NATIONAL QUALITY FORUM

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MONDAY

JUNE 6, 2016

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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 and Christopher Stille, Co-Chairs, presiding.

PRESENT:

LEE PARTRIDGE, Co-Chair CHRISTOPHER STILLE, MD, MPH, FAAP, Co-Chair BETH AVERBECK, MD, HealthPartners, Inc. KATHERINE BEVANS, PhD, Children's Hospital of Philadelphia SAMUEL BIERNER, MD, University of Nebraska Medical Center REBECCA BRADLEY, LCSW, HealthSouth Corporation JENNIFER BRIGHT, MPA, Momentum Health Strategies DAVID CELLA, Northwestern University Feinberg School of Medicine* SHARON CROSS, LISW, Ohio State University Wexner Medical Center DAWN DOWDING, PhD, RN, Visiting Nurse Service of New York* NICOLE FRIEDMAN, Kaiser Permanente STEPHEN HOY, Patient Family Centered Care Partners SHERRIE KAPLAN, PhD, MPH, University of

California Irvine School of Medicine

- LINDA MELILLO, MS, MA, CPHRM, CPXP, Spaulding Rehabilitation Network, Partners Healthcare System
- LISA MORRISE, MA, Patient & Family Engagement Affinity Group, National Partnership for Patients
- ELIZABETH MORT, MD, MPH, Massachusetts General Hospital/Massachusetts General Physicians Organization*
- LENARD PARISI, RN, MA, CPHQ, FNAHQ, Metropolitan Jewish Health System
- DEBRA SALIBA, MD, MPH, UCLA/JH Borun Center for Gerontological Research, VA GRECC, RAND Health*
- LISA GALE SUTER, MD, Yale School of Medicine, Yale Center for Outcomes Research & Evaluation (CORE)
- PETER THOMAS, JD, Powers, Pyles, Sutter & Verville, P.C.
- CARIN VAN ZYL, MD, FACEP, Keck School of Medicine of University of Southern California

NQF STAFF:

HELEN BURSTIN, MD, MPH, Chief Scientific Officer

ANN HAMMERSMITH, JD, General Counsel

ELISA MUNTHALI, MPH, Vice President, Quality

Measurement

ALEXANDRA OGUNGBEMI, Project Analyst

DESMIRRA QUINNONEZ, Project Analyst

KIRSTEN REED, Project Manager

SARAH SAMPSEL, MPH, Senior Director

SUZANNE THEBERGE, MPH, Senior Project Manager

ALSO PRESENT:

SVEN BERG, MD, MPH, CPE, West Virginia Medical Institute/Quality Insights NICHOLAS CASTLE, PhD, University of Pittsburgh Graduate School of Public Health* DEXANNE CLOHAN, MD, Retained Consultant KATHLEEN DANN, UDSMR MAGGIE DIVITA, UDSMR* DAVID GIFFORD, MD, MPH, American Health Care Association DANIEL GREEN, MD, FACOG, Centers for Medicare & Medicaid Services* DEANNA HAYES, PT, DPT, MS, Focus on Therapeutic Outcomes* BETH JACKSON, PhD, Truven Health Analytics KERRY LIDA, PhD, Centers for Medicare & Medicaid Services JANE LUCAS, Quality Insights of Pennsylvania CORETTA MALLERY, PhD, American Institutes for Research JAMES MULLER, American Health Care Association PAULETTE NIEWCZYK, PhD, MPH, UDSMR GARY REZEK, West Virginia Medical Institute* ANITA SOMPLASKY, RN, West Virginia Medical

Institute/Quality Insights of Pennsylvania

* present by teleconference

AGENDA

Welcome		
Introduction and Disclosure of Interest 6		
Project Introduction and Evaluation Process		
Consideration of Candidate Measures 0420: Pain Assessment and Follow-Up		
Consideration of Candidate Measures 2967: Home and Community Based Services 125		
NQF Member and Public Comment		
Consideration of Candidate Measures 2614: CoreQ: Short Stay Discharge Measure 229 2615: CoreQ: Long Stay Resident Measure		
2769: Functional Change: Change in Self Care Score for Skilled Nursing		
Facilities		
Score for Skilled Nursing Facilities 368 2775: Functional Change: Change in Motor		
Score for Skilled Nursing Facilities 368		
Consideration of Candidate Measures 2776: Functional Change: Change in Motor Score in Long Term Acute Care Facilities 370 2777: Functional Change: Change in Self Care		
Score for Long Term Acute Care Facilities		
Care Facilities		
Related and Competing Measures Discussion 390		
NQF Member and Public Comment 403 Adjourn		

1	P-R-O-C-E-E-D-I-N-G-S
2	8:39 a.m.
3	CO-CHAIR PARTRIDGE: Welcome again to
4	Washington, D.C., on a typical June day,
5	temperature nearly 90.
6	So just because I suspect you, like
7	me, wondered what all the construction is across
8	the way, that was for many, many years, as long
9	as I lived here, the site of the Washington Post.
10	But its new owners decided to sell it, and the
11	property is now being developed, I understand,
12	into a mega-complex of residential and
13	commercial.
14	MS. HAMMERSMITH: Fannie Mae.
15	CO-CHAIR PARTRIDGE: Oh, Fannie Mae is
16	the principal tenant? Okay, so the new home of
17	Fannie Mae. It seems very strange because for
18	years we've been looking at those sort of
19	yellowish brick buildings and watching Post
20	reporting.
21	It's Chris and my pleasure to welcome
22	you here today, and Sarah is going to start us

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off with some of the ground rules, et cetera.
 Right?

MS. SAMPSEL: Yes. So, good morning, 3 4 and thank you all. I know a number of us had 5 problems making it across the country yesterday, and we'll have a couple of people joining us a 6 little bit late, but we do have a couple of folks 7 on the phone, as well, so just want to remind 8 9 folks that we will have some Committee members on 10 the phone.

11 But I'm Sarah Sampsel, I'm the Senior 12 Director for this project. And how we're going to 13 start this morning is by doing introductions and disclosures of interest. So we'll have staff do 14 15 introductions first, and then we'll turn things 16 over to our General Counsel, Ann Hammersmith, who 17 will go around and give you the instructions for 18 disclosures of interest.

But again, just want to welcome you all and do hope that you will get a lot out of this meeting. We are very much looking forward to all of your feedback, and we'll talk about

1	some of the logistics and other things after we
2	do our introductions. So why don't we go ahead
3	and start. Desi, do you want to go ahead and
4	start, please?
5	MS. QUINNONEZ: Good morning,
6	everyone. I'm over in the corner. I'm Desmirra
7	Quinnonez. You'll see me often as Desi on my
8	emails, and I'm the Project Analyst on this
9	project.
10	MS. REED: Good morning, everyone. I am
11	Kirsten Reed. I am a Project Manager here at NQF.
12	Today actually marks week seven for me, so I am
13	very excited to really jump right in and get
14	started with everyone today.
15	MS. THEBERGE: Good morning, everyone.
16	I'm Suzanne Theberge. I'm the Senior Project
17	Manager on the team, and enjoying working with
18	you all again.
19	MS. OGUNGBEMI: Good morning. My name
20	is Alexandra Ogungbemi, and I am a Project
21	Analyst at NQF. I just work on the quality
22	measurement department.

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1	MS. MUNTHALI: Good morning. I'm Elisa
2	Munthali. I'm Vice President for Quality
3	Measurement; just wanted to welcome everyone and
4	thank you for serving on the Committee.
5	MS. HAMMERSMITH: Hi, everyone. I'm Ann
6	Hammersmith. I'm NQF's General Counsel. Many of
7	you have heard the little talk I'm going to do
8	before, and I'll do it again just to remind
9	everyone.
10	If you recall I'm sure you do, it's
11	a rather long form we sent you a conflict of
12	interest disclosure form a while ago in which we
13	asked you some detailed information about your
14	professional activities. So what we're going to
15	do this morning is go through an oral disclosure,
16	the purpose of which is transparency so that each
17	of you and the public who are present or
18	listening know where you're coming from.
19	I'll remind you that you sit on the
20	Committee as an individual. You're here because
21	you're an expert in this area. You don't
22	represent your employer, you don't represent

anyone who may have nominated you to serve on this Committee.

Some guidelines for what you should 3 4 disclose. You should only disclose things that 5 are relevant to your service on Committee. In other words, that are relevant to the subject 6 7 matter of the Committee. We are particularly interested in speaking engagements, consulting, 8 9 grants, research. But again, only if it's 10 relevant to the subject matter that's before the 11 Committee. 12 Just a reminder that just because you

disclose doesn't mean that you have a conflict of interest. As I mentioned before, the idea behind this is transparency. So you might be involved in something that's relevant to the subject matter but it's not a conflict of interest, but you may wish to disclose it because it is relevant to the subject matter.

20 So with that, I'll start with the Co-21 Chairs. We'll go around the table. If you're on 22 the phone, I will call on you at the end of the

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in-person disclosures.

2 CO-CHAIR PARTRIDGE: I'm Lee Partridge. I retired on the 1st of April from many years of 3 volunteer service with the National Partnership 4 for Women and Families, here in Washington. 5 And I picked up a new part-time assignment in my new 6 home, which is now New York City, with the United 7 Hospital Fund, a 125-year old nonprofit 8 9 foundation in the city where I am working happily 10 on pediatric care, which is my first love. And I 11 have no conflicts or other issues to disclose. 12 I do want to say, however, as we go 13 around the room, particularly since we have seven new members, not all of whom are here, but most 14 15 of whom are here, just if you would add a 16 sentence or two about where you're from just so 17 that we have a better -- just a little bit better 18 acquaintance. 19 CO-CHAIR STILLE: Good morning, 20 everyone. My name is Chris Stille. I'm a 21 professor and section head at General Academic 22 Pediatrics at the University of Colorado School

of Medicine and Children's Hospital Colorado.
 It's an honor and a pleasure to be working with
 all of you. My academic interests are in
 improving systems of care for children and
 families with special care needs. I have no
 disclosures or conflicts to note today.
 MEMBER THOMAS: My name is Peter

I think this is the third time I've been 8 Thomas. 9 here. I'm happy to be here. I'm a consumer. I 10 have two artificial legs that I kind of wear on 11 my sleeve because it's given me a tremendous 12 front row seat to the healthcare system 13 throughout my life, and kind of went into that 14 field, I'm a lawyer and a lobbyist and do a lot 15 of healthcare work from a disability and 16 rehabilitation perspective.

17 So I represent a lot of different 18 clients in the rehabilitation space. I don't 19 represent UDSMR, which is one of the measure 20 developers. I don't believe I have any conflicts 21 to disclose. I will be speaking to the UDSMR in 22 August, but it's not really about -- it may touch

1	on quality issues but it's really about
2	rehabilitation issues overall. And I've never
3	worked with anyone on measure development, so I
4	don't think I've got any conflicts.
5	My office is two blocks away and I'm
6	from Washington, D.C., and Chevy Chase, Maryland.
7	MEMBER MELILLO: Hi, I'm Linda Melillo.
8	I am the director of quality and compliance at
9	Spaulding Rehabilitation Hospital Cape Cod, and
10	I'm also the Director of Patient Experience for
11	the Spaulding Network, which is part of the
12	Partners Healthcare System out of Boston.
13	I suppose I don't I don't know if
14	you'd call this a conflict or not, but Spaulding
15	Rehabilitation Network includes inpatient
16	rehabilitation facilities, long-term acute care,
17	skilled nursing facilities, and home care. So I
18	just wanted to get that out there.
19	I'm thrilled to be here. I'm also a
20	consumer. I had a traumatic brain injury years
21	ago, so lots of use of the healthcare system. So
22	great to be here, thank you.

MEMBER BRIGHT: Hi, everyone. I'm 1 2 Jennifer Bright. I have my own consulting company, Momentum Health Strategies, and I'm 3 based here in Alexandria, Virginia. I'd like to 4 5 think I have a place at this table today because I grew up on patient advocacy working in the 6 mental health community and started a coalition 7 about 12 years ago, back when it was not 8 9 fashionable to talk about patient engagement. 10 So I started to coalesce a whole bunch 11 of patient groups, from kidney to diabetes, to get involved and to educate their members about 12 13 why patients' rights was important and 14 comparative effectiveness and policy development. 15 And currently, my clients are mostly non-profits, 16 but I also some advisory to -- not currently, but 17 in the past with some healthcare companies on 18 topics related to policy development, patient 19 engagement, which is my passion, as well as care 20 integration for behavioral health and primary 21 care. So thanks. 22 MEMBER MORRISE: I'm Lisa Morrise, and

I'm from Salt Lake City, Utah. I am a patient 1 2 advocate. My daughter, Kirsten, who's now 23 and a student at Utah State studying social work, was 3 born unable to breathe or swallow. And her 4 5 medically intense journey that included a tracheotomy, NG tube, and 45 surgeries to-date 6 has helped me understand the needs that we have 7 for improvement in patient engagement and patient 8 9 and family centered care in the medical system. 10 And while we feel like we've been 11 extremely fortunate with the providers who have worked with Kirsten, especially as I work with 12 13 other parents whose children have the same birth 14 defect but are not getting the kind of care that 15 they need. We found that in general the system 16 really needs patient input. So now I work as a 17 subcontractor to a subcontractor for CMS and work 18 in patient and family engagement on projects like 19 Partnership for Patients and TCPI, and also help 20 hospitals around the country develop patient and 21 family advisory councils, and just in general 22 consult in other areas of patient and family

engagement. And I don't believe I have anything
 to disclose. Thanks so much.

MEMBER BEVANS: Good morning, everyone. 3 I'm Katherine Bevans, I'm an associate professor 4 5 at the University of Pennsylvania School of Medicine and the Children's Hospital of 6 Philadelphia. I'm a researcher who develops 7 patient-reported outcome measures, especially for 8 9 use with children and parents. And I also do work 10 on the development of methods for enhancing patient, family, other stakeholder engagement in 11 12 research. I don't believe I have any conflicts of 13 interest. 14 MEMBER VAN ZYL: Hi, everyone. I'm 15 Carin Van Zyl. I am Assistant Professor of 16 Medicine at the Keck School of Medicine. And I 17 run the programs for palliative care at LA County

15 Carin Van Zyl. I am Assistant Professor of
16 Medicine at the Keck School of Medicine. And I
17 run the programs for palliative care at LA County
18 Hospital and the Keck School. I have no conflicts
19 to disclose.
20 MEMBER HOY: I'm Stephen Hoy. I'm a new
21 member here. I work in a place called Mammoth

Lakes, California. I'm the director of strategy

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and programs for a small consulting company called PFCC Partners that partner with healthcare organizations to advance PFCC practices in their organizations. And I don't think I have any disclosures, conflicts of interest to disclose. Thanks.

7 MEMBER CROSS: Good morning. My name is Sharon Cross. I am currently the Program Director 8 9 for patients care at the Ohio State University 10 Wexner Medical Center. And within my role I am 11 the person that manages all of our patient and 12 family advisors and advisory councils, and work 13 with researchers who are engaging patients and 14 families in their research design. I have 15 participated in some different projects with 16 PCORI but I don't believe I have any conflicts of 17 interest to disclose. Thank you. 18 MEMBER AVERBECK: Good morning. I'm 19 Beth Averbeck from Minneapolis-St. Paul, 20 Minnesota with Health Partners. We're an 21 integrated care delivery and financing

22 organizations. My administrative

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responsibilities, I lead primary care, which is 1 2 about 400 physicians. And my clinical practice is in long-term care, TCU, assisted living. And I've 3 4 also worked with Minnesota Community Measurement 5 on some patient-reported outcomes and electronic health record measure submissions. Thank you. Oh, 6 I have nothing to declare. 7 MEMBER PARISI: Good morning. My name 8 9 is Len Parisi. I am out of New York City, vice 10 president of quality management for MJHS. I'm a post-acute care provider, home care hospice, 11

12 skilled nursing facility. I have no conflicts of
13 interest but I do sit on the Joint Commission
14 Standards and Survey Methods Committee, as well
15 as the Home Care Advisory Committee.

MEMBER BRADLEY: Good morning. My name is Becky Bradley. I'm a social worker by training. I'm currently the National Director for Case Management for HealthSouth Corporation which is a post-acute provider. We are users of many instruments in our settings, and I have nothing to disclose.

MEMBER KAPLAN: I'm Sherrie Kaplan. I'm 1 2 a Professor of Medicine and Assistant Vice Chancellor for Healthcare Measurement and 3 Valuation at University of California Irvine 4 5 School of Medicine. I have currently a grant from PCORI to further the development of the 6 7 children's measure of self-reported functional status. It's animated touchscreen-based. The 8 9 functional status measurement was developed about 10 1996 and is being developed now for anesthesia 11 and perioperative anxiety, post-operative pain 12 management. 13 And I also developed a number of 14 measures in patient-reported outcomes, and 15 participatory decisionmaking style that's 16 relevant. Those two things are relevant but 17 they're not -- for me don't constitute a conflict 18 of interest. 19 MEMBER BIERNER: Good morning. I'm Sam 20 Bierner, Professor and Chair of the Department of 21 Physical Medicine and Rehabilitation, University 22 of Nebraska Medical Center. And I'm medical

1	director of the Madonna Rehabilitation Hospital
2	in Nebraska. And I have no conflicts of interest.
3	MEMBER FRIEDMAN: My name is Nicole
4	Friedman, and I am the medical anthropologist in
5	my background, and currently I am the Regional
6	Manager for Patient Navigation and Community
7	Health Work for Kaiser Permanente in the
8	Northwest. I am from Portland, Oregon. I'm new,
9	and I have no conflicts of interest.
10	MS. HAMMERSMITH: I'm now going to call
11	on the people who are on the phone. Dawn Dowding.
12	Is Dawn Dowding on the phone?
13	MEMBER DOWDING: Yes, hi. Sorry, I was
14	on mute. I'm Dawn Dowding. I'm a professor at the
15	School of Nursing at Columbia University, and I
16	have a joint appointment with the Visiting Nurse
17	Service of New York, and I have no conflicts.
18	MS. HAMMERSMITH: Thank you. David
19	Cella.
20	MEMBER CELLA: Good morning. This is
21	David Cella. I'm Professor of Medical Social
22	Sciences at Northwestern Medical School. This is

my second time on the Committee. I don't have any 1 2 conflicts that are directly related to any of the submissions for this meeting, but I do have a 3 4 grant from NIH to curate and distribute PROMIS 5 and Toolbox and Neuro-Ool measures for use around the country. And some of those at some point may 6 7 be used as performance measures. And I'm co-investigator on a PCORI 8 9 grant to the Rehabilitation Institute of Chicago 10 to develop performance measures for post-acute --11 patient-oriented performance measures for post-12 acute care, none of which are in front of the 13 Committee at this meeting. 14 MS. HAMMERSMITH: Okay, thank you. 15 Saliba. Debra 16 MEMBER SALIBA: Hi, I'm Deb Saliba. I am a geriatrician and health services researcher,

17 am a geriatrician and health services researcher, 18 Professor of Medicine at UCLA, the VA, and the 19 RAND Corporation. I don't have any conflicts of 20 interest. I am, as a researcher, funded by 21 multiple federal agencies and federal 22 foundations, but none of my current work is

developing quality metrics. 1 2 MS. HAMMERSMITH: Okay, thank you. MEMBER SALIBA: And I look forward -- I 3 4 apologize that I can't be there today and look 5 forward to participating. MS. HAMMERSMITH: Okay, thank you. Liz 6 7 Mort. MEMBER MORT: Good morning. This is Liz 8 9 Mort from Mass General. I'm the Senior Vice 10 President of Quality and Safety here. I have a 11 background in health services research and 12 quality measurement. 13 My apologies that I'm not there in 14 person and that I can only participate partially 15 today. My clinical and administrative 16 responsibilities changed dramatically and 17 unexpectedly. 18 I have no conflict of interest other 19 than the fact that I am from Mass General, and 20 tomorrow you will be considering a measure from MGH. Should there be decisions that need to be 21 22 made post the in-person meeting, I will recuse

myself from those decisions. And happy to be
 participating again.

MS. HAMMERSMITH: Okay, thank you. Is 3 4 anyone else on the phone who I've missed? 5 All right. Thank you, everyone, for those disclosures. You have very interesting 6 7 backgrounds. This is one of the most interesting committees I've done disclosures for. 8 9 Anyway, do you have any questions of 10 each other or anything you want to discuss, or 11 any questions for me? 12 Okay, before I leave you, I just want 13 to remind you of one thing, which is if at any 14 point in the meeting you think you may have a 15 conflict, or if you think someone else has a 16 conflict that they haven't declared, or if you 17 think someone is going beyond stating their 18 opinion and heading into bias, we ask you to 19 speak up. 20 What we don't want is to have you pop 21 up three months later and go, "you know, I think

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I may have had a conflict" and you didn't tell us

at the time of the meeting. So if any of the 1 2 things I've described occur, in your opinion, you're always free to bring it up in realtime in 3 4 the meeting. If you don't want to do that, you 5 could approach your Chairs who will work with NQF staff, or you can approach staff directly. So 6 7 with that, I will let you get on with your meeting. Thank you. 8

9 MS. SAMPSEL: Thanks, Ann. And thanks, 10 everyone. A couple of housekeeping issues. First 11 of all, we do have breaks put into the agenda. 12 However, if at any point you still feel you need 13 to stand up, do whatever, the restrooms are out 14 through the lobby and to the right, but we do 15 have breaks at 10:45, and then lunch, and the one 16 in the afternoon, as well.

You should have all hopefully been able to log into our guest network, but if not, the information is on the screen right now. We ask you to mute your cell phone during the meeting. We definitely understand if folks need to get up, but if you have to have a

conversation, if you could leave this area. We do tape these conversations in these meetings, and then we also have a transcriber in the back corner of the room who is documenting everything. So, microphones.

6 MS. THEBERGE: Yes, there's somebody on 7 the phone, I think, who also has the webinar 8 streaming. If you could mute your computer if 9 you're dialed into the open phone line, we would 10 appreciate it. Thank you.

11 MS. SAMPSEL: Suzanne can fix echos; I can't. So with that -- and, again, somebody on 12 13 line does have their computer streaming audio. 14 The microphones, when they're lit it means that 15 they're active. Only two can be active at one 16 time, so we ask that as you speak, once you're 17 done if you'll turn your microphone off, and all 18 of us need reminders about that typically.

And then the way we do it, if somebody wants to speak, if you have a question or a point to make, or whatever, if you will raise your card like this, that way Chris and Lee can identify

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who wants to speak next.

2 So with that, we want to do just a very brief overview, again, of what we're trying 3 4 to accomplish today and do some reminders. But 5 also recognize the fact that we've had a couple of calls already. I think we've had a lot of 6 7 discussions about the criteria. But just a reminder, in this meeting we have one maintenance 8 9 measure for review and then we have 12 -- some 10 with multiple submissions on one form -- but 12 11 additional new measures. 12 So the bulk of our work are new 13 measures. But as a reminder on the maintenance 14 process, these are all measures that are 15 currently endorsed, so they've already been 16 evaluated to meet the criteria in the past. 17 However, you know, NQF criteria have changed over 18 time, so we ask you to look at the measures in 19 light of the criteria that have changed, and the

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have additional questions.

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fact that you all have been actually brought up

in this process with the new criteria, so you may

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For some of the criteria, such as 1 2 evidence and testing, if there is no new evidence or data, you're able to accept the past 3 evaluation without further discussion and voting. 4 5 However, the measure that we're looking at today, there's been some updates to specifications, et 6 cetera, and therefore, we are going to have those 7 conversations about evidence and testing. 8 9 And we want greater focus placed on 10 the current performance and opportunity for 11 improvement. Obviously, you know, one of the 12 goals of measurement is to improve over time and 13 to really show that it's making a difference. And 14 so that's why we want some focus on the 15 performance and if there continues to be growth 16 in the measure. And then usability and use, how 17 well is the measure being used, who is it being 18 used by, et cetera. Next slide. 19 These are just reminders. And, again, 20 we went through these on the conference call. The 21 SDS, or the sociodemographic trial, we convened

an expert panel on demographic factors. And prior

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to this panel, NQF was not asking folks -- and,
 in fact, suggested against including SDS factors
 in performance measures.

There are two perspectives on SDS. One is that when you adjust it will mask disparities. And the other is that you have to adjust because it's necessary to avoid making incorrect inferences about the context.

9 So this expert panel came together and 10 said, yes, we acknowledge that, but we still feel 11 there is a need to understand more about what is 12 going on. You know, for each individual measure 13 perhaps there needs to be more consideration on 14 how the SDS factors are impacting that measure.

So the SDS panel recommended, the NQF
Board approved: a two-year trial period with
adjustment of measures for SDS factors is now no
longer prohibited.

So, basically, this started in April
of 2015. Even though this group has been active
since then, this is the first group of measures
that has been under this trial period even though

we're a year in. So we just want you to be aware
 that these are things that we asked for from the
 developers. The developers have been educated on
 this. And they are part of these measure
 submissions. And we've added questions into those
 preliminary analyses, as well.

So what are these SDS factors? They're 7 patient characteristics that are present prior to 8 9 treatment. And they are known or suspected to be 10 a confounder of the treatment. So these are SES 11 in one group. Socioeconomic status: income, 12 education, occupation and employment. And then 13 the SDS are sociodemographic factors: we're 14 talking about language, insurance, homelessness, 15 marital state, literacy, health literacy.

You know, I think it's important, and as staff went through all of the forms and all of the submissions, we were looking to see if these were noted in the submission forms. And we would either adjust the questions that you're asked to consider as part of that preliminary analyses. Next slide.

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So during your evaluation, and this is 1 2 where something has changed from your past review, you are asked to consider this list of 3 4 questions. And, again, we've talked about these 5 on the phone. And where they were applicable we left all of these questions in the forms, so none 6 7 of them should be new. You should have seen them in looking at any of your forms. 8 9 But, basically, we're looking for 10 conceptual relationships, we're looking for at 11 least some kind of testing and analysis that was 12 done, if someone says there was a relationship or 13 not a relationship. And, hopefully, we would have 14 identified where we felt something was missing, 15 or you should consider if something is missing. 16 Next slide.

Also, as we've talked about, and we're
obviously going to be getting into this, for
those of you who have made it through all of the
forms, we just wanted to give you some reminders
about tool-based measures.

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In the past, and certainly in Phase 1

and Phase 2, we've had a lot of discussions on 1 2 are there differences in the measure evaluation criteria, with specifically PRO-PMs, or the 3 Patient-Reported Outcome Performance Measures. As 4 5 staff have taken back really a lot of the information shared during these meetings, a lot 6 of the pushback from these meetings, a lot of the 7 discussions about interpretation of criteria from 8 9 this Committee specifically, we've really been 10 looking at the NQF criteria and how they're 11 applicable, and are they working for different 12 kinds of measures? Because we're seeing more PRO-13 PMs coming forward, we're seeing more tool-based 14 measures.

15 And just for clarification, when I'm 16 talking about tool-based measures, these are 17 surveys, whether they're patient experience --18 so, therefore, might be a PRO-PM -- or as we did 19 last time, we had 28 functional status tools, 28 20 functional status measures based on various tools 21 or instruments. Those were not PRO-PMs, some of 22 them were clinician-based assessments, but we

really felt the rule should be the same, that we 1 2 should be looking at the same type of data, the same type of analysis, the same understanding of 3 4 the psychometric properties of the instruments. So we've been having back and forth 5 conversations internally, and then we had a 6 conversation with the CSAC. And we're still in 7 the process in rolling some of this out, in 8 9 educating developers. So we're still dealing with 10 criteria, but these are some notes that we want you to know that we have tried, and have been 11 12 pushing the developers to provide in their 13 submissions for this phase of work. 14 MEMBER KAPLAN: I don't mean to 15 interrupt your flow there, but can you clarify 16 that what you're -- for me a survey is a data 17 collection method. 18 MS. SAMPSEL: Yes. 19 MEMBER KAPLAN: It's not -- so what 20 you're talking about, really, it's like the 21 medical record abstraction form. 22 MS. SAMPSEL: Yes.

1	MEMBER KAPLAN: You wouldn't go through
2	the exercise for the form, you'd just go through
3	the exercise for the measure that's represented
4	on the form.
5	MS. SAMPSEL: Correct. Yeah, and I
6	think I have a slide coming up on that. It's a
7	really good question, because in all honesty
8	that's one of the issues and part of the
9	confusion that was internal to NQF as well as
10	what are we talking about, and why is it such a
11	big deal?
12	So the first reminder is we do not
13	currently endorse surveys, tools, or instruments,
14	that even though we have a set of measures coming
15	in on a measure submission that might be about
16	nursing home CAHPS, or may be about the FIM, or
17	may be about the CARE tool, we have not endorsed
18	that tool. Those are the data elements that feed
19	into the actual PRO-PM.
20	That being said, it's really important
21	to consider the fact that by the time something
22	becomes a performance measure, whether it's a

PRO-PM or a tool-based measure, that tool should have been -- its reliability and validity should have been established before coming to this, and 4 that is an NQF policy. So some of those questions are fair game but we just want to make sure the interpretation is clear: we do not endorse those tools per se. Next slide.

Again, you know, and I think folks who 8 9 were here in Phase 2 will remember, there have --10 we had been interpreting the NQF criteria with a 11 higher standard for the PRO-PMs. And this 12 especially happened in Phase 1, when Karen Pace 13 was here, where we were constantly reminding 14 folks -- and if you remember, a lot of data came 15 in after the in-person meeting because folks were 16 providing all of their data on their actual tool 17 and no data on the performance measure.

18 And I think Sherrie, you brought that 19 up repeatedly during Phase 2, and we really 20 struggled with that as a Committee. So this is 21 really -- and we took this to the CSAC, as well, just a reminder. You all are evaluating the 22

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measures, and so it is fair game to say "we want the data on the performance measure." And during the algorithm where it used to almost give you an out if you had the data element or tool-based testing, then we, you know, had let measures go through before. We are evaluating the performance measures, so we want that performance measure data.

9 Staff went through all of these forms, 10 we've worked with all of the developers to make 11 sure that the performance measure data was there. 12 Is it the right data? That's something we still 13 have to work on. But to the same degree, we did 14 look for it and, hopefully, every single 15 submission should have that performance measure 16 data in it for this go-around. Next slide.

17 So this is what I was talking about 18 before. Approximately three years ago, four years 19 ago, NQF convened a panel talking about patient-20 reported outcomes and what happens when you get 21 to PRO-PM. And there are steps. And so, first of 22 all, you have the patient-reported outcome, and,

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obviously, that should be your first step or a developer's first step: what are we trying to get to?

And then you might have the PRO-M, or 4 5 the patient-reported outcome measure, that's typically the tool in this process. So that's 6 where we're talking the FIM is a PROM, the CARE 7 is a PROM, the PHQ-9 itself is a PROM. We expect, 8 9 NQF expects, that before you ever get to that 10 PRO-PM level, that that PROM has already been 11 tested for validity and reliability, and that it 12 is a usable tool or instrument, so that, frankly, 13 by the time they get to these panels we shouldn't 14 have to be evaluating the reliability and 15 validity of the tool. There should be some assumptions made. 16

17 At the same time, that also assumes, 18 well, then aren't we endorsing the tool? Right 19 now, nomenclaturally, no, we're not, but that's 20 something that obviously -- and something we want 21 to talk about tomorrow after we make it through 22 everything today, and then the final measures

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tomorrow, that we still think there needs to be
 some work done there for understanding the
 criteria and how they apply.

4 But really what you're looking at, and 5 what we've pushed the developers for, are this last box, to make sure that the outcome 6 7 performance measure, whatever it is, average change, percentage proved, et cetera, that that 8 9 is what has been tested for reliability, 10 validity, threats to validity, et cetera. And so 11 we've been pushing really hard on that and doing 12 a lot of education on it. Next slide.

13 This is just a reminder on related and 14 competing measures. We will not look at related 15 and competing unless the measure has been 16 recommended for endorsement. We have, I think, a 17 couple of measures in this portfolio that have 18 been identified as related to other measures. And 19 then we have the FIM measures that we'll talk 20 about this afternoon are competing with some 21 measures that were submitted during our last 22 phase of work. Only if those FIM measures are

recommended for endorsement will we have those 1 2 related and competing discussions. And we'll talk about that more, and there are additional 3 materials. Next slide. Suzanne? 4 5 MS. THEBERGE: Next slide. MEMBER THOMAS: Still a little fuzzy on 6 the SES -- SDS did you say? Right, either. And 7 the interplay between that and risk adjustment. 8 9 Probably not an easy answer, but I think you said 10 that by taking those into account you mask the 11 effects of risk adjustment, or you mask risk --12 I'm just not clear of the interplay between the 13 two. 14 MS. SAMPSEL: So there are two kind of 15 schools of thought when it comes to including the 16 SES or the SDS in a risk adjustment methodology. 17 The one school of thought is that if you include 18 them, that you're masking the fact that there 19 might be disparities. 20 MEMBER THOMAS: Okay. 21 MS. SAMPSEL: And then the other is 22 that unless you risk adjust, unless you include

those, you won't know if there are disparities, 1 2 or that they really are impacting the measure. And I can tell you even within NQF that are two 3 4 different schools of thought. Those of us who 5 are trained from NCQA say, no, you don't risk adjust, you don't include SDS, you stratify. And 6 7 then others have a different belief. But what we're looking for is not

8 But what we're looking for is not 9 necessarily that there's a right or a wrong, but 10 if somebody has included the SDS factors, if they 11 have included a risk adjustment strategy, there's 12 a rationale and analysis to support what they've 13 done.

MEMBER THOMAS: Okay, thank you.

15 CO-CHAIR PARTRIDGE: Peter, this is --16 for folks on the phone this is Lee Partridge. 17 CSAC, during my tenure there, which ends actually 18 this month, spent a lot of time on this issue. 19 And it came up mostly in the context of the 20 equity of the hospital related measures and the 21 safety net hospitals, and was there a possibility 22 that we were unintentionally causing harm to the

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safety net network?

2 And the way some of us tended to think about that was the clinical adjustments for 3 things like race, or genetic background, or 4 5 whatever, are embedded in the measure already. Those risk adjustments have been done. What we're 6 looking at is kind of should the measure itself 7 be somehow structured differently or risk 8 9 adjusted to take account of things like -- I 10 think you'll see it here. There's one measure I 11 remember in particular where people said --12 acknowledge there was an impact if there was a 13 different educational background on the part of 14 the patients, but, in fact, they had tested and 15 it didn't make any difference with respect to 16 this measure. So, you'll see it come up. 17 MS. THEBERGE: Okay. So, as you folks 18 are very familiar with our portfolio, we have 19 about 60 endorsed measures in this person and 20 family centered care portfolio. We had a call for 21 measures for this project through last winter, from October to March. And we'll be looking at a 22

1	series of measures on health-related quality of
2	life, functional status, shared decisionmaking,
3	symptom and symptom burden, and experience of
4	care. Next slide.
5	Our maintenance measure, which Sarah
6	was just discussing, is Measure 420, the Pain
7	Assessment Follow-Up. Next slide. The rest of the
8	measures are new measures for endorsement in
9	these areas.
10	We had a few measures that we've
11	rescheduled maintenance review, meaning that they
12	just were not ready for review in this phase and
13	we will look at them at a later date. But you may
14	have seen them in our portfolio and have wondered
15	about them, and that's the series of CCAT
16	measures and a health-related quality of life for
17	COPD patients. Next slide.
18	We also had a number of measures that
19	we'll be losing endorsement for several reasons.
20	Developers have decided not to resubmit these
21	particular measures and so they will lose
22	endorsement and no longer be a part of the

portfolio. And we'll be having a longer 1 2 discussion tomorrow, but your charge in relation to the portfolio of measures is to look for gaps, 3 4 areas where we need more measures and make 5 recommendations on where measures should be developed. We will also ask you to make 6 recommendations on harmonization, provide input 7 to the measure's application partnership, and 8 9 make recommendations on measure concepts for 10 harmonization. Next slide. 11 So just to talk briefly about the role 12 of the Standing Committee in the measure 13 discussion process, we ask you all to stand in 14 as a proxy for our multi-stakeholder membership. 15 And you work with the staff to achieve the goals 16 of the project and evaluate measures against the 17 criteria, respond to the comments that we will 18 receive on this project in the next step of the 19 work, respond to directions from the CSAC, and 20 oversee the PFCC portfolio of measures. Next 21 slide.

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As we talked about during the

orientation call, this is the process for the evaluation that will be happening today. We've asked our developers to provide a very brief overview, two to three minutes, of their measure or set of measures, and they'll be sitting right up here at the table with us when it's their turn to have their measures discussed.

And then we'll ask the lead 8 9 discussant, you've each been assigned as a lead 10 discussant to a couple of measures, and then 11 we'll ask you to kick off that discussion by 12 providing a summary of the comments that were 13 submitted beforehand and any issues that you 14 discovered in your in-depth review on the 15 measures. And we'd really like you to focus on 16 areas of concern or places where there was a 17 difference of opinion.

We'll have time for the developers to answer questions should you wish to ask them, so if you have any questions or anything you want clarified you can just ask our developer colleagues.

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And as Sarah mentioned, we ask you to 1 2 put up your cards when you wish to speak, and then we'll call on you. And for the folks on the 3 4 phone, please do just jump in when you wish to 5 say something and we'll put you in the queue, just let us know that you'd like to speak. 6 And we did have a request from one of our 7 participants on the webinar for folks to make 8 9 sure to lean close to your mic so that they can 10 hear everybody clearly. 11 And then we'll have the Committee 12 discuss all the measures, then they will vote on 13 the criteria. Next slide will get into that 14 here. 15 So voting is in the order that it's 16 presented on the measure worksheet. First, 17 evidence, then performance gap, then reliability, 18 then validity. Those four criteria are all must 19 pass, so if a measure does not pass any of those 20 criteria, it stops. Assuming it passes each of 21 these criteria, then we'll get into usability and 22 use, then feasibility, and then overall

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suitability for endorsement.

2	And we know that folks often have
3	suggestions on how measures could be improved or
4	things they would like to see, but we do ask that
5	you evaluate and vote on the measure
6	specifications as they are presented to you
7	today. Any recommendations the developer can take
8	back and work on for future presentation, but we
9	need to look at what's been submitted today.
10	Next slide.
11	So let's talk for a moment about the
12	voting process. You all have a clicker. It's
13	very important that you keep track of your
14	clicker because it's assigned to you. We will be
15	collecting your votes via Desi over there with
16	the laptop, so when it's time to vote you'll have
17	to point your clicker at Desi, the computer will
18	count up how many votes we received so we'll know
19	if we've gotten everybody, and the computer will
20	calculate. When you're voting the remote will
21	briefly display your vote choice so that you can
22	see, and you can change your vote without

duplicating, so whatever the last thing you press will be your registered vote. The folks on the phone and webinar will be submitting their votes via chat, and Staff will be submitting their -we have special clickers for them and we'll be submitting their votes. Next slide.

7 So talking a little bit about what consensus actually is, a quorum is considered 66 8 9 percent of the Committee that is serving in a 10 particular phase so we have achieved quorum. And 11 so to be recommended, measures must have greater 12 than 60 percent of the Committee voting yes or 13 high plus moderate, so that means 60.001 or, you 14 know, anything in between 40 and 60, so inclusive 15 of both 40 and 60 is considered consensus not 16 reached. You may also hear Staff call it the 17 gray zone. What this means is that the Committee 18 has not achieved consensus. There's really no 19 decision either way, so at that point the measure 20 continues forward. Discussion continues if it's 21 on one of the must pass criteria, and if it's on 22 the final recommendation the measure will go

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forward to public comment, and NQF will 1 2 specifically seek comments on that measure and its consensus not reached status. Anything less 3 4 than 40 percent is not recommended and so it will 5 either stop, depending on if it's one of the criteria, or it will go forward as not 6 recommended to public comment. 7 I will pause here and see if there are 8 9 any questions on the consensus not reached status 10 and achieving consensus in general. No, okay. 11 Next slide. 12 So just some quick ground rules. We 13 have asked you all to have reviewed the measures 14 beforehand, and we do hope that you will all 15 engage in the discussion for every measure 16 unless, of course, you are recused. And because 17 we ask you to serve as a proxy for the NQF 18 membership we really want input from all of our stakeholders and everyone around the table, and 19 20 we do expect that there will be differences of 21 opinion, and that's something that we look for 22 and we want to encourage those discussions.

So as you know, we have quite a full 1 2 agenda and so we ask that you try to help us keep on time; that is Staff and Co-Chairs' job to 3 4 really keep us to the time but, you know, we ask 5 everybody to help with that. And we will also do our best not to cut off any discussion that needs 6 to happen, but just keeping in mind that we have 7 folks coming in and dialing in. We have several 8 9 developers that will be participating by phone, 10 as well as in person. 11 And so with that said, I think we can 12 actually kick off the discussion ahead of 13 schedule, speaking of staying on time, unless 14 anybody has any questions before we begin the 15 measure discussion. 16 CO-CHAIR PARTRIDGE: Sherrie. 17 MEMBER KAPLAN: Just two quick things, 18 if you could comment on the attribution issue and 19 the purpose of measurement, and what the 20 Committee's responsibilities are with respect to 21 how the measure is being used, and does that 22 change the psychometric standards that you would

use in applying the measure? And the second 1 2 thing is to clarify the multi-item measures -the items that are supposed to represent a 3 4 single construct to make it clear that you're 5 endorsing the composite of those multi-item measures, not individual items within the 6 7 composite that's supposed to measure, for example, quality of shared decision making. 8 9 MS. SAMPSEL: Sherrie, it's so early. 10 So kind of regarding attribution, and I just want 11 to make sure I'm using it the same way that you 12 You're not talking about the concept of how are. 13 measures are being used with quality improvement 14 versus accountability. 15 MEMBER KAPLAN: That's what I was talking about, if there's no difference in the 16 17 standard, you're not -- you're supposed to be 18 agnostic to the purpose of measurement for the 19 purposes of this Committee versus ---20 MS. SAMPSEL: Correct. 21 MEMBER KAPLAN: You're supposed to be 22 thinking, for example, about what proportion of

the variation is attributable ---1 2 MS. SAMPSEL: Correct. 3 MEMBER KAPLAN: -- to what you do to 4 the patient, not who you attract in the case of 5 the SDS adjustment, so the attribution of that ---it is supposed to represent quality of 6 7 performance of the unit that's being compared. 8 MS. SAMPSEL: Correct. 9 MEMBER KAPLAN: And you're not 10 supposed to consider how it's being used, i.e., in the penalty phase of the CMS, you know, re-11 admissions thing, for example, or to incent 12 13 physicians. We're supposed to be agnostic --14 MS. SAMPSEL: That is correct. 15 MEMBER KAPLAN: Okav. MS. SAMPSEL: You should be agnostic 16 17 to that. 18 MEMBER KAPLAN: And then the multi-19 item thing, just to clarify what you were --20 because I'm -- it's still resonating as a little 21 bit of a confusion, the term survey versus a 22 multi-item measure of a construct. You don't want

people looking at individual items within that 1 2 multi-item composite's intended use ---MS. SAMPSEL: That's correct. 3 Where there's a little bit of difference for that is, 4 5 for example, the second measure we're looking at today, 2967, which are 19 measures within a 6 7 submission, and there's a difference between the measures that were submitted, those 19 measures, 8 9 and the items that were collected on that survey. 10 So we're not asking you to dive into each 11 individual item on the survey, but how those are 12 then being combined into the measure. 13 CO-CHAIR PARTRIDGE: Sarah, I know 14 it's early in the morning, but I think it will 15 probably come up fairly often. I wonder if we 16 could just talk a tiny bit more about your 17 statement that the -- whatever the data 18 collection tool is, whether we're talking a 19 survey, or as I think Sherrie said a chart 20 abstraction, whatever, we should be comfortable 21 that that tool has been tested. If we're not 22 comfortable that it's been tested, we should be

raising that in the validity, reliability part of
 our discussion, yes?

3 MS. SAMPSEL: Yes, so that would be under -- I mean, technically it's under both 4 5 reliability and validity because if you think about it they both have to -- they both have 6 7 questions about the specifications. And so one analogy we are talking about internally is how 8 9 this kind of translate -- if you have a claims-10 based measure, your data elements are typically 11 some demographic data, age, gender sometimes, 12 things like that, and then you have claims. 13 Those are your data elements, those exact claim 14 numbers. When you're talking about a survey or a 15 tool, your data elements are technically the 16 items on the survey so there is some level of 17 having to have some comfort that the reliability 18 and the validity of that survey, you know, is 19 accurately performing into the measure. It's 20 kind of hard to discern that but that is the data 21 -- the survey and those instrument items are our 22 data elements for these measures. So yes, those

are valid questions. But you guys have
 procrastinated long enough, you have to start
 reviewing measures now.

CO-CHAIR PARTRIDGE: Chris and I are going to tag team throughout these two days. When he's been involved particularly in working on a measure as a lead discussant, I'll take over, and vice versa. In some cases neither of us was, we'll just take turns.

10 I want to start by saying thank you so 11 very much to all of the NQF Staff. Those of us 12 for whom this is the third time around for these 13 measures recognize the tremendous amount of work 14 that has gone into the material that we received 15 in preparation for this face-to-face meeting in 16 comparison to what was available the time that we 17 began in Phase 1. And I know it's been a lot of 18 work for you and for all the developers and their 19 representatives sitting behind me and sitting up 20 here at the table, now we've pestered you with a 21 lot of questions for additional information. You 22 probably thought we were nuts but, particularly,

I think that the measurement -- what do we call 1 2 it, the sheet that we all get to read which records through the process the comments that 3 4 have come in from the public prior to our 5 considering these measures, the questions that were raised by the Standing Committee Members, 6 7 the responses from the developers. They're there and they're now all in one place that we can read 8 9 in preparation for this meeting, so I hope it's 10 going to help everything go a little more 11 smoothly. 12 With that, I am going to turn to our 13 first measure, 0420: Pain Assessment and Follow-14 And this measure steward is CMS. The Up. 15 representatives here are --16 DR. BERG: Yes, I'm Sven Berg. I'm 17 the Chief Medical Officer at Quality Insights, 18 and with me is Jane Lucas. I'll have her introduce herself, as well. 19 20 MS. LUCAS: Hi, I'm Jane Lucas. I'm 21 the Project Manager for this project. 22 CO-CHAIR PARTRIDGE: Thank you. And

our lead discussants are David Cella, Linda Melillo, Rebecca Bradley, and Carin Van, I'm going to pronounce it wrong, Van Zyl. And I apologize if you all on the phone are getting a little bit of the sound of mechanics out there. There's a construction site on the other side of the street.

DR. BERG: All right. Well, thank you 8 9 for the opportunity to come here this morning. 10 It really has been beneficial to us to get many 11 of the comments prior to this meeting, and so we 12 appreciate the new process. Having been here a 13 number of times before myself, I recognize that 14 usually the first presenter gets hit with lots of 15 questions, and so it's with a little bit of 16 trepidation this morning that we begin the list 17 of measures today. However, on behalf of CMS, 18 and as the measures developer for this measure, 19 Quality Insights is pleased to have the 20 opportunity to discuss the maintenance of NQF 21 0420: Pain Assessment and Follow-Up. 22

This measure received initial

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endorsement in 2008. It was originally developed 1 2 under a contract with CMS to allow non-physician providers to report quality measures through 3 4 their reporting programs which have evolved over 5 the years. And it was first implemented in the Physician Quality Reporting Initiative, and most 6 7 recently in the Physician Quality Reporting 8 System program.

9 PQRS uses G-codes for the eligible 10 professionals to document whether the quality 11 action has been performed. The level of detail 12 in defining the G-codes to describe the clinical 13 actions indicates there is a relationship between 14 the assessment of the patient on the date of 15 encounter using a standardized tool and a care 16 plan based on that assessment when the screening 17 is positive.

Pain assessment is the critical first step in determining interventions, establishing goals within a care plan, and measuring the effectiveness of the care plan or treatment interventions. For example, the specification

provides the numerator quality data coding
 options for reporting satisfactorily. G8730,
 which is then a G-code is that the pain
 assessment documented as positive using a
 standardized tool and a follow-up plan is
 documented.

The measure specifications for NQF 7 0420 provide clear definition for each of six G-8 9 codes used for reporting, as well as definitions 10 of what constitutes a follow-up plan. Measure 11 testing by Quality Insights includes chart review 12 to determine that the correct G-code was selected 13 by the eligible professional, a standardized tool 14 was utilized, and document of a follow-up plan 15 was done when indicated.

The intent of this process measure is for an eligible professional to document that an assessment of pain has been performed using a standardized tool and that a follow-up plan, i.e., a treatment plan has been documented in the medical record. The measure focuses on the adult population, those 18 years and older, and the

denominator includes all visits occurring during the 12 months reporting period.

Since implementation the number of 3 eligible professionals reporting the measure has 4 5 increased each year, as well as the scope or the type of professionals that have reported. What I 6 7 would like to point out is that although noting that the evidence surrounding the effect of pain 8 9 screening on treatment prescriptions for the 10 level of pain is of low quality at this point, 11 the Institute for Clinical Systems Improvement 12 included pain assessment in their most recent 13 opioid prescribing protocol and in their 14 guidelines for the assessment and management of 15 chronic pain. In addition, the recently published 16 CDC Opioid Prescribing Guidelines also include an 17 assessment of the characteristics of pain. It 18 notes that an assessment of pain perception over 19 time can be a valuable measurement of pain 20 improvement over time. Failure to assess, 21 address, and treat pain may negatively impact the 22 quality of life, resource use, and productivity.

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A report by the Institute of Medicine 1 2 entitled, "A Blueprint for Transforming Prevention, Care, Education, and Research," 3 suggests that chronic pain rates will continue to 4 5 increase as a result of Americans experiencing disease in which chronic pain is associated like 6 7 diabetes, cardiovascular disease, et cetera, the increase in obesity which is associated with 8 9 chronic conditions that have painful symptoms, 10 progress in lifesaving techniques for 11 catastrophic illnesses and injuries for people 12 who would have previously died, surgical patients 13 that are at risk for acute and chronic pain, and 14 that the public itself has a better understanding 15 of chronic pain syndromes and the new treatments 16 associated with that. Therefore, as a result of 17 all of these things we believe that this measure 18 is still important to improve the quality of 19 life, reduce unnecessary medical treatment, and 20 undue financial burden. 21 We thank you for your consideration of

the endorsement, and we look forward to your

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<pre>1 questions and the discussion that is surely going 2 to follow. Thank you. 3 CO-CHAIR PARTRIDGE: Thank you. David, 4 do you want to David Cella, do you want to 5 lead off? 6 MEMBER CELLA: Yes, hi. Can you hear me 7 okay? 8 CO-CHAIR PARTRIDGE: We can hear you 9 just fine. 10 MEMBER CELLA: Okay. Yes, you know, 11 maybe I could just say a little bit up front and</pre>	
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10 MEMBER CELLA: Okay. Yes, you know,	
11 mouth I could fuct cours little bit up from and	
11 maybe I could just say a little bit up front and	
12 then have somebody in the room that was a primary	
13 reviewer like Linda or Rebecca go through the	
14 criteria. But I just maybe we'll start by	
15 saying this is a maintenance measure. It's the	
16 only maintenance measure we'll be reviewing, and	
17 so some of the criteria don't have to be	
18 discussed, but evidence does have to be	
19 discussed, and it's the first criterion.	
20 The Staff review was that the data	
21 were insufficient. I actually, if we're talking	
22 about evidence, I think that there is evidence in	

the literature, not specific to this measure, but 1 2 in support of this measure that most of the time people study the impact of pain, you know, with 3 4 monitoring and setting up a treatment plan for 5 symptoms that are monitored, not just pain, that there is a benefit to a patient's experience of 6 care fairly consistently. The data on benefit to 7 actual outcomes on that symptom or general 8 9 quality of life are a little more mixed but my 10 personal view is based upon you knowing more 11 about this than chronic disease management like 12 cancer is that there is evidence for this 13 practice being good for patients. 14 CO-CHAIR PARTRIDGE: Linda. I'm sorry, 15 David. I don't want to cut you off. 16 MEMBER CELLA: Yes. Well, I really 17 thought I should just start with a quick 18 introduction. And we are just focusing for now on 19 evidence. Correct? 20 CO-CHAIR PARTRIDGE: Correct. So which 21 of your colleagues here in the room wants to 22 continue? Linda? Carin.

MEMBER VAN ZYL: Yes, as a palliative care provider, pain is the number one thing that I assess, and I also had the interesting experience of trying to develop this measure for our cancer program.

