NATIONAL QUALITY FORUM

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PERSON- AND FAMILY-CENTERED CARE PHASE 2 STANDING COMMITTEE MEETING

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THURSDAY JANUARY 22, 2015

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The Committee met at the National Quality Forum, 9th Floor Conference Room, 1030 15th Street, N.W., Washington, D.C., at 8:30 a.m., Lee Partridge, Co-Chair, and Chris Stille, Acting Co-Chair, presiding.

PRESENT:

- LEE PARTRIDGE, Co-Chair, National Partnership for Women & Families
- CHRIS STILLE, Acting Co-Chair, MD, MPH, FAAP, University of Colorado School of Medicine/Pediatrics University of Colorado School of Medicine & Children's Hospital Colorado

KATHERINE BEVANS, PhD, University of Pennsylvania School of Medicine and Children's Hospital of Philadelphia

SAMUEL BIERNER, MD, UT Southwestern Medical Center

REBECCA BRADLEY, LCSW, National Director of Quality Standards and Case Management HealthSouth Corporation

DAVID CELLA, PhD, Northwestern University

SHARON CROSS, LISW, The Ohio State University Wexner Medical Center

DAWN DOWDING, PhD, RN, Visiting Nurse Service of New York and Columbia University School of Nursing Medicine SHERRI LOEB, RN, BSN, EMMI Solutions ANN MONROE, Health Foundation for Western & Central New York LISA MORRISE, MA, Patient & Family Engagement Affinity Group National Partnership for Patients ELIZABETH MORT, MD, MPH, Massachusetts General Hospital/Massachusetts General Physician

SHERRIE KAPLAN, PhD, MPH, UC Irvine School of

Organization ESTEE NEUWIRTH, PhD, Center for Evaluation and Analytics and Care Management Institute

Analytics and Care Management Institute Kaiser Permanente

LENARD PARISI, RN, MA, CPHQ, FNAHQ, Metropolitan Jewish Health System

- DEBRA SALIBA, MD, MPH, UCLA/JH Borun Center, VA GRECC and Rand Health
- PETER THOMAS, JD, Powers, Pyles, Sutter & Verville, PC
- CARIN van ZYL, MD, FACEP, Palliative Care, Supportive Medicine City of Hope National Medical Center

NQF STAFF:

NADINE ALLEN HELEN BURSTIN MITRA GHAZINOUR ANN HAMMERSMITH MARCIA WILSON

ALSO PRESENT:

SOPHIA AUTREY * JEROME CONNOLLY **KEZIAH COOK *** BETH DEMAKOS ANNE DEUTSCH DANIEL DEUTSCHER DAVID GIFFORD CHRISTINE GOERTZ * JAYNE HART CHAMBERS DAVID HITTLE * BEN JOHNSTON NICOLE KEANE * MARJORIE KING * TRACY KLINE * STEVE LICHTMAN * **JASMINE LARSON *** JANE LUCAS * STACY MANDL TARA MCMULLEN PAULETTE NIEWCZYK * POONAM PARDASANEY COLLETTE PITZEN * LINDA RESNIK * GARY REZEK * ANGELA RICHARD * JEANNETTE SHRIFT * LAURA SMITH ANITA SOMPLASKY * ELLEN STRUNK

MARK WERNEKE

TRACY ZHENG

* Present via telephone

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1	P-R-O-C-E-E-D-I-N-G-S
2	8:34 a.m.
3	CO-CHAIR PARTRIDGE: Good morning
4	everybody. I know we're still getting
5	caffeinated and all that early morning fog is
6	still clearing a bit, at least for me.
7	But, we want to be able to move along
8	pretty expeditiously this morning. We are losing
9	people. We've already lost, I think permanently,
10	Carin van Zyl, who's ill and she indicated she
11	would try to phone in from her hotel room. But,
12	frankly, I'm hoping that she's sleeping and
13	getting better before she has to fly back to
14	California.
15	David is heading off to NIH to make a
16	speech and I know that Deb and Esther, I believe,
17	are both slated to leave at noon, or maybe Esther
18	is not. You're okay.
19	Okay, I've had this in my head that we
20	had a couple of people with planes that were the
21	that they had to leave by noon and Chris has
22	to leave for his plane by 2:00.

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So, we may lose our quorum at noon, in 1 2 which case, I think almost certainly we're losing 3 our quorum at noon, in which case we will continue with our discussion of the measure, we 4 5 will just not vote in person on them. And if we need to discuss then still further on our call, 6 we'll make this judgment at the end of today. 7 If we need to discuss them further on 8 9 our scheduled call next week, we will. If we 10 don't, we'll send a SurveyMonkey survey out fairly promptly after this meeting and we'll vote 11 12 by email. 13 We will probably also not attempt to 14 do the discussion of related and competing 15 However, I do want to call your measures. 16 attention to the part of the package that was in 17 front of us is a cheat sheet that Sarah put 18 together to help us as we think about related and 19 competing. 20 I recommend not losing it because 21 she's laid out quite nicely the difference in a 22 chart form, the differences between the various

1	measures. And I personally find it very useful
2	as I'm trying to keep in my head what I'm
3	considering as related or competing.
4	CO-CHAIR STILLE: That'll be your
5	homework for the trip home is to review that.
6	CO-CHAIR PARTRIDGE: Right. So with
7	that, I'm going to turn the gavel over to Chris
8	who's going to take us through the first set of
9	measures and we'll do housekeeping.
10	MS. SAMPSEL: So, we do have just a
11	couple of things.
12	One, I know for some folks, there were
13	some issues at the hotel with how they were doing
14	charges. Some people they put on the master
15	bill, some people they charged your credit card.
16	They have somebody's suitcase in hostage. And
17	we'll try to you know, we have our meeting
18	department working on that to figure that out.
19	But everything was supposed to be
20	direct billed, so if your credit card was
21	charged, we ask that you watch it, notify us
22	because we'll try to get all the goal is to

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get all of those charges reversed.

2	I somehow got a new scarf last night.
3	It showed up on my chair at the restaurant and I
4	don't think I have kleptomania issues. But if
5	this is anybody's scarf, it started living with
6	me yesterday and I apologize because I didn't
7	intend to take it. And it's nice, it's cashmere,
8	it's made in Germany.
9	And then, you know, I think, Liz, I
10	don't know if you're prepared, I think you had a
11	couple of questions.
12	But I think the other thing we just
13	wanted to do was kind of regroup a little bit and
14	I want to remind you all that you do have the
15	decision logics, algorithms in front of you on
16	how to work through each measure based on what is
17	presented regarding importance in evidence and
18	then through scientific acceptability.
19	You know, I think we want to make sure
20	that if anybody has questions on how they should
21	be voting based on information presented that you
22	ask that before we vote. But, you know, and we

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don't want to spend a whole lot of time kind of
 rehashing criteria, but if you do have that need,
 we can certainly do that.

We also just wanted to revisit where we were yesterday or what we ended up with yesterday and out of the 28 measures, we did make it through 13. So, I think, you know, there's some success there. We got into the doubledigits.

10 And the first slide, just, you know, 11 as a recap with the FOTO measures, so 0422 12 through 0428, those were the measures that are 13 technically in NQF-speak are currently not 14 recommended because they failed at the importance 15 criterion and the developers will have the 16 opportunity to provide more information prior to 17 the end of public comments. So, we will re-18 discuss these measures.

We did not -- we only got to, this is
I think the highlight of the day, 0688 is, you
know, went through as recommended. The other
measures we will be discussing today, actually

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those will be later this morning.

2	And then for long-term care hospitals
3	and some of the outpatient rehab for long-term
4	care, 2631, which was the percent of long-term
5	care hospital patients with admission and
6	discharge functional assessment and a care plan,
7	that measure was not recommended. It did not
8	pass the importance criterion.
9	With outpatient medical, with the
10	outpatient measures, we made it through all of
11	those where we had one recommended, one not
12	recommended and two in the gray zone.
13	The gray zone measures do move forward
14	as recommended but we will re-discuss those as
15	well.
16	So, that's where we were with those
17	and if anybody has any questions regarding
18	process and kind of overall criterion
19	adjustments, if we could do those now before we
20	start heading into the measure discussions.
21	MEMBER MORT: I just had a question
22	about, I felt, and maybe if I read these

algorithms in a more detailed way I would 1 2 understand how we did what we did. But, I thought at the end when we 3 4 recommended the pre- and post- six-minute walk 5 test for pulmonary patients that it passed as an endorsed measure. But what they recommended, 6 7 what they were proposing wasn't the pre- and post-, they're proposing a percent change across 8 9 patients. 10 So, I thought we sort of gave them a 11 by and we went ahead and approved it anyway. And 12 I felt that we had been a little bit more strict 13 in looking at exactly what the recommended 14 measure was and critiqued it based on exactly 15 what the developer was proposing earlier on. 16 Am I the only one who felt that way? 17 And I think in some -- if I am, then --18 MS. SAMPSEL: I think that's what I'm 19 just trying to look around and see if there's 20 folks who are. 21 MEMBER KAPLAN: What bothered me a 22 little bit was the shift from the morning to the

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afternoon and it was some part of sort of a 1 2 direction that -- and maybe this is not what you're getting at, Liz, but I thought we kind of 3 4 were shifting into we're going to look at, you 5 know --Usually, I understood that NQF only 6 reacts to what it sees, not what it thinks it 7 could see if other analyses were done or 8 9 different changes were made or, you know, 10 different assumptions were held or something. 11 And, Sarah, I kind of felt that same 12 shift from morning to afternoon that we were kind 13 of maybe doing things differently in the 14 afternoon than we have done in the morning. 15 MS. SAMPSEL: Well, I guess my question then would be -- I mean there were 16 17 differences in the measures. So, in the morning we really were, I would say the vast majority of 18 19 the measures were patient reported performance 20 measures, the PRO-PMs and in that case, the NQF 21 standard is higher than just the outcomes and the 22 process measures.

So, I don't know if that was part of 1 2 the shift that you were seeing that there really is a difference in the criteria based on those 3 4 measures and I guess, you know, as staff, we can, 5 you know, keep that under consideration of, you know, how do we make sure that we separate those 6 7 out well so that there's an understanding of the shift. 8 9 CO-CHAIR STILLE: I think that was a 10 particular issue with, I think it might have been 11 the last one we talked about because they were 12 proposing to use it for accountability at the 13 organization level and they had only tested it at 14 the patient level and we had a lot of problems 15 with that. That's exactly the one 16 MEMBER MORT:

17 that got me a little muddled at the end. And I 18 think in part it's because these patient-reported 19 performance measures are new.

Having been on the group that worked
through the concepts a couple of years ago, it's
difficult to sort of get through it

methodologically and understand exactly what a PM 1 2 is or a PRO-PM is. So, I can understand the developers are working through that as well. 3 4 So, I guess what I would ask is, 5 today, if the chairs and facilitators would just be really clear as to remind us and help coach us 6 along as to exactly what measure is being 7 proposed so we have the right construct in our 8 9 head and then we can move through it in a more 10 reliable way I guess is what I would say rather 11 than shifting a little bit. 12 MS. SAMPSEL: Okay. And then I think 13 the other thing that, you know, regarding, I 14 think that as your 0701, what we can do with that 15 is, you know, and this with all of the measures, 16 is we have the -- we'll write the report, there's 17 the public comment period and then there's a 18 post-public comment call where you always have 19 the opportunity to say, this isn't what we were, 20 you know, we approved or this is a totally 21 different concept and we can reopen that vote. 22 MEMBER KAPLAN: Can I ask one other --

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and not to slow us down, but can I ask one other 1 2 clarification guestion? Some of what I've been looking at and 3 4 reading the reliability and validity sections in 5 these measures, they use the reliability at the patient level and they're very careful to 6 7 document how reliable it is at the patient level. But then the proposed use is at the 8 9 facility level and there is no evidence of 10 reliability at the facility level. 11 So, is NQF, what's the instruction to 12 us on that issue? 13 MS. SAMPSEL: And we tried to get at 14 that a little bit yesterday. And so, when you 15 follow through the algorithm what it does is that 16 you almost to the bottom. 17 And so, the first criteria is did they 18 perform reliability or validity at that measure 19 of population level that they're reporting at? 20 And if the answer is no, you go down another 21 level and did they do it at the patient level or 22 item level if it's off an instrument?

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And then if you follow that across, 1 2 you get to the point of you can vote it as moderate or low. 3 So, frankly, the criterion is it's an 4 and/or criteria. You either do it at the measure 5 level and the patient level or you do it at the 6 7 other level but you have a lower grade of, you know, you would give them a lower rating when we 8 9 vote. 10 MEMBER KAPLAN: So and now, why 11 wouldn't you give it an insufficient? Because if 12 there's no evidence, I mean if there's one level 13 of evidence but the level of evidence that 14 they're proposing to use the measure at is not 15 there, why wouldn't you give it an insufficient 16 data? Because you don't know if it's going to be 17 low until they run the runs. 18 MS. SAMPSEL: And I'm not sure I'm 19 really the best person to answer that one. But I 20 think technically you could, as a committee 21 member, give it insufficient. So, your choices there at the bottom, you could do that. 22

But I would also say that, you know,
I think even Helen admitted that, you know, the
kind of difference in criterion between if it's
process outcome or the patient-reported outcome
is something that I think NQF needs to revisit.
And especially for these measures.
And I think that's bringing these measures are
bringing that to light that that really is an
issue.
CO-CHAIR STILLE: And Sherrie, you
would say insufficient because the developers
might actually have those data that they can then
bring back and present, yes.
MEMBER KAPLAN: Yes, I mean you want
them to get if they have the data or they have
an opportunity to get you the data, you'd
certainly want to have it rather than give it a
low because it's already been done and it's low,
I would feel much more comfortable
CO-CHAIR STILLE: That makes a lot of
sense, yes.
MEMBER KAPLAN: saying it's

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missing, you know.

2 MEMBER MORT: And I just have one more 3 question about goals.

I was under the impression that when we were approving measures for NQF endorsement, the construct was these measures would be used for accountability purposes and not for QI purposes.

9 And if that's changed, and that's what 10 I thought I heard peppered throughout the 11 conversation yesterday, I just want to have 12 clarity around that because that would change my 13 whole way of thinking about the voting if we were 14 approving them for QI.

Oh, here's Helen.

16And if the criteria for acceptance or17endorsement include both acceptability as an18accountability measure or suitability as an19accountability measure or a QI measure, that20makes me think about it slightly differently.21So, could we get clarity on what we're22endorsing, Dr. Burstin?

1	DR. BURSTIN: Yes, Dr. Mort, yes.
2	It's, again, a perennial issue for us. At this
3	point, we do have an expectation that a measure
4	that's endorsed by NQF is available for all
5	purposes. That could include, you know, QI.
6	I think what we don't have are
7	measures purely for QI. And I think there's
8	always an expectation they can fulfill the full
9	range of accountability applications as well.
10	As I mentioned yesterday, that's in
11	play as we move to potentially moving towards
12	endorsement by ratings or grades or intended use.
13	MEMBER MORT: So, it has to be good
14	enough for accountability, but of course, it
15	could be used for anything?
16	DR. BURSTIN: Exactly.
17	MEMBER MORT: Is that the way we think
18	about it?
19	DR. BURSTIN: Yes.
20	MEMBER MORT: Got it.
21	DR. BURSTIN: Good.
22	MEMBER MORT: Thank you.

1	CO-CHAIR PARTRIDGE: And ideally,
2	accountability and public-reporting, but
3	obviously, in a number of instances the public-
4	reporting is planned as down the road, it hasn't
5	been used that way yet.
6	MEMBER MORT: Thanks for the
7	clarification.
8	CO-CHAIR STILLE: Okay, great. Let's
9	begin our long task this morning.
10	We're going to start, I don't know if
11	we mentioned, the order is going to be pretty
12	different to both facilitate speedy reporting and
13	speedy analysis and also help people that need to
14	go to different places.
15	We're going to start with the UDSMR
16	measures 2287, 2286 and 2321.
17	We're then going to do the American
18	Health Care Association measures 2613 and 2612.
19	After the AHCA, we'll do the CMS
20	measures 0167, 0174, 0175, 0176 and 0177.
21	And then the IRF ones from CMS 2635,
22	2633, 2634, 2636 and 2632.

And hopefully, we'll get through most, 1 2 if not all, of those. If we -- we may well lose our quorum and if that happens, we'll have 3 discussions but not voting right now. 4 So that's 5 going to be the plan. MS. KEANE: 6 Hello? 7 CO-CHAIR STILLE: Hello? Hi, this is Nicole Keane 8 MS. KEANE: 9 from Abt Associates. We're the contractor for 10 the five measures from Home Health that were at 11 the end Day 1. 12 Usually when the day goes over, we 13 start with the measures that were meant to be 14 done on Day 1. 15 And our developers are shifting their 16 schedules so that they can be available this 17 morning. We are going to lose people at 10:30. 18 CO-CHAIR STILLE: Okay, and which 19 measures are those? 20 MS. KEANE: 0167. 21 CO-CHAIR STILLE: Okay, yes. We 22 anticipate --

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1	MS. KEANE: So, I would respectfully
2	request that we could
3	CO-CHAIR STILLE: Right, right, we
4	still need to do UDSMR first. We will I
5	believe we'll be able to get those done this
6	morning, but so we may do some shifting depending
7	on how long the UDSMR measures take. Does that
8	make sense?
9	MS. KEANE: Thank you.
10	CO-CHAIR STILLE: Great. Great.
11	Okay, so we'll start with 2287,
12	Functional Change in Motor Score at IRFs and I
13	believe Sam and no 2287, Sam and Deb were the
14	discussants for that and they're both here and
15	that's good. So, okay, go ahead.
16	MS. DEMAKOS: I'd just like to confirm
17	that Dr. Paulette Niewczyk is on the phone with
18	me as well. Paulette, are you there?
19	MS. NIEWCZYK: Hello, I'm here.
20	MS. DEMAKOS: Okay, great.
21	So, first of all, I would just like to
22	thank everyone. Our schedules are shifted a

little bit, that may be a good or a bad thing, 1 2 depending on how early morning you're used to being. 3 4 But, I'd like to thank the committee 5 for their work and for the opportunity to present 6 our measures to you. 7 Just as a little background, in 1987 a task force of physicians, therapists and 8 9 researchers was charged with establishing an 10 instrument to measure functional outcomes, 11 medical rehabilitation and patient burden of 12 care. 13 After three years of research, measure 14 development and instrument testing and 15 validation, the FIM instrument was developed. 16 The FIM has been endorsed by the 17 American Academy of Physical Medical 18 Rehabilitation and the American Congress of 19 Rehabilitation Medicine. 20 The work was a result of a federal 21 grant awarded to the researchers at the Center 22 for Functional Research, CFR, at the University

Today, CFR remains a division of the 1 of Buffalo. 2 U.B. Foundation and is housed within UDSMR. It's also a not-for-profit division of the U.B. 3 4 Foundation whereby the subsequent maintenance of 5 the FIM has been occurring for the past 25 years. For those not familiar with the FIM, 6 7 it's an 18 item measure that measures patient function and burden of care. It's currently used 8 9 across the post-acute care continuum which speaks 10 to the core measure set that was mentioned 11 yesterday, and we do have subsets that are 12 abbreviated versions for other venues. 13 Each item is rated on a scale from 1 14 to 18, I'm sorry, 1 to 8 7 which refers to -- one 15 refers to complete dependence, seven which refers 16 to complete independence and the overall range is 17 18-126. 18 It might help to bring up the measure 19 form that we submitted with this so that people 20 can see a visual. 21 We're thrilled that the functional 22 measures are now being considered by the Patient

Family Centered CARE Committee.

2	Function affects every person and
3	function is a high priority for patients in all
4	venues of care. A greater level of function
5	allows a greater level of independence for the
6	patient and a decreased burden of care on family
7	members in care settings.
8	The FIM has been used by thousands of
9	clinicians from interdisciplinary rehabilitation
10	teams for case management, monitoring and patient
11	goal setting. And patients can be directly
12	involved and we encourage that by participating
13	in goal setting with their care givers.
14	The FIM provides estimates of patient
15	burden of care. In other words, the number of
16	hours the patient requires one-on-on assistance
17	from another person for personal care on a daily
18	basis in the home setting and community.
19	As the FIM ratings increase, the
20	minutes of care per day decreases. The FIM
21	contains several subsets of measures within,
22	three of which we are putting forth today for

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endorsement.

2	The proposed change in measures score,
3	Measure Number 2287 that has been put forth by
4	UDS is constructed by utilizing a subset of 12
5	items from the FIM, eating, grooming, dressing
6	upper body, dressing lower body, toileting, bowel
7	management, transfers to bed/wheelchair or chair,
8	transfer to toilet, locomotion/walk or
9	wheelchair, locomotion/stairs, expression and
10	memory.
11	These items are currently collected in
12	the IRF setting and imbedded in the IRF-PAI as
13	the instrument developed by CMS and used for the
14	IRFs to assess functional outcomes and for
15	payment by Medicare. So the burden of collection
16	is low as the IRFs have routinely collected these
17	measures.
18	The change in self-care that we're
19	putting forth as well which is Measure 2286 and
20	the change in mobility which is 2321 are also
21	subsets of the FIM and subsets of the form that
22	we're putting forth today for mobility.

And I think I'd like to turn it over 1 2 to Paulette to talk about the evidence. CO-CHAIR STILLE: Just guickly, if any 3 4 of you are following along, it's one of the 5 Appendices in the SharePoint. MS. NIEWCZYK: Hello? Can everybody 6 7 hear me? CO-CHAIR PARTRIDGE: 8 Yes. 9 MS. NIEWCZYK: Okay. Thank you so 10 much, Beth. My name's Paulette Niewczyk and I'm 11 12 sorry I couldn't physically be there in person 13 today. So, I thank you very much for the 14 opportunity to speak on the line. 15 And when we had submitted the measures 16 to the NQF, we had a little bit of back and forth 17 with some of NOF folks because there was a little 18 bit of confusion and I can understand why that 19 may be the case. 20 If you have taken a look, and I know 21 there's a lot of material to review, you may have 22 noticed that the motor score, or I'm sorry, that

1	the motor measure is in essence the self-care
2	measure as well as the mobility measure.
3	So, it is important for us to give you
4	a little bit of that background and history about
5	the FIM. I assume several of you may be, you
6	know, very well versed in it, but some may not.
7	The FIM is the larger entity, so it's
8	18 items and it's been used very widely in
9	inpatient rehab as Beth had mentioned for several
10	decades now. But it's not only been used in the
11	inpatient rehab setting, skilled nursing
12	facilities have used the tool as well as long-
13	term care facilities.
14	So, it has been an instrument that has
15	been used in many different post-acute care
16	venues to look at patient outcomes and function
17	as well as patient burden of care as was already
18	mentioned.
19	These new measures that we're
20	submitting are new in the sense that they're
21	being looked at as a separate entity. But the
22	items are not new.

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1	So, I want to make that clarification
2	because they are verbatim the same items that do
3	exist in that larger FIM instrument.
4	So, and one of them that I mentioned,
5	one of them does contain the self-care plus the
6	mobilities. So, when we talk about motor,
7	there's 12 items, but you'll see that the other
8	two measures are nested within.
9	Now, why did we submit three separate
10	measures?
11	Because depending on the patient for
12	goal setting or depending on the venue, it may be
13	more critical to look at self-care alone without
14	being nested in that composite score, so that
15	total summed score.
16	So, we felt it was important,
17	especially for patients that may not ambulate,
18	and it may not have to do with their course of
19	care for a specific condition. So, if they
20	haven't ambulated their entire life, we didn't
21	feel if we're looking at quality outcomes that it
22	would be important to necessarily fault the

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facility or the clinicians on something that they may not be working on because it has nothing to do with their condition that they're presenting to.

5 If you'll notice the evidence, we 6 reference the FIM extensively and that is 7 because, as I said, the measures are new. We 8 have not been testing them as their own entity, 9 they are exact items that are currently living in 10 this larger instrument.

So, the reliability and the validity have been extensively studied and I did provide bibliography with each of the measures, but I'd be happy to provide a more expanded bibliography on some of the reliability predictive validity, construct validity and so forth.

I do want to clarify that even though
each of these measures, the items within are
being rated on a 1-7 scale, all of them have a
Rasch conversion. So, they can be used not only
in their ordinal properties but also in a linear
property.

