have implications for the value to the people who would be trying to use the data.

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1	So, if anybody has any thoughts about
2	that to help me with my dilemma, I would
3	appreciate that.
4	You found some. Thank you. I knew
5	where they would come from, too.
6	Brock.
7	MEMBER SLABACH: Yes, really it is my
8	memory. No, I think that this is a real problem
9	because if CMS is going to continue this measure,
10	I would much rather have it an eCQM than in an
11	abstracted form. So, I guess that is why I
12	really would prefer this because that is where we
13	need to go. But then NQF is saying that they are
14	not going to consider that because it is topped
15	out.
16	So, we are on a hamster wheel and it
17	is
18	DR. BURSTIN: You know one possibility
19	is, regardless of the vote, your comment could
20	still go forward. So, whatever you say, again,
21	CMS is here. They are actually listening. So
22	you could, regardless of what you ultimately vote

on include the comment that says if this measure 1 2 remains in this program, please move forward and at least consider moving towards an eMeasure as 3 an option. 4 CO-CHAIR TRAVIS: Marty? I did Marty 5 I'm sorry. Oh, it was Greg. 6 before. So sorry. 7 MEMBER ALEXANDER: I just have a 8 process question, I guess, because I don't 9 understand what happens if we keep this measure or if we let this measure go and we don't endorse 10 it, then how do we know at some point that by not 11 requiring the reporting that the vaccine's rates 12 13 will drop? And maybe it is doing a good thing by 14 being high. Maybe that is why we want it. Ι 15 mean do we just stop measuring it because it is 16 -- as output reaches 95 percent, are you dropping 17 all your measures that reach that? 18 DR. BURSTIN: We do have a requirement 19 that measures show a gap in care or show variation across providers if this is otherwise 20 21 topped out without variation. 22 We don't drop it but what Elisa was

saying is it becomes an inactive endorsement with 1 2 reserve status. And the idea would be these would not be the measures you would go to at 3 first choice but you should do some sort of 4 ongoing surveillance to make sure exactly your 5 point that you are not seeing a decrement in 6 7 performance. Obviously, the eMeasure would make 8 9 that a whole lot easier and that goes back to 10 Lindsey's comment. 11 Mimi. CO-CHAIR TRAVIS: 12 MEMBER HUIZINGA: I would just add if 13 we think about what CMS is trying to do on a 14 broad perspective, if you look at the physician measures and the ACO measures in terms of 15 16 immunization, trying to improve reporting to 17 registries that would help improve the care, I 18 would see having these as an eCQM in addition to 19 reducing potentially the fraction burden as also 20 being supportive of trying to have it submitted 21 to those broader registers. 22 So, I think if you look across the

whole portfolio, it might make sense to have this measure as an option.

CO-CHAIR TRAVIS: Akin. 3 MEMBER DEMEHIN: So, I mean I actually 4 5 do think part of our role as the MAP is to say whether we think something has enough importance 6 7 to merit its inclusion in a program, regardless 8 of how that measure happens to be reported. And 9 to me, keeping a measure, even if the eCQM version is easier, and I think, frankly, there is 10 a pretty significant switching cost to go into an 11 12 eCOM that would have to be factored into the 13 conversation as well, but retaining a measure 14 like this, to me, feels a little bit like going back to the future and not really advancing 15 16 quality forward.

I think looking to include eCQMs in programs, I certainly agree that that is a good goal but really to focus the development efforts around something more fruitful, I think would be great. Like tetanus, for example, to me feels a lot more like a topic that would merit exploring

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an eCQM and potentially implementing one in the 1 2 future, rather than a measure that has been around for years and that has already been topped 3 4 out. Okay, Andrea. 5 CO-CHAIR TRAVIS: I will just, I guess, 6 MEMBER BENIN: 7 just make a couple comments. You know as far as metrics that are potentially even feasibly 8 9 measured well electronically, this one has 10 potential to be in that category more than many 11 others. I think certainly more than, I'm sorry, 12 the sepsis measures, which are frightening to think of in an electronic format. 13 14 So, if we were to want to place value 15 on the typed in metrics that may be more readily 16 measured electronically, this would fall, I 17 think, into that category. 18 I will also say, and this is at least 19 an opinion, I don't necessarily have fact, but I would assume that if this metric were to be 20 withdrawn from the measure set, that the 21