In the 10 years that I've been doing 6 7 this, I understand that there is a -- there's sort of a necessary but not sufficient component 8 9 here; meaning you can't make pain better unless 10 you ask about it. So the assessment is crucial, 11 but my clinical experiences, and I think the 12 experience -- the reason that there's so little 13 in literature that supports assessing means 14 better outcomes is because I don't think that 15 there's a very good relationship between them. 16 And, you know, the rating scales are such a poor substitute for the total experience of pain. The 17 18 new medical rating scale is the most commonly 19 used measure but at this point is relegated 20 almost to a joke because it seems to have so 21 little relationship to how a patient functions in 22 the world.

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I thought the evidence was 1 2 insufficient here, and not on the fault of the developers. I think we really grapple with 3 4 anybody studying pain trying to figure out how 5 you put a number to it, and what that really means for somebody, and more importantly what you 6 7 can do about a number that's really high, especially in chronic pain. And when we were 8 9 trying to go through developing an easier way of 10 documenting a pain assessment and a pain plan, it 11 was a year's worth of work, the physicians were 12 furious that they had to document this. They 13 believed that they already were; they weren't. 14 And the only way to go through and make sure that 15 a physician had really sort of ended the sentence 16 with an assessment and a plan was a manual data 17 abstraction. So we tried to come up with a 18 standardized note that made it easier for 19 physicians to document, and after a year's worth 20 of work we couldn't figure out whether there was 21 any way of insuring that this extra step had 22 actually meant a single thing to a patient.

1 I don't -- my comments are not meant 2 as a criticism of the idea, but more a comment on the practicality as a clinician and as somebody 3 4 who tried to implement this measure in the real 5 world. MEMBER MELILLO: So thank you for those 6 7 comments. I would agree that pain is a huge issue. I would also agree it's very difficult to 8 9 measure. One of my concerns is that patients 10 frequently will gain the number scale. You know, 11 the find out very guickly that the higher the number they give it, it changes the medication 12 13 they receive. So also the FACES pain scale was 14 designed for children, and much of the evidence 15 was on low back issues. So I really would like 16 more clarification on the patient populations you 17 would use this with. Is this just for patients 18 diagnosed with chronic pain, or if this is 19 broader, is there any evidence of its use, any 20 broader context that where it's been beneficial? 21 CO-CHAIR PARTRIDGE: We just clarify 22 for Linda the age range. I think it's 18 and up.

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1	DR. BERG: 18 and up, yes.
2	CO-CHAIR PARTRIDGE: Yes, so it
3	wouldn't apply to children.
4	MEMBER BRADLEY: I love going last
5	because I have
6	CO-CHAIR PARTRIDGE: Just a reminder
7	everybody down at that end of the table, we can't
8	see you.
9	MEMBER BRADLEY: Yes. I had the same
10	concerns about that my colleagues previously
11	mentioned about the validity and the evidence.
12	I guess I was also, as I read it
13	you mentioned that the number of provider
14	eligible providers have increased since 2008,
15	but participation, this is a voluntary reported
16	measure, and participation has decreased during
17	that time. And I was wondering if you could
18	address that, and since it is a measure that has
19	been out there a while, what do you attribute the
20	decrease of participation to?
21	MS. SAMPSEL: Actually, I'm going to
22	we have a new member who joined, so I'm going

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to, Jane, give you a second to come up with an
answer. And, Lisa, if you will introduce
yourself, kind of a brief background, but also we
need you to make any comments and disclosures of
interest or conflicts of interest with any of the
measures we are being reviewed.

7 MEMBER SUTER: Can you hear me? Okay. I'm Lisa Suter. I apologize for being late. Can 8 9 you hear me? Okay. I'm an Associate Professor of 10 Medicine and Rheumatology at Yale School of 11 Medicine. I also work for the Center for Outcomes 12 Research and Evaluation as a measure developer on 13 some outcome measures under contract for CMS, 14 none of which are under consideration by this 15 Committee. But that's my main disclosure as a 16 measure developer. I'm also a health services 17 researcher. Again, I apologize for the 18 disruption.

19 CO-CHAIR PARTRIDGE: I'm going to 20 remind everybody again we are having to talk over 21 the sound of digging machines next door. Try to 22 remember to bring the mic a little closer to you

and that way we'll all hear throughout the room. 1 2 Jane. MS. LUCAS: I'm showing on the form 3 that we submitted the number of eligible 4 5 providers reporting the measure is about 10.7 percent, which is an increase of 3.6 percent in 6 7 2010, and then it went up to 7.4 in 2013, and 10.7 in 2014. 8 9 CO-CHAIR PARTRIDGE: Peter, you're up 10 next. 11 MEMBER THOMAS: I guess I'm just having 12 a little trouble understanding when you would 13 apply -- two questions; when you would apply this 14 -- does this apply to anyone who walks in for an 15 office visit to a physician, that the intent is 16 to do a pain assessment, and if there is pain 17 follow-up, or is this only after a patient 18 reports pain or chronic pain? 19 DR. BERG: So the measure is not 20 specific to diagnosis, so the measure was 21 originally developed for individuals like 22 physical therapists, occupational therapists, et

cetera. So it was an important part of their
 practice, and an everyday condition for most of
 the patients.

It is a voluntary measure so it's a measure that a physician can select to perform. I would anticipate it would be used in practices where there is a significant amount of pain in their patients.

9 With regards to the other question 10 about decreasing performance rates, I think was 11 the question that you had. You know, when it was 12 initially adopted then it was very specific 13 towards the type of eligible professionals that 14 were using it. I don't have specific information 15 in front of me, but my -- I would suspect that 16 the performance rates have decreased because 17 there is a broader range of professionals who are using the measure over time, as well. But I don't 18 19 have any evidence to support that.

20 CO-CHAIR STILLE: Any follow-up? 21 MEMBER THOMAS: So the materials, the 22 Staff rated this insufficient for evidence and

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the materials talk about the developer having the 1 2 opportunity to provide additional information. Have you provided them additional information, or 3 4 do you have something more to tell us? DR. BERG: Well, we've provided the 5 information that is available with regards to 6 7 this. It's a fair criticism, and I recognize your comments, that it's been very difficult to take 8 9 pain assessment and study whether or not there is 10 a better outcome because the assessment has been 11 made. And we -- after the comments were provided 12 we did a literature research and we looked for 13 other evidence along those lines, and really 14 those studies have been difficult to do, and the 15 evidence that is there is of fairly low quality 16 on both sides. In other words, studies that have 17 been done that look at the effectiveness of this 18 and have found no effect have also been rated as 19 having low quality, as well, so it's a very 20 difficult topic to address.

21 We believe that because those that are 22 continuing to develop protocols around the

management of pain continue to use pain 1 2 assessment as part of those protocols, we believe that it's justified to continue to utilize this 3 4 measure at this time, but we recognize the 5 criticism that has been raised by the Committee. And our recommendation and take home back to CMS 6 is, is that perhaps this is something that 7 deserves additional study in the future so that 8 9 we can be assured that utilization of a measure 10 like this, which is a process measure, actually 11 has benefit to patients in terms of outcomes. And 12 we recognize that that is a weakness in the 13 current science. 14 CO-CHAIR PARTRIDGE: Lisa. 15 MEMBER MORRISE: Thanks, Lee. I have a 16 couple of questions or comments. As a mom of a 17 kiddo who encounters pain on a really regular 18 basis, and it's really bad, I really think this 19 is important, because if you don't ask you don't 20 know. And as far as the scale goes and using the 21 FACES scale, while I agree that there's probably

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some issues around the scale, if I heard

correctly, Sarah, we're not looking at the scale. We just looking at the measure, so we kind of need to take our concerns around the scale and put them aside. I personally really like the Legos scale. Anyway, Lego FACES, you know. Anyway, so that's one comment.

The comment that was made by the 7 reviewer around the fact that certain ethnicities 8 9 are under assessed, I think is one reason, 10 glaring reason why we need this measure, why we 11 should say that it is essential because there is 12 an under-assessment, and as a consequence of 13 that, under-treatment of pain specifically for 14 the African American population. And that is true 15 in the pediatric population, as well as the adult 16 population. It significantly impacts our friends 17 with sickle cell disease, and we really need to 18 ask.

19 The outcome piece should be paired 20 eventually, but I think that's a separate issue 21 also; that first you have to determine if the 22 pain exists, and then determine if appropriate

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treatment is applied, two separate issues. But if
 you don't ask you don't know, so those are my
 thoughts. I think we should say yes, it's needed.

4 DR. BERG: I appreciate that type of 5 endorsement. One of the things that I would like to point out is that we're not specifying which 6 pain assessment tool to use, so although you 7 might find fault with the FACE scale, et cetera, 8 9 that's -- we're not really -- we're not assigning 10 a particular protocol with this. We're just 11 asking for the use of a pain assessment tool, and 12 so we're allowing clinical judgment to be used 13 within each practice on how to do that.

14 And the other thing that's difficult 15 because most of the study that's been done on 16 whether or not a pain assessment has been 17 performed is looking at just that, and then 18 whether there's an improved outcome. This measure also asks for the addition of a treatment plan 19 20 after the pain assessment, so we recognize that 21 it was not just the assessment of pain that was 22 important but that an appropriate treatment plan

was then provided following that assessment tool. 1 2 And because this measure is looked at for each visit that a patient encounters with that 3 4 provider, then further assessments of pain should 5 be happening, we should be tracking the patient's self-reported pain over time, and as a result of 6 7 that the treatment and the treatment plan can be modified in response to that pain. That's the 8 9 design of this measure so we're not looking just 10 as the assessment, but that a treatment plan has 11 been added, as well. 12 CO-CHAIR PARTRIDGE: Chris. 13 CO-CHAIR STILLE: I think Becky had --14 MEMBER CELLA: This is Dave Cella, 15 again. I might be repeating myself a little bit, 16 but I -- you know, I think that there is -- we're 17 really just focusing on evidence here, not the tool, and there's not even a specific tool 18 19 recommended in this particular measure. I think 20 it's a plus that the addition of a plan to 21 address the assessment of pain is included. I 22 think it moves this process measure on step

closer to outcome because having a plan to management pain is also associated with improved pain.

4 I mean, I go back to 30 years ago, you 5 know, when people starting wearing -- providers starting wearing pain buttons saying "Ask Me 6 7 About Pain," and the No Pain button. The reason we do that is because it helps encourage patients 8 9 to tell us about their pain, and then we have --10 that's when you do something about it. And I'm 11 concerned in this era of worrying about narcotics 12 overuse and the Joint Commission pulling away 13 from its recommendation of pain assessment that 14 we're going to swing in the wrong direction 15 saying hey, we've just come to realize there's no 16 relationship between asking about pain and 17 managing pain. And I don't think that's true. I 18 think there is evidence. I'd like to see this 19 measure go a step further and actually, you know, 20 the pain outcome. And I guess I'm trusting that 21 that's going to happen in time, but just focusing 22 on the evidence criteria and the other issues to

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discuss, I just repeat, I think the evidence is there.

3 CO-CHAIR PARTRIDGE: Becky, you're up. 4 MEMBER BRADLEY: Thank you. Several of 5 the research articles that you cited talked about disparity, and also the -- one of the objectives 6 7 is hopefully to reduce the cost and utilization of healthcare services. But as a -- a G-code is a 8 9 billing code, I assume, and so this is a code 10 that you abstract from claims. And it's kind of 11 confusing how this would reduce cost and 12 utilization. It seems like it might add to the 13 cost and utilization where we have more providers 14 assessing and documenting that they ask about 15 pain, and then they developed a treatment plan 16 because they can bill for those assessments now, 17 where they could not in the past. So maybe they 18 were asking but they weren't documenting. 19 I'm having a little bit of trouble

20 getting from how it become a quality or an 21 outcome measure and meet the goal of reducing 22 costs versus increasing costs.

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1	DR. BERG: And, again, this is not
2	it's not an outcome measure, and so although we
3	would like our processes to be associated with
4	good outcomes, it's not what the measure was
5	designed to do. Our thought process here is that
6	the appropriate assessment of pain and then
7	appropriate treatment plan will result in less
8	pain, and the treatment of those conditions then
9	over time should then decrease healthcare
10	utilization, and so that's the theory. Again,
11	we're looking for that connection and that
12	evidence. And that evidence of what the outcome
13	is from this we agree needs to be stronger than
14	it is right now.
15	CO-CHAIR STILLE: As a pediatrician, I
16	just have to ask this question. Given that there
17	are good tools for measuring pain in patients of
18	all ages, what rationale do you have for
19	excluding patients under 18?
20	DR. BERG: Can you say what that
21	CO-CHAIR STILLE: Well, again, I think
22	it the measure, when the measure was developed

was -- that was the population that was being 1 2 used, and so it hasn't been updated from that time. 3 4 DR. BERG: So just had to get out 5 there. CO-CHAIR STILLE: Sure. 6 7 DR. BERG: I'm a pediatrician, as well, so I understand where you're coming from. 8 9 CO-CHAIR PARTRIDGE: Are there 10 questions from any other Committee Members in the room? I'm sorry, Nicole, I'm just looking right 11 12 past your card. Go ahead. 13 MEMBER FRIEDMAN: I have two quick 14 questions. My first one is in terms of dropping 15 the G-code or the code, is that something a non-16 licensed provider can do, like a community health 17 worker? And is there evidence that increasing the 18 care plan reduces non-pharmacological 19 intervention to improve pain? 20 DR. BERG: We would hope that the care 21 plan would be appropriate for the patient, and so 22 if non-pharmacological intervention was the

intervention that should be used, then we would 1 2 hope that that would be the care plan. Again, we're not specifying what the treatment is, we're 3 4 allowing for the clinician to use their best 5 judgment in determining what that treatment plan should be. So this is not pain assessed, provided 6 7 opiates or other pain medication. That's not the purpose of this measure. 8 9 The first question, give me a little 10 -- remind me again what that was? 11 MEMBER FRIEDMAN: In the documentation 12 part of the --13 DR. BERG: Sure, okay, whether or not 14 non-physicians and community health workers can 15 do that. I don't know the answer to that 16 question. I don't know exactly who can -- who's 17 allowed to build specific G-codes. I don't know 18 if anyone else on our team knows that. 19 MS. LUCAS: It is -- CMS defines who 20 the eligible providers are, so I don't have that 21 list in front of me but it would include like 22 nurse practitioners, chiropractic, social

workers, psychologists, et cetera. But there is a 1 2 list that's out there. DR. BERG: But you specifically 3 addressed community health workers, and I don't 4 5 know the answer to that question. DR. GREEN: So this is -- can you guys 6 7 hear me? CO-CHAIR STILLE: Yes. 8 9 DR. GREEN: This is Dan Green from CMS. 10 So the G-code just to be clear is only to add a 11 quality data code, I believe, in this measure, to 12 indicate that the quality action was performed or 13 not performed. I don't know if that helps at all. 14 CO-CHAIR PARTRIDGE: Peter. 15 MEMBER THOMAS: In other words, it's 16 not a billing code. You don't get paid under a G-17 code, it's just merely a data collection code? 18 DR. GREEN: Generally speaking, G-code 19 -- yes, generally speaking, G-codes are not 20 reimbursable. There are some G-codes for certain 21 services, I want to say Pap smears, for example, 22 that may be associated with reimbursement. But

generally speaking, the G-codes that we have in our program are for quality reporting, just quality data codes where there's not a CPT II code, you know, developed by the AMA, for example.

CO-CHAIR PARTRIDGE: Peter.

7 MEMBER THOMAS: So given the importance of pain management and the opioid epidemic, I 8 9 mean, this is a very important area, so I'm 10 really tossing and turning on this issue of 11 insufficient evidence. And I quess what I'm 12 wondering is -- I'm trying to establish a --13 what's the threshold for this? So in the real 14 practical scenario where a patient comes in to a 15 physician and the physician asks kind of oh --16 even just kind of routine questioning are you --17 you know, do you have pain? And the patient says 18 well, I've got a little low back pain but I'm 19 fine, and they move on in the conversation. Is 20 that an assessment? Does that qualify to the 21 level of an assessment, or is that not really 22 what you're talking about? You're talking a more

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formal thing.

2	DR. BERG: When we do the chart review
3	we are looking to confirm that the G-code
4	actually matched what happened. That's part of
5	the validation that we'll talk about later. We
6	are looking for a specific pain assessment tool.
7	MEMBER THOMAS: Okay.
8	DR. BERG: Not just a
9	MEMBER THOMAS: Not just a random
10	DR. BERG: Not just a question about
11	pain.
12	MEMBER THOMAS: It's higher level than
13	that. Thanks.
14	DR. BERG: Yes.
15	CO-CHAIR PARTRIDGE: Are there more
16	questions from the room? Jennifer.
17	MEMBER BRIGHT: Sorry, I didn't do my
18	tent thing first. Okay, I'm a novice at this, so
19	bear with me while I ask what might be an obvious
20	question. But listening to all this, I certainly
21	agree with Lisa that there is huge value in
22	assessing, asking patients, especially those that

are under-represented what their level of pain 1 2 is. And I certainly agree with the marrying of assessment with a plan. Too often we -- those are 3 4 disjoint. But I guess when I'm thinking about 5 this, what we're talking about is this is a measure of quality, and what I'm hearing is that 6 7 we don't have evidence that we can associate this process with actual quality of care. So we know 8 9 through this process measure the data that you've 10 collected for the last six years or so tells us 11 that there are people doing this, and that it's 12 happening the way it should be happening. But 13 what we don't have evidence for is any indication 14 that it's resulting in quality of care. We're 15 interpreting that. So I guess where I come down 16 on this is, why are doing the -- why is this 17 measure valuable then? It's not to say that pain 18 assessment is not valuable, it's not to say that 19 we shouldn't be doing it better, but what I'm 20 hearing is that we don't have evidence to tell us 21 that this measure is making an impact, or we 22 don't know yet, there needs to be more study.

So in my job in this Committee as I 1 2 understand it, I guess my question is why? Why re-endorse this measure if what we're really 3 4 saying is we need a better measure? 5 DR. BERG: Again, I think it's a fair question. Is that Dr. Green? You can -- I'll 6 7 start then. In many situations when research 8 9 studies are designed and you're going to do a 10 controlled study between one arm or another arm, 11 you have to determine whether harm is going to 12 happen to your patients and what the risk of each 13 of those study arms are. This is a very difficult 14 topic around which to develop a controlled study 15 because obtaining a patient history, and 16 developing then a treatment plan around a history 17 is the standard of care. And to design a study 18 that would exclude that so that you can prove 19 that this is associated with a good outcome might 20 be an unethical study, so this is a very 21 difficult study to develop. About the best you 22 could do is do some type of retrospective review

comparing practices that utilize this tool with practices that don't utilize this tool. Those studies have not been done, but ethically this is a very difficult study that you're asking in order to obtain the evidence that you're asking for.

7 MEMBER CELLA: This is Dave Cella, again. I might be guilty of not understanding the 8 9 evidence criteria. I may be being too broad in my 10 interpretation of it, but although I accept that 11 this particular specific process measure does not 12 have an evidence base in the literature, there is 13 a good size evidence base in support of the 14 practice of monitoring symptoms and altering 15 practice based upon that monitoring and the 16 effect that has upon patients. I mean, there have 17 been enough studies now where there have been 18 reviews of the study that I'm just talking about 19 in oncology and palliative care where, as I 20 mentioned earlier, fairly consistently 21 satisfaction with care has improved by this 22 practice, and less consistently but with a small

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effect overall symptoms are improved with this 1 2 practice in well controlled randomized clinical trials. So that's -- but not with this particular 3 4 performance measure, so if the evidence we're 5 supposed to review is only on this measure or on the practice of monitoring symptoms and making 6 7 treatment plans based upon that monitoring practice, I'm suggesting that the evidence is 8 9 there. And what's not clear to me is whether that 10 is part of what we should be considering as 11 evidence. 12 CO-CHAIR PARTRIDGE: Jennifer, does 13 that help you? 14 MEMBER BRIGHT: It helps me, but it 15 doesn't convince me. 16 CO-CHAIR PARTRIDGE: Fair enough. 17 MEMBER BRIGHT: I guess my take on this 18 is -- a follow-up question is would this practice 19 continue? It's a voluntary measure, number one, 20 so it's not required, but is your sense that the 21 measure is required to keep the focus on this 22 becoming standard of care, because to me that's

the purpose of a quality measure, is to both 1 2 incentivize and insure that there's a consensus understanding of what to do to lead to guality. 3 But if this is (a) a voluntary measure and (b) 4 5 not really demonstrating correlation with quality outcomes, how are we accomplishing that? 6 DR. BERG: So, again, it's -- further 7 in the discussion, if we get past the initial 8 9 vote. But, again, speaking to the gap that 10 exists, there is a practice gap. And it was noted 11 that the performance as more providers have been 12 utilizing the measure, the actual performance has 13 been diminished, and so based on that performance 14 gap we believe that there's still a place for 15 this measure because it's not being utilized by 16 all of the eligible providers that are actually 17 reporting the measure. 18 CO-CHAIR PARTRIDGE: Sherrie. 19 DR. GREEN: So this is Dan Green, also. 20 I mean, I know we're not talking program-21 specific, but for parts of Medicare, I mean, we 22 have over 300 measures in our Ambulatory Quality

Reporting Program. We don't require really any 1 2 specific measures. We do require some specific types of measures in the program. Obviously, I'm 3 4 sure there are other quality reporting programs 5 around, but I think we're probably the biggest. So I understand your point about it not being a 6 mandatory measure, but just for context, none of 7 our measures specifically are mandatory because 8 9 we can't tell a provider, you know, a particular 10 measure is or is not inherent to the care that 11 they give. 12 CO-CHAIR PARTRIDGE: I'm going to go 13 next to Lisa on the phone because she's been 14 waiting. Liz, excuse me. Too many L's, aren't 15 there? MEMBER MORT: Thank you, Lee. I just 16 17 wanted to add into the conversation about the 18 evidence. And I feel that in addition to not 19 knowing whether assessment of pain and an action 20 plan leads to outcome, it's worth noting that --21 and when I read over the detail that the 22 specifications for what the action plan are are

very broad. It really just means you're looking 1 2 for the provider to document that they either gave medication or made a referral. And I think 3 4 that we're really in the throes of trying to 5 understand how to manage pain better, you know, in light of the opioid epidemic, Fentanyl, et 6 7 cetera. We're all getting lots and lots of direction, not all evidence-based but we're 8 9 getting a lot of direction to back off on 10 narcotic opioid prescriptions and use other non-11 pharmacologic or non-opioid prescriptions. So in 12 light of the change in the Joint Commission, in 13 light of what's going on nationally, I feel that 14 there's too much uncertainty in the best approach 15 to pain management to endorse the measure at this 16 point in terms of the evidence. 17 CO-CHAIR PARTRIDGE: Sherrie. 18 MEMBER KAPLAN: I think we're getting 19 a little bit confused between the two competing -20 - I'm hearing two competing kind of issues. One 21 is the under-detection of pain and suffering, and

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the ability of an assessment. And the old wheez

is in public health terms if you monitor it, 1 2 you'll detect more of it. So, you know, there's the sort of is pain really being under-evaluated 3 4 and, therefore, under-detected and unnecessary 5 suffering is going on versus the use and usability issue which is different from the 6 7 evidence-base issue of are there going to be unintended consequences of implementing this 8 9 measure in terms of elevating the prescribed --10 you know, the number of prescribed opioids, et 11 cetera, et cetera? 12 So, Sarah, help. Are we drifting into 13 use and usability here, or are we -- is there --14 what's being -- what evidence are we looking 15 for? 16 MS. SAMPSEL: That's a great question. 17 I mean, yes, I think there have been some other 18 questions that have been trending down the use 19 and usability side, and specifically we're going 20 to talk about that in that section of the 21 measure. But, you know, what I can talk about is 22 the Staff review and the Staff analysis, and to

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interpret why we gave it as insufficient. And 1 2 that was because of the fact that we weren't able, and we were looking specifically for 3 4 clinical guidelines, USPSTF recommendation, or 5 the empirical evidence citing that the actual documentation of a pain assessment and actual 6 documentation of a care plan led to, you know, a 7 change in the intervention or improvement in the 8 9 intervention which then impacted the outcomes, 10 and we weren't able to find that. But that's not 11 inconsistent with other pain measures, and other 12 measures even, you know, kind of how David Cella 13 has been talking about it, that there are some 14 things that, you know, it's kind of if you don't 15 measure it, how are you going to know if it's 16 happening or not? And, actually, the Palliative 17 Care Committee reviewed a very similar measure to this, as well, and they went down the line of 18 19 evidence insufficient but how do you argue 20 against the fact that assessing for pain and 21 putting a treatment plan in place is not 22 important? And, therefore, that's how they

passed, it was insufficient evidence with 1 2 exception, which is available here. So, I do think it's been going down both paths, and what I 3 4 would suggest you all think about is, you know, 5 first of all the requirement for the process measure is some kind of guideline or empirical 6 7 evidence saying it's a good thing. If not, you have the exception possibility, and really kind 8 9 of -- you know, and I think Jennifer got to the 10 question, as well, is then, you know, kind of what does this do with standard of care, and is 11 12 there evidence that supports it? And is there the 13 need for the quality measure, and that's what 14 we're looking for under importance and evidence. 15 CO-CHAIR PARTRIDGE: I saw a card up 16 down at the end of the table. Did it go down? No, 17 all right. 18 MEMBER AVERBECK: A question. You've 19 had about 10 percent it looks like of eligible 20 providers submitting. If the goal is around a 21 screening measure for pain assessment, I'm just 22 curious because it does require a G-code. Are you

finding that the types of practices that are 1 2 using it for the intended use is around sort of general practices, as opposed to practices that 3 4 might be dealing more with oncology patients, 5 palliative care? So just wondering if your field experience is reflective of what the goal is, 6 which is to move it towards population screening. 7 CO-CHAIR PARTRIDGE: Jane, I'm not sure 8 9 you have the data to answer that, but --10 DR. BERG: She's furiously looking to 11 see whether we can answer that question 12 specifically. 13 MS. LUCAS: It looks like in 2014 we 14 have the number of claims submitted by 15 classification of eligible professionals, and it 16 looks like about 50 percent were chiropractic, 17 and about 12 percent were rehab and restorative 18 providers. One of the issues that we have with 19 trying to drill down into the types of providers 20 is that there's a pretty large list of providers 21 that we have, and so we're not always sure which 22 bucket they will fit into, but pretty much it

1	looks like it's physical therapy and chiropractic
2	in 2014. And that was the same year that we
3	actually expanded some of the denominator codes
4	for others to report.
5	CO-CHAIR PARTRIDGE: All right. If
6	there are no further questions, I think am I
7	right? I'm sorry, Linda and Lisa.
8	MEMBER MORRISE: I was just going to
9	suggest that we because I'm hearing mixed
10	responses, that we go ahead with the concept of
11	no, but exception because I think what we're
12	looking at here is that there may not be hard
13	evidence, but we do know that if you don't ask
14	you're never going to get I mean, it's the
15	first step toward collecting that evidence, and
16	so if you take that away then we're not going to
17	get those interventions.
18	The other thing I point out, too, is
19	kind of what was just brought up, is that this
20	isn't just for physician practices, but was meant
21	for expanded use across those who may be
22	assessing pain, so physical therapists,

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chiropractors, et cetera.

2 CO-CHAIR PARTRIDGE: Linda? MEMBER MELILLO: Yes. It's my 3 4 understanding that physical medicine and 5 rehabilitation is one of the few specialties that's not required to submit quality data. Is --6 7 does anybody -- is CMS still on the phone? I believe that's the case, so how would you go 8 9 about -- if -- I mean, you would want to include 10 those folks, including the outpatient physical 11 therapy, so how would you get data from those 12 populations if they're not reporting quality 13 measures? 14 DR. GREEN: This is Dan Green, again, 15 from CMS. PM&R are not excluded from PQRS, for 16 example, and physicians practicing in physical 17 medicine and rehab, at least as proposed under 18 MACRA and the MIPS program will also not be

19 excluded from participation. In fact, they have20 to participate or suffer reimbursement

21 adjustment.

CO-CHAIR PARTRIDGE: I am watching the

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clock a little bit. We still have more work to do on this measure before we conclude, but I think it is time to take our first vote. And Sarah is going to tell me exactly what we're voting on so you all are clear.

MS. SAMPSEL: Yes, I will do that. 6 7 Suzanne just took a drink of water. So the first thing we are going to vote on is the evidence, 8 9 and should -- we'll see how these votes come out, 10 but should the majority fall under insufficient 11 is when we'll talk about the exception, and we'll 12 let the voting tell us which way to go. So, 13 basically, what you're voting on now will be 14 evidence and, Desi, are you ready to take over? 15 MS. QUINNONEZ: Yes. So we are going to 16 be voting on Measure 0420. For those who are on

the phone the first option is high, second option
is moderate, three is low, and four is
insufficient. So option one is high, two is
moderate, three is low, and four is insufficient.
So voting is now open for evidence.

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MS. THEBERGE: Just a reminder for our

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Committee Members on the phone, please submit your votes via the chat. Thank you.

MS. QUINNONEZ: We're looking for 21 3 votes so we're almost there. Okay, voting -- all 4 5 votes are in and voting is now closed. So for option one we have zero percent who voted for 6 7 high, 33 percent for moderate, 24 percent for low, and 43 percent for insufficient. So this 8 9 measure fails for evidence.

10 MS. SAMPSEL: Sorry, we've never seen numbers like this before. Hold on a minute. So 11 12 the measure did not fail. Basically, what we 13 would do is take the moderate plus the 14 insufficient and move forward, and we do think we 15 should vote on the evidence with exception 16 because of the high percentage under insufficient 17 and continue the conversation, but the reality is 18 consensus was not reached on this so we'll 19 continue the discussion, move forward and 20 there'll be an opportunity for reconsideration 21 and revoting after public comment. But let's move 22 forward to evidence with exception just so we

know what that result would be. 1 2 MS. QUINNONEZ: Okay. We will be voting for evidence with exception for Measure 0420. 3 Option one is insufficient evidence with 4 5 exception, and option two is no exception. You can submit your votes. 6 7 MEMBER SALIBA: This is Deb. Can you please explain what no exceptions means in this 8 9 particular vote? 10 CO-CHAIR PARTRIDGE: It's no 11 exceptions. It's with exception. 12 MEMBER SALIBA: I'm sorry. So the first 13 option is -- it's not showing up on my screen 14 what the options are. 15 MS. QUINNONEZ: Yes, I'll repeat. I'm 16 sorry. Option one is insufficient evidence with 17 exception, and option two is no exception. 18 MEMBER SALIBA: Yes, I was asking what 19 -- if you could give me some definitions of what 20 number two, no exception, means. 21 MS. SAMPSEL: It basically means that 22 you do not feel that the measure should move

forward, so it would fail on evidence. So 1 2 insufficient evidence with exception means that you -- you know, there may not be enough evidence 3 4 available to support the exact measure construct 5 but you feel it's an important enough measure despite the lack of evidence. The no exception 6 7 means you don't agree that it doesn't matter what you do with providing more evidence, you still 8 9 don't believe that the measure should be 10 supported based on no evidence. 11 MEMBER SALIBA: Thank you very much, 12 that's helpful. Thank you. 13 MS. THEBERGE: Deb, we still need a 14 vote from you. Thank you. 15 MEMBER SALIBA: Did you get the vote? 16 MS. THEBERGE: Yes. 17 MEMBER SALIBA: Okay. 18 MS. THEBERGE: Can everyone vote one 19 more time? 20 MS. QUINNONEZ: There we are, we have 21 it now. Voting is now closed for evidence with 22 exception for Measure 0420. The results are 90

percent voted yes for insufficient evidence with
 exception, and 10 percent voted for no exception.
 Voting is now closed for the evidence with
 exception for Measure 0420.

5 CO-CHAIR PARTRIDGE: Moving on, Sarah, 6 you have to help me tee up the next part of our 7 discussion.

MS. SAMPSEL: Sure, we'll just move to 8 9 the next set of criteria and so that if -- and, 10 Kirsten, if you want to scroll down on the 11 measure information form now, going into the 12 performance gap and opportunity for improvement, 13 and starting with the lead discussants, if you 14 had any comments about that. And we can start 15 thinking about has it already been said, is there 16 anything you want to -- because I think we 17 crossed over into this a little bit, but are 18 there any remaining comments about performance 19 gap, because there have been some discussions 20 about disparities and percentage of providers 21 reporting, stuff like that.

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MEMBER CELLA: This is Dave Cella, just

1	to say I agree with the review, and have nothing
2	to add. There are disparities on this measure.
3	CO-CHAIR PARTRIDGE: Any of our other
4	lead discussants want to add to David's comment?
5	MEMBER MELILLO: Yes, this is Linda.
6	CO-CHAIR PARTRIDGE: Linda.
7	MEMBER MELILLO: My only comment is
8	that from a patient-centric perspective outcome
9	would be really important, as well. So I know
10	that there's a process when you have to reporting
11	first, but just to keep that in mind.
12	CO-CHAIR PARTRIDGE: Any further
13	comments? Okay, then we can proceed to vote.
14	MS. QUINNONEZ: Voting is now open for
15	performance gap for Measure 0420. Option one is
16	high, option two is moderate, option three is
17	low, and option four is insufficient. All votes
18	are in and voting is now closed for performance
19	gap for Measure 0420. We have 43 percent high, 57
20	percent moderate, zero percent low, and zero
21	percent insufficient.
22	MS. SAMPSEL: So we'll go ahead and

move forward and back to the lead discussants to 1 2 start talking about scientific acceptability, specifically reliability. And the first question 3 there is about specifications. 4 MEMBER CELLA: This is Dave Cella. I 5 think -- is this a category that doesn't require 6 a vote necessarily, because it's a maintenance 7 8 measure? 9 MS. SAMPSEL: So technically, Dave, 10 yes, except for the specifications have changed 11 considerably over time. The first --12 MEMBER CELLA: Okay. Well, I was just 13 -- I would just say, and to repeat the 14 conversation earlier, with regard to the PRO-PM 15 that is the performance measure, reliability is 16 very high. This is not about whether pain is 17 reliably measured itself but whether the pain 18 performance measure -- the performance measure of 19 pain assessment and treatment plan was 20 documented. The reliability is quite high, so I 21 would give it a pass. 22 CO-CHAIR PARTRIDGE: Any other

1 comments? All right, ready? 2 MS. SAMPSEL: Desi, are you ready to move forward? 3 MEMBER KAPLAN: Are we voting on the 4 5 whole reliability issue or just the specs part? MS. SAMPSEL: We vote on the whole 6 reliability, so if there are any additional 7 comments about the testing of the measure as it's 8 9 been retested? 10 CO-CHAIR PARTRIDGE: Sherrie. 11 MEMBER KAPLAN: You have to help me 12 with this because this may be one of those issues 13 where the rules may be about to change and are 14 not applicable in this circumstance. But the 15 between provider variance doesn't look very big, 16 and if you -- I don't know if you actually tested 17 the reliability at the provider level because the 18 unit being compared listed is the clinician or 19 the group level, but the reliability data 20 provided were kappa agreements and it looks like 21 patient level. So can you help us understand what 22 between -- is that a fair issue, or not?

MS. SAMPSEL: Yes. No, they should talk 1 2 about their --MEMBER KAPLAN: Okay. So if it's being 3 used at the provider level, what did you do to 4 5 test the reliability at the provider level like intraclass correlation coefficients? What 6 7 proportion of the variance -- you provided something here that says that only 10 percent of 8 9 the variation is attributable to the provider. 10 DR. BERG: Gary, can you answer that 11 question? 12 MR. REZEK: Yes, I don't think that the 13 percent of the variance attributable to the 14 provider was not something we provided, I don't 15 believe. The -- so the performance score 16 reliability, the signal to noise data was based 17 on all of the claims and registry data. We tested 18 each separately reported. And, again, I'm not 19 quite clear on what the question is, but we also 20 did -- so the kappa results are basically a sample of that data where we extracted data from 21 22 the medical record between two independent

reviewers to basically test repeatability of the 1 2 measure spec. So the inter-rater reliability with the kappa is essentially a different analysis 3 than the performance measure score reliability. 4 MEMBER KAPLAN: So on page 41 there's 5 a column listed between provider variance, and it 6 7 suggests that there's only like 10.5 percent of the variance is attributable to providers so I 8 9 wasn't clear what that meant. Did you do the --10 did you test this at the provider level versus 11 just the agreement between two data sources? 12 MR. REZEK: Yes, that is at -- that is 13 variance at the provider level between providers 14 defined by basically NPI. MEMBER KAPLAN: So just to make sure I 15 16 understand, 10.5 percent of the variance in the 17 claims data, for example, was attributable to the 18 between provider variance. 19 MR. REZEK: I think that that's a fair 20 interpretation. 21 MEMBER MELILLO: So this is Linda. On 22 one of the submission pages, I have the form,

page 3 where you note performance variation, 1 2 showing that 90.6 percent are in the 25th percentile, and there is nobody lower than that. 3 4 Just that there's a very high floor for this 5 measure, and I was wondering how you interpret that? 6 7 MR. REZEK: Yes, I would say the performance scores are sort of highly skewed 8 9 towards high performance. Again, I think where we 10 sort of have difficulty making -- the problem is 11 we have only 10 percent of eligible providers 12 reporting so it's kind of difficult to generalize 13 that, you know, that high performance across the 14 entire population. 15 MEMBER MELILLO: Okay, so the majority 16 of those who are reporting are doing well, 17 obviously. Do you feel that the ones that are not 18 reporting perhaps are not doing as well? 19 MR. REZEK: That is certainly not 20 something that I would --21 MEMBER MELILLO: Okay. 22 MR. REZEK: -- that I have information

1 to --2 (Simultaneous speaking) MEMBER MELILLO: It just struck me 3 4 there was a very high --CO-CHAIR PARTRIDGE: I think that's 5 always an issue with a voluntary measure. 6 7 MEMBER MELILLO: Yes. DR. GREEN: Well, that's exactly right. 8 9 This is -- from our experience with PQRS we can't 10 say with certainty that the folks that aren't 11 reporting are not performing as well but, 12 obviously, people tend to pick the measures that 13 they do perform more highly on. When there's a 14 small percentage of folks reporting, we can't 15 conclude that the measure is tapped out because 16 the argument is well, what about the other 80 17 percent of folks who are not reporting, for 18 example? So we can't say with certainty your 19 assumption, but that's some of the general 20 feeling behind them. 21 MEMBER MELILLO: Yes. Okay, thank you. 22 CO-CHAIR PARTRIDGE: Are we ready to

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vote?

2 MS. QUINNONEZ: All right. Voting is now open for reliability. Oh, one comment? 3 4 MEMBER CELLA: No, okay, it's okay. MS. QUINNONEZ: Voting is now open for 5 reliability of Measure 0420. First option is 6 7 high, second option is moderate, three is low, four is insufficient. First option high, second 8 9 option moderate, third option low, and four for 10 insufficient. Okay. All the votes are in and 11 voting is now closed. For reliability of Measure 12 0420, 24 percent voted high, 67 percent voted 13 moderate, 5 percent voted low, and 5 percent voted insufficient. Measure 0420 for reliability 14 15 passes the reliability criterion. 16 MEMBER CELLA: Okay, for validity? 17 CO-CHAIR PARTRIDGE: Yes, on to 18 validity. 19 MEMBER CELLA: Lee, that was me that 20 caused you to wonder if there was still someone 21 just wanting to say something. This is Dave 22 Cella, again. I think that the latter half of

that reliability conversation is actually a relevant validity conversation, and I think the validity is a little less than high, a little less than clear, also partly related to the original evidence conversation.

I want to just maybe clarify that in 6 7 this case what we're talking about with regard to validity is the validity of that measure as a way 8 9 of differentiating physicians with practices, 10 clinicians with practices on equality and not 11 necessarily our earlier conversation about the 12 validity of the measure in terms of improving 13 care. Is that right? I know that's -- that might 14 sound like a non-distinction, but --15 CO-CHAIR PARTRIDGE: Chris is nodding

16 his head, David.

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17 CO-CHAIR STILLE: Yes. David, I get 18 what you're saying, and I think that's a very 19 important point.

20 MEMBER CELLA: Okay. So, you know, 21 along the lines of, I think, what Sherrie was 22 pointing out and asking about in the

conversation, if you go to 2b5 on the meaningful 1 difference, you'll notice that this 25th 2 percentile even though the mean is 82 percent, 3 4 the 25th percentile is 91 percent if you average 5 up, round up, so there's a -- it's a voluntary program of a small percentage of eligible people. 6 And, apparently, there's a small group of people 7 that are probably doing really badly to pull that 8 9 mean down from a median of 100 percent because 10 there's some people that are participating and 11 just making sure they do it all the time, in fact 12 more than half. There's a group that's 13 participating and maybe they don't realize 14 they're participating and maybe not documenting 15 at all. So I guess it's a matter in terms of the 16 way I'm thinking of it is, you know, do you look 17 at this glass as half full or half empty? Within 18 this narrow band of voluntary participants 19 there's a subgroup of something less than 25 20 percent, maybe only 10 percent given the 21 distribution statistics we have that are really 22 not doing very well at all. And then the question

is, is that distribution which was probably 1 2 contributing to the good reliability but low coefficient that Sherrie pointed out. Is that 3 enough to be not considered a valid measure? And 4 5 I think that may be part of why the Staff review came down moderate at its evaluation. That's 6 7 probably where I land, too, although it's kind of moderate tipping to low in my mind. Welcome other 8 9 discussion. 10 CO-CHAIR PARTRIDGE: Further 11 discussion? 12 MEMBER CELLA: Oh, maybe just one other 13 thing. I'm sorry, Lee. Another thing that I 14 didn't mention that's factoring into that is that 15 low response rate. You know, we don't know about 16 89 percent of eligible people. I don't know how 17 that plays out as a voluntary measure. That just 18 means you do it if you're -- if you want to 19 include it in your panel of performance measures. 20 CO-CHAIR PARTRIDGE: Chris. 21 CO-CHAIR STILLE: This is kind of a 22 shot in the dark but apropos of David's question.

You don't have a visual representation of the 1 2 distribution of responses at all? DR. BERG: Do we? I don't believe that 3 4 we've prepared one in that way. We could provide 5 it for the Committee as a follow-on, but we don't have that right now. 6 7 MEMBER CELLA: But you do see -- I'm sorry to interrupt, but you do see that the 10th 8 9 percentile is zero so, you know, if there's 10 essentially not a lot of people between zero and 11 -- between 1 and 90, so it's just a pretty good 12 group of people that are just not doing it at 13 all. 14 CO-CHAIR PARTRIDGE: Sherrie. 15 MEMBER KAPLAN: I guess to follow-up on 16 David's issue, the issue -- if this is going to 17 be used at the clinician level, then some 18 demonstration that it actually discriminates 19 practices or clinicians one from another would 20 really be helpful. And if you've got a skewed 21 distribution problem that's going to be an issue, 22 and it's going to be tough in a voluntary

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measure. So in fairness to the measures 1 2 developers, that kind of skew in distribution you're really going to see meaningful -- you may 3 be able to demonstrate meaningful differences but 4 5 they're going to be -- or differences but they're going to be so small they wouldn't necessarily 6 7 even be meaningful. So if this is only going to find those few outliers that really have, you 8 9 know, the -- that really are providing crummy 10 care, as mentioned by your current -- the way 11 it's currently being developed, you know, I think 12 we're kind of struggling with if only this had a 13 better distribution, but what we're staring at is 14 the discriminative, the discriminate validity 15 isn't really optimal.

DR. BERG: And again, as it's been pointed out it is a voluntary measure, and so those who are reporting the measure are most likely going to be concentrating on that. I guess one could draw a certain sense of satisfaction from the idea that those who are measuring it are concentrated on using that measure, as well. But,

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again, there are -- as has been pointed out there's a small portion that are not performing well that causes that, you know, overall -- the overall performance rate, you know, amongst all that are using it is still down around 82 percent, and so there is room for improvement there.

MEMBER BRADLEY: I had a question, and 8 9 I guess it relates to the performance and the 10 voluntary participation because there are other 11 measures of pain that other -- that clinicians 12 are using and reporting in addition to this one. 13 So is this one -- do you envision this being on 14 top of or in place of, or -- and does that speak 15 to why you have such low participation because 16 perhaps they're using other measures to report --17

MS. SOMPLASKY: This is Nancy
Somplasky, and I apologize, I was unable to get
through on a speaking line until a few minutes
ago. I'm the Director for this project, so I did
want to offer up some background to help folks

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understand both the history of this measure, but why the importance of it.

The PORS program allows for non-3 physicians, physical therapists, occupational 4 5 therapists, psychologists, social workers to report. This was originally intended as a non-6 7 MD/DO, non-physician type measure so that those physical therapists and occupational therapists 8 9 would have a measure to be able to report. It was 10 so -- it was well received and thought to be 11 important enough that we did have a request from 12 chiropractors to expand to include those MD/DO 13 measures, but it is a claims and registry based 14 measure only. So folks who -- which many folks 15 now with the adoption of electronic health 16 records are reporting electronic pain measures or 17 using their EHR to report their PQRS, their 18 voluntary PQRS reporting program. These measures 19 are only claims or registry based, so what we 20 find is that if a physical therapist is not 21 linked to the Medicare reporting, they are not 22 able to -- they may be measuring the pain but

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they're not able to report that. And that's been 1 2 an important distinction that we've heard that within certain health systems they may not be the 3 4 ones who actually have the billing that 5 submission go in because this is submitted via a claims form into CMS for the program. It's a 6 7 little bit different than what you might see in a hospital for electronic reporting, and certainly 8 9 from a physician practice where I think the mind 10 set tends to be for a lot of the measures being 11 reported. 12 CO-CHAIR PARTRIDGE: Thank you. I hope 13 we're ready to proceed to vote on validity. Desi? 14 MS. QUINNONEZ: Yes. Voting is now open 15 for validity of Measure 0420. Option one is high, 16 option two is moderate, option three is low, and 17 option four is insufficient. 18 MS. THEBERGE: Deb, we still need your 19 vote. 20 MS. QUINNONEZ: Okay, voting is now 21 closed for the validity of Measure 0420. We have 22 10 percent voted high, 52 percent voted moderate,

29 percent voted low, and 10 percent voted 1 2 insufficient. Measure 0420 for validity has 3 entered the gray zone. Now it passes, this measure passes. 4 5 MEMBER CELLA: Feasibility. This is -feasibility is high. It's administrative data 6 7 primarily. It's been in use. CO-CHAIR PARTRIDGE: Looks to me as 8 9 though there are no further comments so, Desi, I 10 think you're up again. 11 MS. QUINNONEZ: All right. We are 12 voting for feasibility for Measure 0420. Option 13 one is high, option two is moderate, option three 14 is low, and option four is insufficient. Okay, 15 we're waiting for one more vote. Voting is now 16 closed for feasibility of Measure 0420. Option 17 one, 67 percent voted high, 29 percent voted 18 moderate, 5 percent voted low, and zero percent 19 voted insufficient. For feasibility Measure 0420, 20 feasibility. CO-CHAIR PARTRIDGE: Usability and use. 21 22 David, any comments?

1	MEMBER CELLA: Yes, it's also high,
2	although, I would add that we probably should at
3	least mention the potential unintended
4	consequence of narcotic overuse, although I think
5	the benefits of the measure outweigh the
6	potential. There's no data that that's the case,
7	but it's on everyone's mind so I thought I would
8	mention it. I think the benefits outweigh the
9	potential.
10	CO-CHAIR PARTRIDGE: Sherrie.
11	MEMBER KAPLAN: Sarah, can you is
12	there an opportunity to put some comment in from
13	the Committee about monitoring unintended
14	CO-CHAIR PARTRIDGE: Yes.
15	MEMBER KAPLAN: consequences of the
16	use in case, you know
17	CO-CHAIR PARTRIDGE: Absolutely. I
18	think, actually, as the summary of this
19	discussion this morning is written up you will
20	clearly see that reflected because it came up
21	right in the very beginning. Any other yes,
22	I'm sorry. Lisa, right in front of me.

MEMBER MORRISE: I'm just going to say 1 2 that while asking about pain is not the same and developing the care plan is not the same as 3 overuse per se, I would point out that in the 4 5 case of many individuals I know with chronic complex conditions, they actually tend to under-6 7 report their pain because they are so used to it. So while some people may game the system as Linda 8 9 suggested to overreport their pain because they 10 are seeking, there are others who don't want 11 intervention, who do the same thing going the 12 other direction, and that's a different study. So 13 I think in terms of the usability, it's easy to 14 use. You ask the question, you develop the plan. 15 So that's my insight. 16 MEMBER CELLA: Agree. 17 MS. QUINNONEZ: Voting is now open for 18 usability and use of Measure 0420. Option one is 19 high, option two is moderate, option three is 20 low, and option four is insufficient information. 21 We're looking for three more votes. Okay, all

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votes are in and voting is now closed. For

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usability and use of Measure 0420, 48 percent 1 2 voted high, 52 percent voted moderate, zero percent voted low, and zero percent voted 3 insufficient information. Usability and use 4 5 passes for Measure 0420. CO-CHAIR PARTRIDGE: Before we take the 6 7 final vote on this measure are there any other comments either from David and company on the 8 9 phone or here in the room? If not ---10 MEMBER CELLA: None here. 11 CO-CHAIR PARTRIDGE: Okay. Sarah? 12 MS. QUINNONEZ: Okay. Voting is now 13 open for the recommendation for overall 14 suitability for endorsement for Measure 0420. 15 Option one is yes, option two is no. 16 CO-CHAIR PARTRIDGE: I think I'm 17 confused. Could we go back to the evidence 18 insufficient with exception issue? If we didn't 19 reach consensus on that point, but we passed 20 everything else, we can now vote yes or no up or 21 down for recommending to go forward. Is that 22 correct?

118

MS. SAMPSEL: That's correct. 1 2 CO-CHAIR PARTRIDGE: Okay. MS. QUINNONEZ: Okay, so we're still 3 looking for votes for overall suitability for 4 5 recommendation for endorsement for Measure 0420. 6 MS. THEBERGE: Liz, we need a yes or a 7 no? Thank you. MS. QUINNONEZ: All votes are in, and 8 9 voting is now closed; 95 percent voted yes, 5 10 percent voted no. For Measure 0420, this measure 11 has passed the usability and use criterion. 12 Excuse me, this measure has passed for 13 recommendation for endorsement. 14 MS. SAMPSEL: So just a couple of 15 comments here. So, first of all, you know, that 16 first vote about, as Lee brought up about the 17 evidence where consensus was not reached, but 18 then there was the pass with exception. What 19 we're going to do there is during -- accept 20 public comment when this measure goes out for 21 public comment, and should anything come up in 22 public comment you'll have an opportunity to re-

discuss in your post-comment call and reconsider if anything is changed. In the same mechanism the developers have an opportunity if they want to pull together more evidence, provide that to you during that public comment section, as well, for re-discussion to see if that vote changes.

7 We've done this in the past where you all, you know, get all the information and you 8 9 make the decision do you want to re-vote or no 10 re-vote, but I think we have a clear indication, 11 or a pretty clear indication that overall this 12 measure is suitable for endorsement. There are 13 some kind of open questions on how to translate 14 that evidence piece.

15 The other thing we just wanted to 16 mention here and kind of because that area was so 17 questionable, we would typically have a related 18 or competing conversation, but I think -- and we 19 would draw your attention to the related and 20 competing section of the measure evaluation form 21 where -- and the original measure information 22 form that Quality Insights presented. There are a

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number of measures that are identified as related, but Quality Insights also provided a lot of information on why those measures are different, and so would technically be related measures.

If you have any comments now about 6 7 opportunities for harmonization, the overall need for measurement on pain, the overall need for 8 9 measure developers to be working together to be 10 measuring pain and documenting correctly, I think 11 we've pulled out a lot of those in the 12 discussion, the overuse issues, potential under-13 use issues, and how to translate those, but this 14 would be the time where if you have any final 15 comments about what the developers should think 16 about related to pain measures, this is where we 17 would have them.