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So, we do have those item level raw to 1 2 Rasch conversions and that will actually be a bit more sensitive to patient change. 3 So, when 4 you're looking and you're trying to compare the 5 patient to themselves or between patients or between facilities, it allows you to do some of 6 7 those facility level comparisons. The data that we presented and 8 9 provided within the submissions have been from 10 actually a random sample from our large data repository. So, this is -- we have data about 11 12 half a million patient level cases per year and 13 that's just in the IRF venue. 14 So, we took a random sample to provide 15 these cases. And, of course, you know, we could 16 certainly expand that in any capacity. 17 And we had presented only the 18 inpatient rehab facility results to you. So, we 19 do have data repositories on skilled nursing 20 facility as well as long-term care hospitals. 21 That is not provided in our submission but if you 22 would like additional analyses we certain could

provide that as well. 1 2 CO-CHAIR STILLE: Great, thank you. I feel it important to 3 MS. NIEWCZYK: 4 mention that in terms of feasibility -- oh, 5 sorry. CO-CHAIR STILLE: I think we need to 6 7 start the discussion. Everyone's kind of looking at me. 8 Sorry. 9 MS. NIEWCZYK: Okay, sure. 10 CO-CHAIR STILLE: So, I just had a 11 clarification question before I turn it over to 12 the discussants. 13 So, all of the items on 2286, 2287 and 14 2321 are part of the FIM and the self-care items 15 plus the mobility items make up the -- so 2286 16 plus 2321 equals 2287, am I right? 17 MS. NIEWCZYK: Correct, exactly. 18 CO-CHAIR STILLE: Okay, okay. so, 19 that's important for people to understand. Good. 20 The other thing is I think just for 21 purposes of doing what we need to do to figure 22 out how to vote, we need to really start to talk

about importance first and then we can jump into 1 2 the methodology. 3 Okay, so, Sam, are you going to start? 4 MEMBER BIERNER: So, this is Sam 5 Bierner. The use of the FIM primarily has been 6 in the inpatient setting. And for those of you 7 just so you understand, this is a clinician-8 9 derived score and requires training of the 10 clinician who can be a therapist or a nurse or a 11 physician has to undergo a training session to be 12 certified to give these scores. So, it's a 13 fairly detailed process to learn to do the FIM 14 scoring. 15 So, as I read it, you're wanting this 16 to be a one year score. This score is going to 17 be scored one year after an event or after 18 discharge from rehab? That's my question. 19 MS. NIEWCZYK: No, so the time period 20 But the way that the patient would is one year. 21 actually be scored is by looking at their rating, 22 the change from their admission to their

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discharge.

2	So, if a patient had stayed in an
3	inpatient rehab for, let's say, 21 days, they
4	would have an admission assessment taken within
5	24 hours of admission to the facility and then
6	they would have another one done within 24 hours
7	of discharge. And it would be that change from
8	the admission to discharge.
9	MEMBER BIERNER: So, really okay,
10	so, what is the purpose of saying it's a one year
11	score? That threw me off in your writeup.
12	MS. DEMAKOS: I think that's for
13	benchmarking purposes, Paulette.
14	MS. NIEWCZYK: Yes, that's exactly it.
15	So, in addition to looking at the
16	patient level which is critical for that patient
17	and that family, we also look at aggregate data
18	comparing, you know, all patient and we adjust
19	the adjustment methodology is included in the
20	submissions, but also at the facility level.
21	And then you can look at some best
22	practices or see what some of the variability is

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over the course of a one year period. 1 2 MS. DEMAKOS: So, I would just like to clarify one thing as far as the training and 3 4 credentialing as well. UDS, I mean if you were to use this 5 instrument through us and request benchmarks and 6 7 outcomes, you would be required to do the training and credentialing. 8 9 However, CMS is using this same 10 instrument within the IRF-PAI and they do not 11 require training or credentialing to use that 12 instrument. 13 So, there's --14 MS. NIEWCZYK: Yes, thank you. That's 15 an excellent point, Beth. 16 So, there is extensive guides that are 17 available to in essence self-teach. So, you 18 could certainly -- we have those available and 19 you can certainly do the assessment without the 20 extensive credentialing and passing on the master 21 exam. 22 However, it's been demonstrated
through a number of studies that in order to display the very high rater reliabilities, it's critical to have some basic understanding of how to do the rating, otherwise it's just -- there's vast inconsistencies.

6 MEMBER BIERNER: Right, and from 7 personally using frequently, I can tell you that 8 the training is necessary. We've had to do a lot 9 to ramp up training of others in our facility to 10 get better inter-rater reliability.

11 But, what about the patient that goes 12 through inpatient rehab and then six months later 13 has had additional therapies as an outpatient? 14 Are you expecting that you'll do another score 15 then? Otherwise, you're just using it during the 16 inpatient rehab state. So, are you expecting 17 you'll use it at other times on the outpatient 18 basis?

MS. NIEWCZYK: That's a great
question. On the outpatient side, the FIM
certainly can be used as an assessment
instrument. However, it's key to look at the

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construct that's being measured and what's being
 measured is, is patient function, but it's also
 burden of care.

And burden of care really refers to how much time that patient would require from a helper, another person, one-on-one if they were living within a community setting.

8 So, if the patient was now in a 9 community setting receiving outpatient therapy, 10 it's not to say that the patient's level of 11 function doesn't require any additional services, 12 that's not what we're saying by any means. 13 However, they may not require an hour or more of 14 helper assistance.

15 So, in essence, you're going to see a 16 ceiling effect or you're going to see patients 17 top out and it's just because the instrument 18 isn't sensitive enough to pick up on some of the 19 very, very small but still important elements of 20 function that a patient may need once they are 21 able to, you know, community-dwell, go back to 22 work and so forth.

1	So, at that point, it might just mean
2	other additional measures would be used to check
3	that patient.
4	MEMBER BIERNER: Okay. So, the
5	MS. NIEWCZYK: I do want to say it's
6	not just used for inpatient rehab. So, we do
7	have, and have for the past 20 years, have
8	patients assessed in the skilled nursing facility
9	as well as in long-term care hospitals.
10	So, all of the items that we have
11	submitted to NQF would be applicable and
12	appropriate for those other levels of inpatient
13	care.
14	CO-CHAIR STILLE: I'm sorry to cut you
15	off again, we just need to be as brief as we can
16	
17	MS. NIEWCZYK: Oh, sure.
18	CO-CHAIR STILLE: in assessing
19	these things.
20	MEMBER BIERNER: So, the instrument
21	itself has been used a long time and has a large
22	database, so I don't have a problem with the

instrument. I'm not quite clear on the 1 2 distinction of the three different scores and how 3 you're calling one a motor score when it 4 encompasses -- it's a composite score of many 5 different functions. But other than that, the instrument 6 7 itself, you know, I think has certainly been validated and has reasonably generated 8 9 reliability when it's used with trained 10 clinicians. 11 CO-CHAIR STILLE: Other thoughts about 12 importance, gap in care or gap demonstrated up to 13 for improvement disparities? MEMBER SALIBA: I did not see the data 14 15 I may have just missed it in on disparities. 16 here. Was there information about disparities? 17 CO-CHAIR STILLE: Not as far as I 18 know. 19 MS. NIEWCZYK: No, thank you for 20 asking that. 21 So, we weren't exactly clear as to how 22 in depth the analyses should be and we absolutely

can and we'd be very thrilled to provide that
 information to you.

We do have patient level as well as facility level data on different patient characteristics, so we certainly can stratify and look at these outcomes by race or by payer source or by age category.

8 And I think it's critical, especially 9 on the heels of last night's discussion, I was on 10 the call I think until nearly the end, and in 11 looking at all payers I think is an important 12 thing.

So, this is not restricted only to a
Medicare/Medicaid population or to an age 65 or
older. We do have data on 18 and above and would
recommend its use among all adults ages 18 and
over, all payers, all races and socio-economic
strata, status, strata and so forth.

So, we do have that available and wecan provide it to NQF.

21 MEMBER SALIBA: An additional follow-22 up question.

I know that you indicated that it is 1 2 done in multiple settings and that's true, the physical therapist in SNFs will often use the FIM 3 because they've been trained in it, but it is not 4 5 required in SNFs or nursing homes. Are you targeting this measure towards 6 7 particular types of facilities? Because I noted in the feasibility section you're talking about 8 9 it being, you know, collected as part of the IRF-10 Are you proposing this as an inpatient PAI. 11 rehab facility measure or are you proposing --12 so, what type of setting or institution are you 13 proposing this measure for? 14 MS. NIEWCZYK: We propose this to be 15 used in inpatient rehab, skilled nursing 16 facilities, long-term care facilities and as well 17 as home health facilities. 18 So, all of this inpatient or quasi-19 inpatient as I like to refer to them, facilities 20 could benefit from using these three measures that we have submitted. All items would be 21 22 applicable to patients in those venues.

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1	So a ceiling effect as I spoke to a
2	couple of minutes ago with an outpatient venue
3	wouldn't be applicable with those four that I had
4	just mentioned.
5	MEMBER SALIBA: So, when you looked at
6	the
7	MS. NIEWCZYK: The data submitted were
8	only on inpatient rehab
9	MEMBER SALIBA: Yes, when you looked
10	at the
11	MS. NIEWCZYK: because that is
12	where it is used in terms of the IRF-PAI,
13	however, as I mentioned before, we do have data
14	in those other venues and we could share that
15	with the committee.
16	MEMBER SALIBA: Okay. So, I guess I'm
17	trying to understand the proposal that you've put
18	in front of us now would be for this to be a
19	measure in all settings or just to be a measure
20	in IRF?
21	MS. NIEWCZYK: In all settings. So,
22	all settings except in outpatient. So, home

health, long-term care, skilled nursing and inpatient rehab.

Again, I guess I'm going reference 3 4 yesterday's conversation late afternoon again, 5 somebody mentioned, I believe it might have been Ann Monroe, but somebody had mentioned the 6 importance to have a tool or a measure that could 7 be appropriate in, I think she referred to it as 8 9 a common core, in all post-acute care venues. 10 I think that's critical and that's 11 really what we're posing here. We have items 12 that have been well tested and validated and used 13 in payment for the IRF facilities but --14 MEMBER SALIBA: Yes, I think --15 MS. NIEWCZYK: -- voluntarily by some 16 other facilities. 17 MEMBER SALIBA: Yes, can I ask --18 CO-CHAIR STILLE: I'm sorry, we're 19 going to have to cut you off again. 20 MEMBER SALIBA: Yes, so the only other 21 point would be that the data that's broken out 22 here right now is not broken out by settings,

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correct?

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2	MS. NIEWCZYK: Correct.
3	MEMBER SALIBA: Okay, all right.
4	MS. NIEWCZYK: This is Just IRF.
5	MEMBER SALIBA: Right, this is just
6	IRF data which is where we would expect the
7	performance to be probably the best.
8	MS. SAMPSEL: Yes.
9	MEMBER SALIBA: Okay.
10	MS. SAMPSEL: Yes, so a couple of
11	things. One, you know, the committee will be
12	asked to review this measure and vote on this
13	measure as it's presented with the data presented
14	which is the inpatient rehab facility.
15	The other thing is I just want to, you
16	know, we're really, again, getting out of control
17	on time, so we'll be asking as we go forward, you
18	know, if the chair's asked the developers to
19	respond then at that point you can respond.
20	Otherwise, developers should not be responding at
21	this time.
22	And I think otherwise, are we ready?

1	CO-CHAIR STILLE: Yes, Peter?
2	MEMBER THOMAS: A quick question. So,
3	I am glad to see that well, clarify for me if
4	you would, I read expression and memory are part
5	of what is recorded in the self-care measure, is
6	that correct?
7	MS. DEMAKOS: Correct.
8	MEMBER THOMAS: So, that's I just
9	want to make a point that that's critical because
10	you, you know, the whole cognitive development of
11	some of the patients that are in this setting is
12	really critical and you're sure you can move to
13	some degree, but you don't know where you're
14	going if you don't have the cognition. That's
15	obviously a big factor.
16	I also wanted to say that if you're
17	looking at just inpatient rehab, I can see these
18	measures being appropriate. I'm a little
19	concerned that outside of the inpatient rehab
20	setting that do these measures go far enough?
21	Are they fairly elementary in terms of
22	the ability of the person to really be fully

mobile as opposed to I see locomotion and
stair climbing, but is that it for locomotion?
I'm Just trying to get a sense for
I can see in the inpatient rehab
setting that's a big those are two big
important measures. But, if you have any further
information about additional measures on mobility
in particular that would round out the experience
or the assessment of someone's real ability to be
mobile and ambulatory?
MS. NIEWCZYK: Yes, so for the
mobility measure there is
CO-CHAIR PARTRIDGE: Paula, sorry.
Peter, again, I just have to go back.
We're judging on what's in front of us and that's
kind of a if you were going to use this
another setting question is where you're heading
and I think
MEMBER THOMAS: Okay.
CO-CHAIR PARTRIDGE: maybe we
should not take time to push it.
CO-CHAIR STILLE: Any other questions

1 on importance before we vote on importance for 2 this measure? 3 Becky? 4 MEMBER BRADLEY: I just had a comment 5 that I think it is important that the measure be applicable to more than just Medicare patients 6 7 because we have more than Medicare patients in the inpatient rehab facilities. And so, it is a 8 9 measure that can be used across all payers. 10 CO-CHAIR STILLE: Okav. David? 11 MEMBER CELLA: Just a proposal that 12 this vote be carried over to the other two so 13 we'll do three at once because they're very 14 overlapping. 15 Right, I think we CO-CHAIR STILLE: 16 might want to do -- should we maybe go all the 17 through this one and then consider the other two 18 kind of quickly and see if the votes for the 19 first will carry to the second? Okay, then the 20 third. Great, thanks. 21 Okay. You're proposing that we vote, 22 yes, okay, great. She's got the clicker in hand.

Okay, so voting on importance for 1 2 Measure 2287. Nadine, tell us when. 3 MS. ALLEN: Voting on evidence, one 4 second, the vote. Please do not begin voting 5 until I say start the votes. That's why I had to qo back. 6 7 Now we're voting on evidence, one yes, 8 two no. Voting starts now. 9 MS. SAMPSEL: I think you're missing 10 one. 11 MS. ALLEN: Oh, we have 17 now. 12 Sorry, guys, it's saying we've got 17 votes but 13 I'm not seeing the votes. 14 CO-CHAIR STILLE: All right, should we 15 just do a hand vote? 16 So, yes? 17 (A SHOW OF HANDS) 18 CO-CHAIR STILLE: Is that everybody? 19 Okay, 17 yes, zero no. 20 MS. ALLEN: Let's try this again. 21 Voting on performance gap, one high, two 22 moderate, three low, four insufficient. Voting

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starts now.

All votes are in, 24 percent high, 47
percent moderate, zero percent low, 29 percent
insufficient.

5 Voting on high priority, one high, two
6 moderate, three low, four insufficient. Voting
7 starts now.

8 All votes are in, 53 percent high, 47
9 percent moderate, zero percent low, zero percent
10 insufficient.

11 CO-CHAIR STILLE: Okay, let's have a
12 brief discussion on reliability and validity.

13 MEMBER BIERNER: Just as I mentioned 14 before, the reliability is very dependent on a 15 trained clinician. It will certainly suffer 16 reliability by someone who isn't trained in the 17 use of it. It's not as easy to use as some 18 measures that we've looked, but when trained, it 19 can have high inter-rated reliability. 20 And it's validity has been well

21 established I think over the last 20 years or so.

CO-CHAIR STILLE: Sherrie?

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1 MEMBER KAPLAN: Yes, can I ask the 2 developer a question? Okay, so especially if this is going 3 to come up again and again, there is a lot of 4 5 evidence obviously for reliability at the patient level and the Rasch modeling that you did looks 6 7 like there's only -- there may be one clunk item in this. 8 9 But that kind of modeling suggests 10 that, you know, the reliability at the patient 11 level certainly is good. But, I'm concerned that 12 the reliability at the agency level, you've got a 13 beta binomial model here and the interclass 14 correlation coefficients, to me, look like a 15 measure level mean variance were used to estimate 16 rates as opposed to the composite score which is 17 what I think you're going to use within 18 dimensions to evaluate the performance of these 19 institutions. 20 So, it doesn't look to me like you 21 actually rated the interclass correlation 22 coefficients at the facility level to compare in

the unit that -- the groups of measures you're 1 2 actually going to compare. You did it at the measures level it 3 4 says on page 33 of your analysis as opposed to 5 the composite across scores by agencies. Is that accurate? 6 7 MS. NIEWCZYK: Yes, that's correct. We just had only so much space at the end to that 8 9 application would allow us to include. But we 10 have that other data and we can make it 11 available. But you are correct in your 12 interpretation. 13 MEMBER KAPLAN: So, you could make those data available to us? 14 15 MS. NIEWCZYK: Between facilities? 16 Absolutely. 17 And, David? CO-CHAIR STILLE: 18 MEMBER CELLA: So, we're talking about 19 the total FIM measure now, but the next two will 20 be subsets of that. So, this question kind of 21 relates to all three. 22 And I mean my first question comes out

of a concern that I've actually in my own work 1 2 been grappling with for ten years now which is, you know, it's just by way of quick background, 3 4 when you convert raw sum scores in to Rasch or 5 IRT scores, you convert them from ordinal measures to integral measures so that the 6 distance between each number is equal no matter 7 where you are on the scale. And that's nice, it 8 9 sounds nice. 10 But what it actually does 11 functionally, and I think this to me is very 12 important to understand here, is that inevitably 13 when you're in the middle of a distribution, it 14 takes more raw score change units to get the same 15 interval change as opposed to the tails. 16 So, therefore, if you're using the 17 black-box Rasch-transformed score and you have 18 somebody that the extreme end, a very small 19 change will look very big on the Rasch interval 20 measure. 21 And I still don't know after thinking 22 about this for years which one's correct.

1	So, my question is, I mean I tend to
2	suspect the raw score is more correct because I'm
3	not convinced that the same amount of change at
4	the extreme means more than in the middle, but
5	it's really a belief, I don't know.
6	So, my question is, since they have so
7	much data, this is to the developers, are all of
8	these determinations and scores based on the
9	Rasch-transformed score? And if so, have you
10	ever compared that to the raw score changes to
11	see if that would change the individual or
12	facility level change?
13	MS. DEMAKOS: Paulette, can I give it
14	the quick
15	MS. NIEWCZYK: Great question.
16	MS. DEMAKOS: Paulette?
17	MS. NIEWCZYK: But this is a project
18	we're working on aside from this. But, yes, the
19	answer is yes.
20	We have looked at raw to Rasch
21	conversion and we've kept it in its raw or its
22	ordinal level state and we're working on a

publication to submit. We didn't provide but the 1 2 data you're seeing are Rasch-converted. So, it's patient level where their 1-7 3 4 have been converted to what their Rasch-5 transformed value would be. Yes, you do see bigger jumps so from 6 7 the 1 to a 2, whether it's in its raw or Raschconverted state is a big jump as well as the 6 to 8 9 7. 10 By converting to a Rasch measure, it 11 helps to correct for some of those drastic 12 It lets you know that they're not differences. 13 all to be assumed equal. A 2 to a 3 is maybe not the same as a 1 to 2 would be. But that also 14 15 adds to its clinical significance as clinicians 16 would probably know that it's probably easier to 17 get a patient from a 2 to a 3 than it is from a 1 18 to 2 in practice. 19 So, it would -- the Rasch-converted 20 value would give you greater sensitivity at that 21 patient level and likely mimic what you'd see in 22 practice with treating a patient in practice.

MS. DEMAKOS: Can I just add quickly 1 2 here, too, that we've also taken the raw scores 3 and taken those and converted those to minutes of 4 care so you know what level, how much time it 5 takes for the burden of care with those raw numbers as well. 6 7 CO-CHAIR STILLE: Okay. Lee has a question then Sherrie. 8 9 CO-CHAIR PARTRIDGE: I just want to 10 understand the risk-adjustment methodology a little bit because I think it's different from 11 12 what we've seen in some other measures. 13 As I understand going through the 14 steps, you'd start by classifying your patient in 15 to one of the impairment groups and you calculate 16 the patient score. And then you take a look at 17 what I call a facility case mix. 18 In other words, sometimes you're 19 looking at the patient and doing the adjustment 20 at the patient level and then saying now we're 21 going to measure the change beginning where that 22 patient was.

1	As I understand it in this process,
2	you're doing that but you're also looking at the
3	facility and stepping back and saying, what does
4	the facility's case mix look like?
5	And I'm calculating what is, in
6	essence, an adjustment at the facility level so
7	that if 80 percent of the patients were this type
8	and 20 were that type, I then adjust the results
9	not based on the patient's you see why I'm
10	getting all tangled up?
11	MS. DEMAKOS: Yes, I do. Yes, I do
12	see what you're saying. So you're saying
13	MS. NIEWCZYK: Yes, you can we do
14	adjust at both the patient level as well as the
15	facility level. That allows for comparisons
16	between facilities.
17	So when we're looking at, you know,
18	actually quality or outcomes by facility, if you
19	were to speak with a facility, they're always
20	going to say, oh, my patients are different. My
21	patients are more severe. My patients are worse.
22	Not only would you be able to look at

that severity, but you can also then compare 1 2 facilities that are truly like the -- meaning if it is a designated, you know, stroke center, you 3 4 can compare that facility to other facilities 5 that are also designated stroke centers or --But I think what you're 6 MS. DEMAKOS: 7 -- Paulette, I think what the question was really is that you're looking to compare patient to 8 9 patient within a facility, is that what you're 10 saying? 11 CO-CHAIR PARTRIDGE: As I understand 12 this --13 MS. NIEWCZYK: You can do that as well. 14 15 CO-CHAIR PARTRIDGE: Wait a second. 16 MS. NIEWCZYK: So, you can get at the 17 patient level but you can also do it at that 18 facility level so that way, you're really seeing 19 apples to apples comparison, correct. 20 MEMBER KAPLAN: I just wanted to 21 follow-up on the earlier question about some of these items in the Rasch scores. 22

1	Could you give us, if you're going to
2	give us the ICCs at the facility level, could you
3	also give us the mean square fit statistics that
4	you use, you know, in-fit and out-fit?
5	MS. NIEWCZYK: Yes, absolutely.
6	MEMBER KAPLAN: Because that would
7	help answer that question I think.
8	MS. NIEWCZYK: Absolutely.
9	CO-CHAIR STILLE: Okay, anything else
10	about reliability and validity?
11	Dave?
12	MEMBER CELLA: It's just I want to
13	make sure I'm clear that we're voting on the use
14	of now the overall motor FIM in inpatient rehab
15	facilities using the Rasch score with an
16	understanding that they do have raw score data to
17	compare and they're working on academic work to -
18	- is that
19	So we're voting on the Rasch score.
20	MS. NIEWCZYK: You're voting on the
21	Rasch score, yes.
22	All of the data has it's collected

1	using the 1-7. So, when the clinician does an
2	assessment, they don't do anything with Rasch,
3	they don't use the Rasch-converted value. They
4	only use a 1-7.
5	On the back end, in order to validate
6	these measures, we performed Rasch analysis and
7	we converted each of those values. So, a 1 then
8	became converted to a Rasch-transformed.
9	So, I'll give you an example. One
10	might be a
11	MEMBER CELLA: I'm sorry I
12	understand all that. I was just clarifying what
13	we're voting on. I know it's all been
14	MS. NIEWCZYK: Yes, it is.
15	MEMBER CELLA: Okay, thank you.
16	MS. NIEWCZYK: Transformed, yes.
17	CO-CHAIR STILLE: So, this is just
18	sort of a question a procedural question, so,
19	it sounds like there's a lot of data people are
20	interested in. We're voting on the data that we
21	have. After the vote, depending on the vote,
22	does that determine whether or not we need to get

more data or can we request that or sort of what 1 2 happens with that? 3 MS. SAMPSEL: We can still request it 4 before public comment. 5 CO-CHAIR STILLE: Okay, before public 6 -- okay, great. MS. ALLEN: Voting on reliability, one 7 high, two moderate, three low, four insufficient. 8 9 Voting starts now. 10 One more vote. Thank you. 11 Thirty-five percent high, 35 percent moderate, six percent low, 24 percent 12 13 insufficient. 14 CO-CHAIR STILLE: Okay. 15 MS. ALLEN: Voting on validity, one 16 high, two moderate, three low, four insufficient. 17 Voting starts now. 18 Twenty-four percent high, 53 percent 19 moderate, zero percent low, 24 percent 20 insufficient. 21 CO-CHAIR STILLE: Okay, any discussion 22 on feasibility?