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performance would drop because there is a

substantial -- and I don't know that -- there is 1 2 a pretty substantial amount of activation energy that goes into getting this done but is not 3 4 inconsequential. And even some of the hard stops 5 that may have been written into various computer things are so painful that there is a lot of work 6 that is going into getting this done. 7 Maybe not 8 just in pediatrics, I don't know. But it is 9 pretty hard to achieve this and so people have hardwired it in various ways but there is a lot 10 11 of resource going into that. 12 So, if we think that this is 13 important, then I think we may need to make a 14 decision that we should keep this metric if we 15 think this is an important enough thing to do. 16 Frankly, immunization is one of the few things we 17 actually do in healthcare, I guess. 18 But if we don't think that this is

important or that because you can easily screen out. Like this measure doesn't mean you get a flu shot. It just means you get screened for a flu shot. So, it is not even that powerful of a

In some ways it is and in some ways it 1 tool. 2 isn't, speaking, again, to the commentary about registries and the other things, which is really 3 where we should be putting our energies in this 4 5 country but that is a different conversation. So, I guess I would just make those 6 7 comments. That depending on how important people 8 consider this, it probably is important to keep 9 it in the measure set and that it is something that could be amenable to being electronic, 10 11 whether it is the right place to put our 12 resources. And maybe we could put our resources somewhere else because I don't think that the 13 abstraction burden in this bowl full of 14 abstraction burdens is the hardest one either. 15 16 So, it is a little bit of six of one, half dozen 17 of the other. 18 CO-CHAIR TRAVIS: Thank you. Greg, 19 you still have yours up. 20 MEMBER ALEXANDER: I just wanted to 21 say so I work in the long-term care world, like I 22 said, so there is some redundancy. Because then

Nursing Homes Compare, which has over two million 1 2 patients across the 16,000 nursing homes in the country, they have vaccination reporting there. 3 4 And those immunization rates are up around 95, 96 5 percent across the country. So, that sort of validates these 6 7 results, I think a little bit, too. CO-CHAIR TRAVIS: That's helpful. 8 9 Lindsey. Just one final 10 MEMBER WISHAM: comment, which is I think if we were to 11 12 transition this to an eCQM and the performance 13 were to remain as high as they are now, which we 14 would hope would be the case, that because it is already going to be implemented as an eCOM would 15 16 make it an ideal measure for surveillance. Even 17 if it were just kind of put off to the side and 18 not necessarily used in the program, hopefully by 19 that point, by that time, the capabilities are already built into electronic health records to 20 21 be reporting with the CDC. So, Lindsey, taking 22 CO-CHAIR TRAVIS:

what you just said and kind of the earlier 1 conversation you had with us around conditional 2 support, to you mind sharing with us what your 3 4 thoughts are about your recommendation on where we come down on this measure? 5 So, it is a little bit 6 MEMBER WISHAM: different how we have been treating conditional 7 8 support, which is take it to NQF because, as 9 Helen points out, this is not one that would be 10 eligible for that process. I guess the condition 11 I would place on this conditional support that if 12 the chart-abstracted measure were to stay in the 13 program, that, to me, tells me that CMS finds 14 this an important measure and that the eCQM should be a reporting action with the idea that 15 16 potentially then performance rates are stable, 17 that the chart-abstracted measure could be 18 removed. 19 So, conditional support and that the 20 chart-abstracted measure is deemed to be 21 important and ultimately in the program. 22 CO-CHAIR TRAVIS: Okay, I think

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1	everybody heard that clearly. Is there something
2	we are huddling on over here?
3	MS. LEMONS: Hey, this is Tara Lemons.
4	May I add a comment?
5	CO-CHAIR TRAVIS: Yes.
6	MS. LEMONS: Yes, I just wanted to
7	clarify. I think there was a comment about the
8	IMM-2 measure not requiring vaccination but it
9	does require vaccination prior to discharge, if
10	indicated by the screening. So, I just wanted to
11	make that clarification.
12	CO-CHAIR TRAVIS: Thank you.
13	All right, well, let's move forward.
14	If people feel comfortable with the way that
15	Lindsey phrased the condition, let's consider
16	that to be the rationale if you decide to vote
17	for conditional support. So, we will vote for
18	all of these measures.
19	Marisa, do you have a comment?
20	You want to read it?
21	MS. MCQUESTON: A brief comment from
22	Marisa Valdes at Baylor Scott & White that they