18 MEMBER CELLA: Can I make a comment 19 there? 20 CO-CHAIR PARTRIDGE: Yes, David, go 21 ahead.

MEMBER CELLA: This is Dave. It's

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really an encouraging or maybe even a pressuring 1 2 to move to pain as an outcome, as a reported outcome measure. This is a process measure, and I 3 4 think a few people, I being one of them, you 5 know, have commented on that along the way but I don't think it came out as an explicit, I guess, 6 7 position or perspective of the Committee. I don't know if others agree with that, but I'd like to 8 9 see it move in that direction. 10 CO-CHAIR PARTRIDGE: Linda. 11 MEMBER MELILLO: Yes, just that a lot 12 of the patient satisfaction surveys include 13 questions on pain, and so that might be an 14 opportunity to see if you can match those 15 numbers, correlate. Thank you. 16 CO-CHAIR PARTRIDGE: Becky. 17 MEMBER BRADLEY: Just to clarify that 18 last conversation from the person from CMS that 19 gave us the history of this measure, so it's 20 currently only being reported in the physician 21 quality reporting as a voluntary measure but it 22 was intended for other providers to be able to

report quality measures, so I'm a little confused 1 2 now as to the sample that you selected to review. Is it from the Physician Quality Reporting 3 4 Program only, or was it from the other providers 5 that are submitting claims for this? DR. BERG: So the PORS Program has 6 7 expanded to include a number of eligible professionals now. 8 9 MEMBER BRADLEY: Okay. 10 DR. BERG: So it includes those 11 professionals for whom this measure was 12 originally built. 13 MEMBER BRADLEY: Intended. 14 DR. BERG: And so as I indicated in our 15 introduction, we built it specifically for the 16 physical therapists, and then as was mentioned 17 chiropractors were added. And then it became part 18 of the PQRS Program after the original 19 development of the measure. 20 MEMBER BRADLEY: Okay. 21 CO-CHAIR PARTRIDGE: I see a card up at 22 the end of the table.

123

1 MEMBER AVERBECK: Yes, one other 2 comment. As this measure concept matures to take a look at both pain and function, because it 3 could be that either decrease in pain but may not 4 5 be completely pain-free, and that balance that sometimes it's around improving your function and 6 7 balancing that with the level of pain. Thank you. CO-CHAIR PARTRIDGE: So it's been a 8 9 long discussion, and as you predicted when you're 10 the first measure up you've probably got a lot of 11 questions that will be abbreviated as we work on 12 some of the others, but frankly, I doubt it. 13 We were scheduled to take a break, we 14 are going to take a break. I'm going to ask that 15 in order to keep us more or less close to our 16 agenda's time frame that we make it 10 minutes 17 rather than 15, so back at 11:10, if I'm seeing the clock correctly, and same for our folks on 18 19 the phone. Thank you for staying with us. 20 (Whereupon, the above-entitled matter 21 went off the record at 11:00 a.m. and resumed at 22 11:14 a.m.)

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1	CO-CHAIR STILLE: Okay. Welcome back.
2	We are going to begin discussion of Measure 2967,
3	the package of Home and Community Based Services
4	Experience of Care Measures, developed by CMS.
5	Lead discussants will be Lee and
6	Nicole, and I think Len, right? And Liz Mort
7	also on the phone. And we'll have a three minute
8	introduction by the measure developers. So,
9	welcome, and take it away.
10	DR. LIDA: Good morning. Can everyone
11	hear me? Okay. I'm Kerry Lida with CMS. And
12	I'm in the Division for Community Systems
13	Transformation and the Disabled and Elderly
14	Health Programs Group. Guess not. Okay. Let's
15	try it again.
16	And I'd like to briefly introduce our
17	team who's been participating in this, and
18	working on this. The experience of care area of
19	work is about five years in existence at this
20	time.
21	And so, I'd like to introduce Dr. Beth
22	Jackson with Truven Health, and also Dr. Coretta

Mallery, with American Institutes of Research, AIR.

On the line we should have other 3 4 colleagues from CMS joining us, including Jean 5 Close, who's our deputy director for this division. And in the room also we have Allison 6 7 Weaver, who works with this area of work with us. And I'd like to briefly introduce some 8 9 of the background information. And this will be 10 very short, again, two minutes. Why we developed 11 this area of work. 12 There is no cross disability 13 beneficiary reported measures of service quality 14 or experience with Medicaid HCBS, Home and 15 Community Based Services. 16 And again, this developed over five 17 years, beginning with NQE, the National Quality 18 Enterprise, a grant. And most recently with the 19 TEFT demonstration, Testing Experience and 20 Functional Tools. 21 The development testing of these 22 measures is directly related to a measurement gap

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that was recently pointed out in the 2015 report 1 2 by NQF. Can everyone hear me? CO-CHAIR STILLE: You're a little soft. 3 DR. LIDA: Okay. And the quality 4 5 report notes that there is a lack of systematic measurement of quality of HCBS across payers and 6 7 delivery systems. A brief overview of who the population 8 9 is that we're serving, home and community based 10 Persons receiving supportive Medicaid services. 11 services so they can live at home and participate 12 in community life and employment. 13 I know a number of you are very 14 familiar with the recent shift in spending that 15 we identified also within the background for 16 this. We are over the 50 percent mark of 17 spending for home and community based services, 18 as opposed to the institutional services at this 19 time. 20 Again, as it was noted, we submitted 21 a package, including 19 experience of care 22 measures, including seven scale measures, global

rating measures and recommendations, and
 individual items measures.

The importance of measures on Home and Community Based Services Experience of Care, CMS, and state Medicaid agencies both -- we require information on performance of Home and Community Based Services, providers and programs.

8 And the focus on the experience of 9 care is very consistent with the recent rule in 10 the end of 2014, that CBS rule, with the focus on 11 person centered care, and person centered 12 planning.

13 And the use of the measures that we 14 are intending, states can voluntarily use these 15 results for quality improvement and public 16 reporting. We are using these in current 17 demonstrations.

18 I noted the TEFT demonstration of
19 which we have eight states participating at this
20 time. This was part, and it was also continued
21 from the NQE, where we had the field test data.
22 Round 2 for TEFT is going to be

starting very soon. And those eight states will 1 2 be testing, will be using it again there. There's a broader interest of experience of care 3 4 measures. 5 We have five states who have indicated they would like to use these at this time, 6 7 including Pennsylvania, Massachusetts, Oregon, Nevada, Louisiana. We've had additional requests 8 9 for information from MACPAC, AARP, researchers 10 and MCOs. 11 We do plan a roll out of the data 12 source for the experience of care areas of work, 13 after we receive the CAHPS trademark, which is 14 pending at this time. 15 And also, we have integrated the 16 experience of care areas of work with a close 17 project with the Office of the National 18 Coordinator for an electronic long term services 19 and supports plan that we're developing as part 20 of the TEFT demonstration also. 21 So, thank you for your consideration 22 of these areas of work. We sincerely appreciate

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the opportunity to share this information with 1 2 you today. And I will turn to the next, I'll turn 3 4 it back to our leads for the next steps, and what 5 I anticipate will be a robust discussion that will continue. So, thank you. 6 CO-CHAIR STILLE: Okay. 7 Thank you. So this is a package of 19 different measures, 8 9 measured, I believe the unit of measurement is at 10 the state level, what you've done you analysis 11 as? 12 DR. JACKSON: At the state program 13 level. 14 CO-CHAIR STILLE: That state program 15 level. 16 DR. JACKSON: The state program level. 17 CO-CHAIR STILLE: Okay. 18 DR. JACKSON: Yes. 19 CO-CHAIR STILLE: Okay. Combining 20 different providers that you've worked with? 21 DR. JACKSON: Yes. And there --22 CO-CHAIR STILLE: Okay.

1 DR. JACKSON: There are multiple 2 programs typically, HCBS programs per state. CO-CHAIR STILLE: Okay. Okay. 3 Great. 4 Good. During the break we had talked about how 5 to ideally try to get all of these discussed within an hour. With some preliminary comments 6 7 that we've received, it's obvious that a few of 8 the measures may require some separate 9 discussion. 10 And what we've decided is that there 11 may be one or more that actually require a 12 separate voting. That if one requires separate 13 voting, then we'll have to do a separate vote for 14 all of the different parameters for that 15 particular measure. 16 But then there are many others that 17 may be able to be considered in one lump. So 18 that's kind of how we're going to run things. Ι 19 will turn it over to the lead discussants now to 20 get into some of these things. And who would 21 like to start? 22 CO-CHAIR PARTRIDGE: I will.

131

1	CO-CHAIR STILLE: Lee would like to
2	start.
3	CO-CHAIR PARTRIDGE: I don't know that
4	I'd like to, Chris, but
5	CO-CHAIR STILLE: Okay.
6	CO-CHAIR PARTRIDGE: I should just, in
7	all fairness to our developers and to my
8	colleagues, should point out here that I was a
9	state Medicaid director for almost ten years.
10	And I in our particular
11	jurisdiction it didn't have any HCBS programs,
12	per se. Because we had an extremely broad
13	benefit package. And most of the kinds of things
14	that people were discussing at that point, that
15	would be in a HCBS program, we were already
16	approving as just standard care.
17	Since then the HCBS program I think
18	has morphed into covering categories that most of
19	us would consider marginally medical, a lot of
20	physical adaptation, et cetera, all of which are
21	good and critical to this program.
22	So, my first question, Chris actually

already asked, which is, we are not measuring at 1 2 the state level, we are measuring at the state program level. 3 4 If you wanted to measure at the state 5 level you would presumably take the average, let's say the state had ten programs, their 6 average score. And that would be that state's 7 And then we would look across the state. 8 score. 9 But we are talking at program level. 10 We have a 95 question survey? Am I 11 reading that correctly? DR. JACKSON: You are. You're correct. 12 13 However, there are many skip patterns within the 14 instrument. 15 CO-CHAIR PARTRIDGE: I know. 16 DR. JACKSON: So not all items are 17 asked of the beneficiary, the program 18 participant. 19 CO-CHAIR PARTRIDGE: Right. But for 20 those of you who work with other CAHPS tools, and 21 this one I know is up for endorsement, but maybe 22 not there yet. Ninety-five questions overall is

a pretty big gulp, and can take a fair amount of
 time to administer.

And I think we'll get into those 3 4 questions when we get to usability and 5 feasibility. But, you know, right now when I looked at this initially, I thought, this is 6 expensive. Particularly since we're still 7 talking mail or telephone follow-up. And, Sam. 8 9 MEMBER BIERNER: I just, I'm still 10 trying to understand the state program. Can you give me a feel for how many -- how big is the 11 12 denominator? How many potential, are these each 13 individual, you know, provider surveys, like a 14 home base provider? Like, is there 100 in a 15 state? 16 CO-CHAIR PARTRIDGE: No. 17 MEMBER BIERNER: How many are you 18 talking? 19 CO-CHAIR PARTRIDGE: You're typically 20 talking -- I'm out of date. I haven't been a 21 director for a good many years. But I keep up. 22 And I would guess that in a lot of states you're

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talking of three, four.

2 It depends in part on the size of your 3 state. VNA is often one of your contractors. 4 You may, I don't know. Linda, you live in 5 Massachusetts. You have some idea, I know. MEMBER MELILLO: I'm not sure what 6 7 level --CO-CHAIR PARTRIDGE: 8 Mic. 9 MEMBER MELILLO: -- it would be. 10 CO-CHAIR PARTRIDGE: Well, this --11 CO-CHAIR STILLE: Linda, use your mic. 12 MEMBER MELILLO: Oh, I'm sorry. No. 13 I'm not sure which groups within the state you 14 would be referring to. Do you --15 DR. JACKSON: May I answer that? 16 CO-CHAIR PARTRIDGE: Please. 17 DR. JACKSON: Yes. Frail elderly, 18 working age disabled, for the most part. Okay. 19 Physically disabled. People with intellectual 20 disabilities --21 CO-CHAIR PARTRIDGE: Okay. 22 DR. JACKSON: -- and developmental

disabilities. People with brain injuries. 1 It 2 encompasses those groups of individuals. And I 3 think the working age disabled could include 4 other, you know, other sub-groupings of people 5 with physical and/or cognitive disabilities. MEMBER MELILLO: 6 Okay. But at the 7 state program level. DR. JACKSON: State program level. 8 9 And they're -- some states may have four or five. 10 There are some who, up to 11 of these separate 11 programs. 12 MEMBER MELILLO: Okay. So, like the 13 Massachusetts Brain Injury Association? 14 DR. JACKSON: It's brain injury waiver 15 typically, the 1915(c) waiver programs. MEMBER MELILLO: 16 Yes. 17 DR. JACKSON: Yes. 18 CO-CHAIR PARTRIDGE: Okay. Great. 19 Thank you. 20 DR. JACKSON: Although there are other 21 authorities as well. 22 CO-CHAIR PARTRIDGE: We are going to

1 talk about these as a group. So, as we think 2 about the different measures, we've got five sets, I think. The data source is the same. 3 4 It's this survey tool. 5 I guess, at what point do we Okay. talk about which ones we might want to pull out? 6 7 Maybe I'll just stop and ask my fellow discussants for comments that they might have. 8 9 Most --10 CO-CHAIR STILLE: Okay. What, yes. 11 Why don't we have general comments from the lead 12 discussants, and then the discussants can 13 recommend any that they really feel should be 14 pulled out for separate voting. And then we'll 15 open it up to everyone. So, Len. 16 MEMBER PARISI: Thank you. So, I 17 quess I still need some clarification on the 18 population. Are these beneficiaries that are 19 enrolled in a managed long term care program? 20 Or, I'm still not clear on who these are. 21 DR. JACKSON: It is both. Both fee-22 for-service as well as Managed Long Term Services

and Supports. There are well over 300 of these 1 2 waiver programs, non MLTSS fee-for-service in the country, nationwide. 3 4 There are also Managed Long Term 5 Services and Supports programs that were part of the testing, and for which these measures would 6 be applicable as well. 7 MEMBER PARISI: So, in a -- I'm 8 9 already at the point where I'm trying to 10 understand what we're really evaluating. So, at 11 the end of the day the goal is to evaluate a 12 Medicaid program? 13 DR. JACKSON: Yes. 14 MEMBER PARISI: For each state? 15 DR. JACKSON: Medicaid programs 16 typically --17 MEMBER PARISI: Not, okay. 18 DR. JACKSON: In a state where you 19 have a unified Managed Long Term Services and 20 Supports program it may be one program that 21 you're evaluating. 22 However, the measures could be applied

and used across MCOs to compare the experience of 1 2 beneficiaries in those different managed care organizations that are part of the Medicaid MLTSS 3 4 program. 5 So, that's how I was MEMBER PARISI: looking at it. But it seems like it's more than 6 7 that. DR. JACKSON: It's both and. 8 9 MEMBER PARISI: Okay. And these are 10 not certified home health agency patients? 11 They're not on a short episode of care? These 12 are long term? 13 DR. JACKSON: Yes. This is long term 14 home and community based services to people who 15 would typically otherwise be being served in an 16 institution. So, it is long term services and 17 supports. 18 MEMBER PARISI: So, there would be no 19 overlap. What if they were on an episode of care 20 in a certified agency while they were still on 21 this program? Would they be excluded in any way? 22 DR. JACKSON: It's -- they may be in,

may be receiving those post-acute care services. 1 2 But in general they're enrolled in this program. They met the eligibility criteria. 3 Say there is an episode, they go to 4 5 the hospital, and they need to go to rehab. And then they would go back home. 6 7 MEMBER PARISI: Thank you. 8 CO-CHAIR PARTRIDGE: I'm now getting 9 totally confused. I thought the entity we were 10 evaluating was typically a subcontractor, an 11 entity with whom the state can, Medicaid agency 12 contracts to run an HCBS program for X, whether 13 it's your DD population or your physically 14 handicapped, or --15 But if this is somebody who's enrolled 16 in a Medicaid managed care program, like a dual, 17 well, forget it's a dual, just Medicaid managed 18 care program, the entity you would be measuring 19 would be the MCO's performance, with respect to 20 that segment of their population? 21 DR. JACKSON: I want to distinguish 22 between managed care for the Medicaid population

in general, and Managed Long Term Services and 1 2 Supports programs, which may include both long term services and supports, as well as 3 4 healthcare. 5 And some states roll the two into one Some separate out the MLTSS. But we're 6 program. 7 talking about the MLTSS portion. If they're being served. If their healthcare is being 8 9 provided as well as long term services and 10 supports. So, we're parsing out the HCBS 11 portion. 12 CO-CHAIR PARTRIDGE: But, you're then, 13 if the -- okay. I just, I tend to go back to 14 thinking, who's the provider in front of me? And 15 what's the score for that provider? And --16 DR. JACKSON: And this is a score for 17 all homemakers that are serving that program, 18 that HCBS, say waiver program. For people who are being served, a waiver that's serving --19 20 CO-CHAIR PARTRIDGE: But those 21 homemakers are being hired and paid by some 22 entity.

1	DR. JACKSON: Typically, right. But
2	they're typically
3	CO-CHAIR PARTRIDGE: It could be the
4	state itself. I understand that.
5	DR. JACKSON: It could be. It could
6	be.
7	CO-CHAIR PARTRIDGE: But, okay.
8	CO-CHAIR STILLE: Okay. Len, did you
9	have some other questions before we
10	MEMBER PARISI: I guess, I guess
11	and that's a really important point. Because, I
12	mean, the goal of measurement is to have that be
13	actionable so there can be some improvement.
14	And when it's in the case that you
15	just described if you have multiple agencies that
16	are providing various homemakers or staff to
17	beneficiaries, it's hard to make that, those
18	measures actionable to improve. Because you
19	don't where to go with that.
20	So that was one of the things. As I
21	was reading this it wasn't clear how you can
22	actually do something with this information.

1	DR. JACKSON: The accountable entity?
2	(Simultaneous speaking.)
3	MEMBER SALIBA: This is Deb Saliba.
4	Can I slip in for a second, to say that, you
5	know, from California's perspective, I'm actually
6	working with the state right now. And sort of
7	trying to come up with a more unified approach to
8	home and community based services.
9	The, I think you want to have some
10	sense of how the state is doing and organizing,
11	and setting up its programs for Home and
12	community based services Based Services.
13	So you're right. It's often a
14	hodgepodge of a lot of different programs. But
15	from the consumer's perspective what matters is
16	whether their needs are being met. Not so much
17	which programs.
18	And if we're seeing variations that,
19	you know, in some states that have a more
20	let's just say is systematically organized, the
21	systems tend to have better performance than in
22	regions where there's less systematic

organization. Or vice versa, where there is sort 1 2 of the more hodgepodge approach, might actually have higher levels of satisfaction. 3 4 I think that would be the way I would, 5 you know, I think that would be very useful and helpful information from an HCBS, the Home and 6 7 community based services perspective. Though I think we -- I agree with you 8 9 that it would also be nice to be able to look at 10 it at the provider level. But, for example, the 11 largest program in California is a program where 12 the consumer gets to hire their own -- basically 13 select their own person to do their in home care. 14 And so, you know, we're really not 15 looking at a specific provider of care. I mean, 16 the state directly pays those people. But it's 17 the consumer that's selecting them and 18 supervising them. 19 So, I think there's a lot of 20 variability. But we really need some way of 21 understanding what's going on in that space. 22 CO-CHAIR STILLE: Great. Deb, thanks.

That's an important thought. And please hold 1 2 that thought. Because I think we can talk about that during the usability and use section. 3 4 I'd like to get Len, and then Nicole to kind of do their -- sort of finish their lead 5 discussant stuff. And then we'll move forward. 6 7 Anything else? The other, I'm focused 8 MEMBER PARISI: 9 on the population. Because it wasn't clear who 10 we're actually trying to evaluate in terms of the 11 services that they receive. But it was clear, 12 based on the discussion, who that is now. So, 13 thank you. 14 CO-CHAIR STILLE: Okay. Nicole. 15 MEMBER FRIEDMAN: And I don't know if 16 these will be more appropriate to get into 17 further in the usability. But also thinking 18 about the population. 19 And if we're evaluating homemakers, 20 and caregivers, and different entities, how does this measure? If there's different levels of 21 22 care that the state deems, you know, a certain

146

2 their need is, how does this measure look at 3 that? 4 And especially around the component 5 around unmet needs. Knowing that it might be that, you know, the person doesn't qualify for a 6 certain amount of hours. Or there's variability 7 in the amount of care in home. 8 9 DR. JACKSON: It does not control for 10 that. What the measures do is tell you whether 11 or not the person's needs are being met, at 12 whatever level of service provision has been 13 authorized for them. 14 CO-CHAIR STILLE: Nicole, any other 15 points as lead discussant that you wanted to 16 make? Questions? 17 MEMBER FRIEDMAN: I think mine are 18 more for the usability. 19 CO-CHAIR STILLE: Okay. Great. So 20 we'll do that then. Good. Okay. Thank you. 21 Sorry. 22 I want to point out MEMBER MORRISE:

amount of hours a person gets, or based on what

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that my daughter was the recipient of a home and 1 2 community based waiver. I'm very familiar with I actually worked in the managed care 3 them. division of Utah Medicaid for awhile in the home 4 5 and community based services area. And while this does not apply to 6 individuals under the age of 18, I have a number 7 of friends who graduate into adult based waivers, 8 9 based on disability services, traumatic brain 10 injury, as you suggest. 11 Individuals in our state also are able 12 to contract privately with providers. And then, 13 based on who their managed care provider may be, 14 they also go through agencies for services. It 15 depends on how the specific waiver is written, 16 and what services they are able to access under 17 the waiver. 18 There is a real need, on an aggregate 19 or composite, to determine if these services are 20 efficacious. And so, I really liked this when 21 looking through it.

I can see where a state could

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potentially find out on an aggregate that needs 1 2 were not being met. And then implement some kind of effort to mitigate that. But they wouldn't 3 4 know, again, they won't know if they don't ask. 5 And these services are vital to being able to be in the community for so many of our 6 7 disabled, but able to function individuals, with minimal support in the community. 8 9 And I'll tell you, these kids hate to 10 still be living with their parents because 11 they're the only ones who will take care of them. 12 And these kinds of waivers get them out. 13 But unlike when my daughter was on the 14 waiver, and I was managing the providers and 15 making sure that the people coming into my home 16 were doing what they were supposed to do, or then 17 reporting them, the kids don't always have the 18 same ability to follow-up unless they're asked. And I think it's really important. 19 20 And when I say kids, I'm sorry, I am 21 getting seasoned. I'm talking about mostly young 22 adults, 20s, 30s, who are able to be in the

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community thanks to these waivers. 1 2 CO-CHAIR STILLE: Okay. MEMBER FRIEDMAN: That's all. 3 4 CO-CHAIR STILLE: Great. Thanks. 5 Sherrie, and then Nicole. And then we'll start to talk about evidence. 6 7 MEMBER KAPLAN: I'm still confused about the attribution, where -- what's being 8 9 evaluated, what's the unit being evaluated. 10 Because it sounded like, it's clearly the state's 11 program that's being evaluated. On the other hand, if there are, as 12 13 suggested, and maybe I heard this wrong, some 14 states have one, and some states have multiple. 15 And so, the sort of nesting, you're going to 16 confound states with programs that only have one 17 program. 18 And for states with multiple programs, 19 how much of the variation within -- where is the 20 attribution going? Is it to the -- because some 21 components are going to attributable to the 22 state.

But, and they're, if you've got 1 2 multiple programs it's more easy to evaluate. Is there a lot of between state, within state 3 4 variation over programs? And how much of this 5 belongs to things that the, you know, the state's program initiatives, et cetera. 6 7 Are you going to be able to distinguish the state variation from the program 8 9 variation? And is there going to be a lot of 10 reliability issues when we come to those, in 11 estimating the within versus the between program 12 variation within a state, across states? 13 DR. MALLERY: So, I think that's 14 important to point out right at the beginning is 15 that these will be administered moving forward by 16 the states. So they might be administered 17 differently within each state. 18 So, I don't think there is a plan to 19 look at, to compare states at this point. So, 20 it's almost like we have to look at within each 21 state what is the different state's plan.

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Because they are very different. So, there isn't

1 a current plan to compare states. 2 CO-CHAIR STILLE: Okay. DR. MALLERY: Does that help clarify? 3 4 MEMBER KAPLAN: Yes. I mean, I was 5 trying to sort of get a sense of where, what your, ultimately the intent is. 6 But if it's 7 still -- you're not going to quite escape the issue of the confounding of state with program --8 Right. 9 DR. MALLERY: 10 MEMBER KAPLAN: -- for states that 11 don't have very many of these things versus 12 states that have multiple of these things. And 13 then you can really look at, you know, is there 14 variation across the state. 15 So, if you're doing it within states, 16 that's even kind of a more perplexing problem, or 17 potentially perplexing problem. 18 DR. JACKSON: I'd just like to add 19 too, that this is going to -- this would be 20 voluntary. 21 CO-CHAIR STILLE: So, Nicole and then 22 And then I think we kind of need to move Beth.

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on to the different parts.

2	MEMBER FRIEDMAN: Sorry. For the
3	population that you would be excluding getting
4	the survey, it says that it's folks that cannot
5	pass cognitive screening. And at least in my
6	experience a lot of the frail elderly who are
7	getting in home service do have cognitive
8	impairment.
9	Would you consider including
10	caregivers or family members? Or how are you
11	going to include this, you know, in my opinion
12	big population that we want to have a to be
13	heard?
14	DR. JACKSON: For the testing, because
15	we were going for a CAHPS trademark, and they
16	historically have not allowed proxies, for the
17	most part we excluded them.
18	It became clear as we were progressing
19	in the field tests that proxies were popping up.
20	And so, we did allow them from a certain point
21	onward.
22	What we are doing in the

demonstration, in the TEFT demonstration for 1 2 Round 2 of data collection is allowing the TEFT state grantees to experiment with that. 3 So 4 moving forward there's an acknowledgment that 5 proxies may be necessary. DR. MALLERY: Can I just clarify that? 6 7 The proxy data are not in the results that are presented in this packet. So we would have had 8 9 about 1,000 more responses if we would have 10 But because it wasn't administered to included. 11 proxies consistently throughout --12 CO-CHAIR STILLE: Okay. 13 DR. MALLERY: -- we excluded those 14 from these analyses that are reported here. 15 CO-CHAIR STILLE: Okay. So your data 16 in which you're applying for is without proxy? 17 DR. MALLERY: That's right. 18 CO-CHAIR STILLE: But maybe that might 19 And then what does TEFT mean? change. I'm 20 sorry. 21 DR. JACKSON: Testing Experience and 22 Functional Tools.

1 CO-CHAIR STILLE: Okay. And, Beth, 2 you've been waiting patiently. MEMBER AVERBECK: I think, Lee, you 3 had mentioned earlier on whether or not we pull 4 5 any of the questions out separately. And I don't if we're getting to that, or if you want any 6 So, I should wait? 7 comments now. CO-CHAIR STILLE: Just wait 30 8 9 seconds. 10 MEMBER AVERBECK: Okay, great. 11 CO-CHAIR STILLE: Okay, great. We'll 12 start to discuss the evidence now. And I'd first 13 ask if any of the lead discussants feel strongly 14 that we need to pull one or more particular 15 measures out of this package. 16 CO-CHAIR PARTRIDGE: I think I would, 17 I'd be more comfortable if we pulled the physical 18 safety question out as a separate one. Because 19 it seems to me it gets close to the never events 20 issues. 21 CO-CHAIR STILLE: Okay. And that, is 22 that Number 19, I guess, in the list they have?

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Okay. Others?

2 CO-CHAIR PARTRIDGE: The other 3 possibility I would maybe note, and I'm not sure. 4 When you look at the performance gaps, as I read 5 the data it wasn't significant on all but the questions relating to unmet needs. And then I 6 7 said the physical safety one. There are the five measures relating 8 9 to unmet needs. And I don't know whether that's 10 appropriate to pull them out separately, or just 11 raise it when we talk about the whole package. 12 Sarah? 13 CO-CHAIR STILLE: Okay. So --14 CO-CHAIR PARTRIDGE: I don't want to 15 see five separate ones. 16 CO-CHAIR STILLE: Right. So 17 potentially the unmet needs is a package. 18 MEMBER PARISI: So, I hate to ask the 19 question. But I'll bring it up. So when Sarah 20 had talked about the concept of approving, or I 21 think maybe you did Chris, approving the tool 22 versus approving the criteria. So, we're looking

1 at this as 19 different measures, and not as a 2 tool, right? CO-CHAIR STILLE: 3 Right. 4 MEMBER PARISI: And that's how it's 5 going to be loaded? Okay. MEMBER BEVANS: That almost got at my 6 But, just so I understand as a 7 question I think. 8 point of process. If we were to approve this 9 measure set, would that be like NQF saying that 10 use of this measure must, is recommended to be 11 used as a full measure set? Or does that mean 12 that it could be used piecemeal? 13 So this is similar MS. SAMPSEL: Yes. 14 to, in Phase 1 with the CAHPS measures. And what 15 we would see is different programs report 16 different measures. So, we would be, you know, 17 potentially endorsing 19 measures. 18 But that's what we're trying to get at 19 Are there any you would like to pull out now. 20 that make you very uncomfortable on making an 21 endorsement decision on? Or do you feel that 22 there needs to be a discussion?

What happened in pediatric project, I 1 2 believe, Suzanne. And maybe, Suzanne, why don't you talk about how it was handled in pediatrics. 3 4 MS. THEBERGE: Sure. We had a 5 It was similar to this. And we ended measure. up, the committee requested that the developer 6 7 split it into 19 separate, or sorry, it wasn't It was ten in that case. Ten separate 8 19. 9 measures. 10 And the committee voted on each one 11 separately. Eight of them were endorsed. And in 12 between the -- before the public comment period 13 we went on the back end and split them out. So 14 they became ten separate measures, with ten 15 separate numbers. And the sub names of measures 16 were the new title of the measure, et cetera. 17 MS. SAMPSEL: But, and back to your 18 question as well, Katherine, is, I mean, I think 19 states in turn, and I think you guys should 20 answer this. 21 States in turn could say, we're only 22 in our -- on our state dashboard for HCBS cert

1 programs we're only going to report the global 2 ratings measures. Even though all are endorsed, states may choose to only report some of them. 3 4 CO-CHAIR STILLE: Okav. 5 I think that's correct. DR. JACKSON: CO-CHAIR STILLE: Others that feel 6 7 strongly about separating any particular -- Len, 8 you have your hand up. 9 MEMBER PARISI: Well, question one and 10 two, when you say staff, I don't even know who that's looking at. Is it the homemaker? 11 Is it 12 the case manager? Is it -- it's very unclear. 13 So, I'm not sure that that would be something 14 that you could even have a discussion about it, 15 in terms of voting. 16 CO-CHAIR STILLE: So, yes. That might 17 be more for the validity discussion. 18 CO-CHAIR PARTRIDGE: Well, I'm going 19 to try to help you out, Len. I don't think you 20 would be directly measuring the individual 21 homemaker. I think you would be --22 In the, and I'm talking really very

much from a common sense, I used to run this 1 2 program kind of perspective, and not from the measurement set issue perhaps. 3 4 If I had, as you do in Utah, and I guess a couple of other states, a family in which 5 you can choose your provider yourself from an 6 approved list, supplied by the state. 7 I would say in that case the entity 8 9 you're measuring is the state agency itself. How 10 well does it select the people with whom it 11 contracts, monitor them, and so on? They're being -- in my state, for 12 13 example, it was run by our Department of Social 14 Services. So that would be, you would be 15 evaluating the state. 16 But if you turned around and 17 contracted with say the ABC Home Health Agency to 18 contract with that group of homemakers, and 19 supply them, and pay them, and monitor them, and 20 vet them, and so on. You'd be evaluating the ABC 21 Home Health Agency. Am I right? I mean, CMS, am 22 I --

1	DR. JACKSON: What I'd like to do is
2	just direct us to the actual items, or questions
3	in the survey that
4	CO-CHAIR PARTRIDGE: They do get
5	there, right.
6	DR. JACKSON: identify who that
7	worker is. And it can be a personal assistant, a
8	behavioral health staff, or a homemaker for this
9	particular scale. So it is identifying in
10	general an individual.
11	CO-CHAIR STILLE: But it's not
12	reported like that in the data? Or just
13	aggregated at least one level above that, right?
14	Okay.
15	DR. JACKSON: It's at the program
16	level
17	CO-CHAIR STILLE: Right.
18	DR. JACKSON: that it's reported.
19	CO-CHAIR STILLE: Right.
20	DR. JACKSON: Yes.
21	CO-CHAIR STILLE: Okay. Sherrie, you
22	had a point?

MEMBER KAPLAN: Just one point about 1 2 if states can cherry pick off from these things? The single item measures are notoriously 3 4 unreliable. So it does change the conversation 5 about whether we want to include those as a group 6 7 discussion and, you know, because the reliability issues do change when you have single item 8 9 measures that could be potentially lifted out of 10 this. 11 If you're going to, you know, attribute to the program, and it's got all this 12 13 kind of variance that's attributable to the 14 program from the kinds of people that are 15 contracted with the providers of the program, 16 yada, yada, single item measures really have that 17 as a separate issue. 18 CO-CHAIR STILLE: And the single item 19 measures would be 11 through 19, I guess, right? 20 Nicole, you have a thing up? Yes. Okay. 21 MEMBER FRIEDMAN: I just had a 22 question to clarify. So for the scale measure,

2 these services that are --As mentioned, there's not a lot of 3 That there's kind of a bundled element 4 choice. 5 of services that Medicaid will pay for. And so, I just don't see how, if there's, how the 6 7 recipient, or the customer would be able to have choice of the services. 8 9 There is typically a DR. JACKSON: 10 package of services per program that the individual can choose from. So for example, 11 12 personal care. An individual may have a personal 13 assistant come into the home. Or they may go to 14 an adult daycare to receive those services. So 15 it's that kind of choice we're talking about 16 here. 17 CO-CHAIR STILLE: And then, Jennifer, 18 did you have a question? 19 MEMBER BRIGHT: Yes. Just, first a 20 point of clarification. We're still talking 21 about how to approach these, as opposed to the 22 evidence part, right?

choosing services that matter to you. Aren't

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1	CO-CHAIR STILLE: That's right.
2	MEMBER BRIGHT: I wanted to make sure
3	I ask a germane question
4	CO-CHAIR STILLE: Yes. That's right.
5	MEMBER BRIGHT: before I do
6	anything. So, this is a question to the
7	developer. Can you differentiate for me why
8	we're talking about both a global ratings set of
9	measures, and a recommendations measures?
10	Because to me they kind of get at the same thing,
11	but just at a different approach.
12	And given that one of the immediate
13	concerns is the scope of the scale of this, why
14	are you trying to lump so many things under one
15	umbrella, is one question.
16	And the second is to reiterate the
17	previous comment about individual items. I would
18	say we should be talking about these as kind of
19	buckets. I mean, there's, the scaled measures
20	are really about specific measures of quality of
21	the services, and types of services that are
22	being provided.

The global ratings and recommendations 1 2 measures are really patient satisfaction. How do you feel about what you're getting? And the 3 4 unmet needs is trying to assess where there are 5 gaps. So, if we're trying to figure out a 6 way to break this up, I would posit that we 7 should be thinking about them in those buckets, 8 9 as opposed to pulling them all apart into 19 10 different painful discussions. 11 CO-CHAIR STILLE: And so we have five 12 buckets with Number 19 in its own bucket. And, 13 you know, that's interesting. So, considering 14 these as five groups of measures, I think would 15 answer everyone's concerns, from what I've gotten 16 so far. 17 MS. REED: Chris, can I just follow-18 up? 19 CO-CHAIR STILLE: Yes. 20 MS. REED: Because this, I didn't want 21 to be misleading. When, like the CAHPS measure, 22 I was involved in the initial CAHPS measure, way,

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way, way long ago.

2	When we did that you put, you sort of
3	general overall ratings and recommendations
4	that's what we call behavior intentions. The
5	latter being behavioral intentions. And the
6	global rating items are used as validation items
7	for these subscales.
8	So, the scales for, you know, the
9	staff are reliable and helpful, and the staff
10	listen to me, and everything, those sort of
11	overall ratings are usually used for validation
12	internal to the instrument construct validation.
13	So, we want to make sure we're
14	measuring where we so, you wouldn't sort of
15	that's why I freaked out. You wouldn't
16	CO-CHAIR STILLE: Right.
17	MS. REED: separate those from the
18	interior of the subscale structure that tells you
19	where you need to focus the improvement. Because
20	you want to use those measures to find the
21	drivers of the overall ratings. For example.
22	CO-CHAIR STILLE: Right. So don't use

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one without the other is kind of what you're 1 2 saying. Yes. MS. REED: I was just saying it 3 4 wouldn't be really, I would feel uncomfortable 5 breaking those out as a separate set when they're usually used in the context, especially HCAHPS 6 7 and CG CAHPS, and so on. 8 They still put those, you wouldn't ever separate 9 those out. 10 CO-CHAIR STILLE: Right. Linda. 11 While we're catching our breath and figuring out 12 what to do next. 13 MEMBER MELILLO: So, I'm going to 14 muddy the water a little bit. Community services 15 frequently offer employment services as well. Ι 16 didn't see that anywhere. 17 DR. JACKSON: You didn't. It is in 18 the instrument. There is what we're considering 19 now a supplement to the instrument, an employment 20 supplement. 21 And the reason that it really was not 22 tested, because so few people who were surveyed

answered the question in a way that said, yes, 1 2 I'm either interested in employment, or I am working. And you had to -- that was the trigger 3 4 for those -- for that battery of questions. And there were so few who said either, 5 yes, I'm interested in working, not currently 6 7 working, or I am currently working, to administer that supplement. So it is a supplement. But we 8 9 did not test it. And I'll defer to my 10 statistician here. 11 DR. MALLERY: So, those items will 12 still be part of the instrument that we're not 13 technically talking about here, but it will be 14 part of the survey. So states will be able to 15 still use those items. But we're not putting those up for endorsement, because we just had too 16 17 few respondents to be able to sort of report 18 reliability and validity --19 MEMBER MELILLO: So, how many 20 additional questions is that? DR. MALLERY: I can tell you in a --21 22 give me a minute. But it -- yeah.

DR. JACKSON: Again there are a lot of 1 2 skip, there are skip patterns. So. CO-CHAIR STILLE: Okay. While you're 3 4 looking, what we've decided to do -- this has 5 been a great discussion, by the way, so, thank We're going to take any more general 6 you. 7 questions, including about, you know, splitting up discussion. We'll take public comment. And 8 9 then we're going to break for lunch and discuss 10 how we're going to vote on these while we're 11 eating lunch. 12 We're going to take a 20 second time 13 out, is really what we're going to do. So a little more than 20 seconds. 20 minutes? 14 Ι 15 don't know. 16 MEMBER THOMAS: I haven't said 17 anything. Oh, I'm sorry. 18 CO-CHAIR STILLE: Okay. Jennifer, I 19 think you were first. 20 MEMBER BRIGHT: I just wanted to go 21 back to the first question I posed to the 22 developers, which is, can you help us understand

the difference in the global ratings measures and
 the recommendations measures?

Because, again, I think they're trying to get at the same thing. And what's the value of having both? Because perhaps there should be some consideration of consolidating. I don't know.

DR. MALLERY: So, I would argue to 8 9 I think they are used somewhat keep both. 10 differently. And the global ratings items, again, are often used to correlate. I think that 11 12 -- I mean, I guess they both could be used for 13 that, for those purposes. But I do think they 14 could be used slightly differently. But I do 15 understand your point that they might be getting 16 at the same concept.

17 CO-CHAIR STILLE: Okay. Becky, and18 then Nicole.

19 MEMBER BRADLEY: I just had a question 20 about the intended use. Do you intend this data 21 to be publicly reported in any way? Because, 22 unlike some other providers, services, patients,

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or communities, I mean, their only option would
 be to move to another state where there's a
 better program.
 So, how do you intend to use the dat

So, how do you intend to use the data from this? And I guess that gets to intended use. But I apologize for that.

DR. MALLERY: Yes, thank you for your 7 And at this time we're just looking at 8 question. 9 states who are voluntarily using it. And so it 10 would be their option for the TEFT states that we 11 We have eight TEFT states who will be have. 12 using this. TEFT again was Testing Experience 13 and Functional Tools. It is their option if they 14 would like to publicly report it.

15 The initial round 1 of the data, we 16 did not publicly report it. It was available in 17 individualized reports to the states. And then 18 we shared information on -- aggregate 19 information, but the states did not want that 20 information reported. They wanted to keep it for 21 their own purposes. And we respect that. But 22 again, that was just for the TEFT demonstration.

We're doing the same thing for Round 1 2 No plans have been made past that, beyond 2. You know, we have five states who have 3 that. 4 expressed interest in using this. That would be 5 their option. I don't know if Beth or Coretta have information to add to that. 6 7 CO-CHAIR STILLE: Okay. Peter. MEMBER THOMAS: Just really quickly, 8 9 as a general comment. I would think this --10 first off, this is an area that is just 11 tremendously important for the disability 12 community, the fact that the 50 percentile has 13 been breached and we're now in a situation where 14 we could provide care under Medicaid through home 15 and community-based services more often than 16 through institution-based services, especially 17 for some of these populations, like brain injury 18 and working age adults with disabilities, and the 19 like. 20 So, this is a critical area that I'm 21 really excited that we're kind of considering 22 this. And I can most definitely see the states

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taking a real stock of their different programs,
 their different waiver programs.

And there's so much variation in the 3 states on how these programs are run that it can 4 5 help the states determine whether the program, and the goals that they need to achieve with a 6 particular program, are actually current, whether 7 the end users feel that they're empowered to hire 8 9 their own personal assistant. Or whether they've 10 gotten too many restrictions in the program that 11 it's not working the way they envisioned it.

12 And that's really valuable information 13 that I think states can use to improve all of 14 these different types of programs. So, 15 tremendous variation across the states. But I 16 can most definitely see these measures being very 17 useful, not only for the states, but for the end 18 users.

19 CO-CHAIR STILLE: So, good. So, where 20 I would like us to be when we finish talking in 21 the next couple of minutes is ready to come back 22 from lunch to talk about evidence, validity,

reliability, usability, use, and that kind of 1 2 thing, in whatever buckets we end up talking about. 3 4 So, other general questions before we 5 open it up to public comment? So, should we? People on the phone? 6 Okay. 7 MEMBER CELLA: None here, thanks. CO-CHAIR STILLE: 8 Okay. 9 So, public comment. MS. THEBERGE: 10 Operator, can you open the lines for public 11 And if anyone in the room would like to comment? 12 make a comment, there's a microphone. 13 OPERATOR: Yes, ma'am. At this time 14 if you'd like to make a public comment, please 15 press star then the number 1. 16 MS. THEBERGE: Comments can also be 17 submitted via the chat function on the webinar. 18 OPERATOR: And at this time there are 19 no public comments from the phoneline. 20 MS. THEBERGE: Okay. 21 CO-CHAIR STILLE: Okay. So we shall 22 break for lunch. And let's see, 30 minutes, 45

1	minutes? Okay. So if you could make it a
2	relatively brief lunch. We have 27 minutes until
3	12:30 p.m.
4	(Whereupon, the above-entitled matter
5	went off the record at 12:04 p.m. and resumed at
6	12:34 p.m.)
7	CO-CHAIR STILLE: All right, great.
8	So, over lunch I was made aware of the
9	possibility of deferring a vote on this package
10	of measures. And it would be good to have a
11	discussion of that. But we need someone to move
12	that first.
13	So, Jennifer, would you like to kind
14	of talk about kind of your thinking behind that?
15	And then we can open it up to some discussion.
16	MEMBER BRIGHT: Yeah, so I'm guilty of
17	raising this question. I just, as a new
18	committee member, was asking procedurally, was
19	there an opportunity to discuss the pros and cons
20	of possibly deferring the consideration of this
21	measure?
22	I think there are sufficient questions

about scale and about lack of data, being that 1 2 this has just been field tested. And I think this is not a question of value. This is not a 3 4 question of the value of doing this, of the 5 considerable amount of work that's been put into this. But I feel that it's important to move to 6 7 consider deferment because I think that this needs to be tested and teased out a little bit 8 9 more.

10 And I do feel like the demonstration 11 project that you mentioned in your introduction 12 has a lot of value to answering some of the 13 questions that I think have come up already and 14 are likely to come up in further discussions.

15 So, for that reason, I'd like to 16 suggest to the committee that we consider the 17 pros and cons of deferring this at this time. 18 CO-CHAIR STILLE: So let's discuss 19 this a little bit. I think I saw a couple of 20 tents going up at some point. No? Yes? Lisa? 21 MEMBER SUTER: So, can I just clarify, 22 what are the -- what's the downstream effect of

176

1 deferment? And what are we asking from the 2 developer that would change our mind in the 3 future?

4 MS. SAMPSEL: So, basically, I mean, 5 what we would do now that there's a motion to defer, there would be kind of a discussion. 6 And 7 it can be some back and forth continuing with the developer on, you know, what your global reasons 8 9 are for suggesting the deferment and seeing if 10 the developer has some information we're just not 11 seeing here.

12 And then there would be a formal vote. 13 And it would be a hand vote of who supports 14 deferment, who doesn't support deferment. And 15 should that deferment move forward, then we would 16 still want you to go through each of the criteria 17 and talk about what additional information you 18 would want to see that would make you more 19 comfortable with a vote, so that the developers 20 would know and be able to come up with a plan 21 that would then come back on how they would 22 address those issues.

1 CO-CHAIR PARTRIDGE: I'm sorry Sarah. 2 Would we vote on the motion to consider to deferment? Is that it? Or do have to decide to 3 4 defer first, and then, as we go through the 5 criteria, we're giving them suggestions? Or do you assume the general discussion will surface 6 7 the issues? I mean, I assumed that. 8 MS. SAMPSEL: 9 How have they done it in other groups? 10 MS. MUNTHALI: Yeah, so you would vote 11 on the motion to defer first, to even consider 12 This measure could go forward if it passes that. 13 all of the major criterion, but you're not sure. 14 It sounds like you're saying you like the idea of 15 this measure but there may be some weaknesses 16 that the developer may be able to address within 17 a time period. 18 And so when you're thinking about deferment, and when we're thinking about it as an 19 20 option for committees, we would be working with 21 the developer to come back with that additional 22 information that Sarah mentioned within a

specified period, no more than a year. 1 2 So that's something to consider for the developers as well. 3 4 MS. SAMPSEL: And what I would just 5 add there, too, I mean, the other option, of course, would be to continue and we vote through. 6 And let's say some of these go down, they don't 7 Remember there's almost that cure period 8 pass. 9 where the developers could come back and say, we 10 want you to reconsider this, reconsider our 11 request. 12 But there's only about two months for 13 that. So it's during the writing period, it's 14 during the public comment period that they could 15 come back to us with a formal reconsideration and 16 you would re-vote in about two months. 17 CO-CHAIR STILLE: Peter? 18 MEMBER THOMAS: I guess I would speak 19 in opposition of the motion because I don't think 20 we've really had the discussion to the point 21 where I could say one way or the other that I 22 think you need to develop more things. I've read

the materials. This is happening. 1 These 2 programs are in effect. Half the Medicaid population is undergoing some form of home and 3 community-based services and there's very few 4 5 measures out there. So it's really important. And I don't 6 7 know if a year delay is appropriate in light of the discussion we've had thus far. Maybe if we 8 9 have more discussion I can get my arms around 10 But I just don't know enough right now to that. 11 say that. I'd prefer to move on with the 12 discussion of the measures. 13 CO-CHAIR STILLE: Other thoughts? 14 CO-CHAIR PARTRIDGE: Sherrie's tent is 15 up. 16 CO-CHAIR STILLE: Oh, Sherrie, sorry. 17 MEMBER KAPLAN: So can you go over, 18 Sarah, the algorithm for our decisionmaking If we say deferral for a year, then what 19 again? 20 happens? If we move on and discuss these and 21 decide, for example, to approve some and not 22 others and do whatever it is we do after the

discussion, what happens? So that we can kind of
 clarify that. Because I think in one case,
 there's a short term and then other cases a more
 long term plan, it sounds like.

So there would be a vote 5 MS. SAMPSEL: on the motion to defer. If it's decided that you 6 7 all want to defer this measure, then we would still ask you to go through the criteria and 8 9 provide recommendations to the developer on what 10 you would want to see to make you more 11 comfortable that this measure is ready for prime 12 time, or measures are ready for prime time.

13 In that case, then the developers will 14 be followed up by staff within 24 hours, 48 15 hours, when we get out of this meeting. And the 16 developers then have two weeks to provide us with 17 their plan to address those issues and a timeline 18 for when that would happen. As Elisa mentioned, 19 we'd want that to happen within a year.

20 Should you not defer that, you know, 21 as Peter suggested, what we're going to do is 22 we're going to break these into five groupings

and talk about each grouping and have five separate votes.

And let's say in the event, you know, 3 4 say physical safety, Number 19, it's voted down. 5 And this could be the case for any of these If any of them go down, as in are not 6 groupings. passed at any of the must-pass criteria, we would 7 still, as we've done before, we continue the 8 9 discussions. But we don't continue voting for 10 each of those additional criteria. Again, to 11 give the developers more information. 12 In that case, where either the

13 consensus is not reached or the measures are not 14 passed at this meeting, they still go out for 15 public comment. And the developer still has a 16 request or is still able to bring more 17 information back, but it's on a much shorter time 18 period. And you would re-vote at the post 19 comment call. Is that clear? 20 CO-CHAIR STILLE: Linda? 21 MEMBER MELILLO: So I was just -- I 22 feel like that it's a little premature to defer

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without having had more discussion about some of 1 2 the actual items. Is there a way to continue to review the items and then decide whether or not 3 4 we -- you know, that that could be an option at 5 the end, is to defer? MS. SAMPSEL: I think we can do that. 6 7 I mean, as long as it's before the overall suitability vote, the very last vote. 8 9 MEMBER MELILLO: So that's my thought. 10 I don't know how the rest of the panel feels. 11 CO-CHAIR STILLE: So should we maybe have a structured discussion, relatively briefly, 12 13 on sort of the five different chunks? You know, 14 the evidence things and the usability and use 15 things. And then maybe have a vote to defer 16 based on how that's going? Should we give 17 ourselves like a time limit perhaps? Okay. 18 So we're supposed to be starting on 19 the other measures, like, in two more minutes. 20 Okay. Well, this is important enough. Let's 21 give ourselves 15 minutes. Does that sound okay? 22 Is that too long? Okay. Len?

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MEMBER PARISI: So, clarification, yet 1 2 What's the implication of looking at this again. document in buckets? And if one component is not 3 acceptable, what's the implication of that? 4 CO-CHAIR STILLE: For the others? 5 6 Yeah, that's a good question. I mean, I think 7 MS. SAMPSEL: so, what we've heard is that, you know, there seems 8 9 to be a level of discomfort in voting on 19 10 measures separately and doing 19 separate votes. 11 And so our suggestion is, we'll talk about the 12 scale measures and go through the voting on the 13 scale measures. And then do it on global rating, 14 do it on recommendations, do it on unmet needs. 15 In the event any of these buckets or 16 individual measures are not passed, it's the same 17 implications of that, you know, there could be 18 something that comes up during public comment. 19 There would be a reconsideration of that vote 20 post-meeting. 21 CO-CHAIR STILLE: Okay. Great. Well, 22 let's do this: let's start to kind of go through

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one-by-one with an eye toward, okay, what's 1 2 needed, what's not needed for these generally. Because obviously they're all related because 3 4 they're part of the same instrument. 5 Should we maybe get up the evidence thing and start going through there? 6 And I'll rely on the primary discussants to put in a point 7 or two to kind of jump start the discussion. 8 9 Nicole? 10 MEMBER FRIEDMAN: I guess one of my 11 thoughts of this is some of the questions on the 12 scale measures are pretty similar to Press Ganey 13 in like, staff reliable and helpful, listen and 14 communicate. And I'm just thinking about how 15 many surveys people potentially get. And would 16 this be duplication of other surveys that they're 17 getting, whether or not their home and community-18 based service is separate from their primary care 19 health system. And is that a concern? 20 DR. JACKSON: Typically, an HCBS 21 program would only field a survey like this, at 22 most, once a year. Certainly, individuals who

receive their services, you know, from primary 1 2 care or a specialist, go to a hospital, of course, they're going to be receiving surveys as 3 4 well. 5 But these will be different in that, for the most part, they will be administered 6 7 face-to-face or over the phone. So it's a different type of survey than what most of us and 8 9 most of them will receive from our healthcare

10 providers.

It hink the states who would be responsible for paying for, for the most part, and choosing a survey vendor, and fielding these surveys with their beneficiaries would be very careful about participant burden and would not do it very frequently.

Plus it would be a cross-section, it
would be a sample. It would not be everyone, in
most instances.