1	I have just a quick question on
2	feasibility. It appears as though the public
3	availability and use of this is dependent on kind
4	of how you're going to use it.
5	For the purposes of accountability and
6	reporting between institutions and benchmarking,
7	is that all within the public domain? I was a
8	little bit confused as to the description.
9	MS. DEMAKOS: The benchmarking piece
10	of that is not available to the public. I mean
11	as far as that's concerned, you would go to a
12	vendor if you wanted benchmarking. So, but this
13	would be made available to the public, obviously,
14	but the purposes of use for a patient level.
15	MS. NIEWCZYK: Measures used, yes.
16	CO-CHAIR STILLE: Okay.
17	CO-CHAIR PARTRIDGE: But, going back
18	to Sam's earlier question, as I understand it, it
19	would be there could be some problems if your
20	staff isn't trained in using FIM.
21	MS. DEMAKOS: We totally promote
22	training and credentialing with this instrument,

1	not everybody does it, but we would highly
2	suggest it and agree with Sam's comment.
3	MS. NIEWCZYK: And there's other
4	models that could be used, like a train the
5	trainer. So, it doesn't mean you have train all
6	clinicians within an entire facility. You may
7	select one or two and those then could go back to
8	the facility and train the others.
9	CO-CHAIR STILLE: Dave?
10	MEMBER CELLA: I'm just going to
11	repeat myself here, but I think it's important
12	that, and particularly with feasibility, that
13	this vote is an inpatient rehab facility vote,
14	it's not other sites. Because there was some
15	comment earlier where there was a recommendation
16	for other inpatient-like sites. But this is an
17	inpatient facility vote on feasibility.
18	MEMBER BIERNER: It's not exactly what
19	she said, though. She said she's going to use it
20	in others I mean because skilled nursing
21	other settings can maybe used in as well. So,
22	it's not as well - those are not, in our view,

those are not inpatient settings even though
 they're classified here.

MEMBER SALIBA: But I think the measure is just that we're voting on that's in front of us, it's just for IRFs. That's what I was trying to clarify earlier.

7 MS. NIEWCZYK: In the submissions we 8 indicated on each of them the settings and we 9 listed all of the four venues that I spoke, IRF, 10 SNF and LTCH and home health.

11 MEMBER SALIBA: So, I'm incorrect in 12 my interpretation that this is a measure just IRF 13 that you've put in front of us?

14CO-CHAIR STILLE: Yes, you're15incorrect about that.

MEMBER SALIBA: Okay.

17DR. BURSTIN: But we only endorse18measures for the levels for which we have19testing. So, if we've only been provided data on20the IRFs, then that is the only setting21applicable today.

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MEMBER SALIBA: So, I'm a little

1	confused about what we're voting on. I'm sorry.
2	So, are we voting on this as a measure
3	for any setting or are we voting on this as an
4	IRF measure?
5	CO-CHAIR STILLE: An IRF.
6	MEMBER SALIBA: IRF, okay, great.
7	Thank you.
8	MS. DEMAKOS: May I ask a question?
9	So, if we've submitted the data just
10	for the IRFs, would it be possible then, again,
11	to submit it for the skilled nursing and the LTCH
12	to be considered for that as well?
13	UNKNOWN PARTICIPANT: Not today.
14	MS. DEMAKOS: Oh, no, not today.
15	MS. SAMPSEL: I mean I think we'll
16	have to think about that internally. But I mean
17	the way that this was submitted and, you know,
18	clearly, even in the measure title were you have
19	IRF, we were considering this as an IRF measure
20	and, therefore, as one measure submission.
21	If, you know, if you want to submit
22	additional data, I almost think that's a new call

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for measures.

2 CO-CHAIR STILLE: Okay. Oh, Liz? I have just a quick 3 MEMBER MORT: 4 question. 5 Since these data are used for IRF-PAI with regard to payment, does Medicare do any 6 7 auditing for quality on sites? That might just mitigate the concerns 8 9 around variability and implementation somewhat. 10 MEMBER BIERNER: I can't -- the 11 facilities can be audited, yes. There's RACs 12 which audit the IRF facilities. 13 CO-CHAIR STILLE: Anything else on the 14 feasibility issue or should we vote? Let's vote. 15 MS. ALLEN: Voting on feasibility, one high, two moderate, three low, four insufficient. 16 17 Voting starts now. 18 All votes are in, 18 percent high, 65 19 percent moderate, 18 percent low, zero percent 20 insufficient. 21 CO-CHAIR STILLE: And usability? Any 22 usability comments? Okay, let's vote.

1	MS. ALLEN: Voting on usability in
2	use, one high, two moderate, three low, four
3	insufficient information. Voting starts now.
4	Thirty-five percent high, 53 percent
5	moderate, zero percent low, 12 percent
6	insufficient.
7	CO-CHAIR STILLE: And then finally,
8	suitability for endorsement. Any other last
9	comments before we vote? Okay, let's vote.
10	MS. ALLEN: Overall suitability for
11	endorsement of Measure 2287 functional change.
12	Change in mode of score, one yes, two
13	no. Voting starts now.
14	All votes are in, 83 percent yes, 12
15	percent no. Sorry, 88 percent yes, 12 percent
16	no.
17	CO-CHAIR STILLE: Okay, so there's
18	been a lot of discussion that crosses the UDSMR
19	measures which is great.
20	What we've decided to do is allow the
21	discussants here on the panel any opportunity for
22	making more comments on 2286 and then 2321 and

then we'll figure out how to vote.
Dave?
MEMBER CELLA: I just have one thing
that's, you know, specific to really these two
subset, or I guess you could say short forms.
But their sub-domain related short forms, and it
relates to the reliability data that were
provided.
The coefficients are kind of moderate
and normally, I would just assume that they are
adjusted for item overlap but I didn't see that
in the report.
So, when you correlate a four item
mobility score with a 12 or 18 item overall total
score that includes those four items, you're
going to inflate that relationship because four
units of information are identical.
So, were those correlations that you
reported on reliability adjusted for item overlap
or do they include the common items in both sides
of the equation?
MS. NIEWCZYK: The inter-item

correlations were specific to that measure. So, for the mobility, they were how well each of those four items correlate with each other in the measure. So, it was not independently correlated to the 18 items.

6 MEMBER CELLA: There's a section 7 though where you talk about the correlation of 8 the four item measure, for example, with the 9 total. That's the one I'm referring to, not the 10 inter-item.

11 Okay. So, what we did MS. NIEWCZYK: 12 is taking those four items, how well do those 13 four items and only those four items predict what 14 the patient's full 18 item FIM score would be. 15 So, that we ran regression analyses to see how well those individual four items of that measure 16 17 could predict the full 18 item value for that 18 patient.

MEMBER CELLA: All right. Well, it
would be useful, yes, I mean just as a comment
then, given the magnitude of the coefficients
which are around .6, that suggests to me that

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that's a relationship between the four items that 1 2 are subbed out and the other items, it's fairly low which ironically may be a case for these two 3 4 sub-measures as better measures than the overall. 5 But that's just what -- I think it would be worth knowing the adjusted correlations 6 7 and you might want to consider over time migrating to these two sub-scores as better than 8 9 the overall since the overall seems a little 10 cloudier. 11 CO-CHAIR STILLE: Interesting. 12 Sherrie? 13 MEMBER KAPLAN: When you reduce item 14 batteries like that, that drastically you take a 15 hit in Cronbach's alpha because of the -- well, 16 what I'm staring at is. 17 And so, you would expect that in 18 Spearman-Brown that that's almost exactly what 19 you'd expect. 20 So, my concern, however, was as with 21 the other measure, you don't have -- you don't do it at the facility -- the inter-class correlation 22

coefficients are missing for facility level 1 2 reliability, is that accurate? MS. NIEWCZYK: Correct. 3 So, this all 4 just done on the whole sample of patients, not at 5 the facility. Now, we do have other data that was not submitted and that's not in front of you. 6 So, this is at that patient level. 7 8 MEMBER CELLA: Okay. 9 MS. NIEWCZYK: And thank you for also 10 stating that. Yes, so the fewer items you have 11 you will take a hit in terms of the reliability, 12 the more items, typically, the more reliable the 13 measure. 14 MEMBER CELLA: I need to just clarify, 15 it's in your validity section, actually, because 16 you're citing it as validity and I'm not talking 17 about the internal consistency or the inter-time 18 correlations within. I'm talking about the 19 relationship of the mobility score with the total 20 FIM and the relationship of the self-care score 21 with the total FIM. 22 Those coefficients are moderate,

they're not high. And given --1 2 MS. NIEWCZYK: That's actually not 3 just correlations, though. We're looking at the 4 proportion of variance accounted for. So, a 5 point --6 MEMBER CELLA: That's true, you've got 7 8 MS. NIEWCZYK: -- that's pretty 9 respected if we know roughly 60 percent of 10 variance could be accounted by those four times 11 alone. That's very respectable. 12 MEMBER CELLA: Yes, that's -- but not 13 when you have common items. You're explaining 14 variance of one side with the same thing on the 15 other side. So, I think you should separate them 16 out. 17 But my point really is not against the 18 measure, it looks okay and I just wanted to make 19 that clear. It's that I think you actually --20 the data suggest over time, you might be better 21 off with the two sub-scores as more valid than 22 the overall. And in some cases, more -- and in
1	some sense, more reliable. But, that's all.
2	Thank you.
3	MEMBER KAPLAN: Can I make on point of
4	clarification?
5	If you square the correlation the
6	inter-items, the reliability coefficient, that's
7	the maximum reliable variance that you can share
8	with another variable.
9	So, if you square the lower
10	reliability coefficient, you get a lower number
11	that's reliable variance to be shared with other
12	variables.
13	So, just for clarification, if you
14	shrink the score, you're going to take a hit in
15	reliability and that in turn is going to
16	compromise your ability to see reliable variation
17	in a different variable.
18	MEMBER CELLA: Okay.
19	CO-CHAIR STILLE: so, the other
20	discussant, let's see, Brian was the other
21	discussant for 2286 but he is not here.
22	Sam, did you have any other specific

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1	things to 2286 or are you pretty much done?
2	MEMBER BIERNER: I'm done.
3	CO-CHAIR STILLE: Okay. And then,
4	2321 was Becky and Dave. Dave, you've made a few
5	comments and Becky, did you have anything else
6	you wanted to say about this particular measure?
7	MEMBER BRADLEY: I just wanted to
8	comment on the question about accountability and
9	auditing and just kind of reiterate, there is a
10	lot of auditing and oversight by CMS related to
11	the payment side of these measures. So, that is
12	occurring.
13	CO-CHAIR STILLE: Okay. Ann?
14	MEMBER MONROE: I'd like to ask Sam a
15	question.
16	You mentioned several times the need
17	to be well trained in delivering this instrument.
18	Because you've raised it so often, do you have
19	concerns that the lack of trained people will
20	impact the strength of the results in terms of
21	how well this tool is being used?
22	MEMBER BIERNER: Yes, because we know

from our own internal data looking at different 1 2 groups that we have to train -- residents and we 3 have to train new therapists and people that 4 without adequate training the inter-rater 5 reliability is very poor. No, I won't say very poor but it's not very good. 6 7 And so, it definitely requires training. That's why I was concerned about them 8 9 talking about using it in LTCHs, SNFs and other 10 settings where they aren't as well trained or may 11 not be as well trained as in an acute or rehab 12 hospital. 13 So, it definitely requires a lot of 14 It's not as easy to administer as some training. 15 instruments are. 16 CO-CHAIR STILLE: Okay. So, should we 17 take separate full votes on each of those 18 quickly? 19 (SIMULTANEOUS SPEAKING) 20 CO-CHAIR STILLE: Yes, all right. 21 Okay, so should we take a vote on assuming the 22 votes from the prior one applying to these? Any

objections at all? 1 2 (NO AUDIBLE RESPONSE) CO-CHAIR STILLE: Okay. 3 Okay, so 4 noted. Great, thanks. 5 So, in response CO-CHAIR PARTRIDGE: to the concerns about whether we have our 6 7 developer resources available, we're going to rearrange again and move to the Home Health 8 9 Measures which begin with 0167 and that's? 10 MS. SAMPSEL: So, that's the Abt folks on the phone. And do we have CMS folks here as 11 12 well? 13 MS. KEANE: So, this is Nicole Keane 14 15 MS. SAMPSEL: And before you start, I just want to be really clear, you really only 16 17 have three to four minutes for any type of 18 introductory statements. 19 If the Committee Members then have 20 questions for clarification, we'll do that. But 21 I really need you to restrict your opening 22 comments.

So, this is Nicole Keane 1 MS. KEANE: 2 from Abt Associates. We have Tara McMullen from CMS in the room and then we also have fellow 3 4 contractors from Acumen, Keziah Cook and then 5 also from Colorado, David Hittle and Angela Richard who'll be presenting information. 6 7 Keziah? MS. COOK: Yes, can everyone hear me? 8 9 CO-CHAIR PARTRIDGE: Yes. 10 So, I think one MS. COOK: Great. 11 thing to keep in mind is these five Home Health 12 Measures are all based on the OASIS instrument 13 and they're all calculated and risk adjusted to 14 getting some more methods and then, additionally, 15 the data we present on reliability and validity 16 are, you know, conceptually very similar. 17 So, there may be some efficiencies of 18 considering some of these features across 19 measures as your discussing results. 20 So, I'll start just with the 21 introduction for 0167 which is Improvement in 22 Ambulation or Locomotion.

Many patients who receive home health 1 2 care are recovering from an illness or injury and have difficulty walking or moving around safely. 3 In particular, they may need help from 4 5 either a person or from special equipment to ambulate or locomote. 6 7 Home health care staff can encourage the patient to be as independent as possible and 8 9 can evaluate the patient's needs for equipment or 10 other devices to help them move around. And very importantly, improving a 11 12 patient's safe ambulation and mobility are 13 absolutely critical to allowing that patient to 14 remain in their home rather than moving to a 15 facility-based setting. 16 Even improving functional status, 17 especially ambulation and locomotion contributes 18 to the patient's quality of life and allows them 19 to continue to live safely for as long as 20 possible in their own environment. 21 So, overall, recovering independence 22 and walking or otherwise moving around with

assistive devices is often a goal of 1 2 rehabilitation provided in the home health So, it makes it a reasonable evaluation 3 setting. 4 indicator of effective and high-value home health 5 care. Overall, about 74 percent of home 6 health patients are eligible for this measure. 7 And the measure is calculated using the 8 Home 9 Health Outcome and Assessment Information test 10 that's called OASIS. 11 There's a specific item on the OASIS 12 that documents several levels of ambulation. 13 So, basically it starts at a level 14 zero which indicates the patient has no 15 impairment to their ambulation, moves through, 16 you know, a couple of values that correlate to 17 using a single-handed devise or a double-handed 18 device to walk around. 19 There another level that indicates 20 requiring assistance from a person for 21 ambulation. 22 And then finally, there are several

categories indicating wheelchair bound but able to wheel independently, wheelchair bound and not able to wheel independently and then finally patients who are bed-fast.

5 So, the improvement in ambulation 6 measure uses this item captured at two different 7 time points. So, it uses the items that's 8 measures when the patient first enters home 9 health care at the start of care and that's based 10 on the OASIS assessment conducted within 48 hours 11 of the beginning of home care.

12 And then there's a second OASIS 13 assessment that's conducted when the patient is 14 discharged to the community setting. So, when 15 home health care has specifically achieved their 16 goals and is going to be no longer caring for the 17 patient.

So, in both cases, the patient is assessed on this six point scale and if their numerical score on that scale decreases, which means they move from a sort of higher need category to a lower need category, then they're

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considered to improved in ambulation. 1 2 The home health agencies as a whole are scored based on all home health quality 3 4 episodes that end during a 12-month period. And 5 the measure is their fraction of patients who improve in ambulation and then for public 6 7 reporting purposes, that fraction is riskadjusted based on patient structure. 8 9 So, I'll stop there. 10 CO-CHAIR PARTRIDGE: Thank you. 11 We have -- Carol Levine was scheduled 12 to be one of the presenters on this one together 13 with Peter. Carol is, unfortunately, not with us 14 today because she is ill. So, Peter, you're up. 15 MEMBER THOMAS: I just have two main 16 comments. 17 First is that I found the rationale to 18 be very supportive of the need for rehabilitation 19 in terms of home health care but less in terms of 20 the value of measuring ambulation or mobility on 21 the individual. 22 I recognize the value of being mobile

and in terms of living independently and
performing manual tasks and all those things.
But, I didn't see any data or any background
about, you know, the say spinal cord injury
patients who are non-ambulatory and lose bone
density or muscle atrophy or the perils of lying
in bed all day and, you know, contractures and
bed sores and things of that nature.
So, I was wondering why that wasn't
that seemed to me to be the obvious correlation
between measuring mobility and ambulation and
improving health care. Why was that omitted from
the packet?
CO-CHAIR PARTRIDGE: Would our
developers like to respond? I'm not getting a
response.
MS. COOK: I can speak up.
So, you know, I think our focus here
has been sort of across the range of ambulatory
abilities.
Our fraction of patients in home
health who are actually bed-bound, I don't have

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the numbers in front of me, but it's quite low 1 2 and, you know, I think it's under five percent. And I guess the important thing to 3 4 note is that if a patient is bed-bound at the 5 beginning of the home health episode and then transitions to being able to even sit in a 6 7 wheelchair, even if they can't move about independently in the wheelchair, that is captured 8 9 as improvement. 10 I think another thing to keep in mind 11 is that one of the core services provided by home 12 health agencies are physical therapy. So, it is 13 a care setting in which significant sort of 14 physical rehabilitation is a goal. 15 We do have other measures that aren't 16 in front of this committee that specifically get 17 at things like pressure ulcers that are 18 potentially more applicable directly to the small 19 sub-population of the home health patients who 20 are bed-fast. 21 CO-CHAIR PARTRIDGE: Thank you. 22 MEMBER THOMAS: Fine, well, let me go

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to my main concern with the measure and that involves the Jimmo v. Sebelius case and settlement. And this is something that Brian raised yesterday. I just need to make sure people are well aware of this if you're not.

The CMS and the Department of Justice 6 7 and the Center for Medical Advocacy and selected beneficiaries settled the case a few years ago 8 9 called Jimmo v. Sebelius that determined that in 10 the home health setting, the SNF setting and in 11 the outpatient therapy setting, Medicare cannot 12 impose an improvement standard that's different 13 than IRF. IRF you have to have an expected 14 improvement in the patient.

15 And so when we're measuring, I kept looking for how you accommodate for that decision 16 17 because if this measure goes to eventually a pay-18 for-performance model, which I can assume all of 19 these measures will eventually be looked at in 20 that light, you're going to have significant 21 incentives to not accept patients that require 22 only maintenance or prevention of deterioration

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kinds of therapy and don't have any expectation of improvement.

3	And if you're just measuring
4	improvement in ambulation in this setting without
5	accommodating for that, that's a major problem.
6	That's a disincentive to treat those patients for
7	home health agencies to accept those patients and
8	provide services because they're going to get
9	dinged for those patients.
10	So, my question is then, all right,
11	well, how do you accommodate for that? Can you
12	put that into the denominator as an exclusion or
13	can you risk-adjust that?
14	If you do it on a I suppose you
15	could do it on a condition-specific basis, but
16	you always leave someone out. If you did it on a
17	functional basis, then you're undercutting the
18	whole purpose of the measure because you wouldn't
19	want to keep out people that weren't improving,
20	you're trying to measure improvement.
21	So, can you help me this? Because
22	this runs not only throughout the home health

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measure but the SNF measures and any outpatient 1 2 measures and I don't see it really accommodated for in any of the materials that I've seen. 3 4 CO-CHAIR STILLE: So, it sounds like 5 this would be a usability issue potentially. MEMBER THOMAS: Well, it may be, but, 6 7 boy, this is a critical for me and for a lot of the folks that I kind of deal with. This is 8 9 critical because you don't want to have a measure 10 that ultimately creates a disincentive to treat 11 the very patients that you're trying to make sure 12 are getting access to good quality care. 13 So, I would hope to elevate it above 14 I think this goes to the evidence usability. 15 issue. 16 MS. COOK: Is David still on the line 17 from Colorado? 18 MR. HITTLE: Yes. Hello, this is David Hittle from the University of Colorado. 19 20 And the fact is that the preponderance 21 of folks who are getting home care are relatively 22 short stay in home care, around 35 to 40 days

generally and are generally those who do have a 1 2 reasonable probability of achieving an improvement in their functional status. 3 4 Jimmo may have changed that somewhat 5 in recent years. I don't have concrete data on exactly how much that would have changed, but we 6 7 certainly are looking into that. But we also have other measures 8 9 actually related to functional status that look 10 at whether or not you manage to keep somebody at 11 the same level of impairment in functional 12 status. 13 Generally, those measures tend to be 14 very heavily topped out and, therefore, you know, 15 usually during the first parts of a home care 16 episode, is it, you know, there's not much differentiation in terms of whether or not you're 17 18 able to keep somebody reasonably stabilized in 19 their functional status. 20 And actually, we had, at one point, 21 there were stabilization measures that were --22 there were one or two stabilization measures that were endorsed by NQF and NQF withdrew that
 endorsement several years ago because of the
 topped out nature of those measures.

4 We are currently exploring whether or 5 not we can look at an overall functional status stabilization measure and whether that would, you 6 7 know, if you look across several different ambulation, bed-transferring, bathing, dressing, 8 9 the different kinds of ADL activities whether or 10 not you would end up getting a greater level of 11 variation, and therefore, a greater ability to 12 distinguish among providers on those measures by 13 like inspecting and, you know, constructing 14 composite measures.

15 CO-CHAIR PARTRIDGE: Thank you, Dr.
16 Hittle. I'm going to cut you off because I think
17 we really need to explore other pieces here.

And Peter, I'm very sensitive to your concern about unintended consequences, so I don't want to terminate the discussion, I just have a feeling that it's probably going a little deeper than we can accommodate right now.

1	MEMBER THOMAS: Yes, and I don't know
2	whether this is more in the validity, but I'll
3	raise it under the validity part so we can move
4	on.
5	CO-CHAIR PARTRIDGE: Okay. I would
6	invite the people who looked at bathing, bed-
7	transferring, management of oral meds and pain to
8	also chime in here since the measures are
9	somewhat similar. So, go ahead.
10	MEMBER PARISI: So, this is Len, and
11	I reviewed the second one on grooming and
12	bathing.
13	I am very familiar with the data
14	collection process and the use of the OASIS.
15	It's been in use for a long time and the rigors
16	involved in educating staff to be able to perform
17	a valid and reliable assessment and a lot of
18	effort goes into that.
19	The only thing that I have a question
20	about is the gap between the measured outcome and
21	the evidence to support those interventions that
22	would support improvement.

Much of the data that we collect 1 2 related to these outcomes are used for performance improvement initiatives and 3 4 benchmarking purposes. But the way the -- and 5 the way it's reported on home health compare, the language is different for the public as it is on 6 these measures as well which sometimes causes 7 confusion among staff members. 8 9 But, I don't see any evidence that 10 supports clinical initiatives or practice parameters around improving these outcomes. 11 That 12 would be my only comment. 13 CO-CHAIR PARTRIDGE: Do the developers 14 want to respond? They've submitted it and we 15 didn't find it or they would submit or? Is Angela on? 16 MS. COOK: 17 MS. RICHARD: Yes, I am. Hi, this is 18 Angela. 19 You know, I think in the literature, 20 we actually, particularly for bathing I guess, 21 there are several studies that really indicate 22 that home health care can really result in

improvements and functional ability, some were 1 2 ever specific to bathing. The Luft study of 2009 particularly calls that one out. 3 4 And, you know, so I'm a little bit unclear about where the literature -- I mean I 5 think the literature really does support this 6 7 home visiting nurse intervention versus care as usual. 8 9 Friedman, Lovell and Powers 2014 found 10 that and those are in the lit review. So, maybe 11 I didn't make those clear enough. 12 MEMBER PARISI: Well, I guess maybe I 13 wasn't clear. 14 So, the improvement in bathing, so if 15 an organization scores poorly, there's no, to my 16 understanding, connection between how you get to 17 improve bathing. 18 So, is it education? There are no 19 practice guidelines around educating people on 20 bathing. It really gets back to their functional 21 ability. 22 Clearly, it's an important indicator

because you want home health patients to be 1 2 independent and to be able to have the ability to bathe themselves. 3 4 So, that was -- it's a little 5 different in an ambulation where you would have a physical therapist and/or some of the other 6 7 measures, so that was the only thing that I was trying to put together. 8 9 MS. RICHARD: Okav. And we did --10 This is Tara McMullen MS. MCMULLEN: 11 from CMS. 12 A lot of these measures, this kind of 13 goes back to our discussion yesterday about the 14 use of the nursing home measure and how they're 15 used and commonly reported and benchmarked for 16 those multiple purposes. 17 Many times we create these outcome 18 based measures so that we can benchmark or set 19 thresholds or publically report beyond that of 20 the guidelines. We know guidelines exist and we 21 take those very seriously. 22 You know, crafting process or crafting

how care is given, we know that these measures 1 2 are a part of that but many times, like with this measure specifically or the other ADL measures, 3 4 they're used as just basically, it's a mark, it's 5 a benchmark and that's how they're reported on Home Health Compare. 6 7 So, they could be used to craft practice, but the means for those outcome 8 9 measures at this time is just a benchmark and 10 publically report what is going on within that 11 setting. 12 CO-CHAIR PARTRIDGE: And I saw 13 multiple other hands over here. 14 Lisa? 15 MEMBER MORRISE: Thank you. 16 I looked at bathing and transfers. 17 The thoughts that I had around these, a couple of 18 thoughts. 19 One is that I understand what Len is 20 saying that there's -- when you determine that an 21 organization does not meet a ceratin level of 22 being able to provide these services, there's no

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follow-up currently.