would support the CMS moving to the eMeasure for 1 2 several reasons, testing of the validity as a possible replacement of the chart-abstracted 3 4 measure. 5 CO-CHAIR TRAVIS: All right, so now we have had an opportunity to hear from everybody. 6 7 It is important not to forget our people on the phone. So, thank you, Marisa. 8 9 Okay, so, let's go to voting. 10 MS. QUINNONEZ: Voting is now open for IQR program measure influenza immunization, IMM-2 11 12 and this is MUC16-053. Option 1, support; Option 13 2, conditional support; Option 3, refine and 14 resubmit; and Option 4, do not support. Option 1, support; Option 2, 15 16 conditional support; Option 3, refine and 17 resubmit; and Option 4, do not support. 18 Thank you, Marisa. Thank you, Jeff. 19 Voting is now closed. The results of 20 the influenza immunization, MCU16-053 16 percent 21 voted for support, 68 percent voted conditional support, zero percent voted for refine and 22

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1	submit, and 16 percent voted for do not support.
2	This yields a conditional support
3	recommendation.
4	CO-CHAIR TRAVIS: Okay, thank you all
5	very much.
6	So, our last item on this Consent
7	Calendar is the safe use of opioids concurrent
8	prescribing MUC16-167. And I believe that Lee
9	and Sean pulled this.
10	Lee.
11	MEMBER FLEISHER: I do not support;
12	ditto from yesterday.
13	CO-CHAIR TRAVIS: Sean.
14	MEMBER MORRISON: Ditto.
15	CO-CHAIR TRAVIS: All right, Woody.
16	MEMBER EISENBERG: I would just like
17	to point out the importance, again, of trying to
18	limit as best we can the combination of opioids
19	and benzodiazepines for sure. Real killers.
20	And if this measure could be refined
21	to just focus on that combination, I would vote
22	for a refine and resubmit.

1	CO-CHAIR TRAVIS: Okay, thank you,
2	Woody. Greg, do you still have a question?
3	Okay.
4	That's okay. Jack.
5	MEMBER JORDAN: I would like to make
6	one suggest or comment to CMS and that would be I
7	think this is something that maybe very ripe to
8	have some selection of in hospitals or QIOs
9	really start to get a little bit of feel for how
10	much of when this is happening it is really
11	problematic and not thoughtful use of the
12	medications and how often it is really
13	thoughtful.
14	I think we would learn a lot from
15	them. I think some people might pick up some
16	things that might, without having pressure of a
17	public website from CMS, you know ranking
18	hospitals on that, may very well get the end
19	results you are really looking for in kind of an
20	alternative manner.
21	CO-CHAIR TRAVIS: Thank you, Jack.
22	Any other comments before we vote, having

discussed this issue yesterday? 1 2 Okay, I think we are ready. MS. QUINNONEZ: Voting is now open for 3 4 IQR Program safe use of opioids -- concurrent 5 prescribing. And this is MUC16-167. Option 1, support; Option 2, conditional support; Option 3, 6 7 refine and resubmit; and Option 4, do not 8 support. 9 Option 1, support; Option 2, conditional support; Option 3, refine and 10 resubmit; and Option 4, do not support. 11 12 Okay, voting is now closed. The results for MUC16-167, 9 percent voted for 13 14 support, 4 percent voted for conditional support, 15 26 percent voted for refine and resubmit, and 61 16 percent voted for do not support. 17 This yields a so not support 18 recommendation. 19 CO-CHAIR TRAVIS: Okay, well, thank 20 you all for that. 21 Now, we have done a little bit if 22 shuffling about our schedule because we know we

are close to our time that we are going to end 1 2 today and we know you have flights. We are going to have a call where we 3 are going to go over the other programs and get 4 feedback. We can do that, we think, over a 5 So, we will get that scheduled. 6 conference call. 7 But before you pack up, we do have some comments that Pierre would like to make 8 9 about the Cures Act and I think that would be 10 very helpful to us. So, thank you. 11 DR. YONG: Great, thanks, Cristie. 12 So, I just wanted to -- we referenced this 13 yesterday. I just wanted to make sure that folks 14 were aware of a provision in the 21st Century Cures Act relating to the hospital readmissions 15 16 reduction program. 17 So, this is relating to Section 15002 18 in the Cures Act, which pertains to adjustment 19 for dual eligibles in the readmissions reduction 20 program. We didn't have any measures for the 21 reduction of readmissions program this year but it has been in prior years, last year, for 22