20 CO-CHAIR STILLE: So, again, this is 21 sort of evidence that this is needed and that 22 kind of thing. So, I mean, your question was

I think it was probably more about 1 great. 2 feasibility. Katherine? A question about the 3 MEMBER BEVANS: 4 data presented for evidence for performance gap. 5 I just want to make sure I understand the means that are presented on Page 6 of the report, which 6 7 are things like staff are reliable and helpful, the mean is 93.23. Could you tell us how that 8 9 was calculated? I understand that the measure 10 itself is a composite. And then there must be a 11 cut point and a percentage calculated? 12 DR. MALLERY: So each of the measures, 13 or each of the items in the underlying measure, 14 is on a "never, sometimes, usually, always" 15 And then we transform those to a 0 to 100 scale. 16 scale, primarily, so they're easier to 17 understand. 18 MEMBER BEVANS: Is it a T-score? 19 DR. MALLERY: Between the means and 20 the -- that's right. 21 MEMBER BEVANS: No? Okay. No. 22 DR. MALLERY: Oh, no, I'm sorry. So

you're saying is this a Z-score? Oh, right, no. 1 2 It's just, you know, take all the items, they're "never, sometimes, usually, always." So, one, 3 4 two, three, four. Create a mean and then 5 transform that to 0 to 100. MEMBER KAPLAN: I think I can help out 6 7 here. 8 DR. MALLERY: Okay. 9 MEMBER KAPLAN: What's usually done in 10 that kind of transformation is you take the item 11 mean, or the average item mean, and you subtract 12 the theoretical minimum from that. And then you 13 divide that by the theoretical maximum of the scale score minus the theoretical minimum and 14 15 multiply it by 100. 16 So it's not a transformation in the 17 sense that you're thinking. 18 CO-CHAIR STILLE: We're finding the 19 table that you're talking about. I know exactly 20 -- there you go. 21 MEMBER BEVANS: Understanding that a 22 little bit more, it might be worth noting that

the scores are quite high on the possible range 1 2 of 100, with obvious exceptions, which suggests there may be not the strongest evidence for room 3 4 for improvement. Although it's kind of 5 surprising given the content of the items. And so I'm wondering whether you have 6 7 any thoughts about sampling, who actually responded to this, how the measures were 8 9 administered, that may be explaining those 10 extraordinarily high scores on some measures that 11 we know there are certainly more variability in 12 prior literature. 13 DR. MALLERY: Yeah, I agree, the 14 scores are quite high. In terms of sampling, you 15 know, I mean, it was a random sample of 16 participants within the programs. Now, in terms 17 of people that responded, there were those 18 cognitive screening items. So that's a 19 consideration. So, only respondents who screened 20 into it past this sort of cognitive screening 21 piece. And that was just -- they asked whether 22 or not they received services. So that might be

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one consideration.

2	In terms of I think we already said
3	that all surveys were administered in person or
4	via phone. So I think the administration was
5	appropriate for the population. So that would
6	sort of mean, you know, we made every
7	accommodation to the participants in that sense.
8	CO-CHAIR STILLE: Sherrie and then
9	Lee.
10	MEMBER KAPLAN: This is a follow-up to
11	Katherine's question, I think. If you look at
12	the interquartile ranges, you get fairly narrow -
13	- you've got ceiling effect problems with some of
14	the measures. And the standard deviations are
15	pretty, you know, pretty tight.
16	So then the question becomes, is there
17	going to be enough you know, an effect size,
18	for example, of .3, which means you multiplied
19	the standard deviation times .3 and you get 1.
20	Well, is one unit difference a meaningful
21	difference?
22	And so that's going to happen to these

kind of ceiling measures. Now, since this is voluntary, your data are voluntary, it's sort of like what happened the last time. You get high performers participating in these voluntary kind of exercises.

6 On the other hand, when you look down 7 at some of the unmet needs things, you've got a 8 huge standard deviation. And therefore, you 9 know, you've got kind of the opposite problem. 10 Some of these things you might even have floor 11 effect problems. Especially, you know, for some 12 of the measures.

13 So when we're kind of trying to wrap 14 our heads around -- I think this is the issue 15 that Peter brought up. When we're trying to wrap 16 around, the collective here, there's a lot of 17 differences here that we're going to have to 18 struggle with. And how to help us, how you can 19 help us understand the potential utility, that 20 gets to the use, but it also gets to the 21 variability and understanding the attributions of 22 the program versus other kinds of things that may

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be causing all of this wide variation in some of 1 2 these measures, but not very much and may not even be meaningful in some of the others. 3 CO-CHAIR STILLE: Okay. So Lee and 4 5 then Linda. CO-CHAIR PARTRIDGE: If you step back 6 7 away from the detail, and overall, as I've worked with these measures over the past two weeks, you 8 9 know, there's no question that Peter is right. 10 We would very much like to have solid quality 11 measures in the HCBS realm. 12 It used to be as the states struggled 13 with them -- and I'm sure some of these are still 14 out there -- what you did was what I would 15 consider sort of dumb stuff. You pulled a sample 16 of the care plans and then you went and checked and found out whether or not Mrs. X got three 17 18 hours or two-and-a-half hours of personal care each day. Well, that's silly. You need 19 20 something more global. In a discussion with a bunch of HCBS 21 22 providers a few years back, unanimously they

1 said, you know, what we really care about is 2 whether people are doing well. Doesn't really 3 matter about all this detail in between. What 4 happened? Are they still functioning okay? If 5 they're not functioning okay, why aren't they 6 functioning okay?

7 At that point, you start to need the 8 detail underneath to say are they not doing well 9 because the agency is letting them down and are 10 not supplying, meeting their needs.

11 So, you know, everything in me wants 12 to say, I want to bless this measure. 13 Nevertheless, I kept looking at some of our 14 criteria. The performance gap really isn't 15 apparent, except with respect to the unmet needs 16 group where you do have a lot of indication that 17 people are feeling that their needs are not being 18 adequately met. Some of that may be under the 19 control of the program. Some of it may be under 20 the control of the state budget office. 21 But I am really terribly, terribly

conflicted on taking our standard algorithm and

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working through this measurement set, whether we 1 2 do it in chunks or whether we do it one-by-one. CO-CHAIR STILLE: Just with the 3 4 differences in data ranges, data analyses, data 5 requirements --Right. 6 CO-CHAIR PARTRIDGE: And you 7 know, if you look further in the testing realm -and I'm jumping ahead a little bit. 8 I was 9 stunned by your comment this morning that there 10 were 2,300 respondents in this material that you 11 gave us. If you had counted the proxy data, you 12 would have had another 1,000. Well, what did 13 that look like? So. 14 CO-CHAIR STILLE: Okay. And then 15 Then I think we should talk about some of Linda. 16 the other realms just to get to the end of this 17 15-minute block so we can decide on whether to 18 defer or not. 19 MEMBER MELILLO: When I worked for the 20 behavioral health organization in Vermont, they 21 had a community service program. And one of the 22 challenges was that any time you have a staff

person who is working with a developmentally disabled young adult, older child, they are heavily influenced by that person. And if they're the person administering this set of measures, I don't know that you're going to get real values that way.

7 So I also wanted to see that other 8 1,000 data points to see if you're going to be 9 getting different types of responses that way. I 10 think the administration of the survey, and 11 really narrowing that down, would be really 12 important because there's just way too many 13 variables.

14DR. MALLERY: Can we clarify that the15survey is administered in-person but not by the16providers. It's administered by trained survey17vendors.

MEMBER MELILLO: Okay. Thank you.
DR. MALLERY: So no case managers.
MEMBER MELILLO: Okay. And family
members, would they be able to answer as well?
DR. MALLERY: Well, so, that's the

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difference, is that initially, no, they weren't 1 2 able to answer. So they would never be administering the survey. It would be a trained 3 4 survey vendor. 5 Right. MEMBER MELILLO: DR. MALLERY: But that was sort of the 6 7 point we were getting to, is that part of the way through we did allow family members to respond, 8 9 not on behalf, or along with or to assist with 10 the survey process. 11 MEMBER MELILLO: Okay. And that data 12 is not in this set? 13 DR. MALLERY: It's not in here, right, 14 because it wasn't consistent throughout 15 MEMBER MELILLO: Yeah, I wouldn't want 16 it to be. 17 DR. MALLERY: So we couldn't reliably 18 say, you know, these are the differences between 19 proxies and non-proxies because it wasn't -- that 20 wasn't how it was designed, the field test. CO-CHAIR STILLE: Okay. Any other 21 22 last important comments on evidence?

1	MEMBER THOMAS: Only that this is a
2	patient-reported outcome measure. And so, in
3	terms of evidence, you're asking the very people
4	who are receiving the services what they think
5	about the various components of what they're
6	getting. I'm kind of sensing that we're maybe
7	making this too complicated. This strikes me as
8	being a real step forward from where we are now.
9	And I guess I'm kind of left with that as a
10	bottom line.
11	CO-CHAIR STILLE: Nicole?
12	MEMBER FRIEDMAN: Sometimes, in my
13	experience, too, working with patients and asking
14	them about their service, especially around
15	Medicaid and help in the home, is a fear of
16	losing the service. And so I'm wondering, is
17	there scripting, when you're delivering this,
18	that this is not about whether or not we're going
19	to take away hours or et cetera, but this is a
20	care optimizing tool.
21	DR. JACKSON: That's part of the
22	consenting process of the survey.

1 CO-CHAIR STILLE: Okay. So just in 2 the spirit of dividing up chunks of measures versus not, Sarah was raising the point that we 3 4 haven't heard anything in the discussion about --5 at least on the evidence part, just thinking about evidence -- that there are big differences 6 7 between chunks of questions. So we were thinking we should vote on 8 9 the evidence kind of by itself and then think 10 about the next few things. Does that seem okay 11 to people? Beth? 12 MEMBER AVERBECK: Specific to 13 evidence, I guess that's my question around the 14 19 and the physical harm. I don't know if you 15 want me to raise that now or if you want me to 16 wait. 17 CO-CHAIR STILLE: Sure. 18 MEMBER AVERBECK: Because I think one 19 of the -- you know, obviously, it's considered a 20 This is a patient-reported, so it's never event. 21 not necessarily a verified result. And so I 22 think that may play into, you know, my

consideration on whether it's just reported and 1 2 verified or just reported, especially if we're going to start looking at comparative data or 3 4 public reporting. 5 CO-CHAIR STILLE: Over to Desi for a vote on evidence, then. And then we'll continue 6 7 the discussions. 8 MS. QUINNONEZ: We are going to open 9 the vote. Voting is now open for evidence, 10 importance to measure and report. The rationale 11 supports the relationship of health outcome, or 12 PRO, to at least -- what are we voting on? 13 Sorry. 14 Oh, thank you. I can get you the 15 screen. 16 The rationale supports the 17 relationship of health outcome, or PRO, to at 18 least one healthcare structure process, 19 intervention, or service. Option 1 is yes, 20 Option 2 is no. Voting is now open. 21 MS. THEBERGE: We're down to 19 22 Committee members now.

1 MS. QUINNONEZ: Thank you. 2 CO-CHAIR STILLE: It doesn't seem 3 open. 4 MS. QUINNONEZ: It's calculating. 5 We're looking for one more vote. 6 MS. THEBERGE: Deb, are you still Operator, is Deb Saliba still on the 7 there? line? 8 9 I do not see her joined. OPERATOR: 10 MS. THEBERGE: Okay. So I think we're 11 good. 12 MS. QUINNONEZ: So we're at 18. All 13 votes are in. So voting is now closed for 14 Measure 2967 for evidence. We have 94 percent --15 that voted no. That's 94 yes and 6 percent no. 16 This measure passes. 17 CO-CHAIR STILLE: Are there other 18 evidence sub-questions? Okay. Performance gap. 19 Okay. Any other questions about performance gap 20 related to this table? I think we've talked 21 about it fairly extensively. Becky and Sherrie? 22 MEMBER BRADLEY: I just had one

1 question. Or comment I guess. In terms of now 2 that you're allowing proxies, I think there might -- it's been my experience in working with 3 4 patients and families that sometimes the 5 caregiver's perception is very different from the patient's perception, in terms of adequacy of 6 service. 7

And so now that you've added those 8 9 kind of as one of the acceptable responses, I 10 think there should be more research into, is 11 there a difference between the patient's and 12 caregiver's responses to adequacy of service? 13 Because if you're just basing this on the 14 patient, there may be a big gap there. 15 CO-CHAIR STILLE: And Sherrie? 16 MEMBER KAPLAN: Okay. So this is 17 already where I'm hitting the wall on, is this a 18 bundle or a bunch of individuals? Yes and no. 19 mean, if you stare at this, you know, what are we 20 supposed to do? Because I can't answer the

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CO-CHAIR STILLE: Right. Answer

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question.

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Number 5.

2	MS. SAMPSEL: I mean, at this point we
3	can separate. You can go ahead and say, okay,
4	we're now going to do one vote on the scale
5	measures, if that's what the suggestion is. Then
6	do one vote on unmet needs, one vote on, you
7	know, through each five.
8	CO-CHAIR STILLE: And I think we were
9	kind of moving toward a consensus of that. So
10	should do that, then? The five buckets being
11	I don't have them up on my screen.
12	CO-CHAIR PARTRIDGE: Scale, global,
13	recommendations, unmet needs, physical safety.
14	CO-CHAIR STILLE: Okay. Scale
15	measures, global measures, recommend measures,
16	unmet needs measures, and physical safety. So
17	then we'll have five quick votes on 1(b), right?
18	Okay. So, good. So this will be on the scale
19	measures.
20	Is voting open yet?
21	CO-CHAIR PARTRIDGE: Desi, is voting
22	open?

1	CO-CHAIR STILLE: I think it's not
2	open yet. Yes, sorry. The splitting causes
3	technical difficulties but we just want to try
4	and get this right.
5	MS. QUINNONEZ: Okay. We will open up
6	the vote for importance to measure and report for
7	performance gaps. Performance gap data
8	demonstrated considerable variation or overall
9	less than optimal performance across providers
10	and/or population groups or disparities in care.
11	And this will be for scale measures. And that's
12	a part of 2967. Voting is now open.
13	MEMBER DOWDING: Hi, this is Dawn.
14	Could you just say what the numbers represent
15	again, please?
16	MS. QUINNONEZ: Absolutely. We're
17	going to be voting for measure we're going to
18	be voting. The criteria is 1 is high, 2 is
19	moderate, 3 is low, and 4 is insufficient.
20	CO-CHAIR STILLE: Dawn, was that your
21	question? Or was it the 100 point scale that the
22	

1 MEMBER DOWDING: No, that was my 2 question. Thank you. CO-CHAIR STILLE: 3 Okay. 4 MS. QUINNONEZ: We're looking for one 5 more vote. And all votes are in. Voting is now 6 7 closed. We have 6 percent voted for high, 11 percent for moderate, 72 percent for low, and 11 8 9 percent for insufficient. 10 CO-CHAIR STILLE: So this is on the 11 scale measures. Okay. Do we continue to vote on 12 the other sets then, right? Yes, we do. Okay. 13 And the next set is global ratings. 14 MS. QUINNONEZ: Okay. Voting is now 15 open for the importance to measure and report 16 performance gaps for global ratings. Performance 17 gap data demonstrated considerable variation or 18 overall less than optimal performance across 19 providers and/or population groups or disparities 20 in care. The criteria is 1 for high, 2 for 21 moderate, 3 for low, and 4 for insufficient. 22 We're looking for two more votes.

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1	And all votes are in. Voting is now
2	closed. We have 0 percent for high, 56 percent
3	moderate, 39 percent voted low, and 6 percent
4	voted insufficient. And this is on global
5	ratings.
6	CO-CHAIR STILLE: So that's consensus
7	not reached, because it's 40 to 60 percent.
8	MS. QUINNONEZ: Would you like to
9	continue?
10	CO-CHAIR STILLE: Okay. Yes. The
11	next group is recommendations. Would you
12	recommend X, Y, Z provider?
13	MS. QUINNONEZ: Okay. Importance to
14	measure and report, performance gap for
15	recommendations. The first criteria is high,
16	second criteria is moderate, third criteria is
17	low, and fourth is insufficient.
18	Okay. All votes are in. Voting is
19	now closed. Zero percent for high, 67 percent
20	moderate, 28 percent low, and 6 percent
21	insufficient.
22	CO-CHAIR STILLE: Okay. So that group

passes. And the fourth group is unmet needs. 1 2 MS. QUINNONEZ: And the last group is unmet needs. 3 4 CO-CHAIR STILLE: That's the fourth of 5 There's five groups and this is number five. four. 6 7 MS. QUINNONEZ: Got it. Unmet needs 8 for the performance gap. The first option is 9 high, second option is moderate, third option is 10 low, and fourth option is insufficient. All votes are in. Voting is 11 Okay. 12 now closed. We have, the results are 50 percent 13 voted for high, 39 percent voted moderate, 11 14 percent voted low, and 0 percent voted 15 insufficient. 16 CO-CHAIR STILLE: Okay. So that one 17 And then the last one is physical passes. 18 safety. 19 MS. QUINNONEZ: For our last category 20 for safety for performance gap, our first option 21 is to vote high, second option moderate, third 22 option low, and fourth option insufficient.

1	All votes are in. Voting is now
2	closed. We have 100 percent high.
3	CO-CHAIR STILLE: No, really? No.
4	MS. QUINNONEZ: Zero percent moderate
5	obviously, 0 percent
6	CO-CHAIR STILLE: No.
7	MS. QUINNONEZ: It's not right?
8	CO-CHAIR STILLE: It's not right. No.
9	MS. QUINNONEZ: What's not right?
10	Let's try this again. One second. Okay. We're
11	going to re-vote on our last category for safety.
12	And it's going to be option number 1 high, option
13	number 2 moderate, option number 3 low, and
14	option 4 insufficient.
15	Voting is now closed. All votes are
16	in. The results are 0 percent high, 22 percent
17	moderate, 39 percent low, and 39 percent
18	insufficient.
19	CO-CHAIR STILLE: All right, 39 and
20	39. Okay. So it does not pass. So we have some
21	groups that passed. Sarah, have you been
22	tallying those?

MS. SAMPSEL: I have. So we have the 1 2 scale measures failed on evidence -- or on performance gap. The global measures, consensus 3 4 not reached. The recommendation measures passed. 5 The unmet needs measures passed. Physical safety 6 measure did not pass. 7 CO-CHAIR STILLE: Okay. MS. SAMPSEL: However, what we'll do 8 9 though is, as we move forward, we'll still have 10 the discussion about all of these for the benefit 11 of the developers. But we'll only vote on those 12 sets that either consensus was not reached, so 13 the global measures and the recommendation and 14 unmet needs measures. 15 CO-CHAIR STILLE: Okay. 16 MS. SAMPSEL: But we'll discuss all of 17 them still. 18 CO-CHAIR STILLE: Yes, great. Okay. 19 Good, thank you. Okay. Let's move on. 20 Composite measure. What? No, never mind. Okay. 21 All right, so let's move to discussion on 22 reliability then. Do the primary discussants

want to talk about a couple things? Lee, Len, or 1 2 Nicole, any thoughts about reliability adjusting? There are two people with their cards 3 Are you waiting? No? Katherine, are you 4 up. 5 waiting? You are waiting? Why don't you talk? That's fine. 6 I think that, for me, 7 MEMBER BEVANS: the primary concern that I have about this 8 9 measure relates to the specifications. Most 10 notably the exclusion of people with cognitive 11 limitations that, for the items that are being 12 used, prohibit them or prevent them, perhaps, 13 from providing reliable or valid scores. 14 And the reason, of course, I'm 15 concerned about that is because, presumably, that 16 makes up a large percentage of the population 17 that you're targeting. 18 On the other hand, I might have missed 19 it in the report. I wasn't sure if you had data 20 on how many people were excluded because of those 21 criteria, which I think will be critically 22 important to know.

1 This, to me, also suggests a couple 2 First, there's obviously been a lot of things. discussion about proxy reporters, which I think 3 4 is important. But it's also been noted, and this 5 relates to specifications as well, that there are typically quite a lot of disagreement, 6 7 differences in opinions, between proxy reporters and people reporting on their own behalf. 8 9 So, getting at specifications, I think 10 that moving forward -- I know that the data you 11 presented were just for the self-report component 12 of the measure. But moving forward, considering 13 whether those, a proxy report measure and a self-14 report version of the measure, should even be 15 considered comparable, or considered as two 16 separate measures for consideration. 17 And the last thing I'll say about 18 that, again, related also to reliability: did you 19 do any cognitive testing with the items 20 themselves to get a better understanding or, for 21 those not excluded, how they understood the 22 items, whether they were they meaningful, whether

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they were well-understood?

2 DR. MALLERY: So, to answer the last 3 question about cognitive testing, we did do two 4 rounds of cognitive testing in both English and 5 Spanish.

6 MEMBER MORT: Actually, we did three7 rounds.

8 DR. MALLERY: Three rounds. Sorry,9 Elizabeth.

10 MEMBER BEVANS: I'm bringing this up 11 just to say that I think that -- and perhaps I 12 missed it, there's a lot of material to look 13 through. But, really, a clear description of 14 that, that's so critically important for the 15 target population -- and for everyone, really, 16 but the target population in particular. Some 17 more information about the results of those 18 cognitive testing I think would go a long way to 19 support the measure.

20 MEMBER MORT: Okay. Do you want 21 written material or do you want a verbal 22 description?

1 CO-CHAIR STILLE: We can follow up 2 afterwards. MEMBER MORT: Thanks. 3 4 CO-CHAIR STILLE: Okay. And let's 5 see, Beth, did you have your --MEMBER AVERBECK: One question on 6 7 reliability. Were the survey methods tested compared to each other? Because you had both in 8 9 person surveys and telephone surveys. And did 10 one give you different results compared to the I know sometimes face-to-face compared to 11 other? 12 mail is a lot different, so I was just wondering 13 about telephone compared to face-to-face. Thank 14 you. 15 DR. MALLERY: We did compare, and the 16 differences were, I think, significant on some 17 measures but not on others. So it was not the 18 same that you typically see in mail versus phone, 19 perhaps because they were both in-person. And I 20 can dig up those, you know, which measures were 21 different. 22 But we do recommend that as a case mix adjustor, the survey mode, to account for the
 differences.

CO-CHAIR STILLE: Lee and then 3 4 Sherrie. And then I have a question. 5 CO-CHAIR PARTRIDGE: I had a quick question about the testing here. You said that 6 you tested in 26 different programs and the total 7 number of respondents was 2,300. That's a fairly 8 9 small average number of respondents. How 10 comfortable should we be -- or why should we be 11 comfortable with numbers of that size? 12 I assume that's an average. I assume 13 you had, in some programs, a much smaller number 14 and a much larger number. But just to have a 15 tiny bit of conversation, if we could. 16 DR. MALLERY: Sure. So I think there 17 is a table that I can show, I believe in this 18 package, that shows the numbers. But you're 19 exactly right. There's a range, I think 150 is 20 about the average. In some programs it was 21 smaller. So some of the programs are smaller.

22 So it was smaller.

And based off of this field test, we 1 2 are recommending a larger sample size moving forward based on calculations for the -- in order 3 4 to get a reliability of .7 for these measures 5 moving forward, we're recommending an effective sample size of 400 for program moving forward. 6 7 And we can talk about that a little bit more. But I mean, that is what most of the 8 9 programs are aiming for, for this next round. 10 Maybe I'm over-speaking. But that's the guidance 11 we've given for the next round. So on many of 12 the programs, it is feasible. 13 CO-CHAIR PARTRIDGE: Yeah, I'm 14 surprised. I actually think in some of these 15 cases, you'd have a pretty small number of 16 respondents. I mean, some of the incidence of 17 this population is going to be quite small, 18 right? For example -- but anyway. Thank you. 19 CO-CHAIR STILLE: And then Sherrie. 20 DR. JACKSON: I actually have 21 statistics on that, if you'd like to hear them. This is for 2012, the data that's most recently 22

available in the HCBS 1915(c) waivers. 1 Twenty-2 right percent have enrollees under 400; 30 percent between 400 and 3,000; and 41 percent 3 4 between 3,000 and 50,000-plus. 5 So there's definitely a range. And the other thing to consider moving forward is, 6 7 with the 2014 HCBS rule, CMS is allowing consolidation of waiver programs. So your size 8 of your waiver programs are going to -- may grow 9 10 over time. 11 Also with managed long-term services 12 and supports, that, essentially, for many 13 programs, is consolidation. So the size of your 14 programs over time is likely to grow. 15 CO-CHAIR STILLE: Sherrie, you had a 16 point? 17 MEMBER KAPLAN: Let me follow up 18 because I'm old and I forget things like crazy. 19 So let me follow up on that point first. The 20 issue of, you know, if you're sampling, if you 21 fix the sample size, you're going to get a very 22 much different, and probably more stable,

estimate of the smaller programs than you are of the larger programs, depending on how you do that sampling.

Because you're going to have to be careful about who you're representing in that. You know, it's really going to have a very strong randomization and sort of random sampling issue to get a stable estimate.

9 So if you fix the sample size, it 10 raises more of a validity than a reliability 11 question. But you're going to estimate some of 12 these programs with half of their population and 13 others with a very small portion.

14 So the other issue is that some of 15 your scales have fairly good precision, in terms 16 of at the patient level anyway. And I'm looking 17 at Exhibit 2. I forget what page it's on. But 18 the three scales that are really fairly strong 19 are staff reliability and helpfulness, staff 20 listening and communication, and case manager 21 helpfulness.

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And then it drops to choosing the

services that matter to you. And the reason I'm going into this I'll come back to in a minute. And that actually drops pretty low. On the other hand, that only has two measures in it, two items in that measure. And that's exactly what you would expect given the way this formula is constructed.

8 And then down to, you know, sort of 9 the personal safety and respect, that's got three 10 items in it. And again, you would get -- you 11 would expect that because it has fewer items in 12 it.

13 So my first question is, have you a 14 done a look, or could we ask you to do a look, at 15 a Spearman-Brown prophecy formula, to say this is 16 an important construct to us but I don't really 17 have enough items in that construct and it's not 18 robust enough.

19 It may actually be really good in 20 discriminating facilities one from another, but 21 because I don't even have very good reliability, 22 I can't tell that. So do you need more sample

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Or do you need more items? And the 1 size? 2 Spearman-Brown prophecy formula data would give So that was question number one. 3 you that. 4 And question number two is, the inter-5 unit reliability issues are problematic for some of these unmet needs measures. And specifically 6 7 the unmet need in toileting. It doesn't have very much variability at all. But it's got 8 9 crummy IUR, it has terrible IURs. But, you know, 10 some of them, unmet need for medication, have 11 pretty good and pretty robust IURs. 12 So, you know, is there a possibility 13 going forward that you can look at maybe the intraclass correlation coefficients at some of 14 15 these units being compared and look at within, 16 versus, between unit comparisons and see if 17 there's some gain that you could, possibly, with 18 an increase in precision of these measures, that 19 you could actually look at. 20 Or -- and this is horrible for NQF and 21 I apologize, Sarah -- the possibility of creating 22 a composite out of this where you're creating a

composite out of unmet needs. It doesn't prevent 1 2 you from drilling down to individual item level but it could help you in the precision. 3 4 CO-CHAIR STILLE: Great, thanks. Sam? 5 MEMBER BIERNER: I want to comment specifically on the table that's just above 1.6 6 where you list the number of returned surveys. 7 There were only 92 brain-injured patients 8 9 surveyed that returned surveys. I don't know how 10 many you actually surveyed, but only 92 counted 11 in this sampling. 12 So it seems like you've under-13 represented TBI for purposes for drawing any 14 conclusions about them. And I wanted to see what 15 your comments were about that and how you would 16 correct it. 17 There's a table that shows number of 18 total returned surveys. From Maryland, there was 19 zero that was thrown out. And then 72 from 20 Minnesota and 20 from New Hampshire in that 21 table. 22 DR. MALLERY: So in that table it

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1	might be a little bit misleading. Because I
2	think that's just within or maybe I'm in
3	Exhibit 1 that goes through the states?
4	MEMBER BIERNER: Yes.
5	DR. MALLERY: Okay. So there were
6	actually, overall, 262 beneficiaries with
7	traumatic brain injury in our sample. So I'm
8	thinking that maybe that that is one TBI program
9	within one state that you might be looking at.
10	MEMBER BIERNER: Right. Yes, I see
11	that in the top part of the table. But there's
12	still a very small sampling. You said you'd need
13	a minimum of 400. So you less than 250.
14	DR. MALLERY: That's correct.
15	CO-CHAIR STILLE: Okay. Good. Great
16	discussion. We are now going to vote on
17	reliability for the three remaining sets, since
18	there seems to be some differences in numbers
19	between the sets, with global rating, recommend,
20	and unmet need.
21	MS. QUINNONEZ: Okay. Give me one
22	second.

1	(Pause.)
2	CO-CHAIR STILLE: Desi, let us know
3	when you're ready.
4	Do a hand vote? Okay. We can do a
5	hand vote if that's easier.
6	MS. QUINNONEZ: Okay. Voting is now
7	open for scientific acceptability and
8	reliability, including precise specifications and
9	testing, for the first group, which is global
10	ratings. And the options are number 1 high,
11	number 2 moderate, number 3 low, and 4
12	insufficient. Voting is now open.
13	Okay. We're looking for four more
14	votes. Two more. Okay. All votes are in and
15	voting is now closed. The results are zero
16	percent high, 39 percent moderate, 44 percent
17	low, and 18 percent insufficient 17 percent
18	insufficient.
19	CO-CHAIR STILLE: Okay. So that's for
20	the global rating group, right? Okay. And that
21	fails. Okay.
22	MS. QUINNONEZ: Okay. Voting is now

open for reliability, including precise 1 2 specifications and testing, for the recommendations group. And the options are 3 number 1 high, number 2 moderate, number 3 low, 4 5 and number 4 insufficient. All votes are in and voting is now 6 7 closed. The results read 0 percent for high, 22 percent moderate, 67 percent low, and 11 percent 8 9 insufficient. 10 CO-CHAIR STILLE: Okay. So that fails on reliability. The last one is unmet needs. 11 12 MS. QUINNONEZ: Voting is now open for 13 scientific acceptability and reliability, 14 including precise specifications and testing, of 15 The options are number 1 high, unmet needs. 16 number 2 moderate, number 3 low, and number 4 17 insufficient. 18 All votes are in and voting is now 19 The results are -- no. We'll do this closed. 20 Give me one second. one over. 21 MS. THEBERGE: Dawn, I don't have your 22 vote yet.

1 MS. QUINNONEZ: We will re-vote again 2 for reliability, including precise specifications and testing, for unmet needs. Number 1 high, 3 4 option number 2 moderate, option number 3 low, 5 and option number 4 insufficient. All votes are in and voting is now 6 7 closed. The results read 6 percent high, 11 percent moderate, 67 percent low, and 17 percent 8 9 insufficient. 10 CO-CHAIR STILLE: Okay. Absolutely 11 So we're done with voting but we'd like right. 12 to continue the discussion to be as helpful as 13 possible to the developers as we can give them 14 some recommendations for where to go next. 15 I'm just trying to recap what I remember so far. One of the points was basically 16 17 more numbers for more populations. One of the 18 points was really looking hard at proxy reports. And both doing more of them and also differences 19 20 with self-report. There was one other big point 21 and I can't remember. Anyone? 22 Intraclass correlation MEMBER KAPLAN:

coefficients, between unit differences. 1 2 MEMBER BEVANS: Maybe showing the evidence from cognitive testing for 3 understandability of items. 4 CO-CHAIR STILLE: The other thing that 5 just came to mind is, especially with some of the 6 7 ones that seem to have the ceiling effect, some quality improvement folks do what's called a top-8 9 box reporting system. And, you know, the 10 validity of that, it kind of depends on what 11 you're trying to say. But that might be useful 12 to look at, too. Lisa? 13 First of all, I'd like MEMBER SUTER: 14 to echo Sherrie's recommendation for looking at 15 the Spearman-Brown prophecy formula. I thought 16 that was a great suggestion. And along those 17 lines, I think understanding the feasibility of 18 getting to your optimal sample size of 400 would 19 be really helpful, since your sampling is much 20 below that level. So, understanding what the 21 burden on providers is to get to that level. 22 I'd also love to see information about

how long it takes patients or family members to
 fill this out. So, the burden on the individual
 patients or caregivers.

4 And the final thing is, can you 5 describe a little bit more -- maybe not now, but in the materials -- what the actual patient input 6 7 was to development of the questions. There's a notation, and I may have missed the more detailed 8 9 information, that this population demonstrated 10 that these were important. But I wasn't sure 11 whether they were actually involved in the 12 development.

13 CO-CHAIR STILLE: Okay. Peter, and14 then Lee.

15 So we had a motion on MEMBER THOMAS: 16 the table at the beginning of this discussion 17 that we never acted on. And this may be 18 inappropriate; let me just put it on the table. 19 You've heard this whole discussion and you've 20 gotten the comments. Is this something that you 21 can "cure" in two months? Or would you rather 22 have a deferral of this whole discussion for some

longer period of time and come back to the table? 1 2 DR. MALLERY: Many of the things you've asked for we could pull together in a few 3 4 days -- I mean, it's stuff we've already done. Ι 5 mean the cognitive testing, how patients were involved -- they certainly were. And we could 6 7 have a report on that, we could pull that 8 together very quickly. 9 More data is a different story. So I 10 think that's what we've have to talk about. Because there is another round -- but just more 11 12 data is a whole other story. 13 MS. SAMPSEL: Chris? 14 Sorry, one more thing. MEMBER KAPLAN: 15 If you're going to do the exercise of going back 16 through the data, you know, factor analyzing, 17 you've got enough subjects to do a factor 18 analysis, would help how multidimensional this 19 construct is. Because you're losing precision if 20 you're doing these fine grain things. 21 It actually may help you more if 22 you're doing a bigger composite. So, you know,

you're kind of crunching things into -- and 1 2 that's why the Spearman-Brown prophecy formula early on would help you understand, am I needing 3 4 more measures or more subjects per measure? 5 And, you know, doing that early and then giving us a factor analysis -- or doing a 6 7 factor analysis and saying, geez, I've cut this too finely, the factor analysis isn't supporting 8 9 it. 10 I don't know if I should DR. MALLERY: 11 respond. But, I mean, all of these measures are 12 based on factor analysis. So we did do that. So 13 there was confirmatory and exploratory. And I 14 think that that is probably written up a little 15 bit here. But happy to give more detail about 16 that. 17 MEMBER KAPLAN: Yeah, that data would 18 have helped. But it depends on how you do those 19 rotations, because these things are notoriously -20 - so an oblique versus a varimax rotation, for 21 example, would help you with that issue, on how 22 multidimensional it is.

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1 MS. SAMPSEL: I guess my comment is 2 just going to be to go back to -- I don't think we need to make a decision on voting on a 3 4 deferment today. I think we need to go back and 5 give you guys some time and be clear on what we want to do and we can have another discussion. 6 7 And it might make sense actually for us to mimic some of your forms so that we have 8 9 five submissions, and so that we can deal with 10 them separately and make it a little bit of a cleaner process as well. Because I think some of 11 12 these are being held hostage, perhaps. Although, 13 you know, they all failed when we got down to it. So let's see what kind of additional 14 15 data and we can bring it back for the post 16 comment. 17 CO-CHAIR STILLE: And then Linda. 18 MEMBER MELILLO: I would just say, if 19 you're going to include employment questions, to 20 bring them, as well, if you're thinking of adding

21 them to this grouping.

DR. MALLERY: I don't think we were

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considering putting them up for endorsement. 1 But 2 they are available on the survey. So I think 3 that's important to note, that for use they'll be 4 available. 5 MEMBER MELILLO: Okay. CO-CHAIR STILLE: Okay. 6 Others? 7 Okay. Well, thank you very much. I'm sorry this was really hard, but it was a good process. And 8 9 I'm sure it will win eventually. Okay. 10 (Pause.) 11 MS. SAMPSEL: Operator, is Nick Castle 12 on the phone? 13 OPERATOR: Yes, he is. 14 MS. SAMPSEL: Okay. Can you just make 15 sure he has an open line? 16 OPERATOR: His line is open. 17 CO-CHAIR PARTRIDGE: All right, we're 18 going to switch over to -- and I think we'll 19 probably pretty easily be able to talk about them 20 as a group. Three measures, all related to 21 discharge -- sorry. I think I'm still tongue tied from the last one. 22

First, 2614 is a measure of taking at discharge from somebody leaving a short stay. 2615 is long stay resident who is presumably not leaving. And 2616, long stay, but this time the family is the respondent and not the patient. So we'll turn it over to our friends from AHCA.

7 MR. MULLER: Very good. So I will 8 keep this brief. So the three CoreQ measures, we 9 really wanted a short set of parsimonious and 10 effectiveness, experience of care measures. And 11 brought Nick Castle, who's on the line, from the 12 University of Pittsburgh in to develop them.

For those who don't know, Nick was probably the core mind in developing the nursing home CAHPS measures. And essentially, this is a short form spiritual descendent of nursing home CAHPS.

To build it, we started with a large set of items and did rounds and rounds of exploratory factor analysis to distill down to a minimum set of measures that captured the bulk of the signal picked up in the larger measure, large

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instrument and larger measure.

2 And then we intensively tested the kind of agreement with patients agreeing that 3 4 they are important measures and clear measures 5 and all of that. And it was backed up very nicely. 6 7 And so, the three measures are short stay discharge, long stay resident, and long stay 8 9 family. And they're all based on a one to five, 10 poor, average, good, very good, and excellent 11 scale. 12 The questions, to give you a flavor of 13 the definition of the measure are one, in 14 recommending this facility to your friends and 15 family, how would you rate it overall? Two, 16 overall how would you rate the staff? Three, how 17 would you rate the care you receive? And then 18 just for the short stay discharge measure, how 19 would you rate how well your discharge needs were 20 So very much kind of an experience of care met? 21 measure that parallels a little bit the five star 22 branches as well. The measures then, the percent

of the responses who averaged, whose answers
 averaged good or better.

The last thing I'll say -- I'll not 3 4 get into any of the other technical details. But 5 we have ten customer satisfaction vendors who have all invested to incorporate the four 6 7 questions into their instruments. And this is, I don't know what portion of the market for the 8 9 skilled nursing market for customer satisfaction 10 surveys is not captured by these guys. But I'm 11 guessing that it's very small. 12 And so, what this represents is ten 13 very serious professional survey firms 14 effectively, you know, a free market sense 15 endorsing the measure for it's sort of 16 appropriateness and all of that as, eventually, 17 kind of a uniform national standard for customer 18 satisfaction measurement in SNFs. 19 So it's an important thing there. And 20 it's currently being administered and it's 21 currently being collected. And in our AHCA

quality initiative, in some of our tools we're

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beginning to collect the measurement themselves.
 And this will just sort of grow over time. And
 with that, the discussion.

4 CO-CHAIR PARTRIDGE: Our lead 5 discussant group has gotten a little smaller. We've lost David. Now I've lost my cheat sheet. 6 7 Sherrie, I think you're one on these. Am I right? And Peter is the other. Okay. 8 Either 9 one of you want to go first? Peter, do you want 10 to go first? Good.

11 MEMBER THOMAS: Yes. I'll just say a 12 couple of things. And again, you don't really 13 want to go into evidence or anything. You just 14 want some overarching comments? So this is a 15 patient reported outcome measure and it's 16 obviously a major area.

Skilled nursing care, skilled nursing
facilities provide care to millions of Americans
each year. I agreed with the -- well I was
already into evidence here. Hold on. I had some
real questions about the exclusions because I
felt that some of them might impact the overall

satisfaction scores in a significant way. 1 But I 2 can go into that in more depth when it's time to do that, during the evidence discussion. 3 But it's obviously a very important 4 5 measure for those people who go to a nursing home or a skilled nursing facility and don't stay 6 7 indefinitely, don't stay a long term period of And that's apparently more and more folks, 8 time. 9 the more rehabilitation is being provided in 10 those settings. And that's obviously a very 11 important thing to measure, is them being satisfied and being ultimately discharged back 12 13 into the community. 14 CO-CHAIR PARTRIDGE: Sherrie? 15 I had some -- first of MEMBER KAPLAN: 16 all, I support all of Peter's comments. And then 17 I had some questions, more questions than 18 anything else to the developers. I agreed that 19 the exclusions actually may limit the 20 generalizability to a small proportion of 21 facility nursing home patients. 22 And then the consistency of the

implementation across facilities actually could be compromised by the low response rate. So I was a little bit concerned about the response rate.

5 Second thing I was concerned about was 6 there was test retest reliability but they give 7 one month as the testing interval. And they give 8 percent agreement but not intra-rater reliability 9 at the patient level. And they didn't give ICCs 10 at the facility level, at least I couldn't find 11 it.

12 The other thing I was, a few other 13 things. The pre-specify, when you do boot 14 strapping, you can't really interpret it without 15 pre-specifying a minimally important difference. 16 So I would like to hear something about what you 17 considered a minimally important difference.

And the sample size varied from 20 to 19 196 per facility. So the stability of estimates 20 across facilities is going to, that's going to 21 affect the stability of those estimates.

And then I didn't get the item to

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total correlation coefficients for the 22 items
 to support the item choice thing and your
 elimination of the items.

And in the validity testing, although your factor analysis looks like it supports a single dimension, you don't say if you did any varimax or oblique rotations to kick the tires on the multi-dimensionality. And so I was interested in hearing your responses on that.

10 And finally, the validity concerns I 11 had were like because, although you note that 12 there are these correlations, some of them are 13 significant with the validity variables you chose 14 but a number of them are very low. And many of 15 them are not significant. And so, then I was 16 wondering what we were going to conclude about 17 the, your take of what that means.

18 CO-CHAIR PARTRIDGE: That's kind of a 19 laundry list. So I'm not sure that we can ask 20 you to respond to all of them right this second. 21 But if you want to tackle, you know, a couple 22 that seem -- either we can knock it off fast or

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it's --1 2 DR. GIFFORD: I assume with the exclusions people are concerned with the 3 4 cognitive impairment piece for it. Because the 5 rest are really minor. And I would think clinically, seeing that makes sense. People die, 6 7 can't really survey them. And we're really split out making sure it was the voice of the patient 8 9 or the voice of the family. We would not combine 10 them. So we exclude them that way. 11 The cognitive impairment one has, you 12 know, been really a difficult one in satisfaction 13 in general in this setting. And I think we ended 14 up setting on, using the BIMS score that Salida 15 developed for MDS. So it was uniform to every 16 nursing home resident out there. So we had a 17 standardized way of assessing that. It wouldn't 18 allow people to game the system. 19 It's currently, something like that is 20 used currently pretty much across the board in 21 most nursing home satisfactions that are out

236

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there thought not everyone can quite do it.

We

set it at the level of where we did because it's 1 2 pretty moderate to severe. It's unclear anyone would have a short term memory to be able to 3 4 recall anything overall. 5 It mainly was -- frankly we don't You can send it to them. But the chance 6 care. 7 that they'll fill it out or not have someone else assist them in filling it out, then their results 8 9 would be excluded anyway because we don't allow 10 proxy individuals. Then you just, you dry the 11 sample, your response rates become a problem. 12 And so, it was also just to help with the 13 response rates frankly. 14 May I ask a follow up MEMBER KAPLAN: 15 question on that? Because the response rates 16 don't look great to begin with. And so, I know 17 this is a vulnerable population and it's 18 difficult to reach and all that stuff. 19 On the other hand, when you've got 20 that limited amount of response rate, can you 21 give us a sense of whether those, the patient

characteristics match the profiles of the

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facilities? Or anything to help us see if that's
 a generalizable sample you got?

I was a part of that and 3 DR. GIFFORD: I don't know if we did the latter part or not. 4 5 But I know that one of the things we did is we talked, we talked a lot with a lot of the, as 6 James said, a lot of the survey vendors out 7 And pretty much across the board, most 8 there. 9 everyone right now is accepting somewhere around 10 15 to 20 percent which we thought -- yes, that 11 was also my response too.

12 And so we boosted it up. And then we 13 really pushed it. We're allowing right now, in 14 sort of initiative, anyone to have any response 15 rate. But when we calculate it or do any 16 reporting or do any reporting, we want a minimum 17 response rate.

I mean, if you look at even the states that are publicly reporting satisfaction out there and there's four or five of them, we talked to those vendors in those states and they're all accepting really low response rates. So we ended

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up deciding to go with that from a pure usability
 standpoint.

Because while I completely agree with 3 4 you, I'd love to see a higher response rate, even 5 in the states where they're doing public reporting, you would essentially probably go down 6 7 to about 10 to 15 percent of SNFs in the country having an adequate response rate. Then I'll turn 8 9 it over to James for the other analysis. 10 So for the technical MR. MULLER: 11 questions, do you want to step through them one 12 by one? 13 MS. SAMPSEL: Actually, can we hold 14 those until we get to scientific acceptability 15 please? 16 MR. MULLER: All right. 17 MEMBER THOMAS: First do the 18 exclusions for a second. 19 MR. MULLER: Sure. 20 Because my concerns MEMBER THOMAS: 21 were a little bit broader than just the cognitive 22

1 MR. MULLER: Okay. 2 MEMBER THOMAS: -- exclusion. And this is going to sound maybe a little tongue in 3 4 cheek. But some would argue that the person that 5 dies is the least satisfied with their care. 6 MR. MULLER: Yes. MEMBER THOMAS: 7 And I'm concerned about also the readmissions issue, about going to 8 9 another facility. It might have nothing to do 10 with the care being provided in the SNF. But it 11 might have something to do with the care being 12 provided in the SNF. And if it is because of 13 some of the things that are being measured here, 14 competency of the staff, you know, responsiveness 15 of the management, if those are in fact 16 contributing factors to why that person has to go 17 to another facility whether they're being 18 readmitted to the acute care hospital or to a 19 higher intensity level of care like an IRF or if 20 they die. 21 Those are perhaps, you might argue, 22 the most egregious cases and they're being pulled

out of the sample. So can you just address that? 1 2 DR. GIFFORD: We talked a lot about We actually would prefer to see a hospice 3 it. 4 level or end of life, you know, some of the 5 survey stuff that Joan Teno's down at Brown. Because I think she's also shown that this group 6 is the experience and the questions -- it's not 7 even clear in the focus groups in cognitive 8 9 testing whether these are the appropriate 10 questions to ask for people who are dying. 11 The experience of the provider 12 community has been sending any sort of survey 13 questionnaire to family members of people who 14 have died has often been very offensive. And so, 15 it was felt to be out of respect of them to 16 collect the data a different way. And they are 17 excluded for that reason as well. 18 MEMBER THOMAS: That's fair. I quess 19 where I'm going is maybe something that's in 20 politic to raise, I'm just trying to understand. If you've got a SNF that's not up to par on 21 22 quality and they're actually contributing to the,

1	some of the things that are happening to these
2	people who are then being excluded from a quality
3	measure, isn't that biasing the data in a
4	favorable way?
5	MR. MULLER: I think if the SNF is
6	systematically poor, it'll be picked up as well
7	by the patients who aren't being excluded. So
8	that will be driven down by that signal as well.
9	DR. GIFFORD: We also have a panel of
10	other measures that we're held accountable to
11	that are using so we have discharge to
12	community. We have rehospitalization rates. We
13	have more functional improvements to come. So we
14	have a whole set of other metrics that are being
15	held accountable to that provide an opportunity
16	to sort of balance, I think, if we're discharging
17	inappropriately or having other problems that are
18	out there.
19	CO-CHAIR PARTRIDGE: Before we move
20	on, Deb you are back on the line with us. Is
21	that right?
22	MEMBER SALIBA: Yes I'm back.

CO-CHAIR PARTRIDGE: And you're one of
 the discussants here. So maybe we should give
 you an opportunity.

4 MEMBER SALIBA: Yes. So I certainly 5 agree with the premise that obtaining resident 6 satisfaction measures is really important. And 7 that this is a gap in the current measurement 8 approach. So I think it's great that this is 9 being done.

10 I was a little bit unclear if the 11 CoreQ analysis that we're seeing is having 12 received a full survey and then answered these 13 summary items. Or if it's just answering these 14 summary items. It seems like in a lot of 15 satisfaction surveys, you tend to have the more 16 granular items leading up to then asking these 17 more summative kinds of scores.

And so, it was a little unclear to me if the testing results that you're showing us are just, you went in and just asked these three very summary questions which seem to be a little bit challenging in terms of providing an actionable

road map. Or if you're going in and doing the
 longer survey and then only scoring the last, the
 summative three questions.

The rest of my questions were about the more, along the lines of the evidence, the correlations and things like that. But I did want to ask about that question.

I mean -- and Nick can 8 MR. MULLER: 9 speak to some of this as well. There were 10 different rounds of development. And some of the 11 earlier rounds of development needed the full set 12 of questions so that we could whittle things 13 And I think the current form that he's down. 14 collecting out there is distilled down to the 15 minimal set.

Some of the vendors that are doing it have integrated into their own instruments with other questions in there and that sort of thing. So it's really a mixture of different things. MEMBER SALIBA: Another thing was the choice of the response scale, poor, average,

good, very good, and excellent. So it seems

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1	pretty heavily weighted towards positive
2	responses. And lumping the good, very good, and
3	excellent together would seem to weight more in
4	the direction of positive response.
5	And I was interested in how you came
6	at that particular response scale.
7	DR. GIFFORD: Well we actually, and
8	Nick had commented, we did focus groups and
9	cognitive testing of different response scales
10	from ten point down to four point Likert scales.
11	And this actually is I mean they all worked
12	reasonably well.
13	And Nick can talk about some of the
14	work he's done with some of the CAHPS. But he
15	found that most of the CAHPS surveys, no one
16	answered below five or six. And so, that's one
17	reason we collapsed, in general, in satisfaction,
18	when you're asking poor or fair, it's bad.
19	To your point, we actually tested five
20	or six different ways to calculate the measure.
21	And I was thinking that we could find a better
22	way of capturing it. And it turned out it did

not matter how you collapsed this together. You just ended up with different satisfaction scores but relative ranking was no different. The only thing that really different was if you just took the top rating of whatever scale you used, that was a fundamentally different measure.

But five other different ways of
averaging them together, you just ended up with a
different national average or group average. But
it didn't vary at all.

And then I think, back to your earlier point, the early round testing was all the questions. And Sherrie, this may go to your points too. Our goal was to get a parsimonious measure for accountability purposes. This was not for quality improvement purposes. Let me make that really clear.

I mean, if you were doing quality improvement purposes, you put food in this question. It doesn't matter whether you ask food. Once you ask these three questions and add them together, your scores don't change. Your

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quality improvement and input is tremendous. 1 2 And so, this was one reason we also recommended that the current vendors -- and why 3 4 they all support it. It gets added as a block 5 set of questions by themselves with the standard -- because they all used different Likert scales 6 7 and do everything differently. And so it's really been important. 8

9 The other is -- Nick do you want to 10 talk about? We asked, would you recommend to a 11 friend? And how satisfied were you overall? And 12 we put it at the beginning. And we put one at 13 the beginning and one at the end and we flipped 14 it beginning to the end. And it is absolutely no 15 different.

16 DR. CASTLE: Yes, I was about to try 17 and comment on that. And I agree with Deb's 18 And we did a decent amount of testing on point. 19 this because we had the opinion that if you have 20 these aggregate items first, you do think aggregate. And then you answer the more granular 21 22 questions -- is that going to have an effect? As

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opposed to answering the very granular questions
 that may then impact your overall opinion of the
 facility at the end.

So in the initial testing, we had the questions at the front and at the back. And in several thousand surveys, we found really very little difference. But again, I agree with Deb. We expected to find something, we didn't.

9 But what difference we did find is if 10 you have the block first of aggregate items, we 11 get all of the items answered and we get a very, 12 very good, complete response rate which of course 13 we need for calculating the score. So it was 14 advantageous to have the items blocked at the 15 beginning.

16 DR. GIFFORD: So we originally 17 calculated from -- I forgot. Nick, how many was 18 it? Like 20 or some odd questions. But then the 19 20 DR. CASTLE: 24. 21 DR. GIFFORD: 24 but then the 22 subsequent reliability and validity of the large

sample size was done just on these three 1 2 questions or four questions for the discharge. And they were done with, either block by vendor 3 4 that was out there added within the survey. 5 CO-CHAIR PARTRIDGE: Are we ready to move on to evidence? Sorry Becky? 6 7 MEMBER BRADLEY: Just as a point of clarification, I guess your previous answer was 8 9 that this is not in addition to the CAHPS surveys 10 that are being done. This would be instead of 11 for the patients who have a short stay of 100 12 days or less in a skilled nursing facility. So 13 it would replace a CAHPS survey for this 14 particular post-acute setting? 15 I guess I'm -- we spent a lot of time 16 at our last meeting talking about how CMS is 17 trying to standardized instruments across post-18 So I guess I'm trying to figure out where acute. 19 this survey would play out in the post-acute 20 And how it would be compared to other setting. 21 post-acute settings going forward. Or is it just 22 unique and by itself?