2	But that's a usability issue and one
3	that we may want to look at if it's going to be
4	used for payment so that there's some kind of
5	motivation to improve. Because there currently
6	is a gap between the small agencies and the large
7	agencies in ability to provide those services.
8	I really appreciate what Peter had to
9	say. I think, though, that that gets to a policy
10	issue in also with usability versus a measure.
11	The measure is still the measure and that we need
12	to look at policy if there are unintended
13	consequences to the measure when we get back to
14	usability so that we have some kind of follow
15	through. So, that's all kind of interconnected.
16	And I know that in our experience with
17	home health interventions like these, we do reach
18	a threshold where we've met goals and then home
19	health goes away and then we fall backwards.
20	So, there needs to be communication
21	with the patient so that there's kind of ongoing
22	assessment.

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1 But anyway, those are just my 2 thoughts. I'd love to vote. CO-CHAIR PARTRIDGE: Managing drugs 3 4 and I'm --5 CO-CHAIR STILLE: Yes, the last two are a little bit different from the others. 6 7 Maybe --CO-CHAIR PARTRIDGE: Yes, I think --8 9 CO-CHAIR STILLE: -- Med Management 10 and Pain. 11 CO-CHAIR PARTRIDGE: Pain's one of my 12 favorites. 13 CO-CHAIR STILLE: SD had Med 14 Management and Sherrie and Deb had pain. 15 CO-CHAIR PARTRIDGE: Esther? 16 MEMBER NEUWIRTH: Yes, so this one is 17 widely in use but -- is it working now? 18 This one's widely in use. I don't 19 think we had many questions in relation to it. 20 But, I would say, you know, because it's widely 21 used and tracked and has a long track record, I 22 guess some of the questions that we had related

to the fact that lots of patients are excluded 1 2 from this measure, so that seems like it -- some questions around applicability and use. 3 4 And then personally, I was wondering 5 why this isn't a real PRO and I think that came up in some of our reviewer comments as well. 6 7 Seems like there could -- this could very well be, you know, directly asked of patients rather 8 9 than simply assessment because there might be 10 some bias there. 11 Then it wasn't also clear how this 12 really drove improvement efforts. 13 CO-CHAIR PARTRIDGE: Sherrie Loeb? 14 MEMBER LOEB: The pain one, I believe 15 is also widely used. Pain is just a really 16 tricky one to assess. You know, what's the worst 17 pain for one person is minimal for someone else. 18 So, you know, we've got to track it. 19 We've got to continue and home health is 20 important to know what they're doing, what 21 they're helping with, what the physician's 22 prescribing at home is going to work.

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1	But, whether we ever can truly find a
2	tool to adequately assess it, you know, good
3	luck. I hate the 1-10 scale. I hate the smiley
4	faces, you know. Someday we're going to come up
5	with
6	MR. HITTLE: This David Hittle from
7	the University of Colorado.
8	I should stress that we're not using
9	the 1-10 scale. We're not using smiley faces.
10	We're using how often does pain interfere with
11	activities.
12	MEMBER LOEB: Right.
13	MR. HITTLE: And that's the scale that
14	we're measuring folks on.
15	MEMBER LOEB: And that's so much
16	better. I mean, you know, when patients come
17	into hospitals and they're saying, you know, rate
18	your pain on a 1-10 scale and it's happened to
19	me, you know, at times. You know, if I'm going
20	into an emergency room, my pain's usually 15.
21	So, I like the fact that, you know, if
22	it's interfering, especially if you have home

health coming to your home, they're helping you 1 2 with your function, with your ADLs and to get 3 back to your --4 You know, at least your baseline or 5 hopefully better, so to help that it's not interfering and you're able to move on. 6 So, I like that. 7 CO-CHAIR PARTRIDGE: Katherine? 8 9 MEMBER BEVANS: I just don't know how 10 we're handling the multiple measures --11 CO-CHAIR STILLE: We're discussing 12 that. 13 MEMBER BEVANS: -- in a minute. 14 Okay, I just want to suggest that I would like to 15 talk a little bit about the appropriateness of other reporters for assessment of pain, in 16 17 particular, so that we can consider that 18 independently. 19 CO-CHAIR STILLE: Yes, we'll consider 20 pain separately, I think. 21 MEMBER BEVANS: Okay, thank you. 22 CO-CHAIR STILLE: As long as everyone

1

feels good about that.

2 CO-CHAIR PARTRIDGE: It's my judgment 3 as we've talked about these five that there are 4 issues and, perhaps, at different levels in 5 whether it's importance or feasibility or usability. 6 7 And probably we should consider voting one by one or if we could do it as a group but I 8 9 wonder --10 Okay, but I would be open to 11 recommendations. 12 CO-CHAIR STILLE: Sure. 13 CO-CHAIR PARTRIDGE: Lisa and Chris? 14 CO-CHAIR STILLE: Lisa first. 15 MEMBER MORRISE: Let's just get on 16 with it. 17 CO-CHAIR STILLE: Okay. I'd like to 18 recommend that we talk about the first three as a 19 group and then the last two med and pain 20 separately. 21 I see some heads nodding. 22 CO-CHAIR PARTRIDGE: Okay. So,

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Nadine, you want to work your magic? 1 2 MS. ALLEN: Voting on evidence, one yes, two no. Voting starts now. 3 For this measure, for the three 4 5 grouped measures, can we do a hand vote? I'm experiencing some difficulties with the evidence 6 7 slide. 8 So, yeses? 9 (A SHOW OF HANDS) 10 MS. ALLEN: Voting on performance gap, one high, two moderate, three low, four 11 12 insufficient. Voting starts now. 13 Still waiting on a couple of votes. 14 All votes are in, 18 percent high, 76 15 percent moderate, six percent low, zero percent 16 insufficient. 17 For evidence, the results were 17 18 yeses and zero no. 19 Voting on high priority, one high, two 20 moderate, three low, four insufficient. Voting 21 starts now. 22 So, all votes are in, 59 percent high,

41 percent moderate, zero percent low, zero 1 2 percent insufficient. Voting on reliability, one high, two 3 moderate, three low, four insufficient. Voting 4 5 starts now. All votes are in, 35 percent high, 47 6 7 percent moderate, six percent low, 12 percent insufficient. 8 9 Voting on validity, one high, two 10 moderate, three low, four insufficient. Voting 11 starts now. All votes are in, 29 percent high, 41 12 13 percent moderate, 12 percent, 18 percent 14 insufficient. 15 Feasibility, one high, two moderate, 16 three low, four insufficient. Voting starts now. 17 Still waiting on one vote. All votes are in, 53 percent high, 41 18 19 percent moderate, six percent low, zero percent 20 insufficient. 21 Voting on usability, one high, two 22 moderate, three low, four insufficient

information. Voting starts now. 1 2 So, all votes are in, 24 percent high, 65 percent moderate, 12 percent low, zero percent 3 insufficient information. 4 Voting on overall suitability for 5 endorsement of measure 0167, 0174 and 0175. 6 Voting starts now, one yes, two no. 7 All votes are in, 100 percent yes, 8 9 zero percent no. 10 But I do not want CO-CHAIR PARTRIDGE: 11 us to lose Peter's point. And the question is 12 how we incorporate that in our comments somehow 13 and perhaps CMS would like to come back to us to 14 talk a little bit about the possibility of 15 amending the exclusions of the denominator. 16 That's one obvious way to look at it. There 17 might be others. 18 But when this gets to CSAC, this issue 19 will come up and both of us who are -- Ann and I 20 are going to have to be able to respond. 21 So, I'm getting a nod from CMS, thank 22 you.

1	MEMBER MORT: If I could just
2	reinforce the importance of that comment.
3	And I looked through the OASIS, a 25-
4	page assessment, and as physician, when I order
5	home care services, I don't order everything.
6	It's in some menu and I'm picking certain things
7	that I want this particular patient to benefit
8	from.
9	That might be some way in which you
10	could identify what the goals of a home care
11	episode are and monitor exactly who gets in the
12	denominator.
13	So, to judge a home care facility on
14	a criterion that I wasn't looking to improve just
15	screws, you know, distorts it. And that would be
16	a way, I think, Peter, to get at what you're
17	concerned about.
18	If I'm ordering home care for nursing
19	care to monitor congestive heart failure and
20	ambulation is not an issue for this patient, the
21	patient is where the patient is going to be.
22	Then I think the home care services should be

judged on their performance on the medical issues, not on the PT issues. PT may not even come.

So, that's a way that I think you could address some of these really important issues.

7 CO-CHAIR STILLE: And when I agree, I mean from a child health standpoint, and these, 8 9 you know, all should basically be extended down 10 once we get them going, right, it's a relatively 11 small number of kinds and adolescents that have 12 ambulation as a piece of their home health care. 13 It's usually a lot of different things, many 14 things on this list, but, yes.

15 MEMBER THOMAS: Just quickly, no one 16 is saying that it's not important, the measure 17 improvement in home health services. That's not 18 what I was getting at for sure.

19 It's very important for most people, 20 but my only concern is that you put -- you don't 21 want to create a system where you've got 22 disincentives to treat the people who may not

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improve but still might need that therapy in order to maintain or prevent deterioration of function.

4 Degenerative, you know, progressive 5 kind of disorders or neurological diseases and things of that nature where they have every right 6 7 to and Medicare is supposed to cover that care. And if there's a system in place that measures 8 9 improvement alone without any recognition of 10 that, there is a real risk that those people 11 would be under served and that's -- it's not 12 something we should do.

MS. MCMULLEN: Yes, I mean -- and I
wanted to say something on behalf of CMS earlier
and I'm with my Deputy Director for the Division
of Chronic and Post-Acute Care.

We hear you and we agree with you and we are moving in the way where we are able to balance out the incentives so that we're not developing measures that are seen as being able to disincentivize care or take away from the actual goals of the resident or the patient or

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the individual whoever that may be. 1 2 So, yes, we hear you and I have taken notes and we will be able to respond to that if 3 need be at the CSAC or what not. 4 MEMBER THOMAS: So, we don't need to 5 talk about this further every time this comes up. 6 7 This applies to home health, SNF and outpatient. And whenever you've got that scenario, if you're 8 9 measuring improvement, you've got to have some 10 way to accommodate this settlement that CMS has 11 signed on to. 12 Thanks. 13 MEMBER KAPLAN: I have one quick 14 question. If we've endorsed these measures, is 15 there -- we would still like to get some of the 16 evidence that we've asked for on, for example, 17 inter-class correlation coefficients, the means 18 for the fit data for Rasch variables, et cetera, 19 et cetera. 20 Is there -- how does that work? 21 MS. THEBERGE: The developers can 22 provide it.

CO-CHAIR PARTRIDGE: I think it's 1 2 always in the developer's interest where we've asked for it to provide it. It makes our case 3 4 for recommendation stronger or weaker, but we 5 hope strong, and particularly when we've got gray zones -- we don't have gray zones here, but where 6 we do, it becomes very important. 7 Sherrie? 8 9 MEMBER LOEB: Just two quick comments. 10 I know that Liz who said as far as, 11 you know, you recommend just a certain thing with 12 home health, I think from the patient standpoint 13 and from the nursing standpoint, when the home 14 health nurses go out there, they may see things 15 that the physician doesn't see in their quick 16 visit. 17 And so, I mean I have had some -- a 18 phenomenal home health nurse who came out and 19 noticed things that maybe the internist didn't 20 because they were only there for a short time. 21 So they may pick up things they do need. 22 And, yes, you may have a CHF patient

who you want, you know, that taken care of, but
 who can't walk because of the CHF and so needs
 that kind of rehab, too.

4 And the other point is, if we know 5 there's not going to be any improvement because of their chronic illness, that, unfortunately, 6 7 hurts the patient in a lot of aspects. They a lot of times won't qualify for any more physical 8 9 There's no improvement so we're not therapy. 10 going to give them physical therapy. But what's 11 going to happen without that physical therapy? 12 Because they're going to go backwards.

So, the same thing can come into play with the home health, you know, visits. You know, there has to be some type of, you know, exclusion much like, you know, not everyone can get a beta blocker with cardiac disease, so there's a way to, you know, exclude it so you're not quote, dinged by accreditation.

20 So, in the future, somehow there has 21 to be a little box so you're not hurt by not 22 improving.

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1	CO-CHAIR PARTRIDGE: All right. We've
2	talked about the first three and we've talked
3	briefly about 0176 and 0177.
4	Is there and Katherine wanted to
5	talk a little bit about those further.
6	MS. RICHARD: So, do you want sort of
7	the brief introduction of those other two
8	measures?
9	MEMBER BEVANS: No, not necessary.
10	CO-CHAIR PARTRIDGE: No, we're
11	comfortable with
12	MS. RICHARD: Okay.
13	CO-CHAIR PARTRIDGE: Thanks anyway.
14	MEMBER BEVANS: Yes.
15	MS. RICHARD: No problem.
16	MEMBER BEVANS: It's really just, you
17	know, as I mentioned, the point that the validity
18	of other reports, other individuals reports of
19	someone's pain has certainly been questioned.
20	And so, to the developers, have there
21	been any validity tests done, evaluations of
22	accuracy of the other reporters in comparison to

the individuals report of pain at the individual 1 2 level? CO-CHAIR STILLE: So, this is for 3 4 0177? 5 **MEMBER BEVANS:** Yes. This is Angela. 6 MS. RICHARD: 7 We've not done those particular studies and in the latest reviews, I haven't 8 9 really seen a comparison of that. 10 This is Keziah. MS. COOK: I think it may also be important to 11 12 note that when the home health agency fills out 13 the assessment item, the assumption is that they 14 are drawing on multiple sources of information. 15 They're drawing on their own observations of the 16 patient, they're drawing on things that the 17 patient has said and also potentially drawing on 18 information from other family members or care 19 givers. 20 So, they may directly ask the patient 21 to what extent is pain interfering with their 22 ability to do certain tasks, they're also

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observing the patient.

2	So, if they notice the patient is
3	really slower, hesitant to stand up and they're
4	grimacing, that may, you know, be sort of
5	evidence that pain is interfering with that
6	patient's ability to do that particular task.
7	CO-CHAIR PARTRIDGE: Okay, further
8	MS. RICHARD: Yes, that's very true.
9	I'm sorry, that's right, multiple sources of
10	information are used for the assessment of their
11	function.
12	CO-CHAIR PARTRIDGE: Further comments
13	or questions about either of these?
14	Lisa?
15	MEMBER MORRISE: In my experience, the
16	ability of a patient to manage their own
17	medications has a number of variables attached to
18	it and I'm not seeing those necessarily here.
19	For example, when you start getting
20	over a certain number of medications or a
21	complicated schedule, it doesn't matter if you
22	sit down and you do a chart and you do everything

possible. It's just you're not going to get
 adherence because of the complexity of the
 situation.

4 So, I'm looking at this measure and 5 thinking, gosh, you know, if they have two medications then this probably works really well. 6 7 But in the realistic scheme of things where I had one mom recently who posted a picture of 8 9 something like 30 medications that her child had 10 to take when he came home, no amount of health 11 care intervention was going to ensure that this 12 very adherent, compliant, trying to do the best 13 for her child mom was going to actually achieve 14 getting all of those medications in her child.

And I realize that the measure isn't looking at pediatrics, but it's analogous to the adult situation.

18 So, I'm questioning that maybe there
19 needs to be some other variables that are looked
20 at.

21 MS. RICHARD: it might be a caveat 22 that we do have a medication cross list measure

that looks at education and it's also possible 1 2 for the home health agency to request that a doctor does sort of have medication 3 reconciliations. 4 5 MEMBER MORRISE: Can I just follow-up and say, medical reconciliation current consists 6 7 mostly of going over a list. It does not help a patient in terms of how they actually take those 8 9 medications. 10 I know when my adult child came home 11 from the hospital a little over a year ago with 12 ten medications to deliver by NJ tube, I 13 practically cried because it was more than I 14 could figure out. And all anybody ever did in 15 terms of MedRec was to say you're taking this med 16 and this med and this med and this med and that 17 is not helpful. 18 CO-CHAIR STILLE: So, Lisa, that's a 19 good point. I went into the validity section and 20 kind of re-read it and it sounds as though that 21 there's been a lot of validation by the fact that 22 they use it a lot and that people find it useful

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1	but not a whole lot of objective things, which
2	would arguably be hard to do, although possible,
3	you know, chart reviews, bottle, you know, bottle
4	validation, stuff like that.
5	So, yes, that's a good point.
6	CO-CHAIR PARTRIDGE: Are we ready to
7	vote?
8	Nadine, 0176 and then 0177.
9	MS. ALLEN: Evidence, one yes, two no.
10	Voting starts now.
11	CO-CHAIR PARTRIDGE: This is a one at
12	a time vote just for any confusion.
13	MS. ALLEN: This is for measures 0176.
14	All votes are in, 94 percent yes, six
15	percent no for evidence.
16	Performance gap, one high, two
17	moderate, three low, four insufficient. Voting
18	starts now.
19	All votes are in, 31 percent high, 63
20	percent moderate, six percent low, zero percent
21	insufficient.
22	Voting on high priority, one high, two

moderate, three low, four insufficient. Voting 1 2 starts now. 3 All votes are in, 75 percent high, 25 percent moderate, zero percent low, zero percent 4 5 insufficient. Voting on reliability, one high, two 6 7 moderate, three low, four insufficient. Voting 8 starts now. 9 MEMBER KAPLAN: I just had the same 10 comment I had for reliability that I had before 11 which is, we don't have the facility level reliability inter-class correlation coefficients, 12 13 et cetera, et cetera. So, as that issue becomes 14 a uniform issue if these get approved and then we 15 don't get those data because there's no incentive 16 for the developer to give us those data. 17 MS. COOK: I'm sorry, this Keziah. 18 We did include our reliability 19 statistics at facility. The beta binomial tests 20 compared with in the between variation at the 21 facility level. And we also reported test, 22 retest, IPC.

MEMBER KAPLAN: No, it says at the 1 2 measure level and the earlier --3 MS. COOK: I mean, so what those are 4 doing is they are calculating the measure at the 5 facility level and then comparing those rates. 6 MEMBER KAPLAN: No, no, no, I 7 understand that. But it's the measures that are being -- it's not the way you're going to use the 8 9 score which is as a composite across the 10 measures. That's what we're looking for. 11 MS. COOK: We're not using these as a 12 composite. These are reported individually. 13 I'm sorry, I feel like we're being 14 conflated with the previous group of measures 15 maybe. Each of these measures are reported 16 separately as rates both for public reporting and 17 for quality improvement. 18 MS. ALLEN: Voting on reliability. 19 Voting starts now. 20 Still waiting on one vote. 21 Please vote again. 22 All votes are in, 13 percent high, 56

1 percent moderate, zero percent low, 31 percent 2 insufficient. Voting on validity, one high, two 3 moderate, three low, four insufficient. Voting 4 5 starts now. Still waiting on a vote. 6 All votes are in, six percent high, 56 7 percent moderate, six percent low, 31 percent 8 9 insufficient. 10 Voting on feasibility, one high, two 11 moderate, three low, four insufficient. Voting 12 starts now. 13 All votes are in, 38 percent high, 56 14 percent moderate, six percent low, zero percent 15 insufficient. 16 Voting on usability and use, one high, 17 two moderate, three low, four insufficient 18 information. Voting starts now. 19 All votes are in, 19 percent high, 56 20 percent moderate, 19 percent low, six percent insufficient information. 21 22 Voting on overall suitability for

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1	endorsement of Measure 0176, Improvement in
2	Management of All Medications, one yes, two no.
3	Voting starts now.
4	Still waiting on a vote.
5	All votes are in, 100 percent yes,
6	zero percent no.
7	CO-CHAIR STILLE: Okay, so let's have
8	a brief discussion of anything else related to
9	the pain measure. I know we've talked about
10	that, there may not be anything left to discuss.
11	CO-CHAIR PARTRIDGE: Silence.
12	CO-CHAIR STILLE: I think we need a
13	break, but I think we need to vote before a
14	break.
15	CO-CHAIR PARTRIDGE: Nadine?
16	MS. ALLEN: Voting on Measure 0177,
17	voting on evidence, one yes, two no. Voting
18	starts now.
19	All votes are in, 100 percent yes,
20	zero percent no.
21	Voting on performance gap, one high,
22	two moderate, three low, four insufficient.

1 Voting starts now. 2 Still missing a vote. All votes are in, 31 percent high, 63 3 4 percent moderate, zero percent low, six percent 5 insufficient. Voting on high priority, one high, two 6 7 moderate, three low, four insufficient. Voting 8 starts now. 9 All votes are in, 69 percent high, 31 10 perfect moderate, zero percent low, zero percent insufficient. 11 12 Voting on reliability, one high, two 13 moderate, three low, four insufficient. Voting 14 starts now. 15 All votes are in, 19 percent high, 56 16 percent moderate, 25 percent insufficient, zero 17 percent low. 18 Voting on validity, one high, two 19 moderate, three low, four insufficient. Voting 20 starts now. 21 All votes are in, 13 percent high, 50 22 percent moderate, 13 percent low, 25 percent

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2 Voting on feasibility, one high, two moderate, three low, four insufficient. Voting 3 4 starts now. 5 Still waiting on a vote. All votes are in, 50 percent high, 50 6 7 percent moderate, zero percent low, zero percent insufficient. 8 9 Voting on usability, one high, two 10 moderate, three low, four insufficient 11 information. Voting starts now. 12 Still waiting on a vote. 13 All votes are in, 31 percent high, 69 14 percent moderate, zero percent low, zero percent 15 insufficient information. 16 Voting on overall suitability for 17 endorsement of Measure 0177, Improvement in Pain 18 Interfering with Activity, one yes, two no. 19 Voting starts now. 20 All votes are in, 94 percent yes, six 21 percent no. 22 CO-CHAIR PARTRIDGE: We are going to

take a break, a stretch. And congratulations for 1 2 moving through a lot of measures in a difficult, 3 fast way. 4 CO-CHAIR STILLE: Yes, great work. 5 And then we'll start with -- do you want to start with the IRF ones or the AHCAs? 6 CO-CHAIR PARTRIDGE: 7 I think -- I'm trying to remember what was yesterday's. 8 9 CO-CHAIR STILLE: AHCA measures, yes, 10 So, let's start with 2613 and 2612. okay. (Whereupon, the above-entitled matter 11 went off the record at 10:44 a.m. and resumed at 12 13 10:59 a.m.) 14 CO-CHAIR PARTRIDGE: If I can -- I 15 hate to do this everybody, but if I can pull us 16 all back together. I'm going to turn - I'm going 17 to just start talking and if nobody's listening 18 then that's the way it is. 19 CO-CHAIR STILLE: Everyone, please sit 20 down. 21 CO-CHAIR PARTRIDGE: All right, we are 22 going to turn next --

1	We are now going to turn to our long-
2	suffering colleagues who have been patiently
3	waiting their turn while we rejiggered the agenda
4	multiple times and proceed to discussion of 2613
5	and to I can't read from the distance 2612?
6	CO-CHAIR STILLE: 2612, yes.
7	CO-CHAIR PARTRIDGE: Okay. And our
8	developers are here and please proceed.
9	MR. GIFFORD: So, my name is David
10	Gifford, I'm a geriatrician. We're from the
11	American Health Care Association and we have
12	before you two different measures, 2613 and 2612.
13	This is Improvement in Self-Care and
14	Improvement in Mobility. They are both based off
15	of the CARE tool, self-care and the mobility
16	components of the CARE tool that was developed
17	and validated by CMS.
18	It calculates risk-adjusted change
19	from admission to discharge for anyone admitted
20	from a hospital to a SNF regardless of payer.
21	And I'm not sure how much you want me
22	to go any more detail given the time and the pace

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1 you guys are going. Better to answer questions 2 from you all. CO-CHAIR PARTRIDGE: Anything further 3 4 you want to add right now or, if not, we will 5 proceed to the -- we'll turn to our discussants. CO-CHAIR STILLE: Sharon and Peter. 6 7 CO-CHAIR PARTRIDGE: Okay. CO-CHAIR STILLE: 8 Yes. 9 CO-CHAIR PARTRIDGE: All right, Peter? 10 MEMBER THOMAS: Well, I won't go -belabor it at all, but the same issue about the 11 12 Jimmo case, I think. 13 Although I do recognize there is risk-14 adjustment in this, am I not correct? I'm 15 looking. 16 I found this to be fairly highly 17 rated, well, the evidence in terms of this 18 measure, I found it to be moderate. 19 I through the rationale speaks of 20 independent living but the measures are pretty 21 basic and I'm wondering whether -- I don't know 22 enough about the CARE tool.