It has been a hot topic in terms of 1 example. 2 risk adjustment and what it is really about, SES. So, I just wanted to make sure you 3 4 were aware of the legislation that is currently and signed by the President, since he supports 5 the bill. 6 7 It requires stratification of the 8 hospitals in the readmission reduction program by 9 status of full eligible dual -- full dual eligibles. So, if folks are familiar with the 10 11 MedPAC report of I don't know there it was 2013 12 or 2014 but where they did the analysis looking 13 at what people call right to life hospitals. So, 14 compensate hospitals that have similar proportions of SES patients, in this case, the 15 16 Cures Act specifically calls out use of dual 17 eligibles. So, that would be the stratification 18 variable that would be used for a calculation of 19 the human adjustments for HRRP. 20 That is sort of the main provision. 21 The other provisions relating to that, although our program would remain budget neutral, there 22

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1 are also some provisions in there relating to 2 consideration of exclusions for certain conditions, consideration of use of certain V 3 codes, as well as potential consideration for any 4 5 recommendations that come forth on this particular topic. 6 CO-CHAIR TRAVIS: All right, thank 7 8 you. 9 Operator, would you see if there are any public comments on the call? 10 At this time, if you would 11 OPERATOR: 12 like to make a public comment, please press star 13 1. 14 And we have no public comments, at 15 this time. 16 CO-CHAIR TRAVIS: Any public comment in the room? 17 18 Okay, well, I am going to turn it over 19 to Kate to talk about what our wrap-up and next 20 steps are. Sounded like a drum roll for Kate. 21 22 MS. MCQUESTON: It must be time for us

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1	to go.
2	So, we will be in touch regarding
3	scheduling our call to discuss the current
4	measure set shortly.
5	I just want to thank you again for all
6	of your input into the discussion today and to
7	thank our wonderful co-chairs. Thank you very
8	much, Cristie and Ron.
9	And please feel free to be in touch
10	with us with any questions in the meantime and we
11	will be back in touch with everyone shortly.
12	Thanks, again.
13	CO-CHAIR TRAVIS: And thank you to the
14	wonderful staff. We couldn't have done this
15	without you, clearly. So, thank you all very
16	much and thanks to all of you.
17	(Whereupon, the above-entitled matter
18	went off the record at 2:41 p.m.)
19	
20	
21	
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Α a.m 1:19 6:2 AAPM 107:1 AAPM&R 3:9 abilities 60:22 ability 16:17 18:4,11 19:5 20:13 35:7.13 37:8 38:2,3 45:5,14 58:17,20 63:11 64:4 64:10 118:6 121:15 177:5 able 6:11 13:15 14:17 23:12 25:4,12,12 27:1 30:22 32:17 52:1,20 55:6 86:2,2 87:14 108:12 109:3 141:21 145:6 150:13 155:19 184:17 185:5 215:5 259:21,22 262:7 268:14 287:11 293:12 above-entitled 237:10 311:17 **ABPP** 2:7 absolute 137:17 161:15 161:17 absolutely 10:14 15:16 33:21 52:4 208:7,17 223:14 abstract 215:2 abstracted 277:3 286:4 286:14 287:15 288:1 294:11 abstracting 126:13 292:5 abstraction 121:1 134:11 287:17 300:14 300:15 abstractor 120:8 134:9 **abstractors** 134:11.12 abuse 113:6,14 117:19 136:8 223:17 academy 3:15 104:20 106:1,17 253:14 accelerate 94:1 accept 111:13 154:5 279:9 acceptability 148:7,10 accepted 154:1 accepting 112:6 access 4:5 5:2 35:15 91:11 92:22 93:4,8,16 104:13 177:20 178:5 178:20,22 179:19 182:2,5,11 183:17 184:13 187:2,13 192:12 197:22 accessible 192:7 accessing 60:6

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In the matter of: Measure Applications Partnership Hospital Workgroup In-Person Meeting

Before: NQF

Date: 12-09-16

Place: Washington, DC

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