MR. MULLER: A little bit of both. 1 Ι 2 mean, it's intended, it wouldn't make sense to do both the nursing home CAHPS survey and this 3 4 survey because they will correlate very highly. 5 Because the additional items, as Giff sort of pointed out, don't really -- it's picking up the 6 signal. And so there's a redundancy between the 7 8 two. 9 This is a shorter, sort of more 10 parsimonious survey that will get a higher 11 response rate because of that. So I guess one 12 could do both. But I don't know why one would. 13 DR. GIFFORD: And nursing home CAHPS 14 is not used right now. No one's using it. 15 There's a handful using it for discharge. But 16 other than that, no one is using it for long stay 17 or anything else. And then CMS just went through 18 the endorsement application. So it's not even an 19 endorsed measure anymore. 20 So right now there is no standard 21 metric out there. And this started because we

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made imprudent satisfaction as a primary focus of

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1	our national quality initiative. And when we
2	went out there and looked at everything being
3	done, it's all over the map.
4	And so, the feeling was we needed a
5	standardized way to do this. And that's why we
6	worked with Nick and all the vendors. And
7	everyone's been really excited because it's the
8	first time there's a standardized metric that you
9	can compare across everyone.
10	MEMBER BRADLEY: Across
11	DR. GIFFORD: Across SNFs, yes.
12	MEMBER BRADLEY: But not across the
13	post-acute?
14	DR. GIFFORD: No. We developed it for
15	we don't have it to bring forth. We developed
16	it for assisted living too. And we've tested it
17	and we've done a lot of collecting. The problem
18	with it, we don't know how to test the validity
19	of it because there aren't good measures of other
20	external measures for validity out there.
21	MEMBER BRADLEY: Okay. Thank you.
22	CO-CHAIR PARTRIDGE: Can we move on to

evidence? Any comments or questions from either 1 2 our discussants or the rest of our membership on evidence starting with 2614 which is the CoreQ 3 4 for short stay discharge? Sherrie? 5 MEMBER KAPLAN: Can I just say something positive? 6 7 CO-CHAIR PARTRIDGE: Yes. 8 MEMBER KAPLAN: So yes, one, I really 9 liked there was a conceptual framework that was 10 provided at the beginning that linked the measure 11 with other things that were going on. Second 12 thing I liked, they really did cite our 13 literature review kind of as a really, a more 14 comprehensive literature review that documented 15 the evidence for a lot of variation. 16 And then they showed that there was a 17 considerable -- although it's still favorably 18 skewed, there was a gap, there was a demonstrated 19 And the interquartile range was like 13 qap. 20 points which is unusual in these satisfaction 21 measures because you get them always bumped up to 22 the top. So I did think there was strong

evidence provided both for the gap and for 1 2 disparities by age and gender. 3 CO-CHAIR PARTRIDGE: Thank you. 4 Linda? 5 MEMBER MELILLO: Yes. I would just like to say there is no required reporting or 6 7 measurement in the SNF population currently. And I appreciate it's short. Because especially in 8 9 that population, which tends to be very sparse in 10 terms of staffing, that would be much more doable 11 than one of the lengthy surveys. 12 MR. MULLER: Yes. We all hate 13 paperwork. 14 CO-CHAIR PARTRIDGE: So are we ready 15 to --16 DR. GIFFORD: There's like five states 17 that do public reporting in the nursing home but 18 none national. And three other states have 19 incorporated this into their questionnaire. 20 MEMBER MELILLO: Massachusetts has a 21 state survey that they do annually. But yes, but 22 again, it's very length. So this would be

preferable by far.

2	CO-CHAIR PARTRIDGE: Desi?
3	MS. QUINNONEZ: Okay. We are now
4	voting on Measure 2614 CoreQ short stay discharge
5	measure on evidence, the rational supports the
6	relationship of the health outcome to at least
7	one healthcare structure, process, intervention,
8	or service. The voting options are number one
9	for yes and number two for no. Voting is now
10	open.
11	Looking for two more votes. Voting,
12	all votes are in and voting is now closed. The
13	results read 94 percent voted yes and 6 percent
14	voted no.
15	CO-CHAIR PARTRIDGE: Okay. Moving on.
16	I think Sherrie has already touched briefly on
17	gap. Any comments specifically on this
18	particular aspect? Deb, chime in here where you
19	wish. And Lisa, you were, I can see your card.
20	MEMBER SUTER: So yes, could I just
21	clarify, are we only voting on one measure
22	through all criteria?

1 CO-CHAIR PARTRIDGE: Yes. I'm sorry. 2 We are going to go through -- because they are slightly different, we are going to go through. 3 4 And we also happen to have a discussion of the 5 other two. So I'm sorry, back to voting on --Desi. 6 7 MS. QUINNONEZ: Are we ready for gaps? Okay. Voting is now open for Measure 2614 for 8 9 gaps, performance gap data demonstrated 10 considerable variation or overall less than 11 optimal performance across providers and/or 12 population groups. Option number one is high, 13 option number two is moderate, option number 14 three is low, and option number four is 15 insufficient. 16 Waiting for one more vote. Okay. All 17 votes are in and voting is now closed. The 18 results read 39 percent voted high, 56 percent 19 voted moderate, 6 percent voted low, zero percent 20 voted insufficient. 21 CO-CHAIR PARTRIDGE: Okay. Moving on 22 to scientific acceptability. First one, our

friend reliability. Floor is open for comments, 1 2 Sherrie? concerns. MEMBER KAPLAN: This is for the 3 4 developers, do you have a sense of, do you have 5 the intraunit reliability, the intraclass correlation coefficients at the facility level 6 7 for these, for this measure? Nick? 8 MR. MULLER: 9 DR. CASTLE: Actually I do not. But 10 when you say interunit, do you mean nursing home 11 unit or --12 MEMBER KAPLAN: Yes, facility level. 13 Whatever unit is being compared. If it's the 14 facility that's being compared, then evidence 15 that it's --16 DR. CASTLE: Oh so this was at just 17 the facility level. I would love to do it at the 18 unit level. But we had names and addresses of 19 residents, clearly. But we don't know which 20 units they were on. 21 MEMBER KAPLAN: I guess I'm asking the 22 facility level with intraclass correlation

coefficients showing that it was more between than within unit facility variability.

DR. CASTLE: No I do not. I was actually trying to look that up right now when you mentioned it earlier. I haven't found that yet, no.

7 MEMBER KAPLAN: And then one quick question on battery reduction. 8 So in this 9 battery reduction exercises -- because these 10 things are going to be really highly correlated 11 with each other, they tend to be. To get from 22 items to 4 items, this is back to the Spearman-12 13 Brown prophecy formulation, you're going to lose 14 some precision when you shrink the number of 15 But you know, if you're losing variation items. 16 -- I didn't get the item to total correlation 17 coefficients for the 22 items.

So if you went through that data, as you probably already did, how did you choose the top performers there? Because if these all have kind of a fairly strong relationship to the total body of items included, how did you pick which

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ones to --

MR. MULLER: Again, a question for Nick.

4 DR. CASTLE: So some of this, as you 5 might have guessed by the application, that this was extremely iterative. We did this many 6 7 hundreds of times. But some of it was when we dropped our doors with the highest correlation. 8 9 Then we continued to drop out that way. We would 10 go partially down and then add some back in to see, as you're saying, that we hadn't actually 11 12 mis-dropped something.

13 So it was almost a reverse process 14 from what folks often do. We were trying to get 15 items that almost were capturing the most 16 satisfaction information that wasn't within 17 another item. So if the items really correlated 18 very, very, very highly, it made sense to drop 19 one of those items. But once we had, later on we 20 would put it back in until we were comfortable 21 with dropping the individual items.

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Now the other thing that was going on

with this is with the three instruments, we were also trying to do, to get items that were similar in the three instruments also. So it was almost a family of instruments.

DR. GIFFORD: The other thing that was 5 going on at the same time is we were trying to 6 7 look for a personalized number for a measure. So it wasn't that we were just trying to get a 8 9 Because they perform well as a full scale. 10 And you can pick, sort of different scale. 11 But it was, what was the minimum number numbers. 12 to get an aggregate measure to hold to assess the 13 facilities overall satisfaction?

14 DR. CASTLE: Actually I think Giff 15 just answered that way better than I did. If I 16 answered a different way, I'd say, so if we had 17 three or four items in there. Let's say we have 18 four and we would calculate the score with those 19 four items. We got somewhere, depending on which 20 instrument we're talking about, 84 percent to 89 21 percent or in some cases 91 percent of the score 22 we would get with the full instrument, or with a

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score using the CAHPS instrument which seems to
 indicate that we're capturing overall
 satisfaction. And if we added another item in,
 we might go up to 86 percent rather than 84
 percent.

So the addition of the item wasn'tgetting, wasn't capturing much for us.

I get it at the 8 MEMBER KAPLAN: 9 patient level. What I was looking for was at the 10 between facility variance versus the within 11 facility variance. And when you've got only 20 12 subjects for some of these facilities, what 13 you've got to go back, what it would be really 14 good to go back and do is look at the Spearman-15 Brown prophecy formula to see how close to the 16 bone are you getting with four items. Especially 17 as you get sample sizes that shrink that far.

So you know, if you're getting too much noise, then you're going to get a lot more within facility variability that's going to mess up your ability to discriminate between facilities. So that's, it's related to that

question.

2	It doesn't necessarily I don't
3	Sarah. It doesn't make the bar right now of the
4	things that NQF is going to ask for. But it may
5	make the next round. Is that right? Or is this
6	a legitimate question for this round?
7	MEMBER SAMPSEL: I don't think so. I
8	mean, because basically what we would like you to
9	get out is have they provided the level that we
10	have, you know, kind of go back to the
11	algorithm, Sherrie, that you questioned earlier.
12	And that, you know, what we've already
13	communicated to the developers is that we want
14	facility level testing in order to be able to
15	interpret the measurement score.
16	So anything beyond that is something
17	we want to see in the future. But we haven't
18	stated it.
19	MEMBER KAPLAN: This would be within
20	then, what you just said. It would be asking for
21	between facility, evidence that there is between
22	facility variation that's not a function of

within facility variation. And my only concern 1 2 is, when you're getting that small number of items, that you could noise up your variable and 3 start causing yourself trouble. 4 CO-CHAIR PARTRIDGE: I see Peter's 5 hand up. 6 7 MEMBER THOMAS: Real quick, there's no 8 risk adjustment here, right? 9 MR. MULLER: Correct. 10 MEMBER THOMAS: And is that because 11 the four questions were, you didn't feel that you 12 needed to do risk adjustment when you're asking 13 those four patient reported outcome measures? 14 It's really the concept. MR. MULLER: 15 So we thought about is there like a clinical 16 driver that would make one person more satisfied 17 than other? If it's appropriate to control that. 18 And we couldn't think of anything. 19 Sociodemographic characteristics, so 20 race or something like that there's, I think there is a small correlation with race. 21 But 22 again, it's like, it feels very inappropriate to,

if one race is systematically more satisfied than 1 2 another, to control that difference. So we sort of could not find a 3 4 reasonable set of factors or any factor to adjust 5 for. You've also got --6 MEMBER THOMAS: I would answer that we 7 DR. CASTLE: searched, as James said. We did look at SES. 8 9 And whatever factors we had available, we 10 searched the scores to see if any kind of risk 11 adjustment was appropriate. And it's actually 12 also not standard to risk adjust for most 13 satisfaction surveys in long term care. But we 14 did look into it and it didn't seem to make 15 sense. 16 MEMBER KAPLAN: Following up on that, 17 in 1B you do note age and gender differences. Is 18 that what you're excluding for risk adjustment? 19 DR. GIFFORD: We don't do any risk 20 adjustment. I mean there are age and gender 21 differences. Part of it also is the general 22 membership of, felt that they want to be held

accountable for who they take care of and not 1 2 risk adjust away differences. MEMBER KAPLAN: But no, older people 3 are more satisfied and women are less satisfied? 4 5 DR. GIFFORD: Yes. 6 MEMBER KAPLAN: Independent of the 7 care they get? DR. GIFFORD: Yes. 8 9 MEMBER KAPLAN: Okay. 10 CO-CHAIR PARTRIDGE: Are we ready to 11 move on to voting? Sarah's nodding. Everybody 12 Are we all awake? Okay. Desi? else? 13 MS. QUINNONEZ: Yes. Voting is now 14 open for Measure 2614 on reliability including 15 precise specifications and testing. Option 16 number one is high, option number two is 17 moderate, option number three is low, and option 18 number four is insufficient. 19 We're looking for one more vote. **All** 20 votes are in. Voting is now closed. The results 21 are 33 percent voted high, 44 percent voted 22 moderate, 22 percent voted low, and 0 percent for

insufficient.

2 CO-CHAIR PARTRIDGE: Variability, again, floor is open for comments. 3 Sherrie is 4 that card up or down? 5 MEMBER KAPLAN: It's up. And I only have one question. My question is on Table 6 2B2.3.J on Page 61, you got a variable going in 7 the wrong direction with respect to readmissions. 8 9 And because most of your variable evidence, the 10 validity evidence is modest at very best and in 11 many cases nonsignificant, what do you make of 12 the one that's going in the wrong direction? 13 MR. MULLER: Which page was that? 14 MEMBER KAPLAN: Page 61. 15 DR. GIFFORD: I remember this. 16 MR. MULLER: Yes. 17 MEMBER KAPLAN: It's a strong 18 positive. It's one of your strongest 19 correlations and it said it in the wrong 20 direction. 21 DR. GIFFORD: I remember that. And we went back and reexamined that to make sure we 22

didn't enter it in wrong. We thought it was a 1 2 typo too. We elected not to make up an excuse because we just couldn't figure how to do it. 3 4 But you know, with any of these 5 correlations, we could always change our hypothesis after the fact to make them fit. 6 And 7 we elected not to. We felt the preponderance was in the way we wanted. And I have no idea 8 9 I really do not know. Sherrie. 10 MEMBER KAPLAN: If they had a done a 11 Fisher's exact test and counted up the number 12 signs that were in the correct direction, this 13 wouldn't have screwed you up, wouldn't have 14 messed you up. But on the other hand --15 That's kind of what we DR. GIFFORD: 16 did. 17 MEMBER KAPLAN: I'm just very curious. 18 It's the highest correlation. 19 DR. GIFFORD: I know. 20 MEMBER KAPLAN: And it's going in the 21 opposite direction. DR. GIFFORD: You should have seen the 22

Actually we didn't even pick it up on 1 reaction. 2 the first draft of this. We talked about how this was the strongest correlation and 3 4 everything. And then someone on the review said, 5 but it's the wrong direction. And we had to go back and rewrite. We just elected to -- I don't 6 I don't know how to explain it. It's just 7 know. 8 one of those things. 9 MEMBER MELILLO: I may have an answer 10 Pressure ulcers, is that what we're for you. 11 talking about? 12 No, rehospitalization. DR. GIFFORD: 13 MEMBER MELILLO: Oh, nevermind then. 14 Oh okay. 15 So this is Deb. MEMBER SALIBA: My 16 only comment was just that the Fleishman that you 17 point to as indicating understanding is more just 18 a reading level test than understanding. You may 19 have also done some cognitive testing with the 20 items to see if people are answering the 21 questions we think they're answering. But the 22 test that you used is probably just a first step

and not really a test of comprehension. 1 2 DR. CASTLE: I can answer that one Deb. Yes, we did cognitive testing with family 3 4 members, with residents, and with short stay 5 residents. We went to facilities in Pittsburgh. And with the cognitive testing, I think we had 6 7 more than 100 in each group by the time we were finished. 8 9 And we did it the classic way of 10 reading questions and having them respond back on 11 what they thought we were asking and if we could 12 ask it differently and what they understood with 13 words. 14 The Fleishman was put in there because 15 it also passed that test. But the cognitive 16 testing was exactly as you describe, the classic 17 way of doing it. 18 MEMBER SALIBA: Great. I figured you 19 probably had. Thank you. 20 DR. GIFFORD: Deb, I think it's in the 21 appendix. We're looking for it right now. 22 CO-CHAIR PARTRIDGE: Okay. Are we

ready to vote on variability? I'm sorry,
 validity.

3 MS. QUINNONEZ: Okay. Voting is now 4 open for validity including specifications consistent with evidence, testing and threats 5 adjust, exclusions, risk adjustment 6 7 stratification, meaningful differences, comparability, multiple specifications, missing 8 9 The options are one high, two moderate, data. 10 three low, and four insufficient. 11 Okay. We're still waiting for two 12 All votes are in. Voting is now closed. votes. 13 The results read 33 percent voted high, 50 14 percent voted moderate, 17 percent voted low, and 15 0 percent voted insufficient. 16 CO-CHAIR PARTRIDGE: Next item or 17 category is feasibility. We've talked about this 18 a tiny bit. Linda was excited that it was short 19 which is the whole point. Are there other 20 comments? Are we ready to vote? Yes? 21 MS. QUINNONEZ: Voting is now open for 22 Measure 2614 for feasibility including data

generated during care, electronic sources, and 1 2 data collection can be implemented. And the options are number one high, two for moderate, 3 4 three for low, and four for insufficient. We're waiting for two votes. One more 5 All votes are in. Voting is now closed. 6 vote. 7 The results are 28 percent voted high, 72 percent voted moderate, 0 percent for low, and 0 percent 8 9 for insufficient. 10 CO-CHAIR PARTRIDGE: Finally we are at 11 usability. Usability, again, any comments? 12 Desi, over to you. Okay. 13 MS. QUINNONEZ: Voting is now open for 14 Measure 2614 usability and use, accountability, 15 transparency, and improvement progress 16 demonstrated and benefits outweigh evidence of 17 unintended negative consequences. The options 18 are one for high, two for moderate, three for low, and four for insufficient information. 19 20 Looking for two more votes. All votes 21 are in and voting is now closed. The results are 22 28 percent voted high, 61 percent voted moderate,

11 percent voted low, and 0 percent for 1 2 insufficient information. CO-CHAIR PARTRIDGE: 3 Before we go on 4 to the final question of recommending 5 endorsement, Peter? Real quick, it says, 6 MEMBER THOMAS: 7 there's a note on the bottom of Page 12 that says that although there's no public reporting now 8 9 that ACHA is planning on public reporting with 10 the CoreQ measures as part of the quality 11 initiative for 2016 through '18 with 9,600 SNFs. 12 I'm just wondering how that compares 13 or contrasts with the measures under the Medicare 14 program that CMS is implementing on the IMPACT 15 Are they duplicative of one another? Act. Are 16 they done together? Or what's happening with 17 that? 18 DR. GIFFORD: IMPACT Act does not 19 require satisfaction. We have shared this with 20 CMS and have asked them that they add this to 21 five star at some point in the future. I know 22 five star is thinking about, in the next five

years, probably adding satisfaction at some 1 2 point. Thanks. MEMBER THOMAS: 3 4 DR. GIFFORD: As an organization, we 5 support and endorse that. Why we undertook this whole process. 6 CO-CHAIR PARTRIDGE: 7 Okay. So final question is whether or not we recommend that this 8 measure be forwarded for with recommendation for 9 10 endorsement by MQF. And Desi? 11 MS. QUINNONEZ: Voting is now open for 12 Measure 2614 for recommendation for overall 13 suitability for endorsement. Option number one 14 is yes. Option number two is no. 15 We're looking for two more votes. 16 We're ready. All votes are in. The results are 17 94 percent voted yes and 6 percent voted no. 18 CO-CHAIR PARTRIDGE: In the past, as 19 we have here, three measures that are almost 20 identical, they're not obviously identical but 21 almost, we have taken the votes on the first 22 measure. And said after discussion, we first

discussed and then made a decision as to whether we would be comfortable about accepting the votes on those, on the first measure. And moving the scores, essentially saying the scores would be the same for the second and third, we don't need to go through all the individual items.

7 Before we even consider such a step, I want to give the people who have so patiently 8 9 been working and studying as lead discussants, 10 both Number 2615 and 2616, an opportunity to say 11 what they want to say. And that's specifically 12 at Lisa and Sharon Cross and Lisa Morrise. So 13 Lisa, do you want to start? Lisa Suter will 14 start.

15 MEMBER SUTER: Thank you. This is 16 Lisa Suter. So I actually think that's a great 17 recommendation. Because, having listened to the 18 discussion of the first measure, I actually find 19 2615 which is for the long term resident measure 20 less controversial, I think, in terms of its 21 exclusions to the denominator than the prior 22 measure. And the liability and validity testing

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is very similar across the board. 1 2 So I actually think it's a very reasonable recommendation to translate scores 3 4 from, at least my scores from that initial vote 5 to this second measure as well as to the third measure which assesses family member care. 6 7 Family member inputs, excuse me. 8 MEMBER MORRISE: I agree. I don't see 9 that there's that much difference. In fact, in 10 reading through all of them, I thought this is 11 the same thing over and over again. It's great. 12 MEMBER CROSS: I agree. I was 13 thinking the same thing as I was reading through 14 them, that they were all very similar. So 15 there's nothing additional that I think I'd want 16 to add to the conversation at this point. 17 CO-CHAIR PARTRIDGE: Then I think we 18 should have a formal vote that we do that. 19 Peter? 20 MEMBER THOMAS: On both the long and 21 short measures, you don't, one of the exclusions 22 is guardians that respond, correct?

DR. GIFFORD: Yes, the legal 1 2 guardians. MEMBER THOMAS: Guardians. 3 4 DR. GIFFORD: Yes or court appointed 5 quardians. MEMBER THOMAS: So at first, I was a 6 7 little concerned about that. Then I read that the next measure is the family. 8 9 DR. GIFFORD: Correct. 10 MEMBER THOMAS: And I don't remember 11 whether guardians are included in -- I guess 12 guardians, that wouldn't be relevant there. So 13 it's really not related. I was thinking about 14 someone else answering on behalf of the patient. 15 But --16 DR. GIFFORD: We don't let anybody 17 answer on behalf of the patient. 18 MEMBER THOMAS: Because it's patient 19 reported, you want to make sure that they are the 20 ones doing it. 21 DR. GIFFORD: Yes. 22 MEMBER THOMAS: Thank you.

MEMBER SALIBA: This is Deb. 1 The only 2 concern I have on the long stay one was it looked like -- and I may have misread your data. 3 But it 4 looked like you were allowing the facility member 5 to fill out the survey for the individual if they were unable to do it themselves. 6 7 DR. GIFFORD: Well there's no way to But if they indicate as such, their 8 stop them. 9 data is excluded. 10 MEMBER SALIBA: Okay. So I was 11 misreading it. It looked like it was allowed. And that, obviously -- so are individuals -- how 12 13 are we making sure that there is no provider 14 influence on scoring with these? I'm assuming 15 the short stay people have a little bit more 16 autonomy. With the long stay people, how are you 17 assuring that they're sort of being able to 18 independently answer these surveys? 19 DR. GIFFORD: Well there's no way of 20 assuring it Deb. 21 MEMBER SALIBA: Okay. 22 DR. GIFFORD: I mean, but it's

administered, it's in the rules and it's in the 1 2 guidance that's out there. But as you know, a lot of places do provide some level of assistance 3 4 out there. You know, we're trying to push that 5 out there. MEMBER SALIBA: So it does not require 6 7 to use an independent --8 DR. GIFFORD: Yes, they have to use an 9 independent vendor. 10 MEMBER SALIBA: To analyze them or to 11 administer them? 12 DR. GIFFORD: Well to both. But 13 independent vendors often have the facility 14 distribute the survey and then collect them and 15 mail them back. So at that point, you can't 16 really -- I mean, I can't assure one way or the 17 other. 18 But yes, this requires an independent 19 vendor to both make sure the samples being drawn 20 and the things being calculated as being 21 administered. But they're not coming in and 22 doing and doing face to face or doing it in the

building.

2	MEMBER SALIBA: I mean, I guess that's
3	just the biggest concern, you know, in terms of
4	threats to validity with the long stay ones,
5	would be someone's comfort level if it's being
6	handed to them by a facility staff member and
7	then collected by a facility staff member. As
8	you know, I mean that could be a little bit of an
9	issue.
10	DR. GIFFORD: I agree. It's just
11	inherent with the whole population.
12	MEMBER MORRISE: I agree that it could
13	be an issue. I also had a concern as I was
14	reading through it and they had to dig deeper to
15	find that it is allowed in the administration of
16	this survey for somebody to act as a scribe which
17	I see as being very important. Especially since
18	my daughter has upper trunk CP and doesn't write
19	well at all. And so, she has me fill out
20	everything for her.
21	So I realize that could have some bias
22	that enters in. Because an individual could fill

out something other than what is being reported. 1 2 But that's probably minimal.

DR. GIFFORD: We do ask did someone 3 4 help, yes, no? And then we ask how they helped. 5 And so, if it's in your scenario and you're just translating the thing, yes we will count them. 6 7 So we wanted to make sure that we didn't lose individuals. 8 9 MEMBER THOMAS: In this day and age of 10 electronic everything, this is a mailed survey? 11 Good old fashioned U.S. mail, right? I mean I 12 don't doubt the fact that --13 DR. GIFFORD: We've not tested the app 14 for it yet. 15 MEMBER THOMAS: I doubt you'd get very 16 far in this population. 17 DR. GIFFORD: Well it is interesting 18 you say because a number of the different survey 19 vendors out there that approached are using 20 different vehicles for how to administer it. And 21 as we're collecting data is getting much wider 22

use, we're looking at whether the method of

1	collecting data differs in any way. But right
2	now it's a paper version, yes.
3	CO-CHAIR PARTRIDGE: Becky?
4	MEMBER BRADLEY: Given the population
5	that you're talking about, is there any
6	accommodation for patients with visual
7	impairments or language? Will this be offered in
8	other languages?
9	DR. GIFFORD: Right now it's offered
10	in English only. Other than a handful of SNFs,
11	would that really cross a sample size? But it
12	definitely is something we would want to pursue
13	down the road to explore that on how to get that
14	broader. Especially as the demographics are
15	changing and the cohorts are aging in other
16	demographics. We'd like to do that.
17	CO-CHAIR PARTRIDGE: Sharon?
18	MEMBER CROSS: Regarding the family
19	measure, I just wanted to ask for clarification
20	about the comparison to related or competing
21	measures. Because there was a mention about a
22	CAHPS nursing home family. Can you just respond

to that?

DR. GIFFORD: Yes. That was before it was withdrawn for endorsement. We submitted this prior to the March 3, 2016 NQF.

And I'll just, in 5 MEMBER CROSS: Yes. comment on that, we reached out to the AHRQ folks 6 7 repeatedly. And they indicated they did not want to continue endorsement because, while they're 8 9 keeping the survey and they're maintaining the 10 survey, as Dave already mentioned, it's not being 11 used.

We also followed up with CMS. And CMS said they had no plans to be putting that into any of their programs any time soon. So you know, that's right, we're dropping that.

16 CO-CHAIR PARTRIDGE: As a formal 17 matter, Sarah tells me that we should vote, to do 18 only the final vote. That is, do we recommend 19 for endorsement both Number 2615 and 2616. So 20 we'll go ahead and do that vote. 21 MS. QUINNONEZ: Voting is now open for

22 the recommendation for overall suitability for

1 endorsement for Measure 2615. Option number one 2 is yes --3 CO-CHAIR PARTRIDGE: Before we vote, 4 Linda? 5 MEMBER MELILLO: Yes. I just, if I 6 understand correctly, you're mailing these to their homes? Yes? 7 The discharge home, it's 8 DR. GIFFORD: 9 going to whatever address the SNF has on file to 10 communicate with them. For family members, it's 11 going to the primary person that they have on 12 And for residents, it's going to the record. 13 resident who's living in the home because they're 14 not, that is their home. 15 MEMBER MELILLO: Okay. So for those 16 that have no potential to discharge, are you 17 serving them as well? 18 DR. GIFFORD: On the long stay, yes. 19 MEMBER MELILLO: So the institution 20 then would administer the survey? 21 DR. GIFFORD: You know, actually it 22 tends to be a little bit different depending on

1	the survey vendor. Some will mail it to the
2	nursing home so it arrives in their mail. Others
3	will go around and deliver it to them in their
4	room and let them then submit it.
5	MEMBER MELILLO: Okay.
6	CO-CHAIR PARTRIDGE: So I think now we
7	are back to you Des.
8	MS. QUINNONEZ: Okay. If there are no
9	more comments, we will have open vote now for
10	Measure 2615 to score the recommendation for
11	overall suitability for endorsement.
12	CO-CHAIR PARTRIDGE: One is yes?
13	MS. QUINNONEZ: We're still waiting
14	for three votes. All votes are in. Voting is
15	now closed. The results read 94 percent vote
16	yes, 6 percent vote no.
17	CO-CHAIR PARTRIDGE: Okay. And going
18	on
19	MS. QUINNONEZ: The voting is now open
20	for overall suitability for recommendation for
21	endorsement for Measure 2616. Voting option
22	number one is yes, voting option number two is

1 no. 2 Looking for two more votes. All votes Voting is now closed. The results read 3 are in. 4 94 percent voted yes and 6 percent voted no. 5 CO-CHAIR PARTRIDGE: Thank our friends from AHCA for taking us through so expeditiously. 6 MR. MULLER: Thank you very much 7 everybody. 8 9 DR. GIFFORD: Thanks Nick. 10 DR. CASTLE: Thank you. Take care. 11 (Whereupon, the above-entitled matter 12 went off the record at 2:44 p.m. and resumed at 13 3:03 p.m.) 14 CO-CHAIR STILLE: We're going to start 15 again, and what we're going to do -- for the six 16 measures developed by UDSMR, is split them into 17 two groups, and actually the agenda reflects 18 that. 19 There are three that apply to skilled 20 nursing facilities and then three more that apply 21 to long term acute facilities. And the three in 22 each group are change in self care score, change

in mobility score, and change in motor score, all 1 2 from the FIM instrument if I remember correctly. So similar to what we've done in the 3 4 last hour, we'll have a rather extensive 5 discussion on the first one and then have some discussion about how much that could be applied 6 to the other two in the group. 7 There are many primary discussants. 8 And so I think there will be a lot of discussion 9 10 with everyone. We will start with Measure 2769 11 which is up on your screen right now. 12 (Off microphone comments.) 13 CO-CHAIR STILLE: Yes. Sure. 14 MS. THEBERGE: Do we have the audio 15 working again, Operator? Deb, Dawn, can you hear 16 us and can you speak? 17 MEMBER DOWDING: Oh hi, yes I can hear 18 Thank you. you now. 19 MS. THEBERGE: Okay, great. Thank 20 you. 21 MEMBER SALIBA: Yes, we're good. 22 We're good. Thanks for checking.

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1	MS. THEBERGE: Thank you.
2	CO-CHAIR STILLE: Okay. So we'll
3	start with Measure 2769 which is the first
4	skilled nursing facility measure. The functional
5	change, change in self-care score by UDSMR.
6	The primary discussants will be Beth
7	Averbeck, Dawn Dowding, and Peter Thomas. And we
8	have the measure developers here, so take it away
9	for about three minutes.
10	MS. DANN: Okay, thank you. I'm Kathy
11	Dann, director of operations for UDSMR. On
12	behalf of UDSMR and our subscribers, we are
13	pleased to be here to offer for endorsement
14	functional quality measures for both the skilled
15	nursing facilities and the long term care
16	populations.
17	These measures have already been
18	endorsed by NQF for inpatient rehabilitation
19	facilities. So endorsing them for these two
20	populations will allow standardization of
21	measurement, of function across all of post-acute
22	care using a common metric which in effect

fulfills the charge of the IMPACT Act. 1 2 With me today I have our Director of Research, Dr. Paulette Niewczyk. Am I too close 3 4 to the microphone? Okay, good. Who is here to 5 answer any questions related to the measurement development process and to answer any questions 6 7 related to the testing of the measures data that we provided to you already. 8

9 I have Dexanne Clohan, a doctor of 10 physical medicine who also has an expertise in 11 functional assessment here also. On the line we 12 have Dr. Maggie DiVita who did some of the 13 analysis that we might defer to for some of your 14 questions.

Now these measures were developed out
of extensive research and experience with a
functional measure known as the FIM instrument.
It's already mandated by CMS for rehab hospital
reporting.

20 Here are a few of the measure's key 21 features. First and foremost, the measures 22 utilize a standardized set of items,

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calculations, and risk adjustment methodology 1 2 regardless of post-acute care setting. This will provide the ability to 3 compare and contrast post-acute care sites and 4 outcomes at a common metric, a truly apples to 5 6 apples comparison. 7 Secondly, the measures are based on data that's been collected for over 20 years in 8 9 all these sites. Third, the measures require 10 data collection of only 20 unique items that 11 already has training materials, industry 12 knowledge available for public use. 13 And lastly, while only mandated for 14 use in the IRFs as part of the Medicare payment 15 system already, CMS does have the rights to a 16 royalty-free license to utilize a FIM instrument 17 in any setting. 18 We thank National Quality Forum and 19 the person and family centered care committee 20 that is here today for their time, and for their 21 consideration of our measures. We stand ready to 22 answer any questions that you might have related

to our university affiliated not for profit 1 2 organization, the measures we've submitted, or the FIM instrument. 3 Thank you. 4 CO-CHAIR STILLE: Thank you for that 5 very concise presentation. Thanks. I would like to have any discussion from the primary 6 7 discussants. Again, start general as much as 8 9 possible, and then after everybody's sort of 10 talked about general things, we'll go into some 11 of the more specifics about evidence and stuff 12 like that. So Len is first. 13 MEMBER PARISI: I didn't review the 14 first measure, I'm not one of the lead 15 discussants of the first measure. But this is an 16 overall question about the use of the instrument. 17 Is this going to be in the public domain or is 18 this now something that still has to be purchased 19 using the ability to use the FIMs instrument? 20 MS. DANN: The ability to use the FIM 21 has been offered to CMS. The exact term public domain needs to be debated. The reason for us 22

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not putting it in the public domain already is 1 2 simply because we want to maintain the integrity of the instrument through uniformity. 3 4 We are offering it free, but that's 5 the concept of the integrity of the instrument, gets maintained through uniformity. 6 7 MEMBER PARISI: So it will be free. MS. DANN: 8 Yes. 9 MEMBER PARISI: Okay. I just wanted 10 clarity on that. Thank you. 11 CO-CHAIR STILLE: And Linda? 12 MEMBER MELILLO: The FIM as it stands 13 in rehab requires certification of those who 14 administer the tool. Is that something that 15 would also be required for these? 16 MS. DANN: CMS does not require that 17 certification. UDS provides that as part of its 18 services to its subscribers. So I don't believe 19 that CMS would require something they don't 20 require today for IRFs in the future. 21 DR. NIEWCZYK: There are training manuals available for use. So certification 22

would be something that if you were subscribing 1 2 to our services, our data reporting services would be requested. But not for use. 3 4 MEMBER MELILLO: So for the data 5 reporting component of this, they can get that for free as well? 6 7 DR. NIEWCZYK: Not through us. MEMBER MELILLO: But there's a venue 8 9 for that? 10 DR. NIEWCZYK: Yes. There could be 11 other than use for that. Correct. 12 MS. DANN: Just the way the IRFs now 13 submit the data to CMS and they're going to have 14 IRF quality reporting, if they were to choose to 15 use the FIM, they would have the rights to report 16 on that. 17 MEMBER MELILLO: Or other health 18 information systems for instance, yes. 19 CO-CHAIR STILLE: Beth, you're one of 20 the primary discussants. Why don't you go? 21 MEMBER AVERBECK: Thanks. And I would 22 encourage those of you that also reviewed this to

1	chime in as well. The measure looks at the
2	change in the self care on admission and on
3	discharge. I think it's really important that we
4	have some measure of assessment for those
5	patients that are in skilled nursing facilities.
6	I did have some questions going
7	through that are just more general questions
8	around some of the specifications and then a
9	couple of the exclusions and some missing data,
10	so maybe I'll go ahead and just raise those right
11	now.
12	DR. NIEWCZYK: Sure.
13	MEMBER AVERBECK: I'm curious as to
14	why a 12 month measure was used for a short term
15	stay. I mean, most of these patients would be
16	discharged beforehand. I'm wondering about what
17	happens for patients that are readmitted to the
18	hospital, you know, that if they are excluded if
19	they're under 18 or if they die, but what happens
20	with hospital re-admissions and those patients.
20 21	with hospital re-admissions and those patients. And then there was a comment around if

1	data, then those patients are excluded. But I
2	wasn't able to tell based on the information
3	submitted what percent does the same across
4	facilities? Is it low, did it not
5	(Simultaneous speaking.)
6	MEMBER AVERBECK: just curious
7	around how the missing data is accounted for and
8	whether that might affect the results as well.
9	So I think those were the main questions I had as
10	I went through this. Thank you.
11	DR. NIEWCZYK: Thank you. And I'll
12	try to answer all your questions. Maggie, I may
13	ask you to chime in on a couple of them.
14	In terms of the age, the measures
15	could be used by patients of any age. However,
16	we have this at 18 and older just because we
17	understand that sometimes, you know, pediatric
18	populations require different modifications to
19	items and there's the function of development
20	versus impairment and so forth.
21	So to simplify things, we kept it as
22	adults early. Clearly, if a patient dies while

1 under care, we don't have any discharge scores to 2 go on. So we have an admission but we have 3 nothing else so certainly can't assess what the 4 change, you know, would have been.

And that's a typical standard way that 5 others have within the industry have excluded on 6 7 that basis. In terms of missing data, we 8 actually have a very, very small percent. 9 Maggie, do you happen to know on average how many 10 cases each year would be missing? I would guess 11 about less than two percent, but I don't want to 12 make something up here.

13 MS. DIVITA: In terms of missing the 14 required elements for the measure, I would say 15 zero because they're required in our system. So 16 something like creating age from birthdate, we 17 need that information, or all of the items are 18 required items. And so there really isn't 19 missing data as it stands.

20 DR. NIEWCZYK: So they could refuse to 21 do the assessment altogether on a patient but 22 they can't, like, --

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(Simultaneous speaking.) 1 2 MS. DIVITA: They could but then, yes, but then it wouldn't be transmitted through our 3 4 So there would be really no way for us system. 5 to understand or to know, you know, the percentage of population they decide not to 6 7 collect the data on. My gut would be that it would be very 8 9 small, because otherwise I'm not sure why they 10 would bother, you know, utilizing the measure 11 essentially. 12 DR. NIEWCZYK: And Maggie, can you 13 also speak to the 12 month window? 14 MS. DIVITA: Yes, I am, it's a good 15 question. It's been quite a while now since we 16 developed these. You know, I think that we tend 17 at UDS to look at things in a really 12 month way 18 to sort of look at how people are doing. 19 We wanted to give them a long enough 20 timeframe to allow for, you know, a good number 21 of patients so that you're not looking at a 22 smaller number of patients. And so I think it's

just sort of something that we tend to utilize at
 UDF.

And so the 12 month timeframe sounded 3 4 pretty good to us. It also gives, you know, a 5 good amount of time and are we talking about SNFs right now or are we talking about long term care? 6 7 I can't remember. But in general --8 (Simultaneous speaking.) 9 DR. NIEWCZYK: We're talking about 10 SNFs, but it's the same method for both. 11 MS. DIVITA: Right, yes. It gives us 12 a good amount of time to follow through. You 13 know, average length of stays aren't nearly a 14 year long, but that 12 month period should allow 15 us to get a good view of a true length of stay. 16 DR. NIEWCZYK: And certainly 17 internally we do look at things by quarter as 18 well. Our facilities do get quarterly reports. 19 But as we indicated in the submission files, 20 facilities had to have at least 30 cases over a year, over that 12 month period. 21 22 So it's really a function to allow

those smaller facilities to have an adequate case 1 2 count for representation. MS. DIVITA: Correct. 3 4 CO-CHAIR STILLE: Dawn, you were one 5 of the primary reviewers as well. Would you like to chime in? 6 Oh yes. Hi. 7 MEMBER DOWDING: My main question was to do with issues to do with data 8 9 burden because a lot of the measures, the things 10 that you're collecting on the FIM are actually 11 included in the MDS assessment and would also be 12 in the catch all when it institutes this hostile 13 approach to acute care settings. 14 And I guess my main concern with all 15 of these measures is that we're, you know, is it 16 going to be something that is instead of the CARE 17 tool or replace those item measures because 18 otherwise there's increased data burden on the users in terms of having to complete these 19 20 measures more than once. 21 DR. NIEWCZYK: So I can try to speak 22 to that. Yes, you know, certainly we understand

that function as something that's assessed in
 other instruments and often a variety of
 different ways.

Our measures that we have submitted here today are part of a larger tool which is the FIM. Certainly, you know, when you get through the measure files, you'll see under concurrent validity that was our gold standard. Right?

9 So how did those measures compare to 10 the full FIM. But this is not, you know, it's 11 not identical to the FIM. How it relates to 12 those other instruments, be it MDS or to the CARE 13 tools, those are measuring components of function 14 as well, although some of the items are quite 15 different.

You know, for instance, I'm not sure what measure we're talking, I think it's selfcare. But for self-care, we have both cognitive items as well as physical function, physically function items.

21 And the CARE measure for self-care 22 includes only physical functioning. There's no

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1	cognitive items. In terms of the MDS, you know,
2	the MedPAC reports from 2013 stated that skilled
3	nursing facilities did not demonstrate any change
4	over 2011 to 2013 from those functional items.
5	So we certainly, and as is indicated
6	within our files, we did see a great deal of
7	change in terms of some of the functional values
8	over the years that have been indicated. So I
9	believe they probably measure different
10	functional domains.
11	CO-CHAIR STILLE: Peter?
12	MEMBER THOMAS: I've got a I'm
13	sorry, was there a follow up?
14	MEMBER DOWDING: Yes, I mean, I'm not
15	disputing that they might measure different
16	things. But a lot of the items of information
17	that go into the different tools are the same.
18	So are you going to ask them to
19	collect the same information twice, or are you
20	going to use the information you collect for the
21	FIM or for CARE tools to feed into the methods

busy clinicians to fill out more than one item to 1 2 do somebody's function is my concern, that's all. MEMBER THOMAS: So the last set of 3 measures excluded readmissions to either an acute 4 5 care hospital or being sent over to a different post-acute care setting as well as death of a 6 7 patient. How do you handle, in this measure how do you handle those readmissions or transfers to 8 9 another setting of care? Are they excluded from 10 the calculation or not? 11 DR. NIEWCZYK: I do not believe that 12 that's an exclusion criteria. Just those that 13 are under ages 18 and who had died while in care. 14 MEMBER THOMAS: Right, those are the 15 only two? 16 DR. NIEWCZYK: That's the only two. 17 MEMBER THOMAS: So I'm just wondering, 18 I mean, which I'm in favor, I appreciate that. I'm just wondering how would you score if someone 19 20 gets readmitted to the acute? 21 DR. NIEWCZYK: Oh, excellent. Yes, we do have one of the additional data collection 22

points that's not part of the measure is
 discharge location.

So clearly, we do ask about discharge back to the community, discharge to another postacute care venue like maybe inpatient rehab or home health outpatient care, back to acute care. So all of that is still collected as part of data elements.

9 MEMBER THOMAS: Okay. So last time we 10 were here and looked at a whole other set of 11 measures, I raised this same issue, I'm going to 12 raise it again now and that's the Jimmo versus 13 Sebelius settlement.

14 And that is a case that states that 15 Medicare law is, and CMS agrees that Medicare law 16 is or requires that skilled nursing facilities, 17 outpatient therapy, and home healthcare provide 18 services, skilled care, skilled therapy or 19 nursing, to an individual, beneficiary who may 20 not be improving in order to maintain their 21 function or prevent deterioration of function. 22 And I'm less concerned in the IRF

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1	because that settlement really doesn't do all
2	that much in the IRF setting. But I'm very
3	concerned in the SNF setting because it does
4	apply to SNFs.
5	And if you've got a quality measure
6	that's based on, and you say it a number of times
7	in your document, the emphasis on restoration.
8	Now you do admit, I will admit you say or
9	maintenance of function which is important. But
10	in other areas you say the primary benefit of
11	rehab is functional improvement, improvement,
12	improvement.
13	And I'm hopeful, I'm trying to figure
14	out a way that you don't create a quality
15	measurement tool that is going to disadvantage
16	individuals who won't necessarily improve but
17	still gain something from their experience in a
18	SNF.
19	And those folks are going to become
20	persona non grata because that SNF doesn't want
21	to have those people in its data mix. Can you
22	tell me how you address that fairly difficult,

what I consider to be a fairly difficult problem? 1 2 DR. NIEWCZYK: So that's an excellent And our measures are sensitive to the 3 question. fact that patients may gain, may not change, so 4 5 maintenance, or may decrease in function. So certainly an aggregate score would 6 7 be at the measure level, right? But you can also look at each item level. So you may see that a 8 9 patient improved in one item but decreased in 10 another. If you look only at that measure score, 11 it's going to show no change, but there was some 12 changes. 13 So it works at both the patient level 14 as well as the population or facility level. 15 Additionally, it's understood that it's a change, it's not a gain. So these measures are not 16 17 functional gain. These are functional changes. 18 So it could be in either direction. 19 We understand that in skilled nursing 20 in particular, you have sometimes two patient 21 populations where you have those that are there 22 for restorative care and those that are there as

residents that might also be getting some rehabilitation.

Within those residents, in all likelihood, you may be seeing more maintenance of functioning, which might be the goal, just not to decrease. So certainly our measures can work in that capacity.

8 And facilities know which patients are 9 which. So there would be, you know, no 10 difficulty in building in an additional variable 11 asking is this patient here for restorative 12 treatment or patient or resident? And certainly 13 we could then look and stratify on those basis.

14 MEMBER THOMAS: I don't know if this 15 is appropriate to ask, but in the documents, in 16 the writeups as you proceed there's a number of 17 measures that have the same concern that I've 18 got, that has been raised.

19 Can you please, can we encourage or 20 require there to be some recognition that it's 21 not just about improvement in function and that, 22 you know, these tools should not be used in any

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way to bias admission against people who won't 1 2 improve --3 DR. NIEWCZYK: Absolutely. 4 MEMBER THOMAS: -- something to 5 protect against that. CO-CHAIR STILLE: Yes, yes. I had the 6 7 same concern with 2775 which it says change in motor function, so same kind of thing. Whether 8 9 it's stratifying among people who are expected or 10 not expected or something. 11 DR. NIEWCZYK: So certainly we can add some language in, you know, in the documentation 12 13 stating that the measures could be used, you 14 know, to assess maintenance of function as well 15 as to identify decreases in functioning. 16 We have users in some outpatient as 17 well as adult day programs. And really the goal 18 there is maintenance. But they sometimes see 19 patient populations that will decrease function. 20 And then it's an early warning sign to add 21 additional patient referrals or resources, or 22 maybe to modify the patient's care plan.

CO-CHAIR STILLE: Could I ask one more real quick? And that is my understanding, and correct me if I'm wrong, is that the FIM really has a very strong connection to the inpatient rehab hospital and unit.

It was created around that patient 6 population and that setting, and it was really 7 geared toward trying to measure function in that 8 9 So is it really that easy to just take setting. 10 that same functional measurement tool and apply 11 it to a SNF or an LTAC? It's an open question. 12 I'm not doubting that it is. But please explain 13 how --

DR. NIEWCZYK: In post-acute care it is. But what we found through the 20 plus years, I don't know what's happening to my mic, but the 20 plus years of study on the tool is that function can be measured and can be assessed with a very small number of items.

Now it's not all-encompassing, it's
not a perfect instrument in any capacity. But a
rough estimate in terms of where the patient's

functional status is, and the fact that you could 1 2 use it in other post-acute care venues, even those like the long term care facilities where 3 4 you may not see drastic improvements in 5 functioning. It gives you a point as to where that 6 7 patient's status was when they came in, when they left, and then when they went to another, you 8 9 know, downstream post-acute care venue using the 10 same items with the same rating scale. 11 CO-CHAIR STILLE: Thank you. 12 MS. DANN: Could I just add to that 13 that with our submission, I believe we put a 14 bibliography of something called burden of care, 15 and the instrument can measure that latent trait 16 in any venue. 17 Therefore it is viable to be used in 18 any venue because it can measure the burden of 19 care regardless. And I don't know how many 20 publications are in that bibliography. I think 21 it's 15. 22 I think we gave a very, DR. NIEWCZYK:

1 we give an annotated one, yes. 2 CO-CHAIR STILLE: Beth? 3 MEMBER AVERBECK: Just a follow up on 4 a question to Peter's comment on the patients 5 that aren't improving. Does a case mix adjustment then account for that, that what you 6 7 might expect since it's a measure to expectation that if someone wasn't seeing improvement and a 8 9 change that would be taken care of by the way 10 that it's case mix grouped? 11 DR. NIEWCZYK: So certainly case mix 12 may come into play, impairment group code would 13 likely be a greater indicator. But, you know, 14 oftentimes it's really hard. Those are things 15 that are probably more obvious in the medical 16 records. But yes. 17 CO-CHAIR STILLE: Okay. Any more general comments before, oh I'm sorry, Linda? 18 19 MEMBER MELILLO: I'll come back to it. 20 CO-CHAIR STILLE: Okay. And yes? I just wanted to make a 21 DR. CLOHAN: 22 comment about Mr. Thomas' remark which is very

pertinent on the Jimmo versus Sebelius case. 1 And 2 I think it's a very good suggestion to put something in NOF's write up as well could enter 3 4 that. The fundamental question you raise 5 though is endemic across all quality measures of 6 whether there could be an inadvertent consequence 7 of a quality measure of suddenly making a patient 8 9 who is at higher risk to "fail" that quality 10 measure become less desirable to a provider. 11 You can look at it on new or worsened 12 pressure sores, you can look at it at fall risk, 13 you can look at it on do you want to take 14 somebody in your site who has refused a pneumonia 15 or flu vaccine. 16 It's an inherent risk. But I think 17 there will be good protection on this one, and I 18 think it's important for us to keep separate in 19 our minds the coverage criteria for Medicare or 20 other payers that entitle people to coverage and 21 care. 22 And that's what Jimmo sort of

addresses, that people are entitled to that level 1 2 of care whether they're expected to improve in their function or whether the purpose of that 3 care is to maintain or even slow deterioration. 4 5 It could be that a person is known to, that their function will deteriorate but medical 6 7 intervention could slow that deterioration. So I think it's great that you brought 8 9 it up, and I think this organization, everybody 10 else interested in quality measures always has to 11 be mindful of potential for unintended consequences. And this one I think you can help 12 13 by having, making sure your literature addresses 14 that point. 15 MEMBER MELILLO: So one of my 16 questions is I have a fear that this data may be 17 used to try to compare the various levels of 18 post-acute care. And they are very different in 19 terms of what a patient or family could expect in 20 terms of services and what patients and families 21 can expect in terms of length of stay. 22 I mean, all of these metrics vary

substantially. So that is a concern of mine.
 And whether or not the patient had an interim
 stay in an IRF before they went to a SNF. These
 levels of care are not interchangeable is the
 point that I'm trying to make. And so I'm just be cautious of that.

7 DR. NIEWCZYK: We sort of believe that 8 too. But unfortunately, there's many others that 9 don't believe that, that think that post-acute 10 care is maybe the same across the board.

I don't think we'll ever really know until we collect it, collect outcomes in a standardized way. But it needs to be the same types of questions asked upon the same patients in all venues.

16 It can't be this item applies to this 17 venue but not this venue. Otherwise you won't 18 know, right?

19 MEMBER MELILLO: Yes, there is some 20 research out there, some new research that I'm 21 sure you're familiar with that helps to 22 differentiate. But I hear what you're saying.