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Other than that, I did find that there 1 2 was a significant variation and room for improvement in terms of performance gap. 3 There 4 was no disparities data. I read that there's too 5 low a sample size. Can you --MR. GIFFORD: Overall, about 15 6 7 percent of the entire nursing home population in the country admitted to a SNF or of any sort of 8 9 ethnicity group, they all tend to be concentrated 10 in individuals. 11 There's a -- most of the studies that 12 have looked at disparity work have shown that 13 there is differences in disparity is to access to 14 whether they go to a SNF or an IRF or an LTCH. 15 There's very little on the differences 16 in quality in the SNF. Those that have looked at 17 it, not in the ADL or mobility section have shown 18 that there are disparities but they relate to the 19 types of providers that are in -- that they tend 20 to go to inner city, poor quality centers where 21 both Caucasian and all ethnicities have equally 22 bad outcomes.

1 So, if you looked at it at a 2 population level, you'd definitely see differences where you don't. 3 We were following the strict guidance 4 5 from NQF that if you are going to look at any ethnicity, you need to stratify that, you don't 6 7 risk-adjust for it. And the sample size is so small in most nursing homes with only about ten 8 9 or 15 percent being of any ethnicity that you 10 would exclude over three-quarters of the SNFs in 11 the country from the measure. 12 Certainly with renewed information out 13 there, there may be a question about now risk-14 adjusting it with the changes in policy at NQF. 15 But the guidance we got when we submitted this was to not to do that. 16 17 MEMBER THOMAS: Did you want to stop 18 at reliability and validity and do that a little 19 later or do you want to continue to go? 20 CO-CHAIR STILLE: Ideally, that would 21 be great, yes. 22 MEMBER THOMAS: Okay. I mean the only

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1	thing I'd say is that there is a, you know, what,
2	2.3 million Medicare admissions to SNFs in 2012
3	data, \$229 billion spent on it. So, obviously,
4	this is a very significant priority to try to
5	assess measurement of mobility in SNFs.
6	CO-CHAIR PARTRIDGE: Any other
7	comments on importance with respect to 2613? For
8	example, gap.
9	MEMBER MONROE: Just one of the things
10	that appealed to me about this measure, that it's
11	regardless of care. And I think some of the
12	other similar measures that we've seen have been
13	payer-specific which I think creates another set
14	of problems and encourages duplication of
15	measure.
16	So, I appreciate that this is
17	regardless of payer which makes it a more widely
18	available use tool.
19	MEMBER THOMAS: And I'll also Just say
20	that the American Occupational Therapy
21	Association submitted some comments and I found
22	them to be very helpful.

Where the description of this measure, 1 2 you know, refers to that these patients are admitted for therapy in a SNF, that they made the 3 4 point, well, they're really admitted for overall 5 need and they received a significant amount therapy typically. 6 7 But that's not necessarily why they're admitted and they made that point. I just wanted 8 9 to call that out. 10 Do you, you know, do you disagree with 11 that? 12 MR. GIFFORD: Right now, 90 percent --13 well, about 85 percent of all admissions to a SNF 14 come from a hospital. Of those, 90 percent of 15 them, whether they are in Medicare or not, end up 16 in a rehab rug, which means they'll be getting 17 PT, OT or speech therapy out there. 18 They often are there for additional 19 information but one of the primary purposes for 20 the skilled services is to improve their ADL 21 function and/or mobility so that they can 22 hopefully return home.

I think what you're touching on is you 1 2 probably need a portfolio of measures to look at post-acute care, not just these measures 3 4 including discharge to the community which we 5 have a risk-adjusted measure we'll be bringing forward to NQF, it just doesn't go to this panel, 6 7 it goes to a different group. We're looking at satisfaction. We're 8 9 looking at rehospitalization measure which just 10 got approved by a different panel from NQF 11 recently. But you almost need to look at those 12 all in conjunction in any of the post-acute 13 providers, not just SNF but IRF or LTCH or anyone 14 else. 15 And I think your point is well taken 16 that if you're looking at a portfolio for overall 17 global care, you do, but we were limited to just 18 looking at function at this point.

I think in your comments about the
items in there, we wanted to use an assessment
instrument that was in the public domain that was
going to comply with the IMPACT Act that was

passed by Congress this last year and that CMS was going to use.

And since they had developed and 3 4 modified it and we approached CMS, they indicated 5 that they were leaning towards using the CARE So, we elected to develop the measure 6 tool. 7 around the CARE tool for that purpose on reason. I think the additional ALDs or IADLs 8 9 that you're talking about would make sense, but 10 probably would be a separate measure because of the differences in the domain and the functional 11 12 level of the individuals that were there. And so 13 we were restricted to that domain. That would be 14 a whole new sort of measurement development 15 aspect. 16 The measure does look at some aspects 17 to getting home which would be going up and down 18 stairs. But some of the more IADLs like cooking 19 and cleaning are not there but clearly you have 20 to be able to do your ADLs to be able to get to 21 your IADLs if you want to get there.

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CO-CHAIR PARTRIDGE: I have a question

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that really goes to the CARE tool. 1 2 Some of the other measures we've been discussing over the past two days include 3 4 questions about the patient's memory and 5 communication skills. Are there questions related to those 6 issues in the CARE tool? 7 So, we took the -- the 8 MR. GIFFORD: 9 CARE tool is a compilation of different 10 standardized assessments. One of them is 11 cognitive function. 12 We took the mobility and the self-care 13 assessment tools and used those for this measure. 14 We had long and lengthy discussion, we risk-15 adjust for cognitive status but we use currently the FIM score which is a validated score out of 16 17 the MDS to do the risk-adjustment. 18 We elected to risk-adjust all for MDS 19 items because they are standardized and reliable 20 and have been tested. Deb Saliba who developed 21 it can probably tell you a lot more about this, 22 but we use that and so we risk-adjust for

dementia.

2 We had a panel of therapists that indicated that was a strong thing there and we 3 4 include that in the risk-adjustment model. Good, thank you 5 CO-CHAIR PARTRIDGE: 6 very much. MR. GIFFORD: We're just not based off 7 the CARE tool one. 8 9 CO-CHAIR PARTRIDGE: Right. 10 If CMS inserts that into MR. GIFFORD: 11 the MDS, OASIS and IRF-PAI, we would switch over 12 and use that at that time but come back to you 13 with the modification of that, but, yes. 14 MEMBER THOMAS: Did that risk-15 adjustment model also include say not just 16 Alzheimer's but something into brain injury or 17 something along those lines? 18 MR. GIFFORD: It includes a FIM score 19 which is overall sort of cognitive status, so we 20 capture a lot of those. So, rather than do it by 21 diagnosis by diagnosis we sort of did it more at that functional level with the FIM score. 22

1 CO-CHAIR PARTRIDGE: Thank you. 2 Becky? MEMBER BRADLEY: And I apologize, this 3 4 may not be the right section to discuss this, but 5 I couldn't find it in your submission and maybe I missed it, but since this measure is based off 6 7 the post-acute care pilot that was done by CMS, how many skilled nursing facilities participated 8 9 in that PAC that this research is based on? 10 MR. GIFFORD: This was not based off 11 the PAC demo. We actually collected our own 12 We trained about 500 therapists and had data. 13 three corporations and did it across a number of SNFs and then validated it in about 600 SNFs 14 15 across the country. 16 Since that time, we've got, what is 17 it, Ellen, how many organizations? Forty-six 18 therapy organizations representing over a 19 thousand SNFs collecting this data across the 20 country. 21 MEMBER BRADLEY: Okay, thank you. 22 MR. GIFFORD: But Ann can probably --

how many were in the PAC demo -- SNFs in the PAC 1 2 demo? About 40 SNFs in the PAC demo, but that was for the validation of the instrument and 3 4 We used it to validate the measure here, tool. 5 used 600. 6 CO-CHAIR PARTRIDGE: Sharon, do you 7 have any comments to add to those that Peter made? 8 9 No, he pretty much MEMBER CROSS: 10 covered everything that I was going to comment 11 about. The only question that I had actually 12 13 was related to feasibility, but I was trying to 14 keep in line so, yes. 15 CO-CHAIR PARTRIDGE: Are people -- I'm 16 sorry, Katherine? 17 MEMBER BEVANS: Yes, I have a question 18 first of all about the mobility measure. Is that 19 fair game at this point? Okay. 20 About the applicability of the tool in 21 looking at, and this sort of I think, echos one 22 of Peter's comments about the level of the items,

how sort of difficult they are in reviewing the Rasch coefficient.

It appears that the items are largely 3 4 pretty good at measuring people on the upper end 5 of the mobility continuum as compared to the kind of extreme low end and I'm curious to know your 6 7 thoughts on whether you feel this mobility -this combination of items is going to do a good 8 9 job of sensitively discriminating people who have 10 very low levels of mobility. 11 Is it going to be able to assess 12 change among people who have low levels of 13 mobility both in and at the end of their care? 14 MR. GIFFORD: I think the tool 15 performs relatively well at those extremes. I'11 16 defer to Ann Deutsch from CMS who developed the 17 actual CARE tool to answer that in more detail. 18 But you see the items that's on page 19 seven of the application, you can see the items 20 there that rate on a 1-6 level. They held 21 together and when we did a separate validation 22 through Rasch, it looked and performed equally

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well as in the PAC demo.

2	We did not use Rasch analysis to
3	transform the scores on this. We used the raw
4	scores based somewhat on the comments earlier and
5	the fact that when we calculate this measure with
6	the transformed sore on Rasch and we calculated
7	it without a transformed score, the correlation
8	was .98.
9	And so, to keep the measure simple for
10	providers and members to understand and use it
11	and be able to more calculate it, we elected not
12	to use Rasch in the transforming of the data that
13	was out there.
14	But, because again, as I think
15	Sherrie's been pointing out over and over again,
16	this is a measure of a provider level not
17	individuals. And when you aggregate all this
18	together, a lot of these questions that have been
19	coming up actually become immaterial because it's
20	aggregating at the provider level. This is a
21	provider level measure as are the other measures.
22	MEMBER KAPLAN: Can I just follow that

1 up? 2 So, all of the reliability we still don't have the reliability at the facility level 3 4 nor do we have the validity at the provider --5 the variables here at the patient level for everything, correct? 6 7 MR. GIFFORD: So, we relied on the -for the reliability, we did do what we could do 8 9 with the availability of the data and use out 10 there. We did a bootstrap analysis looking at it 11 over and over again. 12 Yes, I agree, not perfect but it's --13 we did something. No one else has done anything, 14 we did something. You've got to give us some 15 credit on something. Okay? 16 MEMBER KAPLAN: I'm all over it. 17 MR. GIFFORD: You passed everything 18 else with nothing, so we did something. 19 MEMBER KAPLAN: I appreciate the 20 effort and I'm not trying to smoke anybody. Ι 21 just -- or set the bar too high. 22 But, you could do with the data you

have inter-class correlation coefficients, right? 1 2 MR. GIFFORD: Yes, we could probably try to go back and look at it. 3 We did look at the reliability across 4 5 with other instruments because we did this in a number of the SNFs that were doing other 6 instruments and it was very -- it worked with the 7 Barthell and then the other two were sort of home 8 9 grown instruments that they had done, worked 10 relatively well. 11 As far as the validity, we validated 12 the measure with the individual items. We didn't 13 go back and validate them, we relied on the PAC 14 demo where they had done the validation of that. 15 MEMBER KAPLAN: What we were looking 16 for again and again is a thumb print that 17 suggests that there is a reproducible score 18 within facility that can then be used to compare 19 between facility differences. 20 If there is kind of buckshot within the facility, that really weakens the ability to 21 22 use these to compare facilities.

CO-CHAIR STILLE: Should we start 1 2 voting? Becky, did you have -- okay. 3 CO-CHAIR PARTRIDGE: Are we doing it 4 together? I'm sorry, I'm sorry. 5 CO-CHAIR STILLE: Together or 6 separately? 7 CO-CHAIR PARTRIDGE: Together or 8 separately? 9 MEMBER THOMAS: (OFF MIC) 10 CO-CHAIR PARTRIDGE: Yes. 11 CO-CHAIR STILLE: Yes. Right. 12 CO-CHAIR PARTRIDGE: Right, we're just 13 talking about importance, two measures, is that 14 what we're saying? 15 CO-CHAIR STILLE: I think there's a 16 consensus for together. 17 CO-CHAIR PARTRIDGE: Okay. 18 CO-CHAIR STILLE: I don't see any 19 different. 20 MS. ALLEN: Voting on Measure 2613 and 21 Measure 2612, evidence, one yes, two no. Voting 22 starts now.

All votes are in, 94 percent yes, six 1 2 percent no. Voting on performance gap, one high, 3 4 two moderate, three low, four insufficient. 5 Voting starts now. Still waiting on a vote. 6 7 Please vote again. All votes are in, 31 percent high, 56 8 9 percent moderate, six percent low, six percent 10 insufficient. 11 Voting on high priority, one high, two 12 moderate, three low, four insufficient. Voting 13 starts now. 14 Still missing two votes. 15 All votes are in, 63 percent high, 31 16 percent moderate, six percent low, zero percent 17 insufficient. 18 CO-CHAIR STILLE: Okay, now 19 reliability and validity. 20 CO-CHAIR PARTRIDGE: Discussion on 21 reliability and/or validity? 22 MEMBER THOMAS: There we go. So, the

measure is risk-adjusted and I found it to be
 qualified as kind of easy to administer and
 clear. Two data sets were used.

In terms of validity, the developers 4 5 compared the mobility measure to a whole host of other ratings including the five-star rating, the 6 7 Nursing Home Compare and then some specific measures like pressure ulcers, rehospitalization 8 and the like and received or obtained kind of 9 10 mixed results I would say, some good, some moderate in terms of correlation between those 11 12 measures.

13 The one that I wanted to ask you about 14 is was the rehospitalization measure because you 15 expected a certain outcome and apparently it 16 didn't develop that way. So, apparently there's 17 -- was it a negative correlation between improved 18 mobility and increased rehospitalization? Which 19 really makes no sense.

20 MR. GIFFORD: Yes, probably that is 21 reflecting that patient population and the level 22 of improvement. We correlated with the NQF

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endorsed rehospitalization measure and it was a
 different direction.

The correlation was small but it was 3 4 different than we thought. We thought that if 5 better improvement we'd see a lower rehospitalization, that's what the therapists and 6 7 clinicians and the group thought. But we saw the opposite through our direction, I'm not exactly 8 9 sure. 10 All the rest of the measures that were 11 correlated the way they were with five-star 12 either moderate -- mild or moderate. 13 The strongest correlation was with, as 14 one would expect, was with discharge back to the 15 community and it was very strongly and 16 statistically correlated with being discharged 17 back to, you know, which would make sense with 18 both ADL and mobility that's out there. 19 I will add, we also looked at this 20 measure whether it be a changed score and sort of 21 to what you talked about before, Peter, or we 22 used just a discharge score risk-adjusting for

admission and the measure correlated at .98 and 1 2 essentially, that's the exact same measure. 3 MEMBER THOMAS: Okay. MR. GIFFORD: And so, that's why we 4 5 came with just this one measure for that. And what really drove it is that functional level, 6 7 the admission level which is really highly correlated with, as we all know as clinicians, 8 9 through your clinical coming in point. 10 And that rehospitalization piece is 11 probably what was why we saw the differences, 12 it's about the sort of the acuity that's out 13 there, that if you're really sick, you're not 14 going to see as much improvement and get as much 15 therapy to do that. 16 It ended up being sort of a business, 17 but kind of with anything, you can start making 18 any explanations, so I'm not exactly sure why it 19 was with the rehospitalization. 20 I will say that rehospitalization, you 21 know, all the post-acute measures that we are 22 working on and developing, how you address it in

the measures is really critical because it really 1 2 throws everything out of whack. The exclusions, 3 MEMBER THOMAS: 4 ventilator patients, persistent coma, 5 quadriplegic, hospice, children accounted for about, you said in the data, 1.1 percent of the 6 7 patients were excluded, is that right? MR. GIFFORD: Yes, and we actually 8 9 have national MDS data for all. But all four 10 million admissions to the nursing home from CMS, 11 about two and a half Medicare fee-for-service, 12 the rest are non. And we looked at that and 13 nationally, this would be about one to two 14 percent for the exclusions would be excluded. 15 MEMBER THOMAS: So, just a thought --16 MR. GIFFORD: And when we looked at 17 it, whether it was concentrated, because a lot of 18 those are sometimes concentrated in SNFs. There 19 was only, I think, about five or six percent that 20 had more than five percent of their admissions 21 related to those exclusions. 22 MEMBER THOMAS: So, just a thought in
1	terms of the improvement standard not applying to
2	SNFs. If you're already listing SNF-specific
3	conditions like ventilator and coma, et cetera,
4	quads, you might consider some conditions that
5	are typically degenerative or aggressive in
6	nature, some neuromuscular conditions where
7	patients might need that maintenance therapy and
8	not get dings for not improving, if you see
9	what I'm saying.
10	MR. GIFFORD: Yes. No, and there was
11	some discussion. We had a panel of therapists
12	and clinicians reviewing and this was their list
13	that they thought came up.
14	We had a lot of discussion about
15	making sure the default was we wanted to
16	include as many people in this measure even
17	though many of the clinicians had the same
18	concerns you did because we wanted to avoid the
19	game-ability and the unintended consequence of
20	starting to try to avoid it and moving people
21	around.
22	There was a lot of discussion about

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whether there should be some improvement in those 1 2 individuals with degenerative diseases or not. But we can certainly go back and look 3 at that. It's a small population, it wouldn't 4 5 change it that much. MEMBER THOMAS: Other than that, I 6 think the feasibility, over a thousand SNFs 7 currently, you know, collecting this data using 8 9 this measure, but, what are there, are there --10 how many SNFs are there out there? 11 MR. GIFFORD: There is 15,326 SNFs, I 12 believe, last count, though it fluctuates quarter 13 to quarter. 14 And I think, as I said, the IMPACT Act 15 requires the standardization of assessment tool 16 and CMS has leaned towards, and included with the 17 development of the CARE tool and our membership 18 has fully endorsed the adoption of the CARE tool 19 to be inserted into the MDS. 20 We would see this becoming very 21 feasible once it gets incorporated in the MDS 22 widespread. But in the meantime, we have a lot

of people and now that we developed this, a 1 2 number of our members are switching over and starting to use this and the therapy companies 3 4 are starting use it. And we're starting to work on 5 providing this measure should it get through NQF 6 7 to managed care companies who are very interested in this. 8 9 MEMBER THOMAS: And finally, again, 10 the AOTA submitted comments that talk about how 11 mobility is one thing but is a real precursor for 12 deciding whether a person is ready to go home and 13 be independent. That involves things relating to 14 sequencing and problem-solving and temporal 15 appropriateness and memory and a whole host of 16 other things that really aren't included in this 17 measure. 18 You've already said that there are 19 other measure sets that could add some of this? 20 MR. GIFFORD: Yes, I mean we're not 21 saying this is the only measure for post-acute This is a measure to look at the 22 care.

effectiveness of therapy on mobility and we're 1 2 not claiming it any other way. It does correlate -- I think if you're 3 4 looking -- really the goal is how many people are 5 going home and we do have that measure that's out there which is, I think, a better measure to 6 7 capture all that. And then I think there are other --8 9 clearly there are other purposes for post-acute 10 care and you would need other measures to look at 11 I don't think you would smush them all that. 12 into one measure. 13 CO-CHAIR PARTRIDGE: Becky? 14 MEMBER BRADLEY: Earlier on some of 15 the other measures, we talked about the 16 importance of inter-rater reliability and the 17 training of the clinical staff that were 18 collecting this information. 19 Can you describe a little bit how 20 staff is trained and how you assess your inter-21 rater reliability among these measures? 22 MR. GIFFORD: So, one we relied on the

PAC demo and the test they did with reliability. In doing this, we developed a detailed training around the program, particularly where there were variations in the care focusing on where there were variations in the CARE tool from the current MDS scales or other scales they use.

7 We required them to all go through a 8 webinar training. We taped the webinar training 9 to go through. And then they had to take a post-10 test that was a detailed scenario-based testing 11 and they then had to actually rate on the CARE 12 tool for each of those.

I think there were, I think 12
clinical scenarios for mobility and 12 for selfcare. And if you were going to be doing either
setting, you could do both. And you had to get,
I think, it was an 85 percent pass rate which
means you had to score it exactly right.

And there was a lot of discussion amongst the therapists as to what would be right and oh, well, maybe I would rate it a little bit that way but we had a panel that did it and they

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had to get it right and if they didn't they had 1 2 to, you know, go back and get that test and do that. 3 4 And then once the therapists submitted 5 their first assessment, it was reviewed by a coordinator for each of the companies to make 6 7 sure that they were filling out the items correctly and that they had some basis for it. 8 9 And they compared it to the other tool. 10 And so, before they did that, they 11 passed that, they could not submit the data for 12 this analysis. 13 MEMBER BRADLEY: So, is that a 14 requirement ongoing for the organizations that 15 they do that continued testing and training so 16 that you continue to have inter-rater reliability 17 going forward? 18 MR. GIFFORD: You know, it's an 19 interesting question because we were just doing 20 it for this. We envisioned that it would be 21 incorporated into the training of the MDS which 22 CMS does and everything else. We have provided

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this training to CMS.

2	But what's more interesting, maybe
3	Ellen can comment, is a number of the therapy
4	companies and others have taken our training and
5	using it and do you want to comment on how
6	they're using that training to do that so and
7	actually, it's sort of happening on its own. We
8	weren't going to make it a requirement, but many
9	are.
10	MS. STRUNK: Just to follow-up on what
11	Dr. Gifford said, the industry and professions
12	are very interested in trying to gather
13	information and realizing that we're coming from
14	a place where everybody has their own definitions
15	of things and there's no ability to compare.
16	And so, we find ourselves in the
17	situation we're in today with not being able to,
18	you know, explain and justify the care.
19	So, there is a great interest in the
20	industry out there to have something that is
21	compatible across everyone. So, as Dr. Gifford
22	said, we've had hundreds of therapists, it's a

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three hour training.

2 It's free, it's available and we are just trying to highly encourage anyone who uses 3 4 the tool to go through the training and go 5 through it on a regular basis so that we can feel confident in the information. 6 7 MEMBER KAPLAN: I just want to correct myself because I looked harder at the validity 8 9 evidence that you provided and it looks like, 10 although we don't have the facility level reliability, if you use the patient level of 11 12 reliability, variables that you've gotten 13 correlations with other things that are purported 14 to measure quality at this level are -- they are 15 correlated in the range of a third to about half 16 of the reliable variance. 17 So, I correct myself. I want to go on 18 record to just make that observation. 19 CO-CHAIR PARTRIDGE: Are there further 20 comments? Are we ready to vote? Nadine? 21 22 MS. ALLEN: Voting on reliability, one

high, two moderate, three low, four insufficient. 1 2 Voting starts now. All votes are in, 43 percent high, 38 3 4 percent moderate -- sorry, 44 percent high, 38 5 percent moderate, six percent low, 13 percent insufficient. 6 7 Voting on validity, one high, two moderate, three low, four insufficient. Voting 8 9 starts now. 10 We're still missing a vote. 11 All votes are in, 31 percent high, 63 12 percent moderate, zero percent low, six percent 13 insufficient. 14 Voting on feasibility, one high, two 15 moderate, three low, four insufficient. Voting 16 starts now. 17 All votes are in, 25 percent high, 69 18 percent moderate, six percent low, zero percent 19 insufficient. 20 Voting on usability and use, one high, 21 two moderate, three low, four insufficient information. Voting starts now. 22

All votes are in, 31 percent high, 56 1 2 percent moderate, 13 percent low, zero percent insufficient information. 3 Voting on overall suitability for 4 5 endorsement of Measures 2613, Care Improvement in Self-Care and 2612, Care Improvement in Mobility, 6 7 voting starts now, one yes, two no. All votes are in, 100 percent yes, 8 9 zero percent no. 10 CO-CHAIR PARTRIDGE: And I want to 11 thank the association for your patience, for your 12 presentation, both your written materials and 13 your presentation today. 14 We apologize again for keeping you for 15 so long. But thank you for coming. 16 MR. GIFFORD: Thank you. The ends 17 justify the means. 18 CO-CHAIR PARTRIDGE: We're going to 19 give -- Sarah is going to give us a status 20 How are we doing? Well, we cleared the report. 21 first --22 MS. SAMPSEL: So, we have five

measures left and they are split between 1 2 inpatient rehab and long-term care. But it think it's all the same -- it's RTI and CMS. 3 4 So, we'll have them come up and we'll 5 start and move through those and see how far we 6 get. 7 We will be kind of keeping an eye out, you know, we fully recognize a few folks have to 8 9 leave in the next hour or so and, you know, as 10 was mentioned earlier, at the point that we lose 11 quorum which is losing two more people, then 12 we'll have the discussions and vote later. But, 13 we'll see how these go. 14 CO-CHAIR PARTRIDGE: Okay, 2635 is at 15 the intermediate rehab level and we're going to 16 turn to Anne for her presentation or 17 introduction. 18 MS. DEUTSCH: Great. So, high, I'm 19 Anne RTI. Poonam is also with me from RTI and 20 from CMS, we have Tara, whom you met yesterday 21 and Stacy Mandl. And I think on the phone, Tracy 22 Kline, are you there?