But it is a concern of mine that if we have these 1 2 like measures, that they're going to assume that they're measuring the same thing. And they're 3 4 not but they are. You know what I mean? DR. NIEWCZYK: Well, function is 5 important I believe to all persons. 6 MEMBER MELILLO: Of course. 7 DR. NIEWCZYK: Whether you're a 8 9 patient in a facility or, you know, you're 10 sitting here like us today. So I believe it's 11 important in, you know, all capacities. 12 So looking at some aspects, some very 13 basic aspects of function in terms of things like 14 communication or expression and, you know, 15 ability to eat and how you're, are you eating 16 with assistance of a tube or not. All of those 17 factors do mean something. 18 And certainly, they can be asked in 19 all of those venues because they deal with 20 patients that have those issues in all of those 21 venues. 22 MEMBER MELILLO: So I don't know if

this is the right time to have this discussion. 1 But I did want to also mention the data that you 2 used, the data sets. 3 4 DR. NIEWCZYK: So these should be 5 really general. 6 MEMBER MELILLO: Okay. (Simultaneous speaking.) 7 CO-CHAIR STILLE: Yes, we'll talk 8 9 about data in probably section two. Yes, okay. 10 Really quickly, I just MEMBER THOMAS: 11 would quarrel somewhat with the fact that your 12 statement that we don't really know. We know 13 what's required of an IRF. 14 DR. NIEWCZYK: Oh yes, yes. 15 MEMBER THOMAS: We know what's 16 required of a SNF. 17 DR. NIEWCZYK: The care, yes. 18 MEMBER THOMAS: We know what's 19 required. So there are different levels and 20 intensities and coordination of care being 21 provided now. We all know that. 22 We may not know how risk adjusted, how

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2 But the fact is these are different that. 3 products. 4 DR. NIEWCZYK: So there's parameters 5 what's differentiated both from a SNF, right? But certainly, like, a hip replacement could be 6 7 treated at either venue. What are the outcomes? 8 Did one perform better? Was the care the exact 9 same? 10 We don't know. The cost certainly is 11 different, right, and the intensity of the 12 rehabilitative services could be different. Some 13 skilled nursing facilities believe they're just 14 at par with the requirements of an inpatient. 15 The point is we don't know what those 16 outcomes truly are. And if we're looking at 17 measuring function, I think we need the same 18 types of items within those settings to be able 19 to assess that. 20 CO-CHAIR STILLE: Sam, go ahead. 21 MEMBER BIERNER: I just wanted to say 22 that it's not just, I fully understand what you

they all correlate based on outcomes and I get

said about the function. But when we're looking 1 2 at different levels of care, there are other issues such as the medical complexity, the acuity 3 4 of the medical problems that the patient has and 5 so forth that are not always captured directly in this instrument which was intended just to look 6 at the patient's physical and cognitive function. 7 I understand that. 8

9 But I just wanted to make that clear 10 in case there are others who aren't as familiar 11 with the difference in the IRF versus the skilled 12 nursing and other things.

DR. CLOHAN: And thank you for that clarification because it's very true. I share your concern of sort of the potential for wrong use of any measure.

But I think probably as a Committee and as NQF and as all of us operating under the IMPACT Act, pretty much the marching orders have been put out there for site neutral measurement techniques.

22

And so I think we feel very proud to

be bringing you measures that have been used in 1 2 all of these different settings. They've been used in, you know, we're talking specifically 3 4 about one use in skilled nursing facility now. 5 But you'll see all these six measures, three different functions being measured and then two 6 7 different sites over which they're being measured, proposed to be measured. 8 9 And so the instrument has worked 10 effectively in all of those settings, then I 11 guess it becomes the next stage after endorsement 12 to make sure that these are used properly. 13 And if some day somebody says oh, 14 let's compare this with this, we know the 15 measurements are equal, apples to apples. What 16 conclusions people may draw from that if they 17 don't properly look at different populations, 18 different intensity of care, they could be drawing wrong conclusions. 19 20 But I think the IMPACT Act pretty much

20 But I think the IMPACT Act pretty much 21 sets the requirement out there for us to find 22 common measures. And we believe this is one

1	that's very strong, has a long history behind it
2	and a lot of data, published research.
3	And these measures can actually be
4	used, I'm very proud of them because they can be
5	used for the purpose that I think we all believe
6	quality measures are for, not just a measurement
7	but giving us some leverage to improve quality in
8	the future.
9	So in 2015 there was an article
10	published using FIM data and comparing that with
11	patients who were found to have new or worsened
12	pressure ulcers. And it was discovered that
13	these functional measures correlated with
14	predictive quality.
15	And so that's what I think the quality
16	measurement game is all about, to tell us
17	something that is then actionable. So then we
18	can say oh, we've identified some people who are
19	particularly vulnerable. So that's what we're
20	hoping this can do.
21	CO-CHAIR STILLE: Okay, thank you. I
22	think we're ready to move on to start talking

1	about the evidence. So let's start with 1A,
2	evidence for the measure. Any specific
3	discussion that hasn't already been covered?
4	MEMBER THOMAS: I already said
5	everything, all the comments I had.
6	CO-CHAIR STILLE: They're in there?
7	Okay, we're good. Okay. Should we vote on
8	evidence then, if I can find my clicker. There
9	it is. 2769 1A evidence.
10	MS. QUINNONEZ: Okay, we will now be
11	opening voting on Measure 2769, functional change
12	in self care score as for skilled nursing
13	facilities, and this is for the evidence.
14	Rationale supports the relationship of health
15	outcome or PRO to at least one healthcare
16	structure process, intervention, or service.
17	Option number one is yes, option
18	number two is no. Looking for two more votes.
19	Okay, all votes are in, voting is now closed.
20	The results of this vote was 100 percent yes,
21	zero percent no.
22	CO-CHAIR STILLE: All right. And we

will move on to performance gap. I actually had 1 2 a question. And mine as primary reviewer is in a couple more, but it's still one of the SNF ones. 3 You mention that almost half of 4 5 facilities are below expectations in 2014. But I can't find what expectations are. 6 So what we did 7 DR. NIEWCZYK: Okay. is we took all of the facilities and I believe we 8 9 used 174 facilities, skilled nursing facilities. 10 And we took the admission and the discharge score 11 within the Rasch modeling. 12 We put them together so it, a 13 progression to the mean in essence, to come up 14 with where an average patient's function would be 15 on each item within that measure. 16 So that gave us our, like, expected 17 values. And then you could look to see a given 18 facility, were they above that threshold or 19 below? And then were they that way at admission 20 and then again at discharge. 21 CO-CHAIR STILLE: Okay. 22 So that way we could DR. NIEWCZYK:

see if patients had been maybe low before and now 1 2 they came up really high. Certainly they would have --3 4 CO-CHAIR STILLE: So it's not a 5 benchmark but rather basically a statistical place where all the other places are. 6 Okay. 7 DR. NIEWCZYK: Exactly. Okay, great. 8 CO-CHAIR STILLE: 9 Thanks. 10 MEMBER MELILLO: Did you include IRF 11 and LTAC into that? 12 DR. NIEWCZYK: Not into the, so I know 13 in the measure files you have it broken down so 14 you're able to see what the values are for IRFs 15 as well as LTACs. But we had those separate. 16 MEMBER MELILLO: Okay. 17 CO-CHAIR STILLE: Others? Lisa? 18 MEMBER SUTER: I may have missed it, 19 I was looking at some of these in more detail 20 than others. But anywhere do you provide actual 21 distributions of the facility level scores? Ι 22 know you provide the average and you provide sort

of percent above and below expected. 1 2 But it's a little bit hard to tell what the actual distribution of scores at the 3 4 facility level is and do you have that 5 information anywhere in any of the applications? DR. NIEWCZYK: I don't believe we 6 7 included it in the measure files, but certainly we're able to do that internally, yes. 8 9 MEMBER SUTER: I think that would be 10 really helpful because in determining a 11 performance gap, I will tell you I really can't 12 interpret the information that's provided. 13 CO-CHAIR STILLE: Right, I agree with 14 You know, if half of the facilities are that. 15 below expectation but it's just below the mean or 16 whatever, okay what's the distribution. That 17 would be super helpful. Sherrie? 18 MEMBER KAPLAN: Yes. Lots has been 19 going on over the last six years to try and 20 improve functional status. Do you have any data 21 on whether or not this change in function is 22 mutating in response to efforts to improve

1 quality? 2 DR. NIEWCZYK: We have noticed changes over the years, yes, not only in terms of rating 3 4 and scoring patterns but also in terms of patient 5 populations. MEMBER KAPLAN: But your data don't 6 7 show it. Your data look rock solid stable. If you stratify certain 8 DR. NIEWCZYK: 9 ways it becomes pretty clear. It's just that, 10 you know, we've already incorporated a ton of 11 information already, so we didn't want to belabor 12 you with so much more. But yes, I mean, 13 certainly we could provide you more specific if 14 you want. 15 CO-CHAIR STILLE: Any other discussion 16 of performance gap? Okay, should we vote? 17 MS. QUINNONEZ: Voting is now open for 18 Measure 2769 for importance to measure and report 19 performance gaps. Data demonstrated considerable 20 variation or overall less than optimal 21 performance across providers and/or population 22 groups.

1	Option number one is high, option
2	number two is moderate, option number three is
3	low, and option number four is insufficient.
4	We're looking for one more vote. All votes are
5	in, voting is closed.
6	The results are 16 percent voted high,
7	68 percent voted moderate, 5 percent voted low,
8	and 11 percent voted insufficient.
9	CO-CHAIR STILLE: Okay. So we move on
10	to reliability. The psychometrics discussion. I
11	believe that there were some questions related to
12	this that resulted in data being submitted over
13	the last couple of weeks about inter-class
14	correlations. So I'll call your attention to the
15	one pager that got submitted about two weeks ago
16	that's in your bunch of documents.
17	(Off microphone comments.)
18	CO-CHAIR STILLE: No, no. it was
19	available, just relatively late. It was, I
20	think, on May 24th. Yes, it should be in there
21	if you have everything printed out.
22	CO-CHAIR PARTRIDGE: Maybe you would

1	like to maybe we should
2	(Simultaneous speaking.)
3	CO-CHAIR STILLE: Maybe we should put
4	that on screen, or the developers can talk about
5	it too.
6	DR. NIEWCZYK: I could certainly speak
7	to it if you would like. It might be easier for
8	me to just summarize it for you.
9	CO-CHAIR STILLE: Sure, okay.
10	DR. NIEWCZYK: So for, there's
11	actually a couple different measures for
12	reliability. So what's included in the
13	specification was done on 174 skilled nursing
14	facilities with 3,984 patients.
15	And this is a sample, a random sample
16	of patients. And it was pulled on the patient
17	level data which is why you're seeing such a, you
18	know, variety of facilities represented.
19	The Cronbach's alpha was 0.92. The
20	intra-item correlations were 0.70 to 0.84. And
21	then subsequently we were requested by the
22	Committee to perform inter-class correlations at

the facility level.

2	So we took a random sample of 25
3	skilled nursing facilities. They had to have at
4	last a 30 case patient count in order to be
5	included. And we split, each facility we split
6	randomly into two data sets, and then we did
7	averages at the facility level to run the ICC and
8	compare across facilities.
9	So for the self-care, the ICC was, and
10	this is between facilities, -0.03 with a P value
11	of 0.59. So that's pretty bad. But that's
12	actually good because it shows that there is a
13	good amount of variability between facilities,
14	thus we could identify, you know, performance
15	gaps for instance.
16	We did the same exercise using the
17	exact same data, and we ran within facility
18	inter-class correlations. So within facility,
19	the self-care ICC was 0.87 with a P value of less
20	than 0.001 which means at the facility level
21	there's a very strong degree of consistency in
22	patient function ratings.

But between facilities, it varies. 1 2 And that's what we see pretty much within the field as well. 3 CO-CHAIR STILLE: And Sherrie? 4 MEMBER KAPLAN: I am concerned about 5 what you did because what you're looking for with 6 between facility and class correlation 7 coefficients is you want to see a thumbprint 8 9 across patients within a facility and you want to 10 see a lot of consistency within the facility and 11 you want to see big between facility differences. 12 You're not seeing that. Now what you 13 did within the facility says you have a lot of 14 within facility, you have a lot of within patient 15 across items consistency. So there's tight 16 variations that are not a lot of within patient 17 variation. 18 But there is a lot of between patient 19 variation within the facility. That would drive 20 those results. That's what your bottom paragraph 21 So within a facility there's a lot of says.

22 between patient variation.

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1	But between facilities, there isn't.
2	And there is a lot of within facility variation
3	across patients and that's a problem for these
4	kinds of analyses.
5	Another thing you could do in this
6	kind of circumstance is do generalized estimation
7	equations which give you approximately the kind
8	of same between facility variation.
9	But the concern here is that you don't
10	have a real strong thumbprint across patients
11	within a facility, and that's trouble for these
12	kinds of your ability to then make sense of any
13	between facility variability that you see.
14	DR. NIEWCZYK: So the within facility
15	ICC was 0.87.
16	(Off microphone comments.)
17	MEMBER KAPLAN: That's across
18	patients. The within facility is across items
19	within patients. When you're looking at a within
20	facility, all you're seeing is between patients.
21	DR. NIEWCZYK: Yes.
22	MEMBER KAPLAN: And then across items

within a patient. 1 2 DR. NIEWCZYK: Yes. MEMBER KAPLAN: So the error variance 3 4 is within patient variability. And that's what 5 you would expect to see given the Cronbach's alpha as you know. 6 7 DR. NIEWCZYK: Yes. MEMBER KAPLAN: But between facility 8 9 variation --10 DR. NIEWCZYK: -0.03. 11 MEMBER KAPLAN: Yes, that's trouble. DR. NIEWCZYK: Why would that be 12 13 troubling? We wouldn't want to see a really high 14 15 MEMBER KAPLAN: Oh yes you do, yes you 16 do. It's exactly the opposite. You want to see 17 a lot of tight, you don't want to see, you want 18 to see a thumbprint across patients within a 19 facility. 20 DR. NIEWCZYK: Yes, which we see. 21 MEMBER KAPLAN: And then -- no. And 22 then you want to see a lot of between facility

variability. See, the coefficient is between --1 2 DR. NIEWCZYK: I think we're saying 3 the same thing. 4 MEMBER KAPLAN: No we're not. Here's 5 the dilemma. Within facility variation looks at you got a patient level. You got patients saying 6 7 there's pretty much the same thing across these items in the measure. 8 9 And then you got a lot of between 10 patient, within facility variation. So patients, 11 within a patient you're saying the same thing. 12 But between patients within a facility, there's a 13 lot of difference. 14 That's a problem at the next level 15 because if there's a lot of within facility 16 variability at the patient level, you're going to 17 have trouble seeing between facility variability. 18 DR. NIEWCZYK: So it's kind of, I 19 think you're --20 (Simultaneous speaking.) 21 DR. NIEWCZYK: So Maggie, maybe you 22 could speak to this better because I don't think

I'm communicating it the right way.

2	MS. DIVITA: So I will start off by
3	saying that we did the analysis that was
4	suggested to us by someone in the Committee. The
5	ICC, just my general knowledge of it, I didn't
6	really understand how to do it with our data
7	which is why we had presented it with previous
8	measures.
9	And so someone had suggested well,
10	what you would do is you would, you know,
11	randomly assign half the patients to one data
12	set, randomly assign the other half to look at
13	the averages across your measure.
14	And then do an ICC across facilities
15	in that sense, and that's what we did. And so
16	when we looked across facilities comparing the
17	measures across, so between facilities, that's
18	when we got that very low ICC.
19	When I changed the data just slightly
20	so that we were comparing within, again at the
21	measure level, not at the person level, this is
22	average facility, you know, two data sets, two

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data points essentially per facility, one random,
 one random and half, you know, done half, that's
 where we get the 0.8.

4 So perhaps that we're misunderstanding 5 what we were required to do. But our, what we thought we found is exactly what Paulette was 6 So I guess I'm not following you either. 7 saying. That may be a problem 8 MEMBER KAPLAN: 9 that NQF has in how it's communicating exactly 10 what's wanted here because it wouldn't be fair to 11 hold the measures developer to a standard that 12 they didn't understand. 13 MS. DIVITA: Right. We just argued 14 that the ICC, because, you know, in my 15 understanding the ICC is looking across perhaps

16 items or perhaps a person within Ravers, but 17 that's not really the data that we have.

So we sort of did the ICC as suggested to us and those are the results that you see. MEMBER KAPLAN: So Sarah, is this something that we should just then kind of ignore because it isn't clear that the information got

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communicated correctly, or could we ask them to 1 2 go back and communicate and re-do? How would you want to handle this? 3 MS. SAMPSEL: Well, I think we should 4 5 do a couple things. There's also another document, Maggie, if you remember that you 6 7 submitted and I think you resubmitted --8 MS. DIVITA: Right. 9 MS. SAMPSEL: -- for this as well. 10 MS. DIVITA: Yes. 11 MS. SAMPSEL: And I don't know if that 12 will get to some of these as well. And so, you 13 know, Sherrie, I think this goes back to our 14 conversation we had last Friday is really trying 15 to understand that within and between and how 16 we're communicating for the developers. 17 And you're right, we can't change the 18 rules now. At the same time, you know, I think 19 the Committee needs to make sure that they're 20 comfortable with what this information is, what 21 the data is, and is it truly, is it a good 22 indication of quality.

1	And so I think, is this, no that's not
2	it. There's another document, sorry. Suzanne,
3	it was the one that was submitted after Phase 2
4	and then they resubmitted it
5	MS. DIVITA: Yes, there was, it should
6	have a bunch of graphs, right?
7	MS. SAMPSEL: Yes. And Maggie, you
8	resubmitted it for this one as well I think.
9	MS. DIVITA: Yes. I did, yes.
10	MS. SAMPSEL: Yes, I think it's all
11	the way at the end. It might be
12	MS. DIVITA: So for the item level
13	analysis across facilities to show the
14	consistency.
15	MS. SAMPSEL: Page 308, 308, 309. Yes
16	and it still might not be, Sherrie, what you're
17	looking for.
18	MEMBER KAPLAN: Yes, no.
19	MS. SAMPSEL: But yes, I mean, so I
20	think though that, because I would also say that
21	this is very much the same type of information
22	that was supplied in Phase 2 for the IRF

measures.

2	And as a recollection, you know, the
3	measures were recommended for endorsement at the
4	in-person meeting and then the additional data
5	was still supplied, and additional questions did
6	not come up.
7	So I mean, I think Sherrie, back to
8	your question, it's kind of a consistency as
9	well. It's a consistency in determinations and
10	the level of information we had in front of us.
11	MEMBER KAPLAN: So help us then. What
12	are we to do with the, because
13	(Simultaneous speaking.)
14	MEMBER KAPLAN: Yes, that's not going
15	to help, because of the way the analysis was
16	done, this is not going to help us. So either we
17	say you know, this isn't, there was some not
18	clear, inclarity, unclarity in the way that the
19	kinds of data that were being looked for were
20	communicated, in which case we pretty much have
21	to deal with not the facility level reliability
22	or how do you want us to think about this.

MS. SAMPSEL: So first I'm going to 1 2 ask Paulette and Maggie. I mean, from what Sherrie explained that she would like to see, how 3 4 quickly could something like that be turned 5 around? 6 DR. NIEWCZYK: I mean, we would be 7 happy to get you what you want. And we, you know, we have access to a lot of data. It's just 8 9 the matter that first of all, our repositories 10 are set up at the patient level. 11 We know facility level information, 12 but it's not set up by facilities. So we have, 13 you know, for instance we could have a year's worth of data and we have a half a million or a 14 15 quarter of a million cases. 16 They may then be from, you know, 200 17 facilities or 800 facilities. So then first we 18 have to restructure our data, and then it depends on, you know, which is why we did the subset, why 19 20 we pulled a sample just because we had to 21 reconfigure everything. 22 We would be happy to do what you want

It just depends on what it is, and how 1 to do. 2 long it takes will depend on what the request is. So I mean, I think where 3 MS. SAMPSEL: 4 I'm trying to go with this is kind of, you know, 5 obviously there have been past discussions based on this level of data if not less on endorsement 6 of UDSMR measures. 7 And you know, we also have, although 8 9 they were less so we're not going to deal with 10 that yet. But we would only ask for a subset of 11 data again. So what I'm asking for, you know, so 12 Sherrie, we know you've expressed some discomfort 13 and not only the interpretation of this is saying 14 that the measure is reliable. 15 And that really is the charge, is the 16 measure reliable. And if you don't feel like you 17 can make that decision, then you know, that's 18 kind of how you have to vote on this. And we 19 would just have to work with UDSMR to get the 20 right data. 21 MEMBER KAPLAN: Well it kind of 22 depends. Is the measure reliable at the patient

I mean, you know, we've had 1 level? Looks to me. 2 a lot of experience with these kind of measures at the patient level. So at the patient level it 3 is reliable. 4 5 Then the question was at the unit being compared is it reliable. And that's where 6 7 I get uncomfortable given what's gone on. And I don't know how to deal with that issue yet. 8 9 But you know, you have a lot of data. 10 And even you said there were 20 cases per, 30 11 cases per facility. 12 Thirty cases per MS. SAMPSEL: 13 facility. 14 MEMBER KAPLAN: So even on that set of 15 data, never mind splitting it up into halves, you 16 could do generalized estimation equations on 17 that, you could to the intra class correlation 18 coefficients on that. 19 You could do the analysis that would 20 probably address this issue. What the results 21 show is a whole other issue in how you interpret 22 them. But the analysis could be done fairly

straight away I think.

2 CO-CHAIR STILLE: Good, so I think all 3 the issues are laid out on the table. I think 4 people's understanding is the best it can be. 5 Should we go ahead and vote? Oh, I'm sorry. Linda, one more thing. 6 Yes? MEMBER MELILLO: Do you have data 7 within facilities -- I'm sorry. Do you have the 8 9 data within facilities stratified by diagnostic 10 group? I know the FIM has proven to be extremely 11 sensitive to diagnostic group. 12 DR. NIEWCZYK: Yes. So certainly we 13 can look within facilities at impairment group, 14 as well as CMG. Yes. And we do have a cross 15 over CMG that's applied to a skilled nursing 16 facility as well. 17 MEMBER MELILLO: Okay, because that 18 might be able to break out that inter facility 19 different spread, variability. 20 CO-CHAIR STILLE: Okay. 21 MS. QUINNONEZ: Are we ready to vote? 22 CO-CHAIR STILLE: I think we're ready

338

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to vote.

2 MS. QUINNONEZ: Okay, voting is now open for the reliability of Measure 2769 3 4 including precise specifications in testing. 5 Voting option number one is high, option number two is moderate, option number three is low, and 6 option number four is insufficient. 7 Looking for one more vote. All votes 8 9 are in and voting is now closed. The results are 10 16 percent voted high, 47 percent voted moderate, 11 11 percent voted low, and 26 percent voted 12 insufficient. 13 CO-CHAIR STILLE: So it passes. Okay. 14 On to validity. Specific points about validity, 15 any of the primary discussants. I think my question 16 MEMBER MORRISE: 17 I had earlier was around missing data elements. 18 CO-CHAIR STILLE: Yes. 19 MEMBER MORRISE: And I think that 20 that's been answered. So thank you. 21 CO-CHAIR STILLE: Yes. And I'll put 22 in my usual plug for patients under 18 in the

If this can be adapted to or analyzed 1 future. 2 with same, similar data for somewhat younger age groups it would be very useful. 3 4 MS. SAMPSEL: Well, and I think this 5 isn't part of this review. But I can throw it out there. 6 7 DR. NIEWCZYK: I'll let you comment on that. 8 9 MS. SAMPSEL: We do have a separate 10 measure called the WeeFIM, and that's meant for 11 the pediatric population. Maybe we'll submit 12 those measures someday. 13 CO-CHAIR STILLE: Yes, maybe not the 14 range of facilities you've got here. But you 15 know, one of the rehab facilities, sure. 16 MEMBER SUTER: Do you have data on the 17 response rate at each facility? I know the 18 reliability and validity testing was done on 19 large numbers. But I was just wondering in terms 20 of data collection what the average response rate 21 is across facilities. 22 So that's a good DR. NIEWCZYK:

question. We don't have it because right now, 1 2 the skilled nursing facilities that are electing to use our measures are doing so voluntarily. 3 4 So they're coming to us, they're using 5 the measures on top of the MDS and any other functional measures that they or other medical 6 7 indicators and so forth. So it's likely that there's an intrinsic drive that they're 8 9 interested in assessing function and quality and 10 so forth. 11 So they're probably capturing the 12 majority, but we cannot be certain of that. 13 MEMBER SUTER: And you don't ask them 14 to report --15 We ask them to --DR. NIEWCZYK: 16 MEMBER SUTER: You don't ask them to 17 18 (Simultaneous speaking.) 19 DR. NIEWCZYK: -- assess all patients. 20 That's sort of what we request. 21 MEMBER SUTER: But to include a 22 question that says how many of your --

1	DR. NIEWCZYK: Patients did you
2	submit?
3	MEMBER SUTER: of eligible patients
4	did you submit data on.
5	DR. NIEWCZYK: Yes, no.
6	CO-CHAIR STILLE: Any other discussion
7	about validity? Should we vote?
8	MS. QUINNONEZ: Okay. Well voting is
9	now open for Measure 2769 on scientific
10	acceptability of measure properties and validity
11	including specifications consistent with
12	evidence, testing, exclusions, risk adjustment,
13	stratifications, meaningful differences,
14	comparability in multiple specifications, and
15	missing data.
16	Option number one is high, option
17	number two is moderate, option number three is
18	low, and option number four is insufficient.
19	All votes are in and voting is now
20	closed.
21	The results are 21 percent voted high, 68 percent
22	voted moderate, 5 percent voted low, and 5

percent voted insufficient. 1 2 CO-CHAIR STILLE: Okay, we discuss 3 feasibility. Lee? 4 CO-CHAIR PARTRIDGE: I was actually 5 looking at another one of the SNF measures, but I think the issue is equally relevant here. 6 And that has to do with -- I'm sorry. It's on the 7 next one, usability. 8 9 CO-CHAIR STILLE: Okay. 10 CO-CHAIR PARTRIDGE: But I'm not quite 11 sure, yes. I think it's more appropriate for usability so I'll hold. 12 13 CO-CHAIR STILLE: Oh, we'll have a 14 little bit of discussion there, great. Any 15 feasibility comments? All right, let's vote on 16 feasibility. 17 MS. QUINNONEZ: Voting is now open for 18 Measure 2769 on feasibility including data 19 generated during care, electronic sources, and 20 data collection can be implemented. 21 Vote option number one is high, voting 22 option number two is moderate, voting option

1	number three is low, and option number four is
2	insufficient. Waiting for two votes.
3	All votes are in and the voting is now
4	closed. Results for feasibility are 26 percent
5	voted high, 58 percent voted moderate, 16 percent
6	voted low, and 0 percent voted for insufficient.
7	CO-CHAIR STILLE: Okay, now usability.
8	Lee, it's all yours.
9	CO-CHAIR PARTRIDGE: Okay. We've
10	talked about this before in the context of the
11	USMDR measures. But Linda raised it again. One
12	of the important characteristics is having the
13	staff trained in knowing how to use the tool.
14	And I know that for your purposes, you
15	actually require that the staff be certified. I
16	know CMS does not. But I just wanted to I
17	don't think this, it's kind of a measure of down
18	the road what we might expect would happen with
19	this measure being used more widely.
20	It is a burden for the facility that
21	hasn't trained their staff. And if they want to
22	participate, they're going to have to engage in

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the training. How extensive you expect that
 would be I don't know.

But I remember Sam raising it last
time around these measures. So maybe Sam, you
could comment a tiny bit too.

6 MEMBER BIERNER: I had put that in my 7 written comments about review of this. The 8 implementation in the inpatient rehab setting 9 requires some involvement of all your therapy 10 staff, nursing, and physician staff in learning 11 how to do the rating and establishing good inter 12 rater reliability.

So the groups that will be doing this
will probably be nurses, patient care
technicians, and therapists in the SNF or LTAC
settings. So it will require an investment by
the facility to train their staff.

18 It does require periodic retraining 19 depending upon your turnover of staff at your 20 facility which I think, just anecdotally I know 21 it's somewhat higher in SNFs and LTACs than it is 22 in inpatient units.

CO-CHAIR PARTRIDGE: I don't think 1 2 that it's particularly an issue from the technical sense. It's just that I would caution 3 4 that maybe other than your members and the few 5 others, it may not be as adopted as widely as we would like. 6 7 DR. NIEWCZYK: So here's the thing. There are extensive educational materials, so 8 9 there is a training guide. Certainly, you know, 10 clinicians can self study. We have a master 11 exam. 12 But again, that could, you could 13 certainly use the tool without passing the master 14 However, what we maintain is that if you, exam. 15 you know, function isn't always easy to assess. 16 So if you want to have an accurate 17 measure that you want to invest the time in to 18 know about how to assess the construct of 19 interest. It is an interdisciplinary tool. 20 So it doesn't matter, it's sort of 21 discipline free. It could be done by nurses, it 22 could be done by therapists, it could be done,

you know, by physicians.

2 Often whoever does the rating doesn't have to do the full measure. So you could have a 3 4 couple of items be rated by one clinician and a 5 couple by somebody else. However, if you don't understand what 6 you're measuring, then it's, I use the term 7 garbage in, garbage out. So if you want to 8 9 measure quality, you want to know that you're 10 measuring function correct. 11 CO-CHAIR STILLE: And just to 12 reiterate, oh I'm sorry. I skipped the line. 13 Sorry, Nicole first and then I think Linda, Lisa, 14 and Becky. I think. Nicole's first, I know 15 that. 16 MEMBER FRIEDMAN: Sorry. One of the 17 comments was potentially this leading to longer 18 length of stays to increase the ability for 19 patients to get a higher score. So of course 20 that leaves increased cost. Is that something 21 that has been a concern?

DR. NIEWCZYK: Well, what we've found

anecdotally is that the trend sort of follows the 1 2 policy. So if length of stay is shortened than actual length of stay will be shorter. 3 4 It seems to be less driven by the 5 patient's actual function and more driven in 6 terms of payment. But that's, again that's out 7 of our realm. MEMBER MELILLO: It concerns me that 8 9 if you're using it as a crosscutting measure that 10 you in a rehab setting there's an intense level 11 of rigor. Many rehab facilities have purchased 12 additional software with branching logic that 13 helps them score the FIM. 14 All of that will not, I mean, they 15 would have to pay for these in other settings 16 that aren't currently using the instrument. And 17 you will get a very different, I would think, 18 level of assessment from an OT assessing self 19 care as opposed to a nurse or a nursing aid 20 assessing self care. 21 So those are just some concerns that 22 I have with the level of rigor and the level of

assessment I think you'll see variations in. 1 2 DR. CLOHAN: I think from a clinical point of view that's always going to be a 3 4 challenge unless you are willing to specify 5 exactly what clinician or staff person or technician will perform measures. And so I think 6 7 a number of measures don't specify who will actually perform them. 8 9 And it goes both ways of whether the 10 more rigorous end up with higher scores, lower 11 scores. What we're looking for accurate and 12 consistent scores. You know, we've measured 13 reliability and validity on that to show distinction. 14 15 Some level of training is going to 16 have to be required of any measure that's 17 adopted. But you raise good questions. All of 18 these things can go wrong. But to try to, we've 19 tried to come up with a measure that is as 20 reliable and usable as possible and I think it's 21 done that and they're variations of types of 22 facilities where it's used now, and it's

successfully being used by different clinicians. 1 2 So I feel very optimistic that that's been well demonstrated. 3 MEMBER BRADLEY: And I appreciate 4 5 Lee's comment about the amount of training that may be required and how UDS is held to a standard 6 7 for making sure that their users go through a training credentialing because we've seen these 8 9 measures over the years being used for quality 10 and comparing facilities and now for payment. 11 I think it is important. I think 12 that's a question we should raise on any of the 13 measures that come forward is how much training 14 burden and consistency is there among these tools 15 and among providers using these tools because 16 they are, ultimately, many of them are going to 17 be used for payment and there are ways to game 18 the system if there is not some type of oversight on how clinicians are trained or people 19 20 administering these tools are trained. 21 So I guess it's more of a question for 22 CMS in terms of why would there not be that

requirement for some of these measures that could
 end up in the payment world.

CO-CHAIR STILLE: Lisa? 3 MEMBER SUTER: Thanks. 4 I quess my 5 question about usability is what information is actually given back to the facility to help them 6 use information to understand their performance? 7 Obviously they're submitting the data 8 9 so they have the individual patient level 10 But in terms of comparative data, what results. 11 does the score look like? Are they given their 12 expected rate, you know, their actual to expected 13 ratio? Are they given national results or state 14 results, a spectrum? 15 You know, I'm still struggling how to 16 interpret the value. And so it would be helpful 17 to know what information the hospitals, the 18 facilities, excuse me, get back. And if you

mention that somebody was using this information,how are they using it.

21 An anecdote would actually be really 22 helpful in terms of wrapping my brain around

that. Thanks.

2 MEMBER BIERNER: And I'll try to just 3 tell you something practical about its use in the 4 IRF is that there's something that's not 5 mentioned here is something called FIM efficiency where you look at change in FIM over length of 6 7 stay. And so we get data as being a 8 9 participating member with the UDS system from a 10 regional level. You can look at it at a national 11 level. So you can compare your results to 12 various other larger entities and see where you 13 are. 14 And by looking at things like FIM 15 efficiency, you can see is it an issue of my 16 length of stay or is it more, you can look also 17 at your level of intensity of the type of 18 patients, things like that. 19 So there's a lot of reporting that is 20 available, at least in the IRF. Whether that 21 will be available in this new setting, I think it 22 remains to be determined.

1 MS. DANN: I just want to reiterate 2 one thing if I could two, three questions ago. The measures are derived from the FIM instrument 3 which has been around for 25 or greater years. 4 And we have created things which we 5 have given to CMS over time. When you mentioned 6 branching logic, we do flow charts. 7 They're a part of the training manual. And we are willing 8 9 to continue giving the refinements to whomever. 10 CO-CHAIR STILLE: Sherrie? 11 MEMBER KAPLAN: I just have a concern 12 about the relationship between reliability, 13 validity, and usability because if a measure can 14 be unreliable but it's usually when it's 15 unreliable it's not valid. It's very unusual to have a measure be 16 17 unreliable and valid. It can be consistent and 18 wrong like my bathroom scale. I love my bathroom 19 scale, it's consistently wrong. But it's very 20 unusual to have it be inconsistent and right. 21 So what we just did was kind of said 22 okay, this is inconsistent and it's right. And

then the question is can you use it under those 1 2 circumstances. And I think, you know, I think we may have not been thinking along those lines. 3 But it raises the issue of then can 4 5 you use this measure with any confidence that you're going to do something -- that's why I 6 7 raise the issue of how responsive is this facility to their efforts to try and manipulate, 8 9 to try and improve their performance. 10 Is this responding to quality? That 11 would have helped me a lot, have more confidence 12 that this is actually valid and therefore usable 13 by facilities to act to improve quality. 14 DR. NIEWCZYK: So to answer the 15 question, the FIM is very reliable. It's been 16 heavily published on the stability, the intra 17 rater, the inter rater, and it's been extensively 18 tested. 19 So it is reliable. Our Cronbach's 20 alpha was very strong. Our intra item 21 correlations were all high, you know, highly correlated and statistically significant. 22

1	: ۱
1	So I don't know where the assumption
2	is that it's not reliable. Maybe, you know, it's
3	tracing back to the ICCs that we were asked to
4	provide, we were hesitant. But if we know what
5	you want, we will give it to you.
6	But yes, it's a reliable measure and
7	it is highly predictive. It's predictive in
8	terms of function, it's predictive in terms of
9	discharge location.
10	And additionally, what we do provide
11	facilities is what we call the PEM report. So
12	it's a program evaluation model. And it takes
13	into account the average patient's functional
14	change as well as discharge disposition and it
15	also adjusts for the facility case mix, so the
16	type of patients that are within the facility as
17	well as if it's a freestanding or a unit. So
18	there's other variables that go into this model
19	as well so we're able to rank outcomes.
20	MEMBER KAPLAN: Yes. I just want to
21	be really clear. I'm not talking patient level,
22	it is absolutely reliable. It's the facility

level now that we're worrying about because 1 2 that's the unit being compared. So we kind of left behind the patient 3 4 level reliability which is absolutely totally on 5 board with everything you said. The facility level reliability we're not, we're now struggling 6 7 with. DR. NIEWCZYK: And it's extremely rare 8 9 to find a low performing facility in one quarter 10 jump to the best performing facility in the next 11 quarter. So what we find is that the high 12 performing facilities are usually relatively 13 stable, the mid, you know, the average and then 14 the low stay pretty consistent over time. 15 There's sometimes a bump up or two but 16 you don't see some of those really drastic 17 changes without having some other change occur 18 like administration or something of that nature. 19 CO-CHAIR STILLE: Okay, great. 20 Jennifer and then Linda. And then I think we 21 need to -- oh sorry, okay. 22 MEMBER MELILLO: So the research that

you're citing was done on --1 2 (Simultaneous speaking.) MEMBER MELILLO: 3 -- correct? 4 DR. NIEWCZYK: Yes. 5 MEMBER MELILLO: First level patient? DR. NIEWCZYK: We have published 6 7 papers on IRF patients as well as SNF patients. So it's not exclusive to IRF. 8 9 MEMBER MELILLO: Okay. But did all of 10 those undergo the same training and --11 DR. NIEWCZYK: Yes, they would all 12 have passed a master exam if they're used in our 13 repository. Yes. 14 MEMBER MELILLO: Okay. So, in that 15 case, it's apples to apples. 16 DR. NIEWCZYK: Correct. 17 MEMBER MELILLO: But in order for that 18 to stay apples to apples, then the SNFs and the 19 LTACs would have to invest in that same level of 20 training? 21 DR. NIEWCZYK: Yes, if they wanted to 22 be included in our repository. If they wanted to

use the tools, the instrument and the training 1 2 guide and materials, it would be at their own, 3 you know. 4 MEMBER MELILLO: And that would be a 5 subscriber fee? DR. NIEWCZYK: Not for use. 6 MEMBER MELILLO: For yours? 7 8 DR. NIEWCZYK: But yes, for the 9 services, correct. 10 MEMBER MELILLO: Okay, thank you. 11 So I have two MEMBER BRIGHT: 12 questions and probably the first one piggybacks 13 off of what Linda was just asking. So walk me 14 through a facility that's not a subscriber. Ι 15 mean okay, they have access to the tool which 16 they have to use as is for free. And they can 17 take advantage of your published training guide, 18 but on their own. 19 Where does that information go? Then 20 are they on their own to determine what that says 21 about their facility? Is that information that 22 they're submitting to CMS? I guess what I'm

failing to see is the connect point between a 1 2 facility that is currently not using any kind of valuation and suddenly they have this quality 3 measure tool available to them. But then what? 4 5 And is it -- I understand the free thing, but by definition it's kind of forcing 6 7 everybody to be a subscriber in order for it to be of value. That's what I'm hearing, so 8 9 disabuse me of that conclusion. That's why I'm 10 asking the question. 11 MS. DANN: That's not the case. Go 12 ahead. 13 MEMBER BRIGHT: Okay. And then my 14 second question is kind of following on that 15 which is, is it important -- I'm hearing a lot of 16 concern about inter-facility comparison and being 17 able to use this tool and come out the other end 18 with a picture of what it looks like in one 19 skilled nursing facility but then being able to 20 compare that with 20 others. 21 So does there need to be accompanying 22 guidance to this quality measure that talks about

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1 its appropriate use because I'm concerned like 2 other members are that we're using the word use 3 and it could come out a lot of different ways, 4 and there's nothing here that says it's 5 appropriate to use it this way, it's not 6 appropriate to use it this way.

So, sorry, two questions.

CO-CHAIR PARTRIDGE: I think I'm going 8 9 to forestall that a little bit because Jennifer's 10 a new member and the issue that you raised gets 11 raised around this table all the time. To what 12 extent should the NQF endorsement be accompanied 13 by recommendations for how the measure is used. 14 Is it a QI measure, is it an internal reporting 15 measure and so on.

Theoretically, everything that we endorse is supposed to be able to be used for public reporting. I think that's become to some degree somewhat, I don't want to say soft. But as we have studied the measures, we aren't always saying, is it ready to be publically reported right now.

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So help me you all. 1 I don't want to 2 be the only person saying this. But it does come up time after time throughout NOF standing 3 4 committees. We need to keep talking about it. MS. DANN: And I want to clarify what, 5 if the measures are endorsed and adopted, our 6 7 offer to CMS is to be able to use the measures royalty-free in any venue they choose. 8 So if 9 they choose to report on them in their quality of 10 reporting, we will have given them everything 11 they need to do that 12 DR. NIEWCZYK: Or an industry as a 13 whole. I mean, certainly they'd be at, you know, 14 be within reach. 15 And all sorts of quality DR. CLOHAN: 16 measures can be useful within your site or within 17 your organization, even if you don't have 18 national benchmarks. 19 I mean, even something as simple as 20 hand washing, for example, people all over like 21 to use sort of a consistent methodology of how 22 you score hand washing so that then within your

own site you can make improvements based on that,
 even if you don't have access to other people's
 hand washing data.

And so functional measurement can serve that same purpose. How can you identify which functional areas were strong in achieving improvement or were avoiding any diminution of function in those patients who aren't capable of improving.

So there's value to it, I think, even if you don't have the broadest array of comparison information.

13 CO-CHAIR STILLE: Okay. Are we ready
14 to vote? Oh, I'm sorry. I didn't see, one more
15 --- oh, Lisa, down there. No, everybody? Okay,
16 false alarm. Okay. Usability and use.

MS. QUINNONEZ: Voting is now open for
usability and use of Measure 2769, which includes
accountability, transparency, improvement,
progress demonstrated, benefits outweighed,
evidence of unintended negative consequences.
And the option number 1 is high, option number 2

is moderate, option number 3 is low, and Option 1 2 Number 4 is insufficient information. Okay, it looks like all votes are in. 3 4 Voting is now closed. The results are 16 percent 5 voted high, 58 percent voted moderate, 11 percent voted low, and 16 percent voted insufficient 6 information. 7 CO-CHAIR STILLE: 8 Okay. So overall 9 suitability of 2769. And then we'll have a 10 discussion about the ones that are like it in a 11 few minutes. 12 MS. QUINNONEZ: Voting is now open for 13 overall suitability for endorsement of measure 14 2769. Voting option number 1 is yes, voting 15 option number 2 is no. Okay, all votes are in. 16 Voting is now closed. The results are 84 percent 17 voted yes, 16 percent voted no. 18 CO-CHAIR STILLE: Okay. So, good. So 19 similar to our discussion previously today, 2774 20 and 2775 may be enough alike that we can kind of put them together. But I think we need to have a 21 little bit of discussion, just to make sure there 22

are no major issues if we do decide to do that. 1 2 Anyone, particularly the primary reviewers for the other two, Peter? 3 4 MEMBER THOMAS: With respect to the 5 motor measure and the mobility measure, the motor measure is inclusive of all the same 6 7 characteristics as the mobility measure. And it seemed quite redundant. Why would you have two 8 9 separate ones? 10 The obvious answer is because maybe 11 all you want to measure is mobility. And you 12 don't want to measure the other things. But it 13 just seemed redundant. Can you explain why we 14 should approve two when we can approve one? 15 DR. NIEWCZYK: Yes. So the motor is 16 really encompassing both self care and mobility. 17 So that's the sort of gross, you know, functional 18 assessment. And then the other two are, you 19 know, sub-domains. 20 So certainly if a patient has, you 21 know, very restricted mobility, and that's not 22 going to be functional goal, then it might

behoove the facility to use the self care measure.

Perhaps they may want to use both, but 3 the self care would probably be a better 4 5 assessment in terms of change from admission to It's just providing various levels of 6 discharge. functional measurement for the facility's use. 7 MEMBER THOMAS: It's currently not 8 9 required, right, it's all voluntary right now. 10 If they were ever to require, CMS, for instance, 11 were ever to require something along these lines, 12 my presumption is that they wouldn't have you do, 13 you know, duplicate efforts in that way. So this 14 is almost just kind of protecting the different 15 domains. And maybe you want it all in one, or 16 you want it broken out. 17 DR. NIEWCZYK: Exactly, yes. 18 MEMBER THOMAS: Okay. 19 DR. NIEWCZYK: It wouldn't be 20 duplicate data collection, so it would be looked 21 at only as a composite score if it was done in 22 its entirety.

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1 MEMBER THOMAS: Great. 2 DR. NIEWCZYK: Yes, same elements. CO-CHAIR STILLE: 3 Beth, you're next. 4 MEMBER AVERBECK: This would have 5 applied to the previous measure. So it's more just a question of understanding if it changes 6 7 what we would do with it. You did do some stratification on 8 9 socioeconomic and the demographics. I couldn't 10 tell if anything looked like it was statistically significant or not. It didn't appear that it was 11 12 in looking at it. And so I appreciate you taking 13 a look and at least reporting that. But just for 14 the discussion, if this applies to all the 15 measures it would at least worth noting. 16 DR. NIEWCZYK: Yes. I don't believe 17 there is. Maggie, you can speak to it if I'm 18 misspeaking here. 19 I didn't actually do MS. DIVITA: No. 20 any statistical testing with the large case 21 count. And we always are a little bit wary of 22 looking at p values. But I can certainly do that

if that's something you need. 1 2 DR. NIEWCZYK: In terms of what the averages are, they're almost equal, so yes. 3 MS. DIVITA: Yes. They're pretty 4 5 close across, yes. CO-CHAIR STILLE: Other comments? 6 7 Peter? MEMBER THOMAS: Seeing no others, I'll 8 9 take the opportunity to gratuitously volunteer 10 that I like the measures. There's obviously a 11 very long history in data collection on all these 12 elements. 13 But these really stop somewhat short 14 of the longer term outcomes. And now that we're 15 getting into measuring outcomes, and functional 16 restoration, and functional improvement, and 17 status, I think it's really important that we 18 begin to measure things that people really care 19 about a lot, like the ability to live 20 independently, the ability to return to work, the 21 ability to be active in the community, and to 22 return to their previous leisure, recreational,

athletic activity.

2	All those things that people really
3	care about in terms of long term, functional
4	restoration or status, I think is really
5	critical. So obviously not completely relevant
6	at all to this but just on a broader issue,
7	broader scale, I would encourage you to continue
8	to do more work in the area to try to get into
9	those areas. Because they're really important.
10	DR. NIEWCZYK: Agreed.
11	CO-CHAIR STILLE: Thanks, great
12	comment. So I think there seems to be consensus,
13	please let me know if there isn't, about
14	considering 2774 and 2775 just in terms of their
15	overall suitability, having had the discussion
16	about 2769 previously. Okay, let's do it.
17	MS. QUINNONEZ: Okay. Voting is now
18	open for the recommendation for overall
19	suitability for endorsement for Measure 2774.
20	Option Number one is yes, Option Number 2 is no.
21	Looking for two more, three more
22	votes. Did everyone on the phone submit their

368

votes?

2	Can we have you submit one more time,
3	just click one more time. We're missing two
4	votes. Okay, then we're good. Okay. Voting is
5	now closed. All votes are in. All votes are now
6	in, and voting is closed. The results are 79
7	percent voted yes, and 21 percent voted no.
8	Voting is now open for the overall
9	suitability for recommendation for endorsement of
10	Measure 2775. Option Number 1 is yes, Option
11	Number 2 is no. All votes are in, and voting is
12	now closed. The result is 100 percent yes, zero
13	percent no.
14	We are going to re-vote that one, one
15	second. Okay. I'll have you resubmit your votes
16	for the overall suitability for endorsement of
17	Measure 277, Option 1, yes, Option 2, no. All
18	votes are in, and voting is now closed. Okay.
19	The results are 79 percent yes, and 21 percent
20	voted no.
21	CO-CHAIR PARTRIDGE: Home stretch.
22	Next up we have, again, our colleagues from

We're moving to the other set, which is 1 UDSMR. 2 related to long term acute care facilities, one, two, three measures beginning with 2776, and then 3 4 2777, and 2778. And so the floor is now open for 5 discussion. Let's start again with 2777, which is the self care. 6 7 MEMBER BIERNER: Well, I was one of the leads on that one. 8 9 CO-CHAIR PARTRIDGE: Good. 10 I think it's very MEMBER BIERNER: 11 similar to the issues that have been raised in 12 the previous, just to point out that the LTAC, 13 this is really a new setting for its use. And so 14 I don't really, I'll ask the UDSMR to tell us, 15 but I don't think there's as much data, if any, They said 23 LTACs, I think is what 16 from LTACs. 17 you had. Is that right? 18 DR. NIEWCZYK: So I agree in terms of 19 our repository for the long term care facilities. 20 It is our smallest data site, and it is still --21 use of the measures are still in its infancy in 22 this post-acute care setting.

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However, the files that I had 1 2 submitted for the measures did include almost 4,000 patients, so 3,922 patient level data 3 4 points from six facilities. In the ICC, we 5 exploded that out to 16 facilities. So we do have, you know, a respectable number of 6 7 subscribing facilities, but it's nothing compared to our 800-plus IRFs or, you know, almost 200 8 9 SNFs. So yes, I agree. 10 MEMBER BIERNER: And I found, I put in 11 my comments, in terms of the patients that are 12 ventilator dependent, you quoted a study on your 13 website that about 28 percent of ventilator 14 dependents were discharged to home. And is that 15 --- I'm just concerned about -- what do you think 16 the sensitivity is to detect changes, given the 17 level of some patients like that that might be a 18 much lower level? 19 So often we don't see DR. NIEWCZYK: 20 as drastic functional improvement as we do in 21 other post-acute care venues. However with, you 22 know, measurement of function in mind, there is

some slight improvement.

2	And certainly, you know, we can assess
3	maintenance or those that are, you know, starting
4	to decline and likely to be readmitted to acute
5	care or other intensive care. So there is some
6	utility still to assessing patient function.
7	And again, if we take this in mind
8	with patients measured across the post-acute care
9	continuum, it is noteworthy to know what they
10	look like in the other venues prior to admitted
11	to the, you know, subsequent facilities.
12	The rating scale is seven levels. So
13	it's from one to seven. So there is some, you
14	know, good degree of sensitivity within the
15	functional assessment ranges.
16	MEMBER SUTER: So I agree with
17	Samuel's comments. I was also a lead discussant
18	on the self care measure. And I have very much
19	the same concerns as with the earlier measures,
20	particularly around usability, particularly for
21	this patient group and particularly the fact that
22	it's a change measure.

1	I'm wondering how the information is
2	presented to the facilities, and how that's
3	useful, and whether or not it's broken out so
4	that they can understand how to use the
5	information, I guess.
6	DR. NIEWCZYK: So the same, you know,
7	the same protocol for long-term care as it would
8	be for skilled nursing or for IRF. So if they
9	are subscribing facilities, they have access to
10	all of our materials and credentialing.
11	Certainly they'd have use of those materials,
12	even if they weren't subscribers.
13	But I believe that there is utility
14	for measuring function for patients even that are
15	medically complex and need, you know, stability.
16	And we do capture at the lowest level which is
17	complete dependence. So we can even see small,
18	incremental changes that can be captured.
19	CO-CHAIR PARTRIDGE: Stephen?
20	MEMBER HOY: Are we doing 2777 or 2776
21	still?
22	CO-CHAIR PARTRIDGE: We're beginning
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MEMBER HOY: Okay.

3 CO-CHAIR PARTRIDGE: But that's fine 4 if you --

5 MEMBER HOY: I'm going to hold then. 6 CO-CHAIR PARTRIDGE: Well, no, don't. 7 Go ahead. Because quite possibly it's general. 8 MEMBER HOY: Well, I was a lead 9 discussant on 2777.

10 CO-CHAIR PARTRIDGE: That's okay. 11 MEMBER HOY: And I did notice possibly 12 a shrinking gap in care. Their numbers in this 13 set stops at 2011 data set, I know. But I know 14 you had some limited data. And I don't know what 15 we're supposed to assume about trends, but I just 16 wanted to call attention to the shrinking gap of 17 facilities performing above expectations going 18 into 2010, 2011.

19And I know we can't really speak too20much to the distribution yet of the samples, but21could you speak a little to that trend or if22you've seen anything else that might suggest a

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shrinking gap?

2 DR. NIEWCZYK: Yes. I mean, I would 3 love to think that there's a shrinking gap. Ι 4 think this is just an artifact of small samples. 5 So when we have it at the facility level, you know, the patient count samples are respectable, 6 7 nearly 5,000 and sometimes well over that. However, when you're looking at the 8 9 number of facilities, you know, ten versus three, 10 so you're going to see some, you know, slight 11 differences. But the percentages really, you 12 know, exaggerate those differences. 13 MEMBER HOY: Which is interesting 14 though in the LTAC utilizations kind of trending 15 up right now. 16 DR. CLOHAN: I'll just a make a 17 clinical comment. It harkens back to the 18 committee's discussion much earlier today on 19 measurement of pain and the question of the 20 importance of asking the question if you want the 21 care to change. 22 And so I think LTACs have not

traditionally measured function. And so I think 1 2 there's logic behind believing that asking questions about function could, in fact, lead to 3 4 significant improvements in care. I would use, as an example, if you're 5 not thinking about the importance of helping a 6 7 patient become more independent in transfer, say moving from bed to chair, whatever, and you don't 8 9 think about it, it becomes very easy just to do 10 that function for the patient, not try to help 11 them become more independent. 12 And we know there's good data to show 13 the more a patient can move around, the less 14 they're at risk for pressure ulcers, pneumonia, 15 other things. So I think that the mere asking of 16 the question could be a good leverage to improve 17 on the quality. 18 CO-CHAIR PARTRIDGE: Actually, this is 19 a question of mine for Sam. What's the case load 20 like in the long term acute care facility, Who are your patients? 21 typically? 22 So they're usually MEMBER BIERNER:

medically debilitated persons that have had a 1 2 long hospital stay and require, you know, 3 intravenous therapy or drug therapy. They may 4 require respiratory therapy, ventilator 5 dependency, things like that. So they're a fairly debilitated group of, well, my term, 6 7 medically complex patients. CO-CHAIR PARTRIDGE: That's what I 8 9 kind of thought, but I wasn't sure. And this is 10 a new, more or less, new venture for you too. 11 And I gather, therefore, we've got a really 12 significant small numbers problem. Yes. 13 Are we ready to vote on the evidence 14 question? I think I am. Peter? 15 MEMBER THOMAS: Well, I did ask that 16 question earlier in the day about how you could 17 take a measure set that was primarily developed 18 around IRFs and apply it to SNFs, and then LTACs, 19 and was that doable. 20 And you tended to say yes, because 21 what you're measuring is similar across those 22 settings. And so it may be a small measure set,

but you didn't seem uncomfortable with it then.
 Is that --

3	DR. NIEWCZYK: So if you have a
4	facility, and you have providers that did improve
5	function, but you didn't measure it, and then
6	they were discharged and maybe admitted
7	downstream to an IRF or to a SNF, how are you
8	going to capitalize on the changes that you've
9	made for that patient if you don't measure it?
10	Clearly, they just might maintain.
11	And maybe for the majority that's what happens.
12	But we did see some change within patient
13	function from admission to discharge. So there
14	are LTACs that are completing the assessments on
15	patients that are making some functional gains.
16	DR. CLOHAN: And the measurements, the
17	technique of measuring function is consistent
18	across venue. You're looking at, you know, can
19	the patient take steps, how much assistance do
20	they need to move from a wheelchair to a toilet,
21	those kinds of things.
22	And so the measurement technique is

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consistent. And these things being measured,
 just like a person, who once they're discharged
 out of post-acute care they're interested in the
 things that you talked about, return to job,
 access to community, recreation, those kind of
 things.

7 When you're at LTAC level, and
8 inpatient level, SNF, whatever, you're very
9 interested can you walk, can you get to the
10 bathroom, can you feed yourself, those things.
11 DR. NIEWCZYK: Eat, yes. I mean if --

12 come in with a feeding tube and then were 13 discharged eating independently, even with some 14 modifications, I mean, that's a big improvement.

15 MEMBER THOMAS: Last comment. Yes, my 16 understanding of LTACs is that there is some 17 variation in them. And the ones that come to 18 mind are the ones that are kind of the premier 19 LTACs to me, Craig Rehabilitation Hospital in 20 Denver, Colorado, or Shepherd Center in Atlanta, 21 Spaulding in Massachusetts. You know, they 22 provide significant rehabilitation services to

people with brain injury, spinal cord injury. 1 2 That's not an endorsement of those individual places, they're examples. But they 3 4 certainly provide rehabilitation to improve and 5 to, you know, to address functional status, for sure, so for what it's worth. 6 I think, Peter, 7 CO-CHAIR PARTRIDGE: my question wouldn't be so -- would be if you've 8 9 got -- all you know is something about six 10 facilities. 11 It's kind of hard to sit back and say, 12 well, we're comfortable with a significant 13 variation in performance among six facilities. 14 That's all, as opposed to the other two 15 categories we've discussed here. On the other 16 hand, that doesn't mean it isn't valuable to 17 start. 18 MEMBER BRADLEY: Then my comments may 19 relate more to usability, but since we're talking 20 about change, there is another element to this 21 scale, as well as in terms of how we use it in a 22 hospital.

1	Even if there is no change in a
2	patient, it measures, it kind of goes back to
3	more of the earlier research that was done. It
4	measures the burden of care a patient requires.
5	So even if a patient doesn't make any
6	functional change, it provides providers the
7	information that they need to train the family,
8	to teach the families, and to do the education
9	needed if these patients are projected to go
10	home.
11	So it provides information even if it
12	doesn't measure any change as useful information.
13	And I think sometimes we forget that we're using
14	it for other purposes other than just measuring
15	did the patient go from A to B.
16	MEMBER FRIEDMAN: Yes, I just have a
17	question about in any of these measures and
18	questions, is there anything that addresses
19	caregiver stresses? As a lot of these patients
20	that are going home will likely have a caregiver
21	who need to support them a great deal.
22	DR. NIEWCZYK: It's a great question.

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1 It does not directly measure caregiver stress, 2 however there is published studies whereby the 3 functional status that the patient is at, in 4 terms of where their, you know, total score is, 5 equates to a number of hours of one-on-one helper 6 care.

7 So it can be useful for communications 8 with families and caregivers in terms of, you 9 know, instead of mom's going to need a lot of 10 help, it quantifies what that lot of help would 11 be, meaning eight or more hours per day versus 12 one to two hours per day.

13 CO-CHAIR PARTRIDGE: If there are no 14 more comments, and in view of the time -- I'm 15 sorry, Linda, I don't mean to cut you off. Go 16 ahead.

17 MEMBER MELILLO: So just very quickly, 18 my concern is that, while there were six LTACs, 19 three of them were in Massachusetts. So I think 20 that's very narrow. Also, did you collect your 21 data pre or post 25 percent rule?

DR. NIEWCZYK: So this, when was our

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first step -- so there would have been, you know, 1 2 pre-75 percent rule. Absolutely. MEMBER MELILLO: And then just a 3 general comment. It concerns me that quality 4 5 would be assessed in LTAC populations that may not include measures that are already existing 6 7 for IRF. So like swallowing, vent weaning, you 8 know, that those would also be very good measures 9 to include --10 DR. NIEWCZYK: Absolutely. 11 MEMBER MELILLO: -- in a quality of 12 LTAC service line. And so I just have that 13 concern that, you know, by limiting it to 14 existing measures, that we may not be capturing 15 the essence of what is an LTAC. DR. NIEWCZYK: Absolutely. This is 16 17 not an all-encompassing measure. This is only 18 looking at a narrow focus of function. 19 And I just want to add that the data 20 we supplied for you is from six SNFs, but we 21 don't only have six SNFs in our repository or, 22 I'm sorry, LTAC. I'm on previous --- you know,

in the ICCs we had included 16 facilities. 1 2 We do have much more data. We initially had compiled this at roughly 5,000 3 patients per venue when we submitted for Phase 2 4 5 measures and had all sites included in our applications. So that's why it's looking like 6 7 it's only six. Rest assured, there is more data behind the scenes that we could provide if you 8 9 would like. 10 CO-CHAIR PARTRIDGE: Are we ready to 11 vote on evidence with 2776? 12 MS. QUINNONEZ: We are now voting on 13 measure 2776, functional change, change in motor 14 score, and long term acute care facilities. 15 Rationale supports the relationship of health 16 outcome or PROs to at least one healthcare 17 structure, process, intervention, or service. 18 Option Number 1 is yes, and Option 19 Number 2 is no. Okay, all votes are in. Voting 20 is now closed. The results are 95 percent voted 21 yes, and five percent voted no. 22 Moving on to gap, CO-CHAIR PARTRIDGE:

1 et cetera. 2 MS. QUINNONEZ: Okay. We're voting on Performance gaps, data demonstrated 3 the gaps. considerable variation or overall less than 4 5 optimal performance across providers and/or 6 population groups. Option Number 1 is high, Option Number 7 2 is moderate, Option Number 3 is low, and Option 8 Number 4 is insufficient. 9 10 All votes are in, and voting is now 11 closed. The results are 11 percent voted high, 12 37 percent voted moderate, 21 percent voted low, 13 and 32 percent voted insufficient. 14 Voting on reliability for measure 15 2776, reliability including precise 16 specifications and testing. Option Number 1 is 17 high, Option Number 2 is moderate, Option Number 18 3 is low, and Option Number 4 is insufficient. 19 Looking for three more votes. All 20 votes are in. And voting is now closed. The 21 results are 11 percent voted high, 42 percent 22 voted moderate, 16 percent voted low, and 32

percent voted insufficient.

2	Are we ready to vote on validity?
3	We're voting on validity for Measure 2776,
4	validity including specifications consistent with
5	evidence, testing, exclusions, risk adjustment,
6	stratification, meaningful differences,
7	comparability, and multiple specifications, and
8	missing data. Option Number 1 is high, Option
9	Number 2 is moderate, Option Number 3 is low, and
10	Option 4 is insufficient.
11	All votes are in, and the voting is
12	now closed. The results read five percent voted
13	high, 53 percent voted moderate, 21 percent voted
14	low, and 21 percent voted insufficient.
15	Feasibility of Measure 2776, data
16	generated during care, electronic sources, and
17	data collection can be implemented. Option
18	Number 1 is high, Option Number 2 is moderate,
19	Option Number 3 is low, and Option 4 is
20	insufficient.
21	We're waiting for two more votes. And
22	we have them. All votes are in, and voting is

21 percent voted
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ion Number 1 is yes,
All votes are in,

voting is now closed. The results are 58 percent 1 2 voted yes, and 42 percent voted no. 3 MS. THEBERGE: Operator, can you open the lines for public comment please? 4 OPERATOR: Yes ma'am, at this time if 5 you wanted to make a comment, please press star, 6 7 then the number one. There are no public comments at this time. 8 9 CO-CHAIR PARTRIDGE: So 2777 and 2778 10 remain on our plate. And again, this one's a 11 little awkward. DR. NIEWCZYK: Well, if I can 12 13 respectfully ask, you know, we did supply a great 14 deal of evidence related to reliability and 15 validity. You know, certainly had we sat here 16 with, you know, 100 cases or face validity only, 17 I can understand the outcome. But we not only 18 had, you know, concurrent validity, but we also 19 had predictive validity. 20 To see our square values, you know, in 21 the range that we had, that's highly respectable. 22 Certainly some published literature, you know,

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include in our square of 0.17. And it gets 1 2 published. So I think I'm confused in terms of 3 what the committee wanted for reliability and 4 validity. 5 So the last time, MEMBER THOMAS: earlier today, there was a discussion about we 6 7 have, like, two months to provide additional data and to try to work with the staff and figure out 8 9 whether we can --- some of the, you know, we have 10 a second meeting and talk. Is that the same process that would be used in this instance? 11 12 CO-CHAIR PARTRIDGE: Are you 13 suggesting you might make a motion to defer 14 consideration? 15 MEMBER THOMAS: Oh, I wasn't sure that 16 was the deferral. I thought the deferral was, 17 like, come back to us and we'll talk ---18 CO-CHAIR PARTRIDGE: Well, it is. 19 MEMBER THOMAS: -- talk about this 20 next year. 21 CO-CHAIR PARTRIDGE: It is. As 22 opposed -- if I'm understanding the discussion

earlier correctly, and I may not, so please, 1 2 Suzanne and Sarah, stop me. We were really addressing time frame. 3 4 If the time frame is pretty 5 compressed, if we say essentially, during the public comment period and so on, if there's 6 7 additional data you would like to submit, we will consider it right as part of phase, this ---8 9 MEMBER THOMAS: This phase. 10 CO-CHAIR PARTRIDGE: -- this segment 11 of Phase 3. If you think it would take more time 12 to make the committee comfortable with a 13 recommendation to endorse, say up to a year, then 14 that would be a deferral. Am I right? 15 MEMBER THOMAS: I'm just suggesting 16 that we heard is this six LTACs, and you said no. We have data on much more than that. And you do 17 18 19 DR. NIEWCZYK: I mean, how much is 20 enough? Like, I don't know if it's sample size 21 that you're looking for, you know, certainly I 22 can pull, you know, data from when we first had

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an LTAC start collecting.

2 Sometimes what happens is the larger 3 your database is you have minutiae turn up as 4 being statistically significant when it's not 5 clinically meaningful.

So in an attempt to counter that we, you know, we took a sample and we tried to have the samples equal between settings. Otherwise, clearly our IRFs would have dominated.

10 So if you took a look at, you know, 11 the submission files, they're all roughly 5,000 12 patient counts. Of course, when you have 800 and 13 some-odd subscribers in IRFs, there's going to be 14 more variability of those numbers of facilities 15 versus LTACs. We may have a smaller pool, but nonetheless, there were more than six. So if 16 17 it's just a larger sample you want, that could 18 easily be done.

19 MS. SAMPSEL: So, Peter, your question 20 is a process question as well. And so basically 21 what happens, there were a number. So gap was 22 consensus not reached, reliability, validity, and

then use, usability and overall.

2 And so it does go back to the process of, you know -- and I think what Paulette's 3 trying to find out from all of you all is what do 4 5 you want to see. You know, they don't have to provide 6 7 all their data. I mean, we know if health plans test they probably test in three health plans. 8 9 So kind of, you know, what are those things? And 10 I think that's what we'd like to draw out. Right 11 now, what are those things that, in this eight 12 week period, UDSMR could bring back to you. 13 Because you will re-vote after public 14 comment on these measures. Did I, is that what 15 you're looking for? 16 DR. NIEWCZYK: Absolutely. And it's 17 just, I've been involved in this process for 18 quite some time, not only for our measures but, 19 you know, I've been on the line for other 20 measures under consideration. 21 And it seems to be a great deal of 22 variability between what's submitted for

So sometimes the committee is 1 measures. 2 perfectly fine with, you know, one setting, you know, a handful of -- and other times it's -- so 3 4 if there's some consistency in terms of what you 5 want, you know, we'll try to provide that. Really briefly, I 6 MEMBER BRIGHT: 7 think one criteria that really weighed in for me was the fact that this is a new setting for this, 8 9 okay. 10 So I think that, to some degree, what 11 you're getting from the committee is a sense of, 12 yes, give us a little more data. Because this is 13 a setting that hasn't done this really. And it's 14 really great that you have such a robust data 15 set. 16 But you're talking about a data set of 17 organizations that already have resources and a 18 focus on this. And we're talking about trying to 19 pass a measure that could be applied to settings 20 that aren't doing this at all or definitely 21 aren't doing it well. 22 So I guess, just speaking for myself,

I feel okay with saying could we see some other 1 2 examples, just prove to us that it's not just six facilities. But that's really it. 3 And the newness of the setting was really my litmus test. 4 CO-CHAIR PARTRIDGE: Lisa and then 5 Sherrie. 6 7 MEMBER SUTER: So for gap and for usability, the information that would be really 8 9 helpful to me would be looking at facility level 10 distribution of results and some information 11 about the data that goes back to facilities. 12 I know we heard from Samuel that 13 there's a lot of comparative data, but a little 14 bit more information about that, which it sounds 15 like would be pretty easy to pull together, I 16 think would be very helpful from my ---17 DR. NIEWCZYK: Thank you. 18 CO-CHAIR PARTRIDGE: Sherrie? 19 MEMBER KAPLAN: Yes. Full disclosure, 20 I'm on the National Advisory Committee for 21 Physician Compare. And all of these issues are 22 being raised at the, you know, how do you measure

physician level performance, and how do you discriminate, and at what level should you discriminate. 3

And there's a fairly robust literature 4 5 out there at the physician level which is applicable for this unit of comparison. 6 It's a 7 unit being compared. And the issue of intraclass correlation coefficients comes up there. 8 And 9 there's fairly generalized estimation equation. 10 So there's a fairly robust literature out there. 11 So the kind of facility level 12 comparisons that we were looking for in the 13 reliability, and then validity at the facility 14 level for discriminant validity between 15 facilities, which is what you want if you're 16 going to be the facility, and you're going to 17 either be inappropriately or unfairly compared to 18 folks with different, either sample size distributions or --- you really -- this is not a 19 20 trivial issue anymore. 21 And it brings up the issue of

usability as well. Because if CMS is going to

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then begin to use these for, you know, penalizing 1 2 people or incenting people, in one way or another, for meeting or not meeting these 3 4 benchmarks, then the standard goes up. And so I think that's what NQF right 5 now, Sarah, unless I'm wrong, is dealing with. 6 7 There is some changing in the uses of these measures now and the potential uses of these 8 9 measures, even though we're supposed to be 10 agnostic to use, that's starting to move the 11 psychometric properties that we're going to be 12 expecting from these measures. 13 So I'm still struggling with the issue 14 of what's fair to hold developers accountable 15 Because the Betty Crocker of how to do this for. 16 is in the literature. It's not like we dreamed 17 it all up in this committee. There's a fair 18 amount out there that would be useful and helpful 19 in how to actually do this. 20 The question is whether it's fair 21 right now to hold measure developers accountable for meeting the requirement if, in fact, the 22

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guidance hasn't been clear enough. That's what I'm struggling with.

CO-CHAIR PARTRIDGE: I think you have 3 heard several of these measures that it would be, 4 5 it would perhaps raise the comfort level of a number of members if we had the distribution data 6 7 that Lisa Suter asked for. And you were nodding, which suggests to me that perhaps that's --8 9 DR. NIEWCZYK: That's definitely 10 possible. Yes, absolutely. 11 CO-CHAIR PARTRIDGE: -- possible. So 12 that would be a suggestion that I would also 13 support. 14 MEMBER KAPLAN: And the intraclass 15 correlation coefficients at the facility level in 16 the way we were talking about, not the way it was 17 done. 18 MEMBER THOMAS: Can NQF staff provide 19 some technical assistance or communication with 20 them in order to run that data? 21 MS. SAMPSEL: No. We won't run the 22 data for them.

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1	MEMBER THOMAS: No, no, no. Not to
2	run it, but TA, technical assistance to do it the
3	right way.
4	CO-CHAIR STILLE: Yes. We're going to
5	work with Sherrie on that.
6	MEMBER THOMAS: Yes, okay.
7	MEMBER MELILLO: Yes. I would like to
8	see the training manual to see what the burden
9	would be to those staff who are coming at these
10	measures new, how complicated is it.
11	You know, what's the realistic
12	expectation that, within an organization, they're
13	going to be able to use this material to actually
14	score the FIM in a consistent manner as the IRFs
15	are currently scoring it. In addition, I would
16	love to see a sample size of at least 30
17	facilities.
18	DR. NIEWCZYK: So is that, like, a
19	rule? I mean, because I just see that that there
20	are some different rules for different
21	submissions.
22	It seems, you know, like, nowhere did

it ask to show any training materials or anything 1 2 like that. Had it asked for that, we would've absolutely included it. I just want to be held 3 4 to the same standards that everybody else is 5 being held to. MS. SAMPSEL: Well, but I could say, 6 7 within Phase 1 with the CAHPS measures, the question about how CAHPS was administered and all 8 9 of these similar questions on CAHPS do come up. 10 So, I mean, we don't -- do we have CMS 11 bring their 500 page volume? No. But some of 12 these questions do come to feasibility, 13 usability, and use. And I think you're hearing 14 more of this, at least that's what I'm picking 15 up, because these are new to the LTACs. So I do 16 think this is a fair question. 17 DR. NIEWCZYK: And, you know, we'd be 18 happy to provide it. I'm just, I want as much 19 clarity as possible so we can get you what you 20 want. 21 MEMBER MELILLO: My level of concern 22 is that you mentioned this is a cross cutting

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measure for use with the IMPACT Act which then becomes a compliance related measure and also, potentially, a payment related measure. And so because of that, I think it's critical, it's right.

6 CO-CHAIR PARTRIDGE: I just tested 7 this script with the lady to my left. The 8 question before us is on 2777 and 2778, the two 9 remaining measures for the UDSMR team and us.

10 What is the comfort level with this 11 committee about going through all evidence gap, 12 reliability, validity, feasibility, usability, 13 and overall, for each of those two remaining 14 measures as opposed to doing what we have done 15 earlier, and saying we believe the results for 16 each of those two would be the same as with this 17 2776?

18 And we need only take the overall 19 recommendation for endorsement vote, just on that 20 issue, comfort level, I'm sorry, not for 21 developers. Lisa? Anybody have heart failure if 22 we did it that way? Sure.

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1 DR. CLOHAN: Is there a need to go 2 ahead and record votes for the two? Or if the committee is moving toward just collecting some 3 more information, might you want to just leave 4 5 those other two unaddressed for the moment and get that information back. 6 CO-CHAIR PARTRIDGE: I believe as a 7 process question, in order to allow it to go 8 9 forward for public comment, we need to take the 10 recommendation vote. Am I right? 11 MS. SAMPSEL: Yes. It's also 12 consistent with what we did for the rest of day 13 this morning. So I think we should still do 14 that, realizing that, you know, it still may be 15 consensus not reached. But I think as a process, 16 correct, we do need to do that. MEMBER THOMAS: Similar enough 17 18 measures that we can assume that --19 MS. SAMPSEL: Yes. And in fact, we 20 did this in Phase 2 as well. We carried, even in 21 the report, we carried the discussions forward in 22 the report of saying we had similar discussions.

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These were the highlights of the discussions. 1 2 CO-CHAIR PARTRIDGE: Okay. So Desi? 3 MS. QUINNONEZ: So we are voting for 4 the overall suitability for recommendation for 5 endorsement for Measure 2777. Option 1 is yes, and Option 2 is no. Voting is now open. 6 7 Looking for three more votes. All votes are in, and voting is now closed. 8 The 9 results are 47 percent votes yes and 53 percent 10 for no. 11 We're voting now for the overall 12 suitability for recommendation for endorsement of 13 Measure Number 2778. Option Number 1 is yes, 14 Option Number 2 is no. Looking for two more 15 votes, one. 16 MS. THEBERGE: Deb, we need your vote. 17 Thank you. 18 MS. QUINNONEZ: Okay, all votes are 19 in, and voting is now closed. The results are 37 20 percent voted yes, and 63 percent voted no. 21 MS. SAMPSEL: So this one fails. 22 There's a public comment that we

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missed.

2 MS. THEBERGE: Operator, can you open the line for a public comment please? 3 4 OPERATOR: Yes, ma'am. At this time 5 to make a comment, please press star then the We do have a comment from Deanna 6 number one. 7 Hayes. DR. HAYES: Hi, this is Deanna with 8 9 Focus on Therapeutic Outcomes. I want to thank 10 you for the opportunity to observe this. These 11 were some great conversations and things that 12 were really thought provoking to me. 13 I was unclear with 2769 and why it was 14 passed when it did not appear to meet the 15 standards for being a performance measure. Τ 16 think you probably just addressed this in your 17 most recent comments. But my request for comment 18 was submitted prior to your last discussion. But 19 I was still unclear about 2769 itself, because it 20 was passed. 21 MS. SAMPSEL: Actually, Deanna, 2769 22 was -- hold on a minute. You know, so they were

different measures. I mean, from my
 understanding from the committee, and this is
 just my interpretation, is those first three
 measures were the SNF measures where they have
 been in longer use.

6 And there was more data provided 7 where, with the LTAC measures which were the last 8 three that were not recommended, as of right now 9 consensus was not reached. But that was a 10 difference in voting.

11 DR. HAYES: What I heard in the 12 discussion was a committee member described 13 concerns, and it didn't sound like they were 14 resolved. It sounds like the data is there, and 15 it's available to demonstrate validity and 16 reliability for performance. It's just a matter 17 of continuing to work together to find the right 18 analysis.

MS. SAMPSEL: Right. And so during
these next few weeks, NQF staff will work with
UDSMR, and they will provide that additional data
that was not submitted. And therefore, the

committee will re-vote. 1 2 DR. HAYES: Thank you. And at this time there are 3 OPERATOR: 4 no public comments. 5 CO-CHAIR PARTRIDGE: Peter. MEMBER THOMAS: But on the third 6 measure of the LTACs that just failed, can we 7 assume that that was an accurate vote? I mean, 8 9 there were a couple instances today when it 10 wasn't accurate. Why would it have changed? We 11 didn't discuss anything differently. 12 MS. SAMPSEL: We can definitely re-13 vote that one. I mean, I have the same 14 I mean, if anybody changed their vote questions. 15 between the two, you know, I guess, does somebody 16 want to explain, or do people want to re-vote? 17 I'd like to re-vote. MEMBER THOMAS: 18 CO-CHAIR PARTRIDGE: Okay, let's re-19 vote. 20 MEMBER THOMAS: Only because we've had 21 this happen a few times today. And I just don't 22 know why it would have changed.

1 MS. QUINNONEZ: Okay. We are 2 reopening the vote for overall suitability for endorsement of Measure 2778. Option 1 is yes, 3 4 Option 2 is no. All votes are in, and voting is 5 now closed. Thirty-nine percent voted yes, and 6 61 percent voted no. 7 MEMBER THOMAS: What does that mean? MS. SAMPSEL: Well, it still means 8 9 that UDSMR has the opportunity to bring data back 10 to us, and we'll re-vote after ---11 MEMBER THOMAS: Okay. Fair enough, 12 fair enough. 13 MS. SAMPSEL: -- public comment. It's 14 the same results. 15 CO-CHAIR PARTRIDGE: Any further comments or discussions? If not, I'm going to 16 17 excuse our USMDR people. We've put you through a 18 difficult afternoon. And I'm afraid you're still 19 going to have to work with us. 20 And dinner is at 6:00. I know we lose some of you, because you have other obligations. 21 22 But those of us who are going to be going for

1	dinner, I look forward to that in 40 minutes.
2	But otherwise, we're adjourned for the day.
3	Tomorrow morning we begin at, all
4	right, 8:30 again. Breakfast at 8. We will try,
5	and again, we had some pretty interesting
6	discussions today. We will try to have some time
7	for us to think back over the day and a half
8	before we leave.
9	And one note, we have to leave at
10	1:30, I promise you. Because I have committed to
11	my husband that I will leave by 1:30. Chris can
12	take over but
13	CO-CHAIR STILLE: Okay, that's fine.
14	CO-CHAIR PARTRIDGE: this half of
15	the Chair will be home, but do think of some of
16	the kinds of questions that have been raised
17	today, some of the things that Sherrie said about
18	what is it that their current algorithms dictate
19	that maybe we can't change, but we might want to
20	recommend be rethought, particularly with regard
21	to PRO-PMs and anything else that, particularly
22	from our new members, as you've hit this process

for the first time. How can we do it better, 1 2 make it work better for all of us? Otherwise --3 MEMBER THOMAS: I just want to say that in comparison to the last two times that 4 5 I've done this, the staff briefings on this were unbelievably helpful. And I just really 6 7 appreciate that. 8 (Applause.) 9 MS. THEBERGE: So the restaurant is at 10 16th and K, 1600 K Street. And some folks may 11 wish to go back to their hotel and so if you want 12 to just meet us there. And it's called P.J. 13 Clarke's. 14 (Whereupon, the above-entitled matter 15 went off the record at 5:23 p.m.) 16 17 18 19 20 21 22

Α a.m 1:9 5:2 124:21,22 **AARP** 129:9 abbreviated 124:11 **ABC** 159:17,20 ability 87:22 148:18 260:21 288:3 289:19 289:20 312:15 327:12 347:18 367:19,20,21 able 23:18 26:3 89:3,10 111:4 113:9,22 114:1 122:22 131:17 144:9 147:11,16 148:6,7,22 150:7 162:7 167:14 167:17 176:20 177:16 181:16 194:21 195:2 228:19 237:3 261:14 276:17 293:2 314:18 320:14 321:8 338:18 355:19 359:17,19 360:17 361:7 398:13 above-entitled 124:20 174:4 284:11 408:14 absolutely 116:17 202:16 222:10 247:14 305:3 355:22 356:4 383:2,10,16 392:16 397:10 399:3 abstract 74:10 abstraction 31:21 50:20 62:17 academic 10:21 11:3 accept 26:3 83:10 119:19 acceptability 100:2 220:7 221:13 239:14 255:22 342:10 acceptable 183:4 200:9 accepting 238:9,22 273:2 access 147:16 335:8 358:15 362:2 373:9 379:5 accommodation 189:7 280:6 accompanied 360:12 accompanying 359:21 accomplish 25:4 accomplishing 85:6 account 37:10 39:9 212:1 308:6 355:13 accountability 48:14 246:15 270:14 362:19 387:5 accountable 143:1 242:10,15 264:1 396:14,21 accounted 293:7

accurate 346:16 349:11 405:8,10 accurately 51:19 ACHA 271:9 achieve 41:15 172:6 achieved 45:10,18 achieving 46:10 362:6 acknowledge 27:10 39:12 acknowledgment 153:4 acquaintance 10:18 act 271:15,18 278:16 287:1 315:19 316:20 354:13 400:1 acted 224:17 action 55:11 78:12 86:19,22 actionable 142:13,18 243:22 317:17 actions 55:13 active 24:15,15 27:20 367:21 activities 8:14 activity 368:1 actual 32:19 33:16 60:8 81:8 85:12 89:5.6 160:2 182:2 224:6 320:20 321:3 348:3,5 351:12 acuity 315:3 acute 4:16,17,19 12:16 20:12 58:13 240:18 249:18 284:21 297:13 300:4,20 301:5,6 370:2 372:4 376:20 384:14 adaptation 132:20 adapted 340:1 add 10:15 74:12 78:10 86:17 99:2.4 116:2 151:18 171:6 178:5 246:21 258:10 271:20 274:16 305:11,20 307:12 383:19 added 28:5 72:11 123:17 200:8 247:4 249:4 260:3 adding 227:20 272:1 addition 57:15 71:19 72:20 86:18 112:12 249:9 260:6 398:15 additional 25:11,22 37:3 52:21 68:2,3 69:8 101:7 129:8 167:20 176:17 177:21 181:10 227:14 250:5 274:15 300:22 304:10 305:21 334:4,5

348:12 389:7 390:7 404:21 additionally 303:15 355:10 address 57:21 64:18 68:20 72:21 176:22 177:16 180:17 241:1 282:9 302:22 337:20 380:5 addressed 78:4 403:16 addresses 256:18 310:1,13 381:18 addressing 390:3 adequacy 200:6,12 adequate 239:8 297:1 adequately 192:18 Adjourn 4:22 adjourned 407:2 adjust 27:5,6 28:20 37:22 38:6 263:4,12 264:2 269:6 adjusted 39:9 313:22 adjusting 208:2 adjustment 27:17 37:8 37:11,16 38:11 49:5 93:21 262:8.12 263:11.18.20 269:6 288:1 308:6 342:12 386:5 adjustments 39:3,6 adjustor 212:1 adjusts 355:15 administer 134:2 167:7 277:11 279:20 282:20 290:14 administered 150:15 150:16 153:10 185:6 188:9 189:3 194:15 194:16 231:20 277:1 277:21 399:8 administering 194:4 195:3 350:20 administration 189:4 194:10 278:15 356:18 administrative 16:22 21:15 115:6 admission 292:2 294:2 305:1 319:10,19 365:5 378:13 admissions 49:12 admit 302:8,8 admitted 372:10 378:6 adopted 67:12 346:5 349:17 361:6 adoption 113:15 adult 56:21 70:15 147:8 162:14 194:2 305:17 adults 148:22 171:18

293:22 advance 16:3 advantage 358:17 advantageous 248:14 advisors 16:12 advisory 13:16 14:21 16:12 17:15 394:20 advocacy 13:6 advocate 14:2 affect 234:21 293:8 affiliated 289:1 Affinity 2:3 afraid 406:18 African 70:14 afternoon 23:16 36:20 406:18 age 51:11 63:22 135:18 136:3 147:7 171:18 253:2 263:17,20 279:9 293:14,15 294:16 340:2 agencies 20:21 128:5 142:15 147:14 agency 139:10,20 140:11 159:9,17,21 192:9 agenda 23:11 47:2 284:17 agenda's 124:16 ages 75:18 300:13 aggregate 147:18 148:1 170:18 247:20,21 248:10 259:12 303:6 aggregated 160:13 aging 280:15 agnostic 48:18 49:13 49:16 396:10 ago 8:12 12:21 13:8 34:18,19 73:4 112:21 165:1 323:15 353:2 agree 63:7,8 69:21 75:13 80:21 81:2 97:7 99:1 117:16 122:8 144:8 188:13 239:3 243:5 247:17 248:7 274:8,12 278:10,12 321:13 370:18 371:9 372:16 agreed 232:19 233:18 368:10 agreeing 230:3 agreement 103:11 230:3 234:8 agreements 101:20 agrees 301:15 AHCA 229:6 231:21 284:6 ahead 7:2,3 47:12

76:12 92:10 99:22 121:21 193:8 201:3 281:20 292:10 314:20 338:5 359:12 374:7 382:16 401:2 AHRQ 281:6 aid 348:19 aiming 213:9 AIR 126:2 alarm 362:16 Alexandra 2:18 7:20 Alexandria 13:4 algorithm 34:3 179:18 192:22 261:11 algorithms 407:18 alike 363:20 all-encompassing 306:20 383:17 Allison 126:6 allow 55:2 152:20 195:8 236:18 237:9 286:20 295:20 296:14,22 401:8 allowed 77:17 152:16 276:11 278:15 allowing 71:12 77:4 153:2 200:2 214:7 238:13 276:4 allows 113:3 alpha 324:19 328:6 354:20 altering 83:14 altogether 294:21 **AMA** 79:4 Ambulatory 85:22 American 3:5,10,11 70:14 126:1 Americans 58:5 232:18 amount 52:13 67:7 134:1 146:1,7,8 175:5 237:20 247:18 296:5 296:12 325:13 350:5 396:18 analogy 51:8 analyses 28:6,21 153:14 193:4 327:4 analysis 29:11 31:3 38:12 88:22 103:3 130:10 225:18 226:6 226:7,8,12 229:20 235:5 239:9 243:11 287:13 330:3 333:13 334:15 337:19,22 404:18 Analyst 2:18,19 7:8,21 Analytics 3:8 analyze 277:10 analyzed 340:1

analyzing 225:16 and/or 136:5 202:10 203:19 255:11 322:21 385:5 anecdotally 345:20 348:1 anecdote 351:21 anesthesia 18:10 animated 18:8 **ANITA 3:13** Ann 2:15 6:16 8:5 23:9 annotated 308:1 annually 253:21 answer 37:9 42:19 65:2 77:15 78:5 91:9,11 102:10 135:15 157:20 164:15 194:21 195:2 200:20,22 210:2 247:21 249:8 263:7 267:9 268:2 275:17 276:18 287:5,6 288:22 293:12 354:14 364:10 answered 167:1 243:12 245:16 248:11 259:15 259:16 339:20 answering 175:12 243:13 248:1 267:20 267:21 275:14 answers 231:1 anthropologist 19:4 anticipate 67:6 130:5 anxiety 18:11 anybody 47:14 62:4 93:7 275:16 400:21 405:14 anymore 250:19 395:20 anyway 22:9 70:5,6 213:18 215:16 237:9 apart 164:9 apologies 21:13 apologize 21:4 54:4 65:8,17 112:19 170:6 217:21 app 279:13 apparent 192:15 apparently 108:7 233:8 appear 366:11 403:14 appendix 268:21 **Applause** 408:8 apples 288:5,6 316:15 316:15 357:15,15,18 357:18 applicable 29:5 30:11 101:14 138:7 395:6 application 41:8 250:18 258:5 applications 321:5

384:6 applied 71:1 138:22 285:6 338:15 366:5 393:19 applies 311:16 366:14 apply 36:3 64:3 66:13 66:13,14 147:6 284:19,20 302:4 306:10 377:18 applying 48:1 153:16 appointed 275:4 appointment 19:16 appreciate 24:10 54:12 71:4 129:22 253:8 300:18 350:4 366:12 408:7 approach 23:5,6 87:14 143:7 144:2 162:21 163:11 243:8 297:13 approached 279:19 appropriate 70:22 71:22 75:6,7 76:21 145:16 155:10 179:7 189:5 241:9 262:17 263:11 304:15 343:11 360:1.5.6 appropriateness 231:16 approve 156:8 179:21 364:14,14 approved 27:16 159:7 approving 132:16 155:20,21,22 approximately 34:18 327:7 April 10:3 27:19 apropos 109:22 area 8:21 24:1 79:9 120:16 125:18 126:7 126:11 147:5 171:10 171:20 232:16 368:8 areas 14:22 40:9 41:4 42:16 129:12,16,22 302:10 362:6 368:9 argue 89:19 169:8 240:4,21 argued 331:13 argument 105:16 arm 82:10,10 arms 82:13 179:9 array 362:11 arrives 283:2 article 317:9 articles 74:5 artifact 375:4 artificial 11:10 aside 70:4 **asked** 8:13 28:2,20 29:3

42:3 46:13 133:1,17 148:18 188:21 225:3 243:20 247:10 271:20 311:14 312:18 355:3 397:7 399:2 asking 27:1 50:10 71:11 73:16 74:18 80:22 83:4,5 96:18 107:22 117:2 174:18 176:1 196:3,13 243:16 245:18 256:21 261:20 262:12 268:11 299:22 304:11 336:11 358:13 359:10 375:20 376:2,15 asks 71:19 79:15 aspect 254:18 aspects 312:12,13 assess 57:20 61:3 164:4 259:12 294:3 305:14 314:19 341:19 346:15,18 372:2 assessed 70:9 77:6 298:1 306:18 383:5 assesses 274:6 assessing 61:13 74:14 80:22 89:20 92:22 236:17 341:9 348:18 348:20 372:6 assessment 4:6 40:7 53:13 54:21 55:14,16 55:18 56:4,18 57:12 57:14,17,18 61:10 62:10,16 66:16 68:9 68:10 69:2 71:7.11.16 71:20,21 72:1,10,21 73:13 75:6 79:20,21 80:6 81:3,18 86:19 87:22 89:6 90:21 100:19 287:11 292:4 294:21 297:11 348:18 349:1 364:18 365:5 372:15 assessments 30:22 72:4 74:16 378:14 assign 330:11,12 assigned 42:9 44:14 assigning 71:9 assignment 10:6 assist 195:9 237:8 assistance 277:3 312:16 378:19 397:19 398:2 assistant 15:15 18:2 160:7 162:13 172:9 assisted 17:3 251:16 associate 15:4 65:9 81:7

associated 58:6.8.16 73:2 75:3 78:22 82:19 Association 3:6,11 136:13 assume 74:9 177:6 212:12,12 236:2 312:2 374:15 401:18 405:8 assumed 177:8 assumes 35:17 assuming 43:20 276:14 assumption 105:19 355:1 assumptions 35:16 assure 277:16 assured 69:9 384:7 assuring 276:17,20 athletic 368:1 Atlanta 379:20 attempt 391:6 attention 120:19 323:14 374:16 attract 49:4 attributable 49:1 102:9 102:13 103:8.17 149:21 161:13 attribute 64:19 161:12 attribution 47:18 48:10 49:5 149:8,20 attributions 190:21 audio 24:13 285:14 August 11:22 authorities 136:21 authorized 146:13 autonomy 276:16 available 52:16 68:6 90:2 97:4 170:16 214:1 228:2,4 263:9 288:12 290:22 323:19 352:20,21 359:4 404:15 average 36:7 108:4 133:5,7 187:11 212:9 212:12,20 230:10 244:21 246:9,9 294:9 296:13 319:14 320:22 330:22 340:20 355:13 356:13 averaged 231:1,2 averages 325:7 330:13 367:3 averaging 246:8 Averbeck 1:13 16:18,19 90:18 124:1 154:3,10 197:12,18 211:6 286:7 291:21 292:13 293:6 308:3 366:4 avoid 27:7

avoiding 362:7 awake 264:12 aware 28:1 174:8 awhile 147:4 awkward 388:11

В **b** 85:4 381:15 **back** 13:8 24:3 30:5 31:5 44:8 63:15 69:6 73:4 79:18 87:9 100:1 118:17 124:17 125:1 130:4 140:6 141:13 157:13,17 168:21 172:21 176:7,21 177:21 178:9,15 181:17 191:6,22 216:2 225:1,15 227:2 227:4,15 233:12 242:20,22 246:11 248:5 255:5 257:12 258:10.20 260:13.14 261:10 265:22 267:6 268:10 277:15 283:7 301:4,6 308:19 332:2 332:13 334:7 351:6 351:18 355:3 375:17 380:11 381:2 389:17 392:2,12 394:11 401:6 406:9 407:7 408:11 backed 230:5 background 19:5 21:11 39:4,13 65:3 112:22 126:9 127:15 backgrounds 22:7 **bad** 69:18 245:18 325:11 **badly** 108:8 balance 124:5 242:16 balancing 124:7 band 108:18 bar 261:3 base 83:12,13 134:14 based 4:7 13:4 30:20 51:10 55:16 60:10 83:15 84:7 85:13 97:10 102:16 113:13 113:19 125:3 126:15 127:9,17 128:4,7 139:14 143:8,12,12 144:7 145:12 146:1 147:2,5,8,9,13 182:16 184:18 213:1,3 226:12 230:9 288:7 293:2 302:6 314:1 336:5 362:1 basic 312:13

basically 27:19 29:9 94:13 95:12 96:21 102:20 103:1,14 144:12 176:4 222:16 261:8 320:5 391:20 basing 200:13 basis 69:18 294:7 304:13 bathroom 353:18,18 379:10 battery 167:4 257:8,9 bear 80:19 Becky 17:17 72:13 74:3 122:16 169:17 199:21 249:6 280:3 347:14 becoming 84:22 bed 376:8 began 52:17 beginning 116:21 126:17 150:14 224:16 232:1 247:12,13,14 248:15 252:10 370:3 373.22 behalf 54:17 195:9 209:8 275:14.17 286:12 **behavior** 165:4 behavioral 13:20 160:8 165:5 193:20 behoove 365:1 belabor 322:11 belief 38:7 believe 11:20 15:1,12 16:16 58:17 68:21 69:2 78:11 85:14 93:8 97:9 102:15 110:3 130:9 157:2 212:17 290:18 299:9 300:11 307:13 311:7.9 312:6 312:10 314:13 316:22 317:5 319:8 321:6 323:11 366:16 373:13 400:15 401:7 believed 62:13 believing 376:2 belongs 150:5 benchmark 320:5 benchmarks 361:18 396:4 beneficial 54:10 63:20 beneficiaries 137:18 139:2 142:17 185:14 219:6 beneficiary 126:13 133:17 301:19 benefit 60:6,7 69:11 132:13 207:10 302:10 benefits 116:5,8 270:16

362:20 387:6 Berg 3:2 53:16,16 54:8 64:1 66:19 68:5 71:4 75:1,20 76:4,7,20 77:13 78:3 80:2,8,10 80:14 82:5 85:7 91:10 102:10 110:3 111:16 123:6,10,14 best 47:6 77:4 82:21 87:14 265:10 338:4 356:10 Beth 1:13 3:8 16:19 125:21 151:22 154:1 171:5 197:11 211:5 286:6 291:19 308:2 366:3 better 10:17,17 58:14 61:9,14 68:10 81:19 82:4 87:5 111:13 143:21 170:3 209:20 231:2 245:21 259:15 314:8 329:22 365:4 408:1,2 Betty 396:15 Bevans 1:13 15:3,4 156:6 186:3.18.21 187:21 208:7 210:10 223:2 beyond 22:17 171:2 261:16 bias 22:18 278:21 305:1 biasing 242:3 **bibliography** 307:14,20 **Bierner** 1:14 18:19,20 134:9,17 218:5 219:4 219:10 314:21 345:6 352:2 370:7,10 371:10 376:22 big 32:11 101:15 134:1 134:11 152:12 197:6 200:14 222:20 326:11 379:14 bigger 225:22 biggest 86:5 278:3 bill 74:16 billing 74:9 78:16 114:4 BIMS 236:14 birth 14:13 birthdate 294:16 bit 6:7 10:17 45:7 49:21 50:4,16 54:5,15 59:11 72:15 74:19 87:19 94:1 98:17 114:7 166:14 175:8,19 187:22 193:8 212:15 213:7 219:1 224:5 226:15 227:10 230:21 234:3 239:21 243:10

243:21 250:1 269:18 276:15 278:8 282:22 321:2 343:14 345:5 360:9 363:22 366:21 394:14 bless 192:12 block 193:17 247:4 248:10 249:3 blocked 248:14 blocks 12:5 Blueprint 58:2 **board** 27:16 236:20 238:8 274:1 311:10 356:5 body 257:22 bone 260:16 boosted 238:12 boot 234:13 **born** 14:4 Borun 2:6 **Boston** 12:12 bother 295:10 bottom 196:10 271:7 326:20 box 36:6 223:9 Bradley 1:15 17:16,17 54:2 64:4,9 74:4 112:8 122:17 123:9 123:13,20 169:19 199:22 249:7 251:10 251:12.21 280:4 350:4 380:18 brain 12:20 136:1,13,14 147:9 171:17 219:7 351:22 380:1 brain-injured 218:8 branches 230:22 branching 348:12 353:7 breached 171:13 break 124:13,14 131:4 164:7 168:9 173:22 180:22 338:18 Breakfast 407:4 breaking 166:5 breaks 23:11,15 breath 166:11 breathe 14:4 brick 5:19 brief 25:3 42:3 65:3 127:8 174:2 229:8 briefings 408:5 briefly 41:11 44:21 125:16 126:8 182:12 254:16 393:6 **Bright** 1:16 13:1,2 80:17 84:14,17 162:19 163:2,5

(202) 234-4433

168:20 174:16 358:11 359:13 393:6 bring 23:3 65:22 155:19 181:16 227:15.20 251:15 392:12 399:11 406:9 bringing 210:10 316:1 brings 395:21 broad 83:9 87:1 132:12 broader 63:19,20 67:17 129:3 239:21 280:14 368:6.7 broadest 362:11 broken 320:13 365:16 373:3 brought 25:20 33:18 92:19 119:16 190:15 229:11 310:8 Brown 241:5 257:13 260:15 **bucket** 91:22 164:12 buckets 163:19 164:8 164:12 173:2 183:3 183:15 201:10 budget 192:20 build 77:17 229:18 building 278:1 304:10 buildings 5:19 built 123:12,15 bulk 25:12 229:21 **bump** 356:15 bumped 252:21 **bunch** 13:10 191:21 200:18 323:16 333:6 bundle 200:18 bundled 162:4 **burden** 40:3 58:20 185:15 223:21 224:2 297:9,18 307:14,18 344:20 350:14 381:4 398:8 BURSTIN 2:14 **busy** 300:1 button 73:7 buttons 73:6 С CAHPS 32:16 129:13 133:20 152:15 156:14 164:21,22 166:7 229:15,17 245:14,15 249:9,13 250:3,13 260:1 280:22 399:7,8 399:9 calculate 44:20 238:15 245:20 259:18 calculated 186:9,11

calculating 199:4 248:13 calculation 300:10 calculations 213:3 288:1 California 1:22 2:11 15:22 18:4 144:11 California's 143:5 call 9:22 12:14 19:10 26:20 39:20 42:1 43:3 45:16 53:1 120:1 165:4 181:19 323:14 355:11 374:16 called 15:21 16:2 223:8 307:14 340:10 352:5 408:12 calls 25:6 cancer 60:12 61:5 **Candidate** 4:5,7,9,15 capable 362:8 capacities 312:11 capacity 304:7 306:21 **Cape** 12:9 capitalize 378:8 capture 373:16 captured 229:21 231:10 315:5 373:18 capturing 245:22 258:15 260:2,7 341:11 383:14 card 24:21 76:12 90:15 123:21 254:19 265:4 cardiovascular 58:7 cards 43:2 208:3 care 1:3,20 3:5,11 4:12 4:16,17,18,19 10:10 11:4,5 12:16,17 13:19 13:21 14:9,14 15:17 16:9,21 17:1,3,11,11 17:15 20:12 32:17 35:7 39:20 40:4 55:15 55:20,21 58:3 60:7 61:2 76:18,20 77:2 81:8,14 82:17 83:19 83:21 84:22 86:10 89:7,17 90:11 91:5 107:13 111:10 117:3 125:4,18 127:21 128:4,9,11 129:3,12 129:16 132:16 137:19 139:2,11,19 140:1,16 140:18,22 144:13,15 145:22 146:8 147:3 147:13 148:11 162:12 171:14 184:18 185:2 191:16,18 192:1 196:20 202:10 203:20 229:10 230:17,20

232:17,18 237:6 240:5,10,11,18,19 263:13 264:1,7 270:1 274:6 284:10,22 286:15,22 288:2,4,19 292:2 294:1 296:6 297:13,16 298:12,18 298:21 299:21 300:5 300:6,9,13 301:5,6,6 301:18 303:22 305:22 306:14 307:2,3,9,14 307:19 308:9 309:21 310:2,4,18 311:4,10 313:17,20 314:8 315:2 316:18 318:12 343:19 345:14 348:19 348:20 364:16 365:1 365:4 367:18 368:3 370:2,6,19,22 371:21 372:5,5,8,18 373:7 374:12 375:21 376:4 376:20 379:3 381:4 382:6 384:14 386:16 careful 185:15 215:5 caregiver 381:19,20 382:1 caregiver's 200:5,12 caregivers 145:20 152:10 224:3 382:8 Carin 2:10 15:15 54:2 60:22 carried 401:20,21 case 17:19 49:4 93:8 107:7 116:6,16 117:5 142:14 157:8 158:12 159:8 180:2,13 181:5 181:12 194:19 211:22 215:20 297:1 301:14 308:5,10,11 309:1 315:10 325:4 334:20 355:15 357:15 359:11 366:20 376:19 cases 52:8 180:3 213:15 240:22 259:21 265:11 294:10 296:20 335:15 337:10,11,12 388:16 Castle 3:3 228:11 229:11 247:16 248:20 256:9,16 257:3 258:4 259:14 263:7 268:2 284:10 catastrophic 58:11 catch 297:12 catching 166:11 categories 132:18 380:15 category 100:6 205:19

248:17 277:20

206:11 269:17 caused 106:20 causes 112:3 202:2 causing 38:22 191:1 262:4 caution 346:3 cautious 311:6 CBS 128:10 **CCAT** 40:15 **CDC** 57:16 ceiling 189:13 190:1 223:7 cell 23:20 70:17 Cella 1:16 19:19,20,21 54:1 59:4,6,10 60:16 72:14,14 83:7,7 89:12 98:22,22 100:5,5,12 106:4,16,19,22 107:20 109:12 110:7 115:5 116:1 117:16 118:10 121:18,22 173:7 Center 1:15,18 2:6,8 16:10 18:22 65:11 379:20 centered 1:3.20 14:9 39:20 128:11,11 288:19 **Centers** 3:6,9 cert 157:22 certain 70:8 78:20 111:20 114:3 145:22 146:7 152:20 322:8 341:12 certainly 29:22 80:20 81:2 104:19 114:8 184:22 188:11 225:6 243:4 294:3 296:16 297:22 298:6 299:5 303:6 304:6,12 305:11 308:11 312:18 314:6,10 320:2 321:7 322:13 324:6 338:12 346:9.13 361:13 364:20 366:22 372:2 373:11 380:4 388:15 388:22 390:21 certainty 105:10,18 certification 290:13,17 290:22 certified 139:10,20 344:15 cetera 6:1 26:7,18 36:8 36:10 58:7 67:1 71:8 78:1 87:7 88:11,11 93:1 132:20 150:6 157:16 196:19 385:1 CG 166:7

chair 18:20 376:8 407:15 Chairs 9:21 23:5 challenge 349:4 challenges 193:22 challenging 243:22 chance 237:6 Chancellor 18:3 **change** 4:11,11,13,13 4:14,14,16,16,17,17 4:18,18 36:8 44:22 47:22 87:12 89:8 101:13 153:19 161:5 161:8 176:2 246:22 266:5 284:22,22 285:1 286:5,5 292:2 294:4 299:3,7 303:4 303:11,15 305:7 308:9 318:11 321:21 332:17 352:6 355:14 356:17 365:5 372:22 375:21 378:12 380:20 381:1,6,12 384:13,13 387:20 407:19 changed 21:16 25:17 25:19 29:2 100:10 120:2 330:19 405:10 405:14,22 changes 63:12 120:6 303:12,17 322:2 356:17 366:6 371:16 373:18 378:8 changing 280:15 396:7 characteristics 28:8 57:17 237:22 262:19 344:12 364:7 charge 41:2 287:1 336:15 chart 50:19 56:11 80:2 charts 353:7 **Chase** 12:6 chat 45:4 95:2 173:17 cheat 232:6 checked 191:16 checking 285:22 **cheek** 240:4 cherry 161:2 Chevy 12:6 **Chicago** 20:9 Chief 2:14 53:17 **child** 194:2 children 11:4 14:13 15:9 63:14 64:3 children's 1:13 11:1 15:6 18:7 chime 254:18 292:1 293:13 297:6 chiropractic 77:22