1	MS. KLINE: Yes, I am.
2	MS. DEUTSCH: Great, thanks.
3	So, for efficiency, I thought it would
4	be helpful to kind of talk about what the item
5	what the measures have in common and talk about
6	CARE tool in general, clarify a few issues that
7	have come up and then I'll get into talking about
8	each of the different measures. So hopefully,
9	that helps.
10	So, again, the items that we are
11	talking about as part of these four measures for
12	inpatient rehab facilities are care items. We
13	have split the items up into self-care and
14	mobility and the reason that we did that is
15	actually consistent with what Dave Cella had
16	mentioned earlier.
17	So, there was a lot of research done
18	on a lot of functional assessment instruments in
19	the past looking at adding motor-type items and
20	cognitive items together as well as bowel and
21	bladder.
22	And the research showed that those are
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really different constructs or different concepts 1 2 and they really need to be split up. And that's especially important when 3 you're looking at very heterogeneous patients 4 5 across different types of inpatient rehab facilities and potentially long-term hospitals. 6 7 So, that's one of the reasons we ended up doing self-care and mobility as separate 8 9 quality measures. 10 So, and, you know, cognitive, we 11 absolutely believe is very, very important. We 12 think that's actually should be measured in a 13 different quality measure. 14 I also wanted to clarify that the way 15 that the items are scored, for example, with 16 walking, if somebody walked extremely well but 17 they have a -- this individual, let's say, they 18 have a cognitive problem, and therefore, requires 19 supervision, the care score would reflect this 20 cognitive problem. 21 So, even though we consider them kind 22 of motor items, self-care and mobility, there is

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a cognitive component to each of the items. 1 If 2 somebody has cognitive problems, they will not score independently on any of these items. 3 So, again, seven self-care items were 4 5 As mentioned earlier, additional items selected. were tested as part of the post-acute care, post-6 7 acute payment reform demonstration and the items that didn't have good reliability or didn't 8 9 really measure to the construct well were not 10 included in this particular measure. 11 We have 15 mobility items to speak to. 12 I think, Peter, you had a comment about range of 13 ability being measured. So, we do have low 14 functioning items, things like bed mobility and 15 so we do go to a low end. 16 And then we also go to a high end by 17 looking at things like whether the person can 18 from a standing position, pick up an object from 19 the floor. And that's really important because 20 those are the kinds of things that individuals 21 sometimes fall when they're doing those kinds of 22 things after being hospitalized.

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We also have things like car transfers 1 2 which, now a days, is a daily activity whether the person is driving or not after they go back 3 4 to the community or take a taxi, getting in and 5 out of a car is important. So, we have some harder items also across. 6 7 So, we talked a little bit about testing yesterday. We presented in our materials 8 9 the testing across all post-acute care settings 10 as well as testing related to inpatient rehab 11 facilities. 12 Again, the development including 13 expert panels. We had patient representatives on 14 each of our panels. 15 So, we have four measures. The first 16 one is the mean risk-adjusted change in mobility 17 score between admission and discharge for 18 inpatient rehab facility and Medicare patients. 19 The second one is mean risk-adjusted 20 change in self-care score between admission and 21 discharge for inpatient rehab facility and 22 Medicare patients.

The third one is the percentage of 1 2 Medicare inpatient rehab facility patients who meet or exceed an expected discharge mobility 3 4 score. 5 And the fourth one is the percentage of Medicare IRF patients who meet or exceed an 6 expected discharge self-care score. 7 So, the items in the two self-care 8 9 measures are the same. The items in the two 10 mobility measures are the same. We're just 11 aggregating the data differently at the measure 12 level. 13 And the reason that we do that is 14 based on previous research where I created kind 15 of fake public reporting report cards. We went 16 out to consumers and showed them mean change in 17 function scores, self-care mobility. It was 18 fictitious data that we made up. 19 And consumers really didn't understand 20 what that meant. They understood measures that 21 are reported as percentage much better. 22 And so, we felt it was important given

that there's different stakeholders that have 1 2 interest in this data, that for consumers, the percent measures would really be more 3 4 understandable. And for the industry inpatient rehab facilities in this case, looking at mean 5 change in scores is actually what they are used 6 to looking at. So, that's why we have the two 7 sets of measures. 8 9 So, in terms of importance, I want to 10 address, you know, this is the reason inpatient 11 rehab facilities exist, improvement in function. 12 I think we mentioned in our 13 application that there are differences in outcome 14 in the literature that people have reported in 15 terms of race/ethnicity, also length of stay has 16 gone down in inpatient rehab facilities over time 17 and function has actually gone down as length of 18 stay. 19 So, it's really important to pay 20 attention to the financial incentives that are 21 lowering length of stay and could impact the

functional outcomes of patients.

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So, we don't really have a numerator 1 2 denominator, so we -- similar to readmission measures that have been presented, we have an 3 4 observed value that we create, an expected value 5 that's a risk adjusted value and then we multiply the national average so you get a risk-adjusted 6 7 value. Our risk-adjustment model, we spent a 8 9 lot of time, we've got a lot of feedback. We did 10 a public comment and got tons of feedback from I 11 think it was -- I don't remember how many people, 12 but, you know, we have a document, 300 pages of 13 public comment and everything that people 14 suggested we test, we tested in our regression 15 models to see if they were important risk-16 adjusters. 17 We considered both clinical, 18 statistical literature when we put our models together. We were very thoughtful, I think, 19 20 about our exclusion criteria. 21 So, for example, inpatient rehab 22 facilities admit patients with locked-in syndrome

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sometimes in tetraplegic complete. And those
 patients would not be expected to improve in
 walking and so, we have exclusion criteria when
 it is clinically appropriate these patients be
 excluded.

6 Our expert panel was very supportive 7 of all of these exclusions because, as Peter 8 mentioned, unintended consequence, we don't want 9 people to have limited access because they're not 10 going to improve on these particular items.

So, this is a clinician-rated instrument, not patient reported. CMS has historically provided training, I know that's come up. And as part of quality reporting programs has done auditing.

16 Let's see, I want to bring the work
17 comments that were submitted, so I want to
18 address those comments.

So, somebody wrote in and said it was data are based on a cross section study, that's not accurate. It's actually a prospective cohort study that we conducted. So, that's why we have

admission/discharge data. 1 2 We also link claims data so we could look at readmission rates and all that related to 3 4 the data. We did not use CART regression, so I'm 5 not sure where that comment came from. 6 7 We used a generalized linear model with general estimation equations. 8 9 There was a comment that we only had 10 20 or 30 rain injury patients. In fact, we had 11 403, so I'm not sure where that comment is from. 12 Let's see, I guess Dave Cella made a 13 comment earlier about the raw versus Rasch. So, 14 I just wanted to address that because we chose 15 similar to the previous measure, we chose to do 16 the raw sum scores. 17 And that was based on research that I 18 was involved in that looks at minute of the 19 assistants and the raw scores, as Dave Cella 20 suggested, actually were more correlated with 21 minutes of assistance than the Rasch measures. 22 So, happy to provide a reference if people would

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like that.

2 But, basically, minutes of assistance is our gold standard. Minutes of assistance is 3 ratio level data integral level so that is an 4 5 appropriate gold standard I think. I think that's it. So, did you want 6 7 to add anything else? MS. MANDL: All right, I've been 8 9 asked, this is Stacy Mandl from CMS. 10 I've been asked to clarify on the submission of data for Medicare beneficiaries. 11 12 Currently, through regulatory 13 requirement, through regulation, the data for the 14 IRF-PAI to CMS is required on Medicare 15 beneficiaries. And so, therefore, and the cohort 16 for this particular measure is going to be 17 Medicare for the IRF-PAI data that comes in. 18 Thank you. 19 MS. DEUTSCH: So, I'll pass it back to 20 the chairs. 21 CO-CHAIR PARTRIDGE: All right. So, 22 would we want to start with 2635 as our

discussion?

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2	And it's Ann and Dawn.
3	MEMBER MONROE: I was concerned that
4	it was Medicare-only. I think that's a limited
5	look at the world and could result in a lot of
6	duplication of effort on the part of the
7	facilities, but that is what it is.
8	I want to ask you about, when I read
9	this, I had trouble distinguishing what it was
10	you were really trying to measure.
11	Was it how well the therapies or the
12	work within the IRF had done by the time someone
13	left or was it that the score when they left was
14	a predictor of how they would do in the
15	community?
16	And you said that in a couple of
17	places, but if that's going to be the case, then
18	I need to better understand why you think the
19	five today is a predictor of success in the
20	community and what you did to answer that
21	question.
22	Because this one seems, in my mind,

that you're taking a longer view than some of the 1 2 others we've seen which has changed from pre- to post-. Is that clear? Do you understand what 3 4 I'm saying? So, we are looking at 5 MS. DEUTSCH: the change between admission and discharge. 6 7 MEMBER MONROE: Right, but --So, that's consistent 8 MS. DEUTSCH: 9 with the other measures that have been presented. 10 MEMBER MONROE: But one of the things 11 you say in here is that because that score at discharge, I thought, is predictive of success in 12 13 the community. 14 Right. MS. DEUTSCH: 15 MEMBER MONROE: And so, I'm asking for the connection between the score at discharge and 16 17 success in the community. 18 MS. DEUTSCH: Yes, so that was part of 19 the general literature overview. And we did do 20 analyses and maybe, Poonam, you can look this up 21 specifically, but we looked at what the 22 relationship between the discharge scores and

whether people went back to the community or not. 1 2 So, a patients who were --MEMBER MONROE: Or how well they did 3 in the community, is that different than going 4 5 back? MS. DEUTSCH: Well, so we reported 6 like, I think in our supplemental material, the 7 average scores of patients who went in the 8 9 community versus those who didn't to show that 10 relationship. 11 And that reference to doing well in the community is just part of our literature 12 13 review. We didn't -- so that's just part of the 14 evidence from the literature, not specific 15 analyses. 16 Does that help? 17 MEMBER MONROE: Well, it answers my 18 question, I guess. Because, to me, the outcome, 19 when you talk about it as an outcome measure, 20 you're really saying it's not patient outcome in 21 terms of their success in their functioning in 22 the community, it's the outcome is how they left. Right? Which I would wonder is perhaps not an outcome measure but, I don't want to pursue this too.

MS. MCMULLEN: So, one of the many uses of this measure is to be able to assess an individual as they traverse the care continuum.

7 It's our idea of standardization, so 8 you'll see that presented in the panel the last 9 two days. We had two LTCH measures, we have 10 these four IRF measures and under the IMPACT Act, 11 you know, we have to standardize in all these 12 settings and things of that nature.

These measures are developed in a way that from admission to discharge, we are able to see a change in functional independence in either self-care or mobility so that we, through these measures, have uniform outcomes so we can link all these outcomes.

So, if someone enters into an LTCH,
they move into and IRF, they move into a SNF,
they go into a home health agency and their
service is in that setting, that we're able to

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follow them and to assess the complexity within
 those changes.

3 So, simply at this very point in time, 4 these measures were created for those linking 5 purposes among other purposes. It was for the 6 purpose of standardization.

So, you'll see that the one LTCH
measure with the vent, but with the four RIF,
they are created there so we have those uniform
outcomes.

I don't know if that helps with some of the outcome and kind of conceptualizing the form measures and why they're developed, but it was for the sake of uniformity.

15 MEMBER DOWDING: I just have a query because this particular measure we're talking 16 17 about, just for the benefit of the people around 18 the room who may not have read it in detail, is 19 that, with this particular measure, you're 20 calculating an expected score on discharge on 21 admission and then comparing their actual score 22 on discharge to that expected score. And that's

different to the mean change in function or self 1 2 care at discharge. That's very different in terms of conceptualization, and it depends a lot 3 4 on the accuracy of the risk-adjusted expected 5 It's not a normal risk adjustment. models. The risk adjustment is actually saying what do we 6 7 expect this person to do on discharge, so that's quite a different conceptualization, if I've 8 9 understood it right because I might not have 10 understood it right. It's quite a complicated 11 thing to get your head around. 12 MS. DEUTSCH: So there's four 13 measures. 14 MEMBER DOWDING: Yes. 15 MS. DEUTSCH: So there's two self-care 16 measures and two mobility measures. So for one 17 self-care measure and one mobility measure, we're 18 looking at change in function. 19 MEMBER DOWDING: Yes, because that's 20 not this measure. This is the expected change --21 MS. DEUTSCH: I was kind of describing 22 all four together at first, and then you're

1 right. I mean, there's two that are change, and 2 those are risk-adjusted values. And then we 3 also, secondarily, have this percent of patient 4 who meet or exceed a benchmark, which in this 5 case is the risk-adjusted value. So there's one 6 self-care measure for that and one mobility 7 measure for that, yes.

8 MEMBER DOWDING: Yes. So why have we 9 got four? Why don't we just have the two and 10 change? Why have we got this very complicated 11 expected risk-adjusted model, which, actually, 12 for the discharge self care isn't actually that 13 bad, but for the other ones the actual predicted 14 values are pretty low. So I would be really, 15 really unhappy if I was an IRF and I was being 16 expected to reach a functional score which only 17 predicted 30 percent of patient outcomes. So I 18 don't understand why we've got four, why we don't 19 have the two. And it's just, you know, why are 20 we over-complicating things, in my view. 21 MS. DEUTSCH: So I guess, I mean, the

data collection isn't different for the two

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measures.

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2 MEMBER DOWDING: No, I know, which, again, my reason is why are you calculating two 3 different scores, which, essentially, you're 4 5 using the same data? I just don't understand why we have four and not two. 6 It's just a --7 MS. DEUTSCH: Right. So as I mentioned, in other research that I've done we 8 9 actually prevented change scores to consumers. Ι 10 went out to some, you know, day programs for 11 elderly, and the consumers that we presented, 12 they did not understand what a change score was. 13 They did understand quality measures that were 14 reported as percentages, so I think it's really 15 the issue that we have different audiences for 16 these quality measures and so they have a 17 different understanding and ability to understand 18 some of these things, I think. 19 CO-CHAIR PARTRIDGE: Anne, it seems to

20 me what you're talking about is we've got the 21 same data, we can furnish either, we can present 22 it to you either way, and it's really a question

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for the ultimate user which way they want to go. 1 2 And so I think I'm echoing Dawn's question: do we 3 have to have separate measures, or can we have a 4 single measure with the option to report? MS. DEUTSCH: I wouldn't know how to 5 fill out an NQF application and not make it 6 7 complicated by doing it two ways, and so that's why we presented it as two different quality 8 9 measures. 10 Helen and Sarah? CO-CHAIR PARTRIDGE: 11 DR. BURSTIN: It's a good question. 12 I mean, it probably is a complexity of our form 13 that makes that hard to do. We do sometimes have 14 measures that are submitted with two rates in the 15 I think, just given the complexity same measure. 16 that I think was just pointed out, that's 17 probably hard to do. I mean, one question might 18 be should they at least be paired so that you at 19 least have an option of when you see one you see 20 the other, which might be one way of getting 21 around the idea of looking --

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MEMBER DOWDING: And that also goes to

my anxiety about what then these are used for 1 2 because if you have two different measures, they're using the same data but just analyzing it 3 4 slightly differently, which one of the IRF 5 facilities are actually going to be held accountable to and which one their pay going to 6 be accountable to? It can't be both because 7 you're using the same information. And, again, I 8 9 would be very worried about the expected change 10 one, them being held accountable to that one, 11 because of the variation in the predictive models 12 that you're using.

13 MS. MANDL: This is Stacy from CMS. 14 I'd like to jump in on the policy question. 15 These measures aren't used for pay for 16 performance. They're not, we're not seeking 17 endorsement for measures for use for pay for 18 performance. That's a whole other ball of wax. 19 It's the same data elements used to be able to 20 calculate the two variations of the same measure. 21 Consumer feedback, which moves beyond what Anne 22 has suggested, is it's an exponential request

1 that the consumers be able to use this data. The 2 facilities need the data, as well, for other 3 purposes. They're very separate but both very 4 meaningful.

5 But I just wanted to just make sure 6 that the data coming in and the completeness of 7 the data coming in and the accuracy of the data 8 coming in is of the same data. So I just wanted 9 to clarify. These are penalty for failure to 10 report programs. Thanks.

11 So I don't have a MEMBER BIERNER: 12 concern with it. I think it will be very useful 13 for us, as an institution, to report to our 14 consumers, the clients that we seek to attract, 15 to present it in the percentage format or the 16 benchmark kind of format for public purposes and 17 then the other format for internal or for 18 reporting purposes.

19 So I like this score overall, but my 20 question is compare for me what you see as the 21 differences between this and what we've heard 22 earlier from the uniform data system measure,

which is using this Rasch format. Compare to me 1 2 how you think yours is better or in what way it's different from that. 3 4 CO-CHAIR PARTRIDGE: We aren't in that 5 discussion, but, if you want to answer the question, go ahead. 6 7 DR. BURSTIN: We typically look at comparison to other measures after something has 8 9 been approved, so we probably don't need to do 10 that right now. MEMBER BIERNER: Well, then tell me 11 12 about the six-point scale that you use. 13 MS. DEUTSCH: Yes, sure, sure. I'11 14 talk about the instrument, the items. So six-15 level scale. Six is independent, five is setup 16 or clean-up, level four is supervision/minimal 17 assistance, level three is moderate assistance, 18 level two is substantial assistance, and level 19 one is dependent. Basically, as part of the 20 post-care payment reform demonstration and 21 instrument development, we had a lot of expert 22 panels. We reviewed all of the existing

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instruments: the OASIS, the FIM, IRF-PAI, you know, MDS. We asked for input. We also looked at literature, you know, what fit within what construct, what was reasonable in terms of scoring.

6 So for example, we got a lot of 7 feedback that supervision takes a lot of time 8 with patients, especially at the time of 9 admission, the cognitive scores. So supervision 10 is actually coded level four on the CARE tool, 11 which is different than the FIM. And that was 12 the rationale.

13 Also, you know, the FIM allows up to 14 25 percent effort from the patient for level one. 15 But in talking to clinicians, they felt that 16 having a dependent score that was truly somebody 17 dependent was really important. So then if 18 somebody came in totally dependent, perhaps, you 19 know, minimally conscious, and then they made 20 some improvement, there would be documentation on 21 the CARE tool. They would go from a one to a 22 two.

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And so, you know, again, this goes 1 2 back to what Peter said. Somebody who comes in very low level, are you going to see improvement? 3 4 And in this case, that was the feedback that we 5 heard from clinicians. They wanted to have that. So does that help? 6 MEMBER BIERNER: 7 Yes. 8 MEMBER BRADLEY: And maybe I 9 misunderstood the representative from CMS that 10 addressed the payment. Did I understand you to 11 say that, for payment for IRF, they would 12 continue to use the IRF-PAI? Would the uniform -13 - with the FIM embedded in that and going 14 forward. So is that what you said? I'm sorry. 15 I didn't understand that. 16 MS. MANDL: I'm not sure I'm 17 understanding. 18 MEMBER BRADLEY: So right now, for 19 payment purposes, there is a tool, the IRF-PAI, 20 inpatient rehabilitation hospitals are required 21 to use, and it has a scale already embedded in 22 that that drives our payment system.

No. What I was referring 1 MS. MANDL: 2 to is the question about Medicare only. Our data source is the IRF-PAI, and it's submitted, the 3 4 regulation dates way back for multiple purposes, 5 including care planning, as well as payment. But that's the regulatory requirement, and that's 6 7 what drove -- when responding to the questions on the form for NQF, what's the population, it's 8 9 So that's all I was referring to. Medicare. 10 MEMBER BRADLEY: So I guess my 11 question is is that scale going to continue to be 12 Because here this, I guess, not so much used? 13 competing measures but inter-rater reliability. 14 So if they're using a seven-point scale for the 15 payment on the IRF-PAI and then a six-point scale 16 of the same types of items and collecting 17 different measures, it seems like it would be 18 very confusing and the possibility of clinicians 19 getting confused about do I use a six-point scale 20 here or a seven point because the measures are so 21 similar but different.

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MS. MCMULLEN: Right. So we can't
speak to what will happen with IRF. As it stands 1 2 today, we have the scales that we use. We've developed these measures, the CARE measures, to 3 4 see, and even out of the Post-Acute Care Payment 5 Reform Demonstration and the development of the CARE tool, the idea was to see if standardization 6 7 could happen between multiple different types of assessment items within multiple different types 8 9 of assessment instruments. And we have, CMS has 10 been moving in the way with RTI as our contractor 11 to be able to develop measures to see if 12 standardization is possible. So that's where we 13 are today is we're presenting these measures for 14 consideration of endorsement, and these are the 15 first set of standardized measures that we've 16 been developing.

17 MEMBER BIERNER: Can I just say that 18 the six is actually more intuitive for most of us 19 who've worked in rehab and for a lot of 20 therapists and others than the seven have been, 21 so, actually, the terminology is more 22 conventional. So I like the six.

1 CO-CHAIR PARTRIDGE: All right. I see 2 Sherrie's card and I see Peter's hand up, so Sherrie? 3 4 MEMBER KAPLAN: This is, you know, the 5 same old, same old. So on table one, these are average Cronbach's alphas at the patient level by 6 7 facility. They're not the ICCs that we've been talking about. 8 9 MS. DEUTSCH: Correct. So our data 10 are from the Post-Acute Care Payment Reform 11 Demonstration, and we only had data for either 12 six or nine months from the facilities, so we 13 weren't able to compare data over time. The measure time frame is 12 months. 14 15 MEMBER KAPLAN: But you said something 16 about generalized estimation equations, and then 17 I was thinking, well, where are the splines? You 18 know, where are the nice little facility-level 19 error bars on the splines? 20 MS. DEUTSCH: We can get those for 21 you. 22 MEMBER THOMAS: I want to go back to

1 the two different measures that you are using for 2 both mobility and self care. So it seems to me, and I just want to get your point of view, it 3 4 seems to me that it's probably, it seems to me to 5 be more accurate to assess the change in function between admission and discharge, assuming that 6 7 some gaming, I suppose, could take place, etcetera, than to come up with an expected 8 9 functional level and then see how you achieve 10 that, whether you exceeded it or didn't exceed it or hit it. So it strikes me as being less 11 12 reliable to introduce that kind of subjective, 13 somewhat subjective, kind of expectation of how 14 well a person is going to do, and it's got all to 15 do, I'm sure, with all kinds of comorbidities and 16 all kinds of things. 17 And I guess my concern is what's to 18 prevent providers from expecting low and exceeding high and looking really good in terms 19 20 of how well they do? 21 MS. DEUTSCH: So to address your first 22 comment, so certainly looking at change. We've

got much more granular data. We're taking 1 2 advantage of every piece of data that we have. So you're absolutely right, there is more detail. 3 I think the percent measures, it's 4 5 just to make it more understandable to consumers, So I can't speak to reliability. 6 again. We didn't have enough data to be able to test it. 7 And, certainly, I think that it's a great 8 9 question and we should do that. But in terms of 10 the expected value, I mean, the self care, I 11 think, is like 85 covariance. And we look at 12 comorbidities. We look at, you know, the 13 clinical condition. We included interactions in 14 our models. We tried to adjust for as much as we 15 could. Our mobility, I think, has 85 covariance 16 and our self care has, like, 74. So, I mean, we 17 did a lot of work on the risk adjustment to do as 18 good a job as we can. Does that address it, 19 Peter? 20 MEMBER THOMAS: It does. Thank you. 21 CO-CHAIR PARTRIDGE: Are we ready to 22 The staff's suggestion is that we vote? Yes?

take a look at two by two, 2635 and 2633, both of 1 2 which are the met or exceeded with respect to self care. 3 4 MEMBER DOWDING: Can I just clarify? 5 Are we going to discuss reliability and validity of these particular measures after --6 7 CO-CHAIR PARTRIDGE: Yes, importance Is that acceptable? Okay. The two that 8 first. 9 relate to -- no, no, I'm sorry. Met or exceeded 10 and the other self care one. 11 MEMBER BIERNER: Self care, self care. 12 CO-CHAIR PARTRIDGE: Self care, self 13 I'm having trouble reading my own care, yes. 14 Okay. Nadine? notes. 15 MS. ALLEN: Voting on measure 2635 and 16 2633, discharge self-care score and change in 17 self-care score evidence: one yes, two no. 18 Voting starts now. All votes are in: 94 percent 19 yes, 6 percent no. 20 Voting on performance gap: one high, 21 two moderate, three low, four insufficient. 22 Voting starts now. All votes are in: 13 percent

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high, 75 percent moderate, 6 percent low, 6
 percent insufficient.