91:16 92:1 chiropractors 93:1 113:12 123:17 choice 44:21 162:4,8 162:15 235:2 244:21 choose 158:3 159:6 162:11 257:19 291:14 361:8,9 choosing 162:1 185:13 215:22 **chose** 235:13 Chris 5:21 10:20 24:22 52:4 72:12 107:15 109:20 132:4,22 155:21 164:17 225:13 407:11 Christopher 1:9,12 chronic 57:15 58:4,6,9 58:13,15 60:11 62:8 63:18 66:18 117:5 chunks 182:13 193:2 197:2,7 circumstance 101:14 327:6 circumstances 354:2 cite 252:12 cited 74:5 citing 89:5 357:1 city 10:7,9 14:1 17:9 claim 51:13 claims 51:12 74:10 91:14 102:17 103:17 113:13,19 114:6 123:5 claims- 51:9 clarification 30:15 63:16 137:17 162:20 183:1 249:8 280:19 315:14 clarified 42:21 clarify 31:15 48:2 49:19 63:21 107:6 122:17 151:3 153:6 161:22 175:21 180:2 194:14 254:21 361:5 clarity 290:10 399:19 Clarke's 408:13 class 326:7 337:17 classic 268:9,16 classification 91:15 cleaner 227:11 clear 33:6 37:12 48:4 56:8 78:10 84:9 94:5 102:19 103:9 107:4 120:10,11 137:20 142:21 145:9,11 152:18 181:19 210:13 227:5 230:4 241:8

246:17 315:9 322:9 331:22 334:18 355:21 397:1 clearly 43:10 116:20 149:10 256:19 293:22 301:3 378:10 391:9 click 369:3 clicker 44:12,14,17 318:8 clickers 45:5 clients 11:18 13:15 clinical 17:2 21:15 39:3 55:12 57:11 61:11 71:12 84:2 89:4 262:15 349:2 375:17 clinically 236:6 391:5 clinician 63:3 77:4 101:18 110:17 347:4 349:5 clinician-based 30:22 **clinicians** 107:10 110:19 112:11 300:1 346:10 350:1,19 clock 94:1 124:18 Clohan 3:4 287:9 308:21 315:13 349:2 361:15 375:16 378:16 401:1 close 43:9 124:15 126:5 129:16 154:19 260:15 287:3 367:5 closed 95:5 97:21 98:3 99:18 106:11 114:21 115:16 117:22 119:9 199:13 203:7 204:2 204:19 205:12 206:2 206:15 220:15 221:7 221:19 222:7 254:12 255:17 264:20 269:12 270:6,21 283:15 284:3 318:19 323:5 339:9 342:20 344:4 363:4,16 369:5,6,12 369:18 384:20 385:11 385:20 386:12 387:1 387:13 388:1 402:8 402:19 406:5 closer 65:22 73:1 CMG 338:14.15 **CMS** 14:17 49:11 53:14 54:17 55:2 65:13 69:6 77:19 78:9 93:7,15 114:6 122:18 125:4 125:11 126:4 128:4 159:21 214:7 249:16 250:17 271:14,20 281:12,12 287:18 288:15 289:21 290:16

			414
	I	I	I
290:19 291:13 301:15	212:5 213:13,19	188:18,20 208:10	148:15 277:21 341:4
344:16 350:22 353:6	214:15 218:4 219:15	209:19 210:3,4,18	398:9
358:22 361:7 365:10	220:2,19 221:10	223:3 225:5 236:4,11	comment 4:8,21 46:1,7
395:22 399:10	222:10 223:5 224:13	239:21 241:8 245:9	47:18 63:2 70:6,7
Co- 9:20	227:17 228:6,17	267:19 268:3,6,15	95:21 99:4,7 106:3
Co-Chair 1:12,12 5:3,15	232:4 233:14 235:18	298:18 299:1 315:7	116:12 119:20,21,22
10:2,19 38:15 47:16			
	242:19 243:1 249:5	cohorts 280:15	120:5 121:18 124:2
50:13 52:4 53:22 59:3	251:22 252:7 253:3	collapsed 245:17 246:1	157:12 163:17 168:8
59:8 60:14,20 63:21	253:14 254:2,15	colleagues 42:22 60:21	171:9 173:5,9,11,12
64:2,6 65:19 66:9	255:1,21 262:5	64:10 126:4 132:8	173:14 178:14 181:15
67:20 69:14 72:12,13	264:10 265:2 268:22	369:22	181:19 183:18 193:9
74:3 75:15,21 76:6,9	269:16 270:10 271:3	collect 232:1 241:16	200:1 218:5 227:1,16
78:8,14 79:6 80:15	272:7,18 274:17	277:14 295:7 299:19	247:17 267:16 281:6
84:12,16 85:18 86:12	280:3,17 281:16	299:20 311:12,12	292:21 308:4,22
87:17 90:15 91:8 92:5	282:3 283:6,12,17	382:20	340:7 345:5 350:5
93:2,22 96:10 98:5	284:5,14 285:13	collected 50:9 81:10	368:12 375:17 379:15
99:3,6,12 100:22	286:2 289:4 290:11	231:21 278:7 288:8	383:4 388:4,6 390:6
101:10 105:5,22	291:19 297:4 299:11	301:7	392:14 401:9 402:22
106:17 107:15,17		collecting 44:15 92:15	403:3,5,6,17 406:13
	305:6 306:1 307:11	244:14 251:17 279:21	commented 122:5
109:10,20,21 110:14	308:2,17,20 313:8		
114:12 115:8,21	314:20 317:21 318:6	280:1 297:10 391:1	245:8
116:10,14,17 118:6	318:22 319:21 320:4	401:3	comments 41:17 42:12
118:11,16 119:2	320:8,17 321:13	collection 31:17 50:18	46:2 53:3 54:11 63:1
121:20 122:10,16	322:15 323:9,18,22	78:17 153:2 270:2	63:7 65:4 68:8,11
123:21 124:8 125:1	324:3,9 326:4 338:2	288:10 300:22 340:20	69:16 98:14,18 99:13
127:3 130:7,14,17,19	338:20,22 339:13,18	343:20 365:20 367:11	101:1,8 115:9,22
130:22 131:3,22	339:21 340:13 342:6	386:17	118:8 119:15 121:6
132:1,3,5,6 133:15,19	343:2,4,9,10,13 344:7	collective 190:16	121:15 131:6 137:8
134:16,19 135:8,10	344:9 346:1 347:11	Colorado 10:22 11:1	137:11 154:7 173:16
135:11,16,21 136:18	351:3 353:10 356:19	379:20	173:19 195:22 218:15
136:22 137:10 140:8	360:8 362:13 363:8	Columbia 19:15	224:20 232:14 233:16
141:12,20 142:3,7,8	363:18 366:3 367:6	column 103:6	252:1 254:17 256:1
144:22 145:14 146:14	368:11 369:21 370:9	combine 236:9	265:3 269:20 270:11
146:19 149:2,4 151:2	373:19,22 374:3,6,10	combined 50:12	283:9 285:12 308:18
151:21 153:12,15,18	376:18 377:8 380:7	Combining 130:19	318:5 323:17 327:16
154:1,8,11,16,21	382:13 384:10,22	come 39:16 50:15 53:4	343:15 345:7 347:17
155:2,13,14,16 156:3	388:9 389:12,18,21	54:9 62:17 65:1 73:15	367:6 371:11 372:17
158:4,6,16,18 160:4	390:10 394:5,18	81:15 94:9 119:21	380:18 382:14 388:8
160:11,17,19,21	397:3,11 398:4 400:6	143:7 150:10 162:13	403:17 405:4 406:16
161:18 162:17 163:1	401:7 402:2 405:5,18	172:21 175:13,14	commercial 5:13
163:4 164:11,19	406:15 407:13,14	176:20,21 177:21	Commission 17:13
165:16,22 166:10	Co-Chairs 1:9	178:9,15 216:2 225:1	73:12 87:12
168:3,18 169:17	Co-Chairs' 47:3	242:13 308:12,19	committed 407:10
171:7 172:19 173:8	co-investigator 20:8	319:13 334:6 349:19	committee 1:8 6:9 8:4
173:21 174:7 175:18	coalesce 13:10	350:13 359:17 360:3	8:20 9:2,5,7,11 17:14
177:1 178:17 179:13	coalition 13:7	361:2 379:12,17	17:15 20:1,13 30:9
179:14,16 181:20	Cod 12:9	389:17 399:9,12	33:20 41:12 43:11
182:11 183:5,21	code 74:9,9 76:15	comes 37:15 79:14	45:9,12,17 48:19 53:6
185:20 187:18 189:8	78:11,16,17,17 79:4	183:18 395:8	65:15 69:5 76:10 82:1
191:4,6 193:3,6,14	308:12	comfort 51:17 278:5	89:17 95:1 110:5
195:21 196:11 197:1	codes 56:9 79:3 92:3	397:5 400:10,20	116:13 122:7 157:6
197:17 198:5 199:2	coding 56:1	comfortable 50:20,22	157:10 174:18 175:16
199:17 200:15,22	coefficient 109:3 329:1	154:17 176:19 180:11	198:22 288:19 315:17
201:8,12,14,21 202:1	coefficients 102:6	212:10,11 258:20	324:22 330:4 332:19
202:20 203:3,10	217:14 223:1 235:1	273:2 332:20 380:12	389:3 390:12 393:1
204:6,10,22 205:4,16	256:6 257:1,17 326:8	390:12	393:11 394:20 396:17
206:3,6,8,19 207:7,15	337:18 395:8 397:15	coming 8:18 30:13 32:6	400:11 401:3 404:2
207:18 211:1,4 212:3	cognitive 136:5 152:5,7	32:14 33:3 47:8 76:8	404:12 405:1
,			
н			

committee's 47:20 375:18 committees 22:8 177:20 361:4 common 159:1 286:22 288:5 316:22 **commonly** 61:18 communicate 184:14 282:10 332:2 communicated 261:13 332:1 334:20 communicating 330:1 331:9 332:16 communication 215:20 312:14 397:19 communications 382:7 communities 170:1 community 4:7 13:7 17:4 19:6 76:16 77:14 78:4 125:3,12 126:15 127:9,12,17 128:4,6 139:14 143:8,12 144:7 147:2,5 148:6,8 149:1 166:14 171:12 193:21 233:13 241:12 242:12 301:4 367:21 379:5 community-184:17 community-based 171:15 179:4 companies 13:17 company 13:3 16:1 118:8 comparability 269:8 342:14 386:7 comparable 209:15 comparative 13:14 198:3 351:10 394:13 compare 139:1 150:19 151:1 211:15 251:9 288:4 298:9 310:17 316:14 325:8 352:11 359:20 394:21 compared 49:7 101:18 211:8,10,11,13 217:15 249:20 256:13 256:14 337:6 356:2 371:7 395:7,17 compares 271:12 comparing 83:1 317:10 330:16,20 350:10 comparison 52:16 280:20 288:6 359:16 362:12 395:6 408:4 comparisons 217:16 395:12 competency 240:14 competing 4:20 36:14

36:15,20 37:2 87:19 87:20 120:18,20 280:20 compiled 384:3 complete 248:12 292:22 297:19 373:17 completely 124:5 239:3 368:5 completing 378:14 complex 117:6 373:15 377:7 complexity 315:3 compliance 12:8 400:2 complicated 196:7 398:10 component 61:8 146:4 183:3 209:11 291:5 components 149:21 196:5 298:13 composite 48:5,7 147:19 186:10 207:20 217:22 218:1 225:22 365:21 composite's 50:2 comprehension 268:1 comprehensive 252:14 compressed 390:5 compromised 234:2 **computer** 24:8,13 44:17,19 concentrated 111:22 concentrating 111:19 concept 48:12 92:10 124:2 155:20 169:16 262:14 290:5 concepts 41:9 conceptual 29:10 252:9 concern 42:16 184:19 208:8 262:1 276:2 278:3,13 297:14 300:2 304:17 305:7 311:1 312:1 315:15 327:9 347:21 353:11 359:16 382:18 383:13 399:21 concerned 73:11 208:15 234:3,5 236:3 240:7 275:7 301:22 302:3 326:5 360:1 371:15 concerns 63:9 64:10 70:3 163:13 164:15 235:10 239:20 256:2 348:8,21 372:19 383:4 404:13 concise 289:5 conclude 94:2 105:15 235:16

conclusion 359:9 conclusions 218:14 316:16,19 concurrent 298:7 388:18 condition 67:2 conditions 58:9 75:8 117:6 conference 1:8 26:20 confidence 354:5,11 **confirm** 80:3 confirmatory 226:13 conflict 8:11 9:13,17 12:14 18:17 21:18 22:15,16,22 conflicted 192:22 conflicts 10:11 11:6,20 12:4 15:12,18 16:5,16 17:12 19:2,9,17 20:2 20:19 65:5 confound 149:16 confounder 28:10 confounding 151:8 confused 87:19 118:17 123:1 140:9 149:7 389:2 confusing 74:11 confusion 32:9 49:21 connect 359:1 connection 75:11 306:4 cons 174:19 175:17 consensus 45:8,15,18 46:3,9,10 85:2 95:18 118:19 119:17 181:13 201:9 204:6 207:3.12 368:12 391:22 401:15 404:9 consenting 196:22 consequence 70:12 116:4 309:7 consequences 88:8 116:15 270:17 310:12 362:21 387:8 consider 28:21 29:3.15 32:21 49:10 132:19 152:9 175:7,16 177:2 177:11 178:2 191:15 214:6 273:7 303:1 390:8 considerable 175:5 202:8 203:17 252:17 255:10 322:19 385:4 considerably 100:11 consideration 4:5,7,9 4:15 27:13 58:21 65:14 129:21 169:6 174:20 188:19 189:1 198:1 209:16 288:21

389:14 392:20 considered 45:8,15 109:4 131:17 197:19 209:15,15 234:17 considering 21:20 53:5 84:10 164:13 166:18 171:21 209:12 228:1 368:14 consistency 233:22 325:21 326:10,15 333:14 334:8,9 350:14 393:4 consistent 128:9 195:14 269:5 342:11 349:12 353:17 356:14 361:21 378:17 379:1 386:4 398:14 401:12 consistently 60:7 83:20 83:22 153:11 353:19 consolidating 169:6 consolidation 214:8,13 constantly 33:13 constitute 18:17 constitutes 56:10 **construct** 48:4 49:22 97:4 165:12 216:16 216:17 225:19 346:18 constructed 216:7 construction 5:7 54:6 **consult** 14:22 Consultant 3:4 **consulting** 9:8 13:2 16:1 consumer 11:9 12:20 144:12.17 consumer's 143:15 content 188:5 **context** 27:8 38:19 63:20 86:7 166:6 344:10 continue 58:4 60:22 69:1,3 84:19 95:17,19 130:6 178:6 181:8,9 182:2 198:6 203:11 204:9 222:12 281:8 353:9 368:7 continued 128:20 258:9 continues 26:15 45:20 45:20 continuing 68:22 176:7 404:17 continuum 372:9 contract 55:2 65:13 147:12 159:18 contracted 159:17 161:15 contractors 135:3 contracts 140:12

159:11 contrast 288:4 contrasts 271:13 contributing 109:2 240:16 241:22 control 146:9 192:19,20 262:17 263:2 **controlled** 82:10,14 84:2 controversial 273:20 convened 26:21 34:19 conversation 24:1 31:7 79:19 86:17 95:17 100:14 107:1,2,5,11 108:1 120:18 122:18 161:5 212:15 274:16 332:14 conversations 24:2 26:8 31:6 403:11 convince 84:15 coordination 313:20 Coordinator 129:18 COPD 40:17 cord 380:1 core 2:9 229:14 CoreQ 4:10.10.11 229:8 243:11 252:3 254:4 271:10 **Coretta** 3:10 125:22 171:5 corner 7:6 24:4 **Corporation** 1:15 17:19 20:19 correct 32:5 48:20 49:2 49:8.14 50:3 56:12 60:19,20 118:22 119:1 133:12 158:5 218:16 219:14 262:9 266:12 274:22 275:9 291:11 297:3 306:3 347:10 357:3,16 358:9 401:16 correctly 70:1 121:10 124:18 133:11 282:6 285:2 332:1 390:1 correlate 122:15 169:11 250:4 314:1 correlated 257:10 258:17 317:13 354:22 correlation 85:5 102:6 217:14 222:22 235:1 256:6,22 257:16 258:8 262:21 266:18 267:3 326:7 337:17 395:8 397:15 correlations 235:12 244:6 265:19 266:5 323:14 324:20,22

325:18 354:21 cost 74:7,11,13 314:10 347:20 costs 74:22,22 councils 14:21 16:12 Counsel 2:15 6:16 8:6 count 44:18 279:6 297:2 325:4 366:21 375:6 counted 193:11 218:10 266:11 counter 391:6 country 6:5 14:20 20:6 138:3 239:7 counts 391:12 **County** 15:17 couple 6:6,7 23:10 25:5 36:17 42:10 69:16 119:14 159:5 172:21 175:19 208:1 209:1 232:12 235:21 292:9 293:13 319:3 323:13 324:11 332:5 347:4,5 405:9 course 46:16 178:6 185:3 208:14 248:12 312:7 347:19 391:12 court 275:4 coverage 309:19,20 covered 318:3 covering 132:18 CP 278:18 **CPE** 3:2 CPHQ 2:5 **CPHRM** 2:1 **CPT** 79:3 CPXP 2:1 Craig 379:19 crazy 214:18 create 187:4 302:14 created 306:6 353:5 creating 217:21,22 294:16 credentialing 350:8 373:10 criteria 25:7,16,17,19 25:21 26:1 30:3,8,10 31:10 33:10 36:3 41:17 43:13,18,20,21 45:21 46:6 59:14,17 73:22 83:9 98:9 140:3 155:22 176:16 177:5 180:8 181:7,10 192:14 202:18 203:20 204:15,16,16 208:21 254:22 300:12 309:19 393:7 criterion 59:19 106:15

119:11 177:13 critical 55:18 132:21 171:20 368:5 400:4 critically 208:21 210:14 criticism 63:2 68:7 69:5 Crocker 396:15 Cronbach's 324:19 328:5 354:19 cross 1:17 16:7,8 126:12 273:12 274:12 280:11,18 281:5 338:14 399:22 cross-section 185:17 crosscutting 348:9 crossed 98:17 crucial 61:10 crummy 111:9 217:9 crunching 226:1 CSAC 31:7 33:21 38:17 41:19 curate 20:4 cure 178:8 224:21 curious 90:22 266:17 292:13 293:6 current 20:22 26:10 69:13 111:10 128:16 151:1 172:7 243:7 244:13 247:3 407:18 currently 13:15,16 16:8 17:18 18:5 19:5 25:15 32:13 111:11 122:20 167:6,7 231:20,21 236:19,20 253:7 348:16 359:2 365:8 398:15 customer 162:7 231:5,9 231:17 cut 47:6 60:15 186:11 226:7 382:15 cutting 399:22 D **D** 4:1 **D.C** 1:9 5:4 12:6 Dan 78:9 85:19 93:14 **DANIEL** 3:6 Dann 3:4 286:10,11 289:20 290:8,16 291:12 307:12 353:1 359:11 361:5 dark 109:22 dashboard 157:22 data 26:3 31:2,16 32:18 33:14,16,17 34:2,4,8 34:11,12,16 50:17 51:10,11,13,15,20,22 56:1 59:20 60:7 62:16 78:11,17 79:3 81:9

91:9 93:6.11 101:19 102:16,17,21,21 103:11,17 115:6 116:6 128:21 129:11 137:3 153:2,7,15 155:5 160:12 169:20 170:4,15 175:1 186:4 190:2 193:4,4,4,11 194:8 195:11 198:3 202:7 203:17 208:19 209:10 213:22 217:2 225:9,12,16 226:17 227:15 241:16 242:3 255:9 257:18 269:9 269:22 270:2 276:3,9 279:21 280:1 287:7 288:8,10 291:2,4,13 292:9,22 293:1,7 294:7,19 295:7 297:8 297:18 300:22 301:7 302:21 310:16 313:2 313:3,9 317:2,10 321:20 322:6,7,19 323:12 324:17 325:6 325:17 330:6,11,19 330:22 331:1.17 332:21 334:4,19 335:8,14,18 336:6,11 336:20 337:9,15 338:7,9 339:17 340:2 340:16,20 342:4,15 343:18,20 351:8,10 352:8 362:3 365:20 367:11 370:15,20 371:3 374:13.14 376:12 382:21 383:19 384:2,7 385:3 386:8 386:15,17 389:7 390:7,17,22 392:7 393:12,14,16 394:11 394:13 397:6,20,22 404:6,14,21 406:9 database 391:3 date 40:13 55:14 134:20 daughter 14:2 147:1 148:13 278:18 Dave 72:14 83:7 98:22 100:5,9 106:21 121:22 281:10 David 1:16 3:5 19:18,21 54:1 59:3,4 60:15 89:12 107:16,17 115:22 118:8 121:20 232:6 David's 99:4 109:22 110:16 Dawn 1:18 19:11,12,14

202:13,20 221:21 285:15 286:7 297:4 day 5:4 138:11 191:19 279:9 305:17 316:13 377:16 382:11,12 401:12 407:2,7 daycare 162:14 days 52:5 225:4 249:12 **DD** 140:13 deal 32:11 227:9 299:6 312:19 334:21 336:9 337:8 381:21 388:14 392:21 dealing 31:9 91:4 396:6 Deanna 3:7 403:6,8,21 death 300:6 **Deb** 20:16 96:7 97:13 114:18 143:3 144:22 199:6,7 242:20 248:7 254:18 267:15 268:3 268:20 276:1,20 285:15 402:16 Deb's 247:17 debated 289:22 debilitated 377:1.6 Debra 2:6 20:15 decent 247:18 decide 177:3 179:21 182:3 193:17 295:6 364:1 decided 5:10 40:20 131:10 168:4 180:6 deciding 239:1 decision 45:19 48:8 120:9 156:21 227:3 273:1 336:17 decisionmaking 18:15 40:2 179:18 decisions 21:21 22:1 declare 17:7 declared 22:16 decline 372:4 decrease 64:20 75:9 124:4 303:5 304:6 305:19 decreased 64:16 67:16 303:9 decreases 305:15 decreasing 67:10 deems 145:22 deeper 278:14 defect 14:14 defer 167:9 176:6 177:4 177:11 180:6,7,20 181:22 182:5,15 193:18 287:13 389:13 deferment 175:7 176:1 176:9,14,14,15 177:3

177:19 227:4 deferral 179:19 224:22 389:16,16 390:14 **deferring** 174:9,20 175:17 defined 103:14 defines 77:19 defining 55:12 definitely 23:21 171:22 172:16 214:5 280:12 393:20 397:9 405:12 definition 56:8 230:13 359:6 definitions 56:9 96:19 degree 34:13 325:21 360:19 372:14 393:10 delay 179:7 deliver 283:3 delivering 196:17 delivery 16:21 127:7 demographic 26:22 51:11 demographics 280:14 280:16 366:9 demonstrate 111:4 299:3 404:15 demonstrated 202:8 203:17 224:9 252:18 255:9 270:16 322:19 350:3 362:20 385:3 387:6 demonstrating 85:5 demonstration 110:18 126:19 128:18 129:20 153:1.1 170:22 175:10 demonstrations 128:17 denominator 57:1 92:3 134:12 273:21 Denver 379:20 department 7:22 18:20 159:13 depend 336:2 dependence 373:17 dependency 377:5 dependent 371:12 dependents 371:14 depending 46:5 215:2 259:19 282:22 345:19 depends 135:2 147:15 223:10 226:18 335:18 336:1,22 depth 233:2 deputy 126:5 derived 353:3 Des 283:7 descendent 229:16 describe 55:12 224:5

268:16 described 23:2 142:15 404:12 description 210:13,22 deserves 69:8 **Desi** 7:3,7 44:15,17 94:14 101:2 114:13 115:9 198:5 201:21 220:2 254:2 255:6 264:12 270:12 272:10 402:2 design 16:14 72:9 82:17 designed 63:14 75:5 82:9 195:20 desirable 309:10 **Desmirra** 2:19 7:6 despite 97:6 detail 55:11 86:21 191:7 192:3,8 226:15 320:19 detailed 8:13 224:8 details 231:4 detect 88:2 371:16 deteriorate 310:6 deterioration 301:21 310:4.7 determinations 334:9 determine 56:12 70:21 70:22 82:11 147:19 172:5 358:20 determined 352:22 determining 55:19 77:5 321:10 develop 14:20 20:10 61:4 68:22 82:14,21 117:14 178:22 229:12 developed 5:11 18:9,10 18:13 41:6 55:1 66:21 74:15 75:22 79:4 111:11 125:4 126:10 126:16 236:15 251:14 251:15 284:16 287:15 295:16 377:17 developer 42:21 44:7 54:18 65:12,16 68:1 157:6 163:7 176:2,8 176:10 177:16,21 180:9 181:15 331:11 developer's 35:2 developers 11:20 28:3 28:3 31:9,12 34:10 36:5 40:20 42:3,18 47:9 52:18 53:7 62:3 111:2 120:3 121:9,15 125:8 132:7 168:22 176:19 178:3,9 180:13,16 181:11

207:11 222:13 233:18 256:4 261:13 286:8 324:4 332:16 396:14 396:21 400:21 developing 21:1 62:9 82:16 117:3 129:19 229:14 development 12:3 13:14,18 15:10 18:6 123:19 126:21 224:7 224:12 244:10,11 287:6 293:19 developmental 135:22 developmentally 194:1 develops 15:7 deviation 189:19 190:8 deviations 189:14 Dexanne 3:4 287:9 diabetes 13:11 58:7 diagnosed 63:18 diagnosis 66:20 diagnostic 338:9,11 dialed 24:9 dialing 47:8 dictate 407:18 die 236:6 240:20 292:19 died 58:12 241:14 300:13 dies 240:5 293:22 difference 26:13 39:15 42:17 48:16 50:4,7 108:2 169:1 189:20 189:21 195:1 200:11 234:15,17 248:7,9 263:2 274:9 315:11 329:13 404:10 differences 30:2 46:20 111:4,5 190:17 193:4 195:18 197:6 209:7 211:16 212:2 219:18 222:19 223:1 263:17 263:21 264:2 269:7 326:11 342:13 375:11 375:12 386:6 different 11:17 16:15 30:11 38:4,7 39:13 88:6 103:3 114:7 117:12 121:4 130:8 130:20 131:14 137:2 139:2 143:14 145:20 145:21 150:21,22 152:1 156:1,15,16 163:11 164:10 172:1 172:2,14 182:13 185:5,8 194:9 200:5 211:10,12,21 212:7 214:22 225:9 241:16 244:10,19 245:9,20

246:2,3,4,6,7,9 247:6 247:15 255:3 259:10 259:16 279:18,20 282:22 293:18 298:3 298:15 299:9,15,17 300:5 310:18 313:19 314:2,11,12 315:2 316:2,6,7,17,18 324:11 338:19 348:17 350:1 360:3 365:14 395:18 398:20,20 404:1 differentiate 163:7 311:22 differentiated 314:5 differentiating 107:9 differently 39:8 150:17 169:10,14 247:7 268:12 405:11 differs 280:1 difficult 63:8 68:8,14,20 71:14 82:13,21 83:4 104:12 236:12 237:18 302:22 303:1 406:18 difficulties 202:3 difficulty 104:10 304:10 dig 211:20 278:14 digging 65:21 dilemma 329:5 dimension 235:6 diminished 85:13 diminution 362:7 dinner 406:20 407:1 direct 160:2 direction 73:14 87:8.9 117:12 122:9 245:4 265:8,12,20 266:12 266:21 267:5 303:18 directions 41:19 directly 20:2 23:6 126:22 144:16 158:20 315:5 382:1 director 2:21 6:12 12:8 12:10 15:22 16:8 17:18 19:1 112:21 126:5 132:9 134:21 286:11 287:2 disabilities 135:20 136:1,5 171:18 disability 11:15 126:12 147:9 171:11 disabled 125:13 135:18 135:19 136:3 148:7 194:2 disabuse 359:9 disadvantage 302:15 disagreement 209:6 discern 51:20

discharge 4:10 228:21 229:2 230:8,18,19 242:11 249:2 250:15 252:4 254:4 282:8,16 292:3 294:1 301:2,3,4 319:10,20 355:9,14 365:6 378:13 discharged 233:12 292:16 371:14 378:6 379:2,13 discharging 242:16 discipline 346:21 disclose 9:4,4,13,18 10:11 11:21 15:2,19 16:5,17 17:22 disclosure 4:3 8:12,15 65:15 394:19 disclosures 6:14,18 10:1 11:6 16:5 22:6,8 65:4 discomfort 183:9 336:12 discovered 42:14 317:12 discriminant 395:14 discriminate 111:14 260:21 395:2.3 discriminates 110:18 discriminating 216:20 discriminative 111:14 discuss 22:10 43:12 54:20 74:1 120:1 154:12 168:9 174:19 175:18 179:20 207:16 343:2 405:11 discussant 42:9.10 52:7 145:6 146:15 232:5 372:17 374:9 discussants 54:1 98:13 99:4 100:1 125:5 131:19 137:8,12,12 154:13 184:7 207:22 243:2 252:2 273:9 285:8 286:6 289:7,15 291:20 339:15 discussed 42:7 59:18 59:19 131:5 273:1 380:15 discussing 40:6 132:14 discussion 4:20 26:4 41:2,13 42:11 45:20 46:15 47:6,12,15 51:2 59:1 85:8 95:19 98:7 109:9,11 116:19 121:12 124:9 125:2 130:5 131:9 145:12 156:22 158:14,17 161:7 168:5,8 174:11

174:15 176:6 177:6 178:20 179:8,9,12 180:1 182:1,12 184:8 191:21 197:4 207:10 207:21 209:3 219:16 222:12 224:16,19,22 227:6 232:3 233:3 255:4 272:22 273:18 285:5,6,9 289:6 313:1 318:3 322:15 323:10 342:6 343:14 363:10 363:19,22 366:14 368:15 370:5 375:18 389:6.22 403:18 404:12 discussions 25:7 30:1 30:8 37:2 46:22 98:19 164:10 175:14 181:9 198:7 336:5 401:21 401:22 402:1 406:16 407:6 disease 58:6,7 60:11 70:17 disjoint 81:4 disparities 27:5 37:19 38:1 98:20 99:2 202:10 203:19 253:2 disparity 74:6 display 44:21 disposition 355:14 disputing 299:15 disruption 65:18 distill 229:20 distilled 244:14 distinction 114:2 349:14 distinguish 140:21 150:8 distribute 20:4 277:14 distribution 108:21 109:1 110:2,21 111:2 111:13 321:3,16 374:20 394:10 397:6 distributions 320:21 395:19 dive 50:10 divide 187:13 dividing 197:2 division 125:12 126:6 147:4 **DiVita** 3:5 287:12 294:13 295:2,14 296:11 297:3 330:2 331:13 332:8,10 333:5,9,12 366:19 367:4 doable 253:10 377:19 doctor 287:9

document 55:10 56:14 56:17 62:12,19 87:2 183:3 302:7 332:6 333:2 documentation 77:11 89:6,7 305:12 documented 56:4,6,20 100:20 252:14 documenting 24:4 62:10 74:14,18 108:14 121:10 documents 304:15 323:16 doing 6:13 36:11 61:6 81:11,16,19 104:16 104:18 108:8,22 110:12 143:10 148:16 151:15 152:22 171:1 175:4 183:10 192:2,8 222:19 225:20,22 226:5,6 239:5 244:1 244:16 246:18 268:17 275:20 277:22,22,22 295:18 341:3 345:13 373:20 393:20,21 400:14 domain 289:17,22 290:1 domains 299:10 365:15 dominated 391:9 door 65:21 doors 258:8 doubt 124:12 279:12,15 doubting 306:12 **Dowding** 1:18 19:11,12 19:13,14 202:13 203:1 285:17 286:7 297:7 299:14 downstream 175:22 307:9 378:7 **DPT** 3:7 Dr 53:16 54:8 64:1 66:19 68:5 71:4 75:1 75:20 76:4,7,20 77:13 78:3,6,9,18 80:2,8,10 80:14 82:5,6 85:7,19 91:10 93:14 102:10 105:8 110:3 111:16 123:6,10,14 125:10 125:21,22 127:4 130:12,16,18,21 131:1 133:12,16 135:15,17,22 136:8 136:14,17,20 137:21 138:13,15,18 139:8 139:13,22 140:21 141:16 142:1,5 143:1 146:9 150:13 151:3,9

151:18 152:14 153:6 153:13,17,21 158:5 160:1,6,15,18,20 162:9 166:17 167:11 167:21 168:1 169:8 170:7 184:20 186:12 186:19,22 187:8 188:13 194:14,19,22 195:6,13,17 196:21 210:2,8 211:15 212:16 213:20 218:22 219:5,14 225:2 226:10 227:22 236:2 238:3 241:2 242:9 245:7 247:16 248:16 248:20,21 250:13 251:11,14 253:16 256:9,16 257:3 258:4 259:5,14 263:7,19 264:5,8 265:15,21 266:15,19,22 267:12 268:2,20 271:18 272:4 275:1,4,9,16,21 276:7,19,22 277:8,12 278:10 279:3,13,17 280:9 281:2 282:8.18 282:21 284:9.10 287:3,12 290:21 291:7,10 292:12 293:11 294:20 295:12 296:9.16 297:21 300:11,16,21 303:2 305:3,11 306:14 307:22 308:11,21 311:7 312:5,8 313:4 313:14,17 314:4 315:13 319:7,22 320:7,12 321:6 322:2 322:8 324:6,10 327:14,21 328:2,7,10 328:12,20 329:2,18 329:21 335:6 338:12 340:7,22 341:15,19 342:1,5 346:7 347:22 349:2 354:14 356:8 357:4,6,11,16,21 358:6,8 361:12,15 364:15 365:17,19 366:2.16 367:2 368:10 370:18 371:19 373:6 375:2,16 378:3 378:16 379:11 381:22 382:22 383:10,16 388:12 390:19 392:16 394:17 397:9 398:18 399:17 401:1 403:8 404:11 405:2 draft 267:2

dramatically 21:16 drastic 307:4 356:16 371:20 draw 111:20 120:19 316:16 392:10 drawing 218:13 316:19 drawn 277:19 dreamed 396:16 drifting 88:12 drill 91:19 drilling 218:2 drink 94:7 drive 326:19 341:8 driven 242:8 348:4,5 driver 262:16 drivers 165:21 drop 258:9,18 dropped 258:8 dropping 76:14 258:21 281:15 drops 215:22 216:3 drug 377:3 dry 237:10 dual 140:16,17 dumb 191:15 duplicate 365:13.20 duplicating 45:1 duplication 184:16 duplicative 271:15 dying 241:10

. .

E 4:1 earlier 83:20 100:14 107:11 154:4 244:11 246:11 257:5 261:11 339:17 372:19 375:18 377:16 381:3 389:6 390:1 400:15 early 48:9 50:14 226:3 226:5 246:12 293:22 305:20 easier 62:9,18 186:16 220:5 324:7 easily 228:19 391:18 easy 37:9 117:13 150:2 306:9 346:15 376:9 394:15 eat 312:15 379:11 eating 168:11 312:15 379:13 echo 223:14 echos 24:11 educate 13:12 educated 28:3 educating 31:9 education 28:12 36:12 58:3 381:8

Ε

educational 39:13 346:8 effect 57:8 68:18 83:16 84:1 175:22 179:2 189:13,17 190:11 223:7 247:22 286:22 effective 213:5 effectively 231:14 316:10 effectiveness 13:14 55:21 68:17 229:10 effects 37:11 efficacious 147:20 efficiency 352:5,15 effort 148:3 efforts 321:22 354:8 365:13 egregious 240:22 **EHR** 113:17 eight 128:19 129:1 157:11 170:11 382:11 392:11 either 28:20 37:7 45:19 46:5 87:2 118:8 124:4 167:2,5 181:12 207:12 232:8 235:22 249:3 252:1 300:4 303:18 314:7 331:7 334:16 395:17,18 elderly 125:13 135:17 152:6 elected 266:2,7 267:6 electing 341:2 electronic 17:5 113:15 113:16 114:8 129:18 270:1 279:10 343:19 386:16 element 34:4 162:4 380:20 elements 32:18 51:10 51:13,15,22 294:14 301:8 339:17 366:2 367:12 elevating 88:9 eligibility 140:3 eligible 55:9 56:13,17 57:4 64:14 66:4 67:13 77:20 85:16 90:19 91:15 104:11 108:6 109:16 123:7 342:3 elimination 235:3 Elisa 2:16 8:1 180:18 Elizabeth 2:4 210:9 emails 7:8 embedded 39:5 emphasis 302:7 empirical 89:5 90:6 employer 8:22

employment 28:12 127:12 166:15,19 167:2 227:19 empowered 172:8 empty 108:17 encompasses 136:2 encompassing 364:16 encounter 55:15 encounters 69:17 72:3 encourage 46:22 73:8 291:22 304:19 368:7 encouraging 122:1 ended 62:15 157:5 236:13 238:22 246:2 246:8 endemic 309:6 endorse 32:13 33:6 87:15 272:5 360:17 390:13 endorsed 25:15 32:17 39:19 157:11 158:2 250:19 286:18 361:6 endorsement 36:16 37:1 40:8,19,22 44:1 55:1 58:22 71:5 118:14 119:5.13 120:12 133:21 156:21 167:16 228:1 250:18 271:5 272:10,13 281:3,8,19 282:1 283:11,21 286:13 316:11 334:3 336:6 360:12 363:13 368:19 369:9.16 380:2 387:18 400:19 402:5 402:12 406:3 endorsing 35:18 48:5 156:17 231:15 286:19 ends 38:17 engage 46:15 344:22 engagement 2:2 13:9 13:19 14:8,18 15:1,11 engagements 9:8 engaging 16:13 English 210:4 280:10 enhancing 15:10 enjoying 7:17 enrolled 137:19 140:2 140:15 enrollees 214:2 enter 266:1 309:3 entered 115:3 Enterprise 126:18 enters 278:22 entire 104:14 entirety 365:22 entities 145:20 352:12 entitle 309:20

entitled 58:2 310:1 entity 140:9,11,18 141:22 143:1 159:8 envision 112:13 envisioned 172:11 epidemic 79:8 87:6 **episode** 139:11,19 140:4 equal 316:15 367:3 391:8 equality 107:10 equally 343:6 equates 382:5 equation 395:9 equations 327:7 337:16 equity 38:20 era 73:11 error 328:3 escape 151:7 especially 14:12 15:8 33:12 62:8 80:22 146:4 166:6 171:16 190:11 196:14 198:2 223:6 253:8 260:16 278:17 280:14 essence 319:13 383:15 essential 70:11 essentially 103:3 110:10 214:12 229:15 239:6 273:4 295:11 331:1 390:5 establish 79:12 established 33:3 establishing 55:19 345:11 estimate 215:1,8,11 306:22 estimates 234:19,21 estimating 150:11 estimation 327:6 337:16 395:9 et 6:1 26:6,18 36:8,10 58:7 66:22 71:8 78:1 87:6 88:10.11 93:1 132:20 150:6 157:16 196:19 385:1 ethically 83:3 ethnicities 70:8 evaluate 41:16 44:5 138:11 145:10 150:2 evaluated 25:16 149:9 149:9,11 evaluating 33:22 34:6 35:14 138:10,21 140:10 145:19 159:15 159:20 evaluation 2:9 4:4 26:4 29:1 30:2 42:2 65:12

109:6 120:20 355:12 event 181:3 183:15 197:20 events 154:19 eventually 70:20 228:9 231:16 everybody 43:10 44:19 47:5 64:7 65:20 264:11 284:8 310:9 359:7 362:15 399:4 everybody's 289:9 everyday 67:2 everyone's 116:7 164:15 251:7 evidence 26:2,2,8 43:17 57:8 59:18,22 59:22 60:12,19 62:1 63:14,19 64:11 67:19 67:22 68:13,15 72:17 73:18,22 74:1 75:12 75:12 76:17 79:11 81:7,13,20 83:5,9,12 83:13 84:4,8,11 86:18 87:16 88:14 89:5,19 90:1,7,12,14 92:13,15 94:8.14.21 95:9.15.22 96:3,4,16 97:1,2,3,6,8 97:10,21 98:1,3 107:5 118:17 119:17 120:4 120:14 149:6 154:12 162:22 172:22 182:14 184:5 185:21 186:4 188:3 195:22 196:3 197:5,6,9,13 198:6,9 199:14,18 207:2 223:3 232:13,20 233:3 244:5 249:6 252:1,3,15 253:1 254:5 256:14 261:21 265:9,10 269:5 270:16 289:11 318:1 318:2,8,9,13 342:12 362:21 377:13 384:11 386:5 387:7 388:14 400:11 evidence-base 88:7 evidence-based 87:8 evolved 55:4 exact 51:13 97:4 266:11 289:21 314:8 325:17 exactly 77:16 94:4 105:8 187:19 212:19 216:5 268:16 320:7 328:16 331:6,9 349:5 365:17 exaggerate 375:12 exam 346:11,14 357:12 example 48:8,22 49:12

50:5 55:22 78:21 79:5 93:16 103:17 105:18 144:10 159:13 162:11 165:21 179:21 189:18 213:18 226:21 361:20 376:5 examples 380:3 394:2 excellent 230:10 244:22 245:3 300:21 303:2 exception 90:2,8 92:11 94:11 95:15,22 96:3,5 96:5,11,17,17,20 97:2 97:6,22 98:2,2,4 118:18 119:18 exceptions 96:8,11 188:2 excited 7:13 171:21 251:7 269:18 exclude 82:18 236:10 **excluded** 93:15,19 139:21 152:17 153:13 208:20 209:21 237:9 241:17 242:2,7 276:9 292:18 293:1 294:6 300:4.9 excluding 75:19 152:3 263:18 exclusion 208:10 240:2 300:12 exclusions 232:21 233:19 236:3 239:18 269:6 273:21 274:21 292:9 342:12 386:5 exclusive 357:8 excuse 86:14 119:12 266:2 274:7 351:18 406:17 exercise 32:2,3 225:15 325:16 exercises 190:5 257:9 Exhibit 215:17 219:3 existence 125:19 existing 383:6,14 exists 70:22 85:10 expand 113:12 expanded 92:3,21 123:7 expect 35:8 46:20 216:6,11 308:7 310:19,21 328:5 344:18 345:1 expectation 308:7 321:15 398:12 expectations 319:5,6 374:17 expected 248:8 305:9 305:10 310:2 319:16

321:1 351:12.12 expecting 396:12 expects 35:9 expeditiously 284:6 expensive 134:7 experience 12:10 30:17 40:3 60:6 61:4,12,17 91:6 105:9 125:4,18 126:14,19 127:21 128:4,8 129:3,12,16 139:1 152:6 153:21 170:12 196:13 200:3 229:10 230:20 241:7 241:11 287:16 302:17 337:2 experiences 61:11 experiencing 58:5 experiment 153:3 expert 8:21 26:22 27:9 expertise 287:10 explain 96:8 267:7 306:12 364:13 405:16 explained 335:3 explaining 188:9 explicit 122:6 exploded 371:5 exploratory 226:13 229:20 explore 280:13 expressed 171:4 336:12 expression 312:14 extensive 285:4 287:16 345:1 346:8 extensively 199:21 354:17 extent 360:12 external 251:20 extra 62:21 extracted 102:21 extraordinarily 188:10 extremely 14:11 132:12 258:6 338:10 356:8 eye 184:1 F FAAP 1:12 face 71:8 277:22,22 388:16 face-to-face 52:15 185:7 211:11,13 **FACEP** 2:10 FACES 63:13 69:21 70:5 facilities 4:12,13,14,16 4:18,19 12:16,17 216:20 232:18 234:1 234:20 238:1 259:13

Neal R. Gross and Co., Inc.

Washington DC

260:12,22 268:5 284:20,21 286:15,19 292:5 293:4 296:18 296:20 297:1 299:3 301:16 304:8 307:3 314:13 318:13 319:5 319:8,9,9 321:14 324:14,18 325:3,8,10 325:13 326:1 327:1 330:14,16,17 333:13 335:12,17,17 338:8,9 338:13 340:14,15,21 341:2 348:11 349:22 350:10 351:18 354:13 355:11 356:12 370:2 370:19 371:4,5,7 372:11 373:2,9 374:17 375:9 380:10 380:13 384:1,14 391:14 394:3,11 395:15 398:17 facility 17:12 230:14 233:6,21 234:10,19 240:9,17 248:3 249:12 256:6,12,14 256:17,22 257:2 260:10,11,20 261:14 261:21,22 262:1 276:4 277:13 278:6,7 286:4 303:14 312:9 316:4 319:18 320:21 321:4 325:1,5,7,17,18 325:20 326:7,9,10,11 326:13,14,19,21 327:2,8,11,13,14,18 327:20 328:8,19,22 329:5,10,12,15,17 330:22 331:1 334:21 335:11 337:11.13 338:16,18 340:17 344:20 345:17,20 351:6 354:8 355:15 355:16,22 356:5,9,10 358:14,21 359:2,19 365:1 375:5 376:20 378:4 394:9 395:11 395:13,16 397:15 facility's 365:7 **FACOG** 3:6 fact 21:19 25:5,20 27:2 32:21 37:18 39:14 70:8 89:2,20 93:19 108:11 171:12 240:15 266:6 274:9 279:12 303:4 307:1 313:11 314:2 372:21 376:3 393:8 396:22 401:19 factor 225:16,17 226:6

226:7,8,12 229:20 235:5 263:4 factoring 109:14 factors 26:22 27:2,14 27:17 28:7,13 38:10 240:16 263:4,9 312:17 fail 95:12 97:1 309:9 failed 207:2 227:13 405:7 failing 359:1 fails 95:9 220:21 221:10 402:21 failure 57:20 400:21 fair 33:5 34:1 68:7 82:5 84:16 101:22 103:19 134:1 241:18 245:18 331:10 396:14,17,20 399:16 406:11,12 fairly 50:15 60:7 68:15 83:20 189:12 199:21 212:8 215:15,18 257:21 302:22 303:1 337:22 377:6 395:4,9 395:10 fairness 111:1 132:7 fall 94:10 309:12 false 362:16 familiar 39:18 127:14 147:2 311:21 315:10 families 10:5 11:5 16:14 200:4 310:20 381:8 382:8 family 1:3,20 2:2 4:11 14:9,18,21,22 15:11 16:12 39:20 152:10 159:5 194:20 195:8 224:1 229:5 230:9,15 236:9 241:13 259:4 268:3 274:6,7 275:8 280:18,22 282:10 288:19 310:19 381:7 Fannie 5:14,15,17 far 69:20 164:16 179:8 222:16 254:1 260:17 279:16 fashionable 13:9 fashioned 279:11 fast 235:22 fault 62:2 71:8 favor 300:18 favorable 242:4 favorably 252:17 fear 196:15 310:16 feasibility 43:22 115:5 115:6,12,16,19,20 134:5 186:2 223:17 269:17,22 343:3,15

Neal R. Gross and Co., Inc.

Washington DC

343:16,18 344:4 386:15 399:12 400:12 feasible 213:12 features 287:21 federal 20:21,21 fee 358:5 fee- 137:21 fee-for-service 138:2 feed 32:18 299:21 379:10 feedback 6:22 feeding 379:12 feel 14:10 23:12 27:10 86:18 87:13 96:22 97:5 104:17 134:11 137:13 154:13 156:21 158:6 164:3 166:4 172:8 175:6,10 181:22 262:11 315:22 336:16 350:2 394:1 feeling 105:20 192:17 251:4 feels 182:10 262:22 Feinberg 1:16 fellow 137:7 felt 29:14 31:1 232:22 241:15 263:22 266:7 Fentanyl 87:6 fewer 216:11 field 11:14 91:5 128:21 152:19 175:2 184:21 195:20 213:1 326:3 fielding 185:13 figure 62:4,20 164:6 249:18 266:3 302:13 389:8 figured 268:18 figuring 166:11 file 282:9 files 296:19 298:7 299:6 320:13 321:7 371:1 391:11 fill 224:2 237:7 276:5 278:19,22 300:1 filling 237:8 FIM 32:16 35:7 36:19,22 285:2 287:17 288:16 289:3,20 290:12 291:15 297:10 298:6 298:10,11 299:21 306:3 317:10 338:10 348:13 352:5,6,14 353:3 354:15 398:14 FIMs 289:19 final 35:22 45:22 118:7 121:14 224:4 271:4 272:7 281:18 finally 235:10 270:10

financial 58:20 financing 16:21 find 63:11 71:8 89:10 111:8 113:20 148:1 165:20 234:10 245:21 248:8,9 263:3 273:18 278:15 316:21 318:8 319:6 356:9,11 392:4 404:17 finding 91:1 187:18 fine 59:9 79:19 208:6 225:20 374:3 393:2 407:13 finely 226:8 finish 145:5 172:20 finished 268:8 firms 231:13 first 6:15 10:10 23:10 27:21 32:12 34:21 35:1,2 43:16 53:13 54:14 55:5,18 59:19 70:21 76:14 77:9 80:18 90:5 92:15 94:3 94:7,17 96:12 99:11 100:3,11 106:6,8 119:15.16 124:10 132:22 154:12 162:19 168:19,21 171:10 174:12 177:4,11 204:15 205:8,20 209:2 214:19 216:13 220:9 223:13 229:1 232:9,10 233:15 239:17 247:20 248:10 251:8 255:22 267:2 267:22 272:21,22 273:3,18 275:6 285:5 286:3 287:21 289:12 289:14,15 335:1,9,17 347:13,14 357:5 358:12 383:1 390:22 404:3 408:1 Fisher's 266:11 fit 91:22 266:6 five 125:19 126:16 129:5 136:9 137:2 155:8,15 164:11,14 171:3 180:22 181:1 182:13 201:7,10,17 205:5,5 227:9 230:9 230:21 238:20 245:16 245:19 246:7 253:16 271:21,22,22 384:21 386:12 387:3 fix 24:11 214:21 215:9 flavor 230:12 Fleishman 267:16 268:14

flipped 247:13 floor 1:8 104:4 190:10 256:1 265:3 370:4 flow 31:15 353:7 flu 309:15 **FNAHQ** 2:5 focus 3:7 26:9,14 42:15 84:21 128:8,10 165:19 241:8 245:8 250:22 383:18 393:18 403:9 focused 145:8 focuses 56:21 focusing 60:18 72:17 73:21 folks 6:7,9 23:21 27:1 33:8,14,15 38:16 39:17 43:3,8 44:2 45:2 47:8 93:10 105:10,14,17 112:22 113:14,14 124:18 152:4 223:8 233:8 258:14 281:6 302:19 395:18 408:10 follow 59:2 211:1 214:17,19 237:14 296:12 299:13 308:3 follow- 53:13 164:17 follow-on 110:5 follow-up 4:6 40:7 54:21 56:5,10,14,19 66:17 67:20 84:18 110:15 134:8 148:18 189:10 followed 180:14 281:12 following 72:1 263:16 331:7 359:14 follows 348:1 food 246:19,21 for-service 137:22 forcing 359:6 foremost 287:21 forestall 360:9 forget 140:17 214:18 215:17 381:13 forgot 248:17 form 8:11,12 25:10 31:21 32:2,4 66:3 98:11 103:22 114:6 120:20,22 179:3 229:16 244:13 formal 80:1 176:12 178:15 274:18 281:16 forms 28:17,19 29:6,8 29:20 34:9 227:8 formula 216:6,15 217:2 223:15 226:2 260:15 formulation 257:13

forth 31:5 176:7 251:15 293:20 315:5 341:7 341:10 fortunate 14:11 Forum 1:1,8 288:18 forward 6:21 21:3,5 30:13 45:20 46:1,6 58:22 95:14,19,22 97:1 100:1 101:3 118:21 145:6 150:15 153:4 176:15 177:12 196:8 207:9 209:10 209:12 213:3,5,6 214:6 217:13 249:21 350:13 401:9,21 407:1 forwarded 272:9 found 14:15 68:18 191:17 245:15 248:6 257:5 306:15 317:11 331:6 347:22 371:10 foundation 10:9 foundations 20:22 four 34:18 43:18 94:18 94:20 99:17 106:8.9 114:17 115:14 117:20 135:1 136:9 187:4 205:6 220:13 231:6 238:20 245:10 249:2 255:14 259:17,18,19 260:16 262:11,13 264:18 269:10 270:4 270:19 323:3 339:7 342:18 344:1 fourth 204:17 205:1,4 205:10,22 frail 135:17 152:6 frame 124:16 390:3,