Voting on high priority: one high, two moderate, three low, four insufficient. Voting starts now. All votes are in: 56 percent high, 38 percent moderate, 6 percent low, zero percent insufficient.

8 CO-CHAIR PARTRIDGE: Scientific
9 acceptability. Either. Reliability and
10 validity, Dawn?

11 Okay. Well, this is MEMBER DOWDING: 12 specifically with 2635, which is the one that I 13 was asked to review in detail, which is the 14 expected versus actual discharge, self-care 15 discharge scores. And I just, I mean, I read 16 through it a couple of times and you've got 17 really good data on the reliability and validity 18 of the CARE scale. I mean, we've demonstrated, I 19 think, fairly comprehensively that it's a 20 reliable and valid way of connecting data, but 21 that's not the measure we're being asked to 22 endorse. We're being asked to endorse your

1 calculation of a score related to somebody's
2 function at discharge compared to what their
3 expected score would be based on this risk4 adjusted predictive model, and I couldn't see any
5 data on the reliability and validity of that
6 measure.

7 MS. DEUTSCH: So let's see. We sent some supplemental information that had the 8 9 relationship between discharge scores and 10 discharge to community. I'm sorry. Oh, and also 11 the relationship between the CARE scores and 12 length of stay, so that kind of speaks to some 13 validity issues. At the scale level, you know, 14 we presented several scale-level analyses. So, 15 like, the discharge score is basically what the 16 items as a group together and whether people meet 17 that benchmark or not.

So we provided reliability. I called it scale level because it's the group of items. So does that help? MEMBER DOWDING: Well, I mean, I don't

have a problem with the score or the status.

It's this whole distinction between the scale 1 2 that you're using to develop the measure and the measure itself, and the measure itself is this 3 4 expected versus actual function at discharge. 5 And that's the measure we're being asked to endorse. So we're not being asked to endorse how 6 7 good the CARE scale is. We're being asked to endorse your ability to measure this at 8 9 discharge. 10 And I didn't see the additional data, 11 so I apologize. Can we bring it up so we can 12 have a quick look to see how the -- because 13 that's predicted validity, but there's still no 14 data on the reliability of that measure. Does 15 that make sense? 16 MS. DEUTSCH: So are you asking for 17 facility-level reliability? 18 MEMBER DOWDING: Yes. So we didn't --19 MS. DEUTSCH: Yes. 20 yes, this is similar to what Sherrie asked. Ι 21 mean, we don't have multiple years of data, so 22 we're not able to do that. So, I mean, I think

1	NQF provides guidance that the measure can't be
2	high, but it certainly can be moderate if you
3	provide item level and scale level
4	MEMBER DOWDING: And I think that the
5	care-level data is exceptional. It was more a
6	query than anything else because, I mean,
7	conceptually, I'm just having trouble getting my
8	head around this expected versus actual. And for
9	this particular measure, the actual predictive
10	model, I think, is 0.53 prediction, so it's not
11	too bad. I would be concerned about the other
12	one.
13	MS. DEUTSCH: Great. Believe me, I'd
14	love to have more data.
15	MEMBER DOWDING: Yes, I'm sure you
16	would. I'm sure you would. I mean, it would
17	help if we could see the predictive stuff.
18	CO-CHAIR PARTRIDGE: We're all taking
19	a deep breath up here because I think this issue
20	has come up 16 times over the past two days, and
21	we're all extremely uncomfortable with trying to
22	assess a measure at the level of a specific

provider entity without having that data. 1 2 MEMBER DOWDING: Yes, I mean, I sort of feel quite uncomfortable about being asked to 3 4 endorse a measure for which we have no 5 reliability data. I mean, it's just, you know, the scale measure is one thing, but it's going to 6 be used at the facility level as a measure and 7 being fed back to patients, and we don't have the 8 9 data to assess it. It's not, it's just not 10 there. 11 And in some CO-CHAIR PARTRIDGE: 12 situations, we have had the capacity to go back 13 and get it. In this particular situation, I 14 think it's very clear we don't. 15 MEMBER KAPLAN: Can I weigh in here, 16 though? Because --17 CO-CHAIR PARTRIDGE: Sherrie? 18 MEMBER KAPLAN: -- they do have some 19 You've obviously got generalized data. 20 estimation equation data that have splines with 21 error bars around each facility's performance 22 that, actually, we could use to see how good we

are at, you know, discriminating versus errors in
 the distribution of facilities. So if you could
 give us those data, that would actually help a
 lot.

5 MS. DEUTSCH: Sure. And, I mean, we 6 did present facility-level data, a mean, median, 7 range, from the facilities we had.

A brief comment. 8 DR. BURSTIN: Ι 9 mean, I think sometimes what we see, as measures 10 get out into use, we start getting a lot of this 11 information. And so, you know, as we continue to 12 explore what are requirements are for these 13 issues, it's not simple, by any means. You know, 14 one question might be, for example, by the annual 15 update or something like that, can we ask that 16 some of these additional data be brought back. 17 You are a standing committee. You will still 18 have standing in a year. There may just be ways 19 for us to fully recognize there's only so much 20 they can when the measures are not yet in play. 21 MEMBER KAPLAN: But aren't you guys 22 exploring at NQF tiering approvals, too, levels

of, like, you know, phase one, you know, tiering
 for these purposes or those, generating data
 versus accountability?

4 DR. BURSTIN: Not yet. Right. And 5 that's, I think, what we're finding to be the rub these days is that, you know, with the increasing 6 influence of pay for performance, the anxiety 7 about pay for performance, there is higher 8 9 expectation of wanting to see some of those data. 10 We get that, and that's what we're exploring.

But, again, there are opportunities, with you being a standing committee, to potentially get that information as they gather it and bring it back to you for additional rereview at a later date.

16 MEMBER BRADLEY: Could I just ask 17 then, so it sounds like you're hoping to gather 18 more data. How many IRFs do you have using this 19 tool right now and how will you collect that data 20 so that you have enough data to bring back? 21 MS. MCMULLEN: So we can't speak to 22 future direction of measurement use at this point

because, as you know, I mean, with the IMPACT Act 1 2 or whatnot, we're in a tough, difficult time line, and CMS is basically in the planning stages 3 4 of figuring out how to specifically meet that 5 mandate. At the current time, the data that we do have is from the CARE tool, the PAC PRD 6 7 demonstration. It is our full intent in the future to be able to collect data on this so we 8 9 can come to the table with measure-level data to 10 be able to present a more accurate case for the 11 outcomes and how appropriate the outcomes are for 12 this specific area and domain.

13 But there's a lot, there's a lot up in 14 the air right now because the IMPACT Act is not 15 only our only mandate that we're faced with right 16 now. We were given about two mandates within a 17 month and a half. So to the future direction at 18 this time, we can't speak to, but when CMS knows 19 a future direction they will absolutely make that 20 known.

21 MEMBER BRADLEY: Okay. So I guess 22 then you really don't have the capability of

collecting a lot of the ongoing data at this
 point in time.

MS. MCMULLEN: I don't know if it's 3 4 about the capability. I think the capability is 5 always there. It's just the plans for CMS and what CMS intends to do in terms of collecting 6 that data, and I -- definitely above my paygrade 7 -- can't speak to that. Sorry. 8 9 CO-CHAIR PARTRIDGE: The question 10 before us, again, and it's common to both 11 measures, is we don't have facility-level data. 12 They can supply some data which might make 13 Sherrie Kaplan happy and, thereby, perhaps some 14 other member so of the Committee happy. And we 15 have faced this issue before. So I think, unless 16 people object, we're ready to proceed on. Again, 17 it would be both. And Nadine? We believe it 18 works for both because it's the common issue. 19 The facility issue is common, yes. 20 MS. ALLEN: Voting on reliability: one

21 high, two moderate, three low, four insufficient.
22 Voting starts now. All votes are in: zero

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percent high, 47 percent moderate, 13 percent 1 2 low, 40 percent insufficient. Voting on validity: one high, two 3 moderate, three low, four insufficient. Voting 4 5 starts now. All votes are in: 7 percent high, 47 percent moderate, 7 percent low, 40 percent 6 7 insufficient. Voting on feasibility: one high, two 8 9 moderate, three low, four insufficient. Voting 10 starts now. All votes are in: 27 percent high, 11 53 percent moderate, 20 percent low, zero percent 12 insufficient. 13 Voting on usability and use: one high, 14 two moderate, three low, four insufficient 15 information. Voting starts now. All votes are 16 in: 20 percent high, 47 percent moderate, 20 17 percent low, 13 percent insufficient. 18 Voting on overall suitability for 19 endorsement of Measure 2635, discharge self-care 20 score for medical rehabilitation patients, and 21 Measure 2633, change in self-care score for medical rehabilitation patients: one yes, two no. 22

Voting starts now. Still missing a vote. 1 All 2 votes are in: 67 percent yes, 33 percent no. DR. BURSTIN: Any of the developers 3 4 who have to stay around for this, please feel 5 free to partake. 6 MS. SAMPSEL: Operator, can you open 7 the line for public comment? OPERATOR: All right. If you'd like 8 9 to make a public comment, please press star and 10 then a number one. No, no public comments at 11 this time. 12 MS. SAMPSEL: Okay. Thank you very 13 much. We're taking a break for lunch. 14 (Whereupon, the above-referred to 15 matter went off the record at 12:23 p.m. and went 16 back on the record at 12:55 p.m.) 17 CO-CHAIR STILLE: Welcome back. Let's 18 get started. 19 CO-CHAIR PARTRIDGE: We are going on 20 to voting. I think she's going to take root 21 here. 22 CO-CHAIR STILLE: Sure. Yes, I think,

1	you know, we need to have some just sort of
2	discussion about stuff, but then we're voting.
3	No, I don't think we need any more from you, I
4	don't think.
5	CO-CHAIR PARTRIDGE: But don't go
6	away.
7	CO-CHAIR STILLE: But don't go away.
8	We appreciate your presence.
9	CO-CHAIR PARTRIDGE: Yes, that's our
10	third.
11	CO-CHAIR STILLE: Yes.
12	CO-CHAIR PARTRIDGE: It's the last one?
13	CO-CHAIR STILLE: It is. It is the
14	last one. Okay, all right. The first one we're
15	going to consider is do we have a quorum? We
16	have 14. They're just somewhere in the room
17	eating. Okay.
18	The first measure we'll consider is
19	2634, inpatient rehab facility functional outcome
20	measure change in mobility score for medical
21	rehab patients. And I and someone who is sick
22	are the primary discussions, so I'll talk about

1

that.

2	Essentially, it looks at the change in
3	mobility score between admission and discharge,
4	does risk adjustment, and that's for IRF Medicare
5	patients. So all those clauses and caveats in
6	there. And let's see. In general, I'll just
7	sort of summarize some of the comments and add a
8	couple of things myself. The rationale for
9	having a measure of this is important medical
10	rehab for almost everyone. Enhancing mobility is
11	a primary goal, so it seems to be supported.
12	There is a good score distribution and
13	definitely room for improvement, given the
14	numbers that are there. And there are some
15	disparities that are also mentioned with race,
16	ethnicity, insurance type, and region of the
17	country. So that is good.
18	Other things. Well, there's a lot of
19	validity and reliability things that we could
20	talk about, but I think, in terms of the face,
21	you know, it's Medicare patients only, so that's
22	a little bit of a limitation in terms of the

It's IRF only, but it is what that is. 1 group. 2 And so, in terms of importance, I think it's got, you know, pretty good stuff on the surface. 3 4 So other thoughts and comments about 5 importance? Again, this is 6 CO-CHAIR PARTRIDGE: 7 the same pair of measures as we discussed just before our lunch break. The companion is 2632. 8 9 CO-CHAIR STILLE: Thirty-six? 10 CO-CHAIR PARTRIDGE: I'm sorry. 11 Thirty-four and thirty-six. Only in this case, 12 we're talking about mobility, rather than self 13 care. 14 CO-CHAIR STILLE: Right. So 36, which 15 I didn't review in detail, is the difference from 16 expected, I guess, right? 17 CO-CHAIR PARTRIDGE: Okay. Any comments 18 or questions? Any comments or questions? Peter? 19 MEMBER THOMAS: Okay. So can we just 20 assume that all of the prior discussion we had on 21 the self care that applied, you know, just kind 22 of incorporate by reference, so to speak?

	2
1	CO-CHAIR STILLE: Sure.
2	MEMBER THOMAS: I'm not sure that
3	fully does justice to airing those issues, but I
4	had the same basic concerns that I had in the
5	first one with this one and the same questions.
6	They weren't all concerns. They were just.
7	CO-CHAIR PARTRIDGE: Becky?
8	MEMBER BRADLEY: I just wanted a
9	little bit of clarification. Since it's Medicare
10	only, were the disparities you found related to
11	insurance payments? I wasn't sure how was it
12	within the insurance, like managed Medicare
13	versus Medicare, or could you just address the
14	disparity?
15	MS. DEUTSCH: All right. Can you hear
16	me now. So that was literature that we cited, so
17	Tim Reistetter at University of Texas Medical
18	Branch did that study and he looked at,
19	basically, public versus private. So it wasn't
20	from our data. That was from the literature.
21	MEMBER BRADLEY: And just help me
22	understand because some of the measures aren't

200

1	limited to Medicare patients with the CARE tool
2	and some are. Can you explain why this one is
3	and some of the others that were presented
4	earlier are not?
5	MS. DEUTSCH: So the IRF ones are
6	limited to Medicare only, and, again, Stacy
7	provided the rationale. The Long-Term Care
8	Hospital Quality Reporting Program was
9	established as an all-payer program, and so,
10	obviously, when we're able to get all-payer data,
11	we want the measure to be all-payer. So anything
12	no, that's it.
13	CO-CHAIR PARTRIDGE: Are there any
14	other questions or comments before we vote on
15	importance?
16	CO-CHAIR STILLE: Peter?
17	MEMBER THOMAS: Forgive me. I just
18	wanted to say, in case people weren't aware of
19	it, that you talk about these measures as being
20	quality measures or pay-for-performance measures,
21	but I think there's an assumption by many people
22	around the room, probably rightly so, that

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today's quality measure will eventually become or 1 2 is likely to become some kind of a pay-for-3 performance measure. But in IRFs, there's 4 currently requirements for pay for performance. 5 There's a two-percent reduction in payments if you don't submit certain quality data, and I 6 7 don't know how these specific measures factor into that, but I was trying to figure out what 8 9 that connection might be. 10 MS. MANDL: So the Inpatient Rehabilitation Quality Reporting Program was 11 12 established with Affordable Care Act, Section 13 3004. It is a penalty for failure to report. 14 It's not a pay-for-performance program. So I 15 just wanted to clarify that. So does that --It's helpful. 16 MEMBER THOMAS: That's 17 helpful. The larger comment I made, I think, 18 still stands, but thanks for clarifying that. 19 MS. MANDL: Sure. 20 CO-CHAIR PARTRIDGE: Are there further 21 questions? Are we ready to vote? 22 MS. SAMPSEL: For a quorum right now,

we need 13 of 17, so we had two members that are 1 2 not participating today. We're still okay. The doors are now locked. 3 4 MEMBER BRADLEY: Are we voting on 5 these as a pair, like we did --CO-CHAIR PARTRIDGE: We are voting on 6 7 these as a pair. MS. ALLEN: Voting on evidence for 8 9 Measure 2634, change in mobility score, and 10 Measure 2636, discharge mobility score evidence: 11 one yes, two no. Voting starts now. All votes 12 are in: 100 percent yes, zero percent no. 13 Voting on performance gap: one high, 14 two moderate, three low, four insufficient. 15 Voting starts now. All votes are in: 23 percent high, 62 percent moderate, 15 percent low, zero 16 17 percent insufficient. 18 Voting on high priority: one high, two 19 moderate, three low, four insufficient. Voting 20 starts now. All votes are in: 54 percent high, 21 46 percent moderate, zero percent low, zero 22 percent insufficient.

So now we'll 1 CO-CHAIR STILLE: Okay. 2 talk about reliability and validity. I think there's a little bit more to talk about in that 3 way, although some of the discussion from the 4 5 last thing is important. Generally, you know, for 2634, inter-6 rater reliability was calculated a couple of 7 Item and scale reliability were done and 8 ways. 9 It was tested in a variety of venues. were good. 10 There was content validity that was tested 11 against several other instruments for most of the 12 A few didn't have a counterpart. items. 13 Then I just wanted to kind of go over 14 some of the comments from the rest of the 15 Committee, too, as well as an external comment, 16 which was important. I think Dawn's concern 17 about 2635 extends to 2636, given the expected 18 versus actual score calculation. We don't have 19 good data about that, I don't think. And there 20 was no detail on exactly how that was developed. 21 There was a critique from UDSMR that 22 was concerned with test-re-test reliability.

Maybe the developers can talk about that because 1 2 I know you talked about some of their other concerns for the other one. And maybe I'll stop 3 there and then talk about the validity concern. 4 Are you ready to talk about that 5 quickly? You need a minute? Okay, I'll talk 6 7 about -- oh. 8 MS. DEUTSCH: Okay, great. So we 9 presented inter-rater reliability, so I guess 10 I'll just generally speak to that overall. So 11 the first inter-rater reliability is kind of this 12 traditional where we had two therapists or two 13 nurses go into a patient's room. They both did 14 an assessment. So let's say Poonam and I worked 15 at the same facility. We would go in and do the 16 assessment. The instructions were people could 17 not talk, but then we'd both independently score, 18 and that was compared. Laura spent the evening 19 yesterday and did a lot of the analyses, and we 20 did both weighted and unweighted kappas. 21 Overall, that was good. We 22 definitely, in the PAC demo, had some items that

didn't test as well, and those are not being 1 2 proposed. So, you know, I just want to be sure you understand that we tested like a whole, a 3 4 very long instrument, data tool, but not 5 everything is being moved forward. Because perhaps Poonam and I were both trained at the 6 same facility, you know, whether Tara and Stacy 7 at another facility might be scoring the same was 8 9 That's why we did the standardized important. 10 patient videos, reliability, so that we were able 11 to test if the four of us all came to the same 12 agreement, and those of us who were PTs, nurses, 13 you know, did we agree with each other? So 14 that's why we did different types of reliability, 15 so I feel like we've done a fair bit of 16 reliability and our results were very comparable 17 to anything that's out there in the literature 18 with the existing. 19 CO-CHAIR STILLE: The only thing that

19 CO-CHAIR STILLE: The only thing that 20 I didn't see that was, the only thing I saw in 21 the critiques that I didn't see in your thing was 22 test-retest reliability. But, yes, I agree there

was lots of other reliability things that you
 guys --

3	MS. DEUTSCH: Yes. So with function,
4	a patient can change. Like somebody with
5	arthritis, they can be very limited in the
6	morning and very independent in the afternoon.
7	So function changes, so you can't really do test-
8	retest reliability when somebody is changing. So
9	I think that's not something that's generally
10	done with function data. It's just not possible.
11	CO-CHAIR STILLE: Yes. And, yes,
12	Peter and then Dawn.
13	MEMBER THOMAS: Dawn first.
14	CO-CHAIR STILLE: Well, Dawn first and
15	then Peter. Okay.
16	MEMBER DOWDING: Okay. I'm just going
17	to sound like a stuck record again. It's, again,
18	just to highlight my concern that the reliability
19	and validity data we have is at the level of the
20	care scale and not the measure we're being asked
21	to endorse, which are the two, the expected
22	versus actual and the mean change. And we don't,

you know, we need the data on that, I think.
 Well, I need that data on that to be happy to
 endorse it. And, again, just to reiterate those
 concerns.

5 MS. DEUTSCH: Can I respond to that? So just maybe I can ask the NQF staff. 6 My 7 understanding is that the rating, if you don't have facility-level data but you have item 8 9 reliability data, that it can be moderate. It 10 just can't be high. So this is very acceptable, 11 and a moderate would be the appropriate. Is that 12

MS. SAMPSEL: That is correct. So
that's consistent. This is an outcome measure.
These are both outcome measures, not patientreported outcome measures, meaning that when you
go through the algorithm your choices would be
moderate and low.

19CO-CHAIR STILLE: Okay, good. And20then Peter. Right, sorry.21MEMBER THOMAS: I'm sorry to do this.

But can we just return to this expected

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1 functional level in terms of mobility and just 2 walk me through a little bit more, just give me a 3 little more comfort that there's a system in 4 place where you really are not going to find a 5 lot of gaming going on or that you accommodate --6 how do you determine what that expected 7 functional level is? How does that happen?

So the expected score is 8 MS. DEUTSCH: 9 calculated based on our regression model. So, 10 for example, you take the characteristics of the patient and then, you know, if the patient is in 11 12 a certain age category, then you apply the 13 regression coefficient that we reported on our 14 risk adjustment model and, basically, you know, 15 add up the scores that you get and the intercept 16 and based on whether people have comorbidities or 17 not, and the expected score is calculated based 18 on summing the regression coefficients based on 19 that person's characteristics.

20 MEMBER THOMAS: And, like, what was 21 the sample for that, for those coefficients to be 22 created?

1 MS. DEUTSCH: Right. So we had, after 2 the exclusion criteria, we had what? About 4,776. 3 4 MEMBER THOMAS: Okay. And that's all 5 considered valid and reliable in terms of expounding upon those, the experience of that 6 7 sample group? 8 MS. DEUTSCH: Yes. I mean, we ran the 9 analyses and we feel the estimates are pretty 10 stable. I mean, we would always like to have more data, and I think any quality measure 11 12 developer would love to test this out over and 13 over again just for maintenance and that. So I 14 certainly would love to have more data and get 15 additional data, but I do feel like we have a 16 decent sample for this. 17 MEMBER THOMAS: Great, thank you. 18 MEMBER MORT: So just since this has 19 come up a few times, the data elements that 20 you're using either in the risk adjustment model 21 or in the observed or expected calculation, are 22 those all derived from staff data elements put in

the medical record or are any of those from 1 2 coding sources, administrative data sources? Sure. So most of the --3 MS. DEUTSCH: 4 like age, we actually, I think we used the claims 5 data for that. But a lot of it comes from the chair assessment data, but we did use 6 7 comorbidities from the claims data. In part, we don't know that, necessarily, every inpatient 8 9 rehab facility codes the same way. And 10 consistent with other, like, readmission 11 So if measures, we went back to acute care. 12 there was somebody who was listed as having 13 diabetes in the acute care claims record, we 14 accepted that, even if it wasn't maybe in the IRF 15 claims record. So we did use claims data from 16 the IRF stay, as well as the acute care stay, in 17 addition to the assessment data. 18 MEMBER MORT: And that would be the 19 way it would continue to be analyzed. You go 20 back to the incident in admission that led to the

22 that database? That's --

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IRF stay and you pull ICD-9 comorbidities from

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1	MS. DEUTSCH: Yes, so ICD-10. Right.
2	MEMBER MORT: ICD-10. Excuse me,
3	excuse me. So my comment about reliability,
4	Peter, just is that the gameability, in my mind,
5	is highest when it's totally relying on
6	administrative data alone. And these data
7	elements come from two sources. The fact that
8	you go back to the incident and hospitalization
9	to look for additional comorbidities suggests
10	it's pretty thorough, but, regardless, it's the
11	same data used for either the risk adjustment or
12	the O-to-E calculation. So if there's bias in
13	it, it's biased in either methodology is how I
14	understand it.
15	CO-CHAIR PARTRIDGE: Okay. Any
16	further? Becky? Sorry.
17	MEMBER BRADLEY: Just to help me
18	understand it because I know there is a great
19	interest in using this tool. How long does it
20	take to get to the data pool that you would like
21	to see to use for expected scores? I mean, is
22	that years, is that months, to have enough data

collected to be able to provide the information 1 2 for the predictive piece that seems to be 3 missing? 4 MS. DEUTSCH: So if you're asking what 5 the time frame is for the measure, each measure, there's a time frame, so what patients are 6 7 included. So we have in our application 12 months of data would be used. Is that, is that 8 9 what you were asking? 10 So it would take 12 MEMBER BRADLEY: 11 months to build a database to have the predictive 12 number, the predictive validity and reliability 13 that --14 MS. DEUTSCH: So we're proposing 15 creating the quality measure at the facility 16 level with 12 months of data, and that's 17 consistent with other measures. Some measures 24 18 months. 19 CO-CHAIR STILLE: Okay. And for the 20 testing, did you use like a retrospective data 21 set from a few years ago or. 22 MS. DEUTSCH: The data were collected

between 2008 and 2010. 1 2 CO-CHAIR PARTRIDGE: If there's no 3 further discussion. MS. ALLEN: Voting on reliability: one 4 5 high, two moderate, three low, four insufficient. Voting starts now. All votes are in: zero 6 7 percent high, 77 percent moderate, zero percent low, 23 percent insufficient. 8 9 Voting on validity: one high, two 10 moderate, three low, four insufficient. Voting starts now. All votes are in: 8 percent high, 69 11 12 percent moderate, 8 percent low, 15 percent 13 insufficient. 14 CO-CHAIR PARTRIDGE: Moving on to 15 feasability. Any discussion on this element? 16 Sam? 17 MEMBER THOMAS: I just want to ask do 18 you have any data on how long it takes to 19 administer or to grade this instrument? 20 MS. DEUTSCH: So clinicians are assessing patients on these activities pretty 21 22 typically. Some of the items are things like car

transfers that are done at best-practice 1 2 facilities. I'm not sure that I could say 100 percent of IRFs are looking at things like car 3 4 transfers at discharge, but the best-practices 5 facilities recommended all of these items. So the assessment is happening anyway 6 in most cases, and so, in terms of, like, the 7 documentation piece, I'd have to look up the 8 9 specifics, but, I mean, there's basically taking 10 the information and then thinking through what 11 the score is and documenting it. And so there's 12 seven self-care items and 15 mobility items. 13 MEMBER THOMAS: So any member of the 14 rehab team, a therapist, nurse, physician, any 15 member could conceivably do this grade and 16 there's not a restriction on that. 17 MS. DEUTSCH: Correct. 18 CO-CHAIR PARTRIDGE: If there are no 19 further comments on feasibility, we want to vote. 20 MS. ALLEN: Voting on feasibility: one 21 high, two moderate, three low, four insufficient. 22

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Voting starts now. All votes are in: 46 percent

high, 38 percent moderate, 15 percent low, zero
 percent insufficient.

Voting on usability and use: one high, two moderate, three low, four insufficient information. Voting starts now. All votes are in: 46 percent high, 38 percent moderate, zero percent low, 15 percent insufficient.

8 Voting on overall suitability for 9 endorsement of Measure 2634, change in mobility 10 score for medical rehabilitation patients, and 11 Measure 2636, discharge mobility score for 12 medical rehabilitation patients: one yes, two no. 13 Voting starts now. All votes are in: 85 percent 14 yes, 15 percent no.

15 CO-CHAIR PARTRIDGE: Take a deep
16 breath. Move on to our last measure, and our
17 friends to our left are up again.

MS. DEUTSCH: All right. Thank you.
Okay, great. So this last measure is change in
mobility for patients admitted to a long-term
care hospital on a ventilator. So just in terms
of the background, I mentioned, I think

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yesterday, that long-term care hospital patients
are very, very sick and they are often having
limitations in mobility, as well as self care,
mobility in particular. There are risks for
additional limitations to develop because
somebody is basically on a ventilator and not
able to move around a lot sometimes.

8 So this measure is a risk-adjusted 9 change in mobility measure between admission and 10 discharge. And, again, it only applies to long-11 term care hospitals who are admitted on a 12 ventilator.

13 We looked at our PAC PRD data and 14 selected items that we thought made sense based 15 on that data, what's feasible to collect in a 16 long-term care hospital for these very sick 17 patients. We presented this to our technical 18 expert panel, so we only have eight mobility items just because it's not feasible to expect 19 20 people to go up and down the stairs, for example. 21 So we have bed mobility items. So we have some low-functioning, items that work for patients 22

with low function, as well as transfer items, so 1 2 important things like getting on and off a toilet, as well as up to walking. This is 3 4 consistent with items that are reported in the 5 literature for patients in long-term care The period of time for the measure is 6 hospitals. 24 months just because it takes a longer time to 7 have enough patients who are admitted with this 8 9 particular condition.

10 So in terms of importance, I kind of 11 mentioned that these patients are very high risk 12 for having further decline in their function, so 13 that's important. And also Congress has actually 14 weighed in on this. There is law, the Bipartisan 15 Budget Act, that was passed in 2013 that requires 16 Medicare to establish this quality measure by 17 2016. And the reason that that is such an issue 18 is that there's a lot of payment reform happening 19 in the long-term care hospital, so it's important 20 to have a counter in terms of measure and quality 21 when there's, again, pressures related to payment 22 reform.

1	We have several exclusion criteria.
2	This was based on input from the expert panel, as
3	well as our public comment, so it's similar to
4	measures we presented before. Incomplete stays,
5	we only included people 21 years and older. We
6	have a risk-adjustment model that we presented,
7	and, again, we used generalized linear models
8	with general estimation equations. We calculate
9	an observed over expected times the national
10	average, so you get a risk-adjusted change score.
11	I think you've heard enough from me on
12	other things, so, Stacy, do you want to talk
13	about standardization?
14	MS. MANDL: Sure. So, again, this is
15	Stacy from CMS. It's come up a couple of times,
16	and I thought I would just use this as an
17	opportunity between the two measures to sort of
18	touch on this concept of uniformity and
19	standardization at the data element level.
20	So here's a great example where a law
21	was passed that requires a measure. Data elements
22	and the importance of having data elements that

are standardized, especially at the assessment 1 2 level, really helps to make sure that you have apples to apples. I get it. It's very critical to 3 4 have the trainings in place and all of the 5 iterative trainings in place and so forth because of that, but it's far better to have that than to 6 have a measure that doesn't specify the data 7 element level to the level of detail that we do. 8 9 I just wanted to touch on that. And 10 it's such an important concept that Congress also 11 just passed another law called the IMPACT Act 12 that requires that for multiple purposes, not 13 just for quality reporting but also for the 14 purposes of transferability of information, 15 interoperability. 16 So I just wanted to just sort of touch 17 on that why, yes, we're hearing you loud and 18 clear at facility, but at the data element level 19 there has been testing. So I'll hand it back 20 over. 21 CO-CHAIR STILLE: And I'm the 22 discussant for this one, as well. I think,

overall, I think it's a very interesting measure. 1 I appreciate the discussion of law in need of a 2 measure because my primary quibble is we don't 3 4 have a whole lot of data yet. You know, it's 5 103 patients, basically, to kind of look for -am I look at the --6 7 MS. DEUTSCH: Four hundred and fiftyfive. 8 9 CO-CHAIR STILLE: Okay. So the 103 10 must have been a subset. So a still relatively 11 small number, but not that many patients need 12 ventilator support, so it was probably hard to 13 get a sample that was big enough. So we need to 14 get more data as times goes on with that. 15 I had a couple of comments and sort of worries about exclusions. One, I need some input 16 17 from the commissions that are used to dealing 18 with adults. But it seems maybe inappropriate to 19 exclude all progressive neurologic conditions, 20 especially the ones that go up and down. MS and 21 Parkinson's I'm wondering, in particular, you 22 know, a lot of patients with MS and Parkinson's,

they do great, they do terrible, they do great, 1 2 they do terrible. Even if they need to be on a ventilator, they may not need to be on a 3 4 ventilator in six months to a year if they do 5 And so I was sort of wondering about the better. reasons for some of those exclusions. 6 7 MS. DEUTSCH: Do you want me to 8 address that or are you asking --9 CO-CHAIR STILLE: If I could hear from 10 another clinician, that would be good. And then 11 -- yes. So maybe Liz? 12 MEMBER MORT: Well, the neurologic 13 deterioration or conditions that lead to either 14 fluctuations or deteriorations over the long term 15 are highly variable. I'm hesitating. I can 16 understand why they excluded that population. On 17 the other hand, I wonder, of the 300,000 people 18 on ventilators every year, what proportion of 19 that --20 CO-CHAIR STILLE: Exactly. That was 21 my point. 22 MEMBER MORT: -- and it might be

worthwhile taking a look at the data to see how 1 2 many patients, what proportion of the 300,000 ventilated patients annually fall under those 3 4 categories and which categories. There might be 5 some that you would leave excluded, like ALS for example, but others that you might include. 6 So I think it's worth exploring with a bit more 7 detail. 8 9 CO-CHAIR STILLE: Great. 10 CO-CHAIR PARTRIDGE: Becky? 11 MEMBER BRADLEY: In keeping with the 12 idea of developing measures that cut across all 13 settings, I was just curious because there are 14 people on ventilators at home and people on 15 ventilators in nursing homes and in inpatient 16 rehab, why was this one limited, especially since 17 you're trying to collect data on as many patients 18 as possible, why did you limit it? 19 CO-CHAIR STILLE: Go ahead. 20 MS. DEUTSCH: Okay. So I have a 21 question from Chris and then went from Becky, so 22 I'll deal with Becky's first and then we can come

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back to the other.

2 So inpatient rehab facilities have very few patients overall, and it's a select 3 4 group of IRFs that admit patients with 5 ventilator. So I don't think we would get a big enough sample. So, I mean, if I could just say, 6 you know, anybody on a ventilator, I'd love to 7 include in this measure, great. But then 8 9 facility-level analysis would be very difficult 10 at the IRF level. It would be very difficult at 11 home care. I just, there wouldn't be many home 12 care agencies that would have a whole lot of 13 data. 14 So long-term care hospitals, part of

15 this law that was passed that I mentioned before, 16 they basically say, you know, patients who are 17 chronically critically ill, include patients 18 admitted on a ventilator. And there's criteria 19 within the law in terms of what chronically 20 critically ill is, but ventilator is their prime 21 example. So that's really where patients are at 22 this point, in terms of the post-acute care

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1 world. So does that help, Becky? 2 MEMBER BRADLEY: Well, it helps understand because I do recognize in inpatient 3 rehab, you know, you don't have that many. 4 But 5 if you're looking at where they're best served and being able to take them from one level of 6 7 care to another and share information and, you know, hands off providers, it seems like it would 8 9 be useful if that is the intent of developing a 10 core measure that cuts across all.

11 MS. DEUTSCH: So that's actually a 12 So I think this goes to Stacy's great comment. 13 comment. Standardizing assessment data cross all 14 the post-acute care settings would allow us to do 15 research studies to examine exactly this point 16 and be able to risk adjust. So without the data, 17 you just cannot, you know, do this at this point. 18 So this would really open up the door 19 to be able to do research and then, you know, 20 potentially develop quality measures, as 21 appropriate. And then you'd be able to look at 22 function, you know, our people who are home and

have, you know, on ventilators, do they actually 1 2 do better? So great, great point. MS. MANDL: CMS thanks the comment. 3 MS. DEUTSCH: So can I answer, Chris, 4 5 your question, unless, Sam, did you also want to weigh in? 6 7 MEMBER BIERNER: I mean, I understand or I assume that your reason for excluding some 8 9 of these was because some of them have a variable 10 course and, for the purposes of creating this 11 instrument, you know, you don't want to introduce 12 unnecessary variability into your study. I would 13 hope that, you know, over time, if this gets 14 implemented, then one could use it and see what 15 kind of data one gets from that population. But 16 I assumed it was excluded mainly for the purposes 17 of developing the instrument. 18 MS. DEUTSCH: Yes, that was exactly 19 the point. In fact, we talked with our expert 20 panel about these diagnoses in particular, and 21 they said, well, if the person is admitted to an

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IRF they should be included in that measure

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because IRFs should be focused on functional 1 2 improvement. But if somebody is admitted to an LTCH they may or may not have necessarily the 3 4 same prognosis, and so it's really unfair. 5 And to Peter's, I know, Peter, you have brought up several times potential 6 7 unintended consequences. If you have patients who you know may not do well on a particular 8 9 measure, they might be excluded from access to 10 that level of care, which may be very 11 appropriate. So that was really the rationale, 12 and we did present data from our sample. We had 13 12 patients who had ALS, which was 1.59 percent. 14 The multiple sclerosis/Parkinson's, it was fewer 15 than 11. CMS data use agreement, we can't report 16 raw data when it's less than 11, but a very small 17 percentage. 18 CO-CHAIR STILLE: Okay. So, I mean, 19 that just points out that it's really important 20 to potentially change the measure if you're

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looking at it in different settings, you know.

Include it in one group, exclude it in another

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group, because they're different people.

2 MS. DEUTSCH: This is all about goals 3 of care.

CO-CHAIR STILLE: Yes, yes, great. Okay. My only other question was I didn't see a whole lot of data, and maybe there aren't, about a performance gap at this point so.

Yes, I mean, there's not 8 MS. DEUTSCH: 9 a lot of literature about long-term care hospital 10 patients, in particular ventilator patients. And 11 I think our literature review speaks to the idea 12 of early mobilization being a pretty new concept 13 in providing care, and so it's just a really 14 early thing and we're just trying to get ahead of 15 the curve and make sure patients are getting the 16 best care possible and functioning as 17 independently as possible.

18 CO-CHAIR STILLE: Other comments on
19 importance? Becky and Liz, can you put your
20 things down? Thanks. Unless you had another
21 point? Okay.

MS. ALLEN: Voting on evidence for

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7 percent insufficient. 8 9 Voting on high priority: one high, two 10 moderate, three low, four insufficient. Voting 11 starts now. All votes are in: 23 percent high, 12 77 percent moderate, zero percent low, zero 13 percent insufficient. 14 CO-CHAIR STILLE: Okay. So in terms 15 of reliability and validity, again, it's a little 16 bit tough because there's not a whole lot of data 17 out there. So I want to rely on the 18 psychometricians in the group to talk about whether it's enough for what we have right now. 19 20 There is item-level reliability for the items that feed into the overall assessment. 21 22 There's not much data on the reliability on the

2 All votes are in: 100 percent yes, zero now. percent no.

Measure 2632: one yes, two no. Voting starts

Voting on performance gap: one high, 5 two moderate, three low, four insufficient. Voting starts now. All votes are in: 8 percent 6 high, 62 percent moderate, zero percent low, 31

3 4

whole measure. And I'm a little bit out of my 1 2 depth when it comes to talking more sophisticatedly than that. So, Dawn, please, 3 4 thank you. 5 MEMBER DOWDING: I don't think I'm any more expert, but I just want to clarify because 6 7 it's a bit unclear from the description. This isn't a change score. This is another one of the 8 9 ones where you're calculating an expected 10 functional score at discharge and comparing that 11 to what the observed score actually is. 12 MS. DEUTSCH: So this is a risk-13 adjusted change score. It's mobility. So we 14 calculate an observed change for the eight 15 So we look at the discharge mobility items. 16 score minus the admission score. So we calculate 17 that as the observed. We apply the risk 18 adjustment data to the patient-level data to 19 calculate an expected. We then divide or create 20 a ratio from observed over expected, and then 21 that ratio is multiplied by the national average, 22 which is similar to what we did with the IRF

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change in mobility.

2 MEMBER DOWDING: Yes. And I guess my question is, given the small population on which 3 4 you have got data for and given the, unless I'm 5 reasoning it wrong, your predictive model only predicts 26 percent of the variant, so there's a 6 7 huge amount of noise in that model, why have you gone for that very complicated calculation for 8 9 this score? Why haven't you gone for a simpler 10 change in function score? Because I guess I'm 11 really supportive of this, and I understand that 12 you don't have a huge amount of data. But given 13 all of that, I would have expected to see a less 14 complicated calculation than a more complicated 15 one. And, also, could you also give us some ideas 16 about the number of patients that we use to 17 develop the predictive score? Sorry. That's a lot 18 of. 19 MS. DEUTSCH: So our sample was 455 20 for the model. So our observed over expected 21 times the national average is the same that we

had presented for IRF. I guess it's a pretty

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standard thing. I mean, I'm an epidemiologist.
It's an epidemiology 101 risk adjustment. It
really is important to risk adjust. We tried all
kinds of comorbidities. We actually tried every
HCC or groups of HCCs that we could. And, again,
we went back to acute care, so I think -- if you
have that question.

8 So, I mean, we tried our best to risk 9 adjust, and I guess I feel like it is critical to 10 risk adjust. So I guess --

11 MEMBER DOWDING: I mean, I'm not an 12 expert in this, but there are other ways of risk 13 adjusting which don't involve a predictive score. 14 I mean, it's this whole business about expected 15 versus observed. You can risk adjust the change 16 without having an expected score that you then 17 calculate. I mean, I'm not an expert, but we've 18 seen other measures where they've done risk 19 adjustment which doesn't involve this expected --20 I think all of the MS. DEUTSCH: 21 measures we've heard about today used observed 22 and expected.

1	CO-CHAIR STILLE: So it's risk
2	adjusted, as opposed to proportion passing a
3	certain expected, difference with expected, so I
4	think the number is a little different then.
5	MEMBER BRADLEY: Well, I guess, if
6	we're looking at a quality measure and a
7	performance measure and we were kind of shooting
8	in the dark with an expected, how will that
9	expected score be used for performance
10	improvement or in a facility level?
11	MS. DEUTSCH: You're asking how it
12	would be used, the performance one? So the
13	facilities could get a report and realize that
14	they are different than a national benchmark, so
15	they would get their facility data and there
16	would be national benchmark data ranges, and so
17	they would get a sense about whether they're
18	performing better than the national average,
19	worse than the national average, and so they
20	could respond to that, obviously, if they think
21	they have room for improvement.
22	MEMBER BRADLEY: Well, and I guess

1 that's where, not being a statistician, I would 2 be concerned because if we're not certain that 3 that predictive score is reliable, we may be 4 spending a lot of resources trying to adjust on 5 something that hasn't really been fully tested 6 for reliability from the predictive standpoint.

MS. DEUTSCH: So I think, I mean, our
score was about 26 percent. I guess I don't know
if NQF staff can comment about, relative to other
measures, how that -- because, I mean, I've
definitely seen worse.

12 Well, I mean, MEMBER BIERNER: 13 compared to just, maybe not just specifically 14 other measures, but that would mean the lower end 15 of the, you know, lower end, beginning of 16 moderate level, for R-squared value. But I would 17 assume that, because you have a relatively small 18 sample size, that, over time, you would revise 19 this regression model based on your data. So 20 then we'd expect that we'd get updated as new 21 data comes in, and every year or two years or 22 something it would be updated.

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But in terms of how it would be used, I would assume that it would allow facilities to compare their population and their performance to others in their region or nationally. And so it would become more useful over time as more data is accumulated.

7 MS. DEUTSCH: Yes. And this was finalized in the Long-Term Care Quality Reporting 8 9 Program this August 2014, so this is being 10 implemented April 1, 2016. So there will be more 11 data available, and I guess, in terms of R-12 squared, if you had a really, really high R-13 squared, that means that you're explaining all 14 the variants. And so, you know, we think there's 15 facility input that makes a difference here. So 16 we definitely would love to do a whole lot more 17 and try to get a higher R-squared, but we did try 18 everything that we got in terms of suggestions 19 from public comment, as well as our expert panel. 20 MS. MANDL: I just want to add there's 21 only 400 LTCHs in the whole United States, if

22 that matters.

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1 MEMBER MORT: Since we're talking 2 about the O-to-E, 400 patients in your sample size, obviously, is small. And as you revise it, 3 you'll have more patients in that sample. 4 I had 5 a comment about a slightly different aspect of it, which is mobilizing patients on vents is a 6 7 relatively new area of focus clinically, so expected based on current practice is not where 8 9 we necessarily want to be. So I think you want 10 to beware of having people focus on a goal that 11 probably isn't aspirational, and that doesn't 12 necessarily relate to some of the other things 13 that we've been working on for a long time. We 14 have a better level of understanding about where 15 we can expect patients to get. Do you know what 16 I mean? 17 So this is MS. DEUTSCH: Yes. 18 absolutely an area that's evolving, and that's 19 part of -- I think NQF has maintenance 20 endorsement renewal and all that that's needed, 21 and I think CMS is looking at measures, every 22 single measure every year to make sure that it's

keeping up with the evidence. So absolutely. 1 2 CO-CHAIR PARTRIDGE: Ready to vote? MS. ALLEN: Voting on reliability: one 3 4 high, two moderate, three low, four insufficient. 5 Voting starts now. All votes are in: 8 percent high, 54 percent moderate, 23 percent low, 15 6 7 percent insufficient. Voting on validity: one high, two 8 9 moderate, three low, four insufficient. Voting 10 starts now. All votes are in: zero percent high, 11 69 percent moderate, 15 percent low, 15 percent 12 insufficient. 13 CO-CHAIR PARTRIDGE: Discussion on 14 feasibility? Liz, is that a card up or --15 MEMBER MORT: No, I'm sorry. 16 CO-CHAIR PARTRIDGE: All right. Ι 17 think -- Nadine? 18 MS. ALLEN: Voting on feasibility: one 19 high, two moderate, three low, four insufficient. 20 Voting starts now. All votes are in: 23 percent 21 high, 69 percent moderate, 8 percent low, zero 22 percent insufficient.

Voting on usability and use: one high, 1 2 two moderate, three low, four insufficient information. Voting starts now. All votes are 3 in: 23 percent high, 54 percent moderate, 8 4 5 percent low, 15 percent insufficient information. Voting on overall suitability for 6 endorsement of Measure 2632, change in mobility 7 among patients requiring ventilator support: one 8 9 yes, two no. Voting starts now. All votes are 10 in: 92 percent yes, 8 percent no. 11 CO-CHAIR STILLE: Great job, everyone. 12 (Applause.) 13 CO-CHAIR PARTRIDGE: And our deep 14 thanks to the team at CMS and RDI. We appreciate 15 your patience, your willingness to sit through 16 two days. Peter has some comments. 17 MEMBER THOMAS: I just want to 18 underscore what Lee said at the very beginning of 19 this yesterday morning with the comparison 20 between the staff preparation of the measures 21 last time around and this time around and pay a 22 huge compliment to the staff of the NQF for

putting together the materials in the way you did 1 2 and the staff review and eliminating the prep call and instead focusing on the way you did it 3 4 this time. We could have never have gotten 5 through this 28 measures if it were done the other way, and so I strongly endorse sticking 6 with this approach, even though it's a lot more 7 work for you, I know, in going through it. But, 8 9 boy, it just made this -- this is a long process 10 to get through 28 measures as it was, but it made 11 it so much easier. And I just wanted to say 12 thank you very much. 13 (Applause.) 14 CO-CHAIR PARTRIDGE: We're going to 15 open the mic for public comment. I'm going to 16 turn first to the people in the room behind me. 17 Please, just introduce yourself and then go 18 ahead. 19 MS. HART CHAMBERS: So I think we have 20 it now. Okay, thanks. So I'm Jayne Hart 21 Chambers with the Federation of American 22 Hospitals. I thank you all for your hard work

over the last two days. I was unable to be here in person yesterday.

But this is a challenge looking at 3 4 this particular set of measures, and the 5 discussion that Peter raised about the difference between public reporting and accountability 6 7 programs and what's considered a value-based 8 payment program on public reporting. It's going 9 to be very difficult if some of these measures 10 are deployed in different ways. And to have a measure deployed in the IRF Quality Reporting 11 12 Program where there still is the opportunity if 13 you don't report appropriately or get all your 14 data in on time or whatever to be penalized and 15 have a different measure in a pay-for-performance program will create a lot of confusion. And I 16 17 just encourage, as we go forward, to try to find 18 ways to create measures so that we have a smaller 19 measure set that's more simplified that can get 20 at the issues that are really important to both 21 patients, providers, and improving care. I mean, 22 ultimately, what we're trying to do with quality

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1 measures is improve care. 2 So, you know, we're making steps. But I am very concerned that we still have a lot more 3 4 to do. Thank you. 5 CO-CHAIR PARTRIDGE: Thank you, Jayne. On the phone? 6 7 OPERATOR: If you'd like to make a 8 public comment, please press star and then the 9 There are no public comments on the number one. 10 phone line. 11 CO-CHAIR PARTRIDGE: Okay, thank you. 12 As we all know, we did not have a chance to 13 discuss today related and competing measures. We 14 will do that, and staff will be back in touch 15 with us about when. 16 For the balance of this day, we have 17 a little bit more than an hour. We propose to go 18 into executive session, have a chance to debrief 19 from these two days of work, chat a little bit 20 about our staff here at NQF about ways that we 21 think this process is terrific and ways that we 22 think it might be improved. And then we'll go

1 home by subway. 2 So thank you all for coming behind us, and we'll stretch a little bit and then regroup 3 at 2:00 and say goodbye to Chris and hope he 4 5 makes it to the airport. DR. BURSTIN: And a special thanks to 6 7 Chris and Lee for really leading what was a 8 pretty difficult couple of days. So thank you. Great chairing. 9 10 (Applause.) 11 (Whereupon, the above-entitled matter 12 went off the record at 1:54 p.m.) 13 14 15 16 17 18 19 20 21 22

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CERTIFICATE

This is to certify that the foregoing transcript

In the matter of: Person- and Family-Centered Care Phase 2 Standing Committee Meeting

Before: NQF

Date: 01-22-15

Place: Washington, DC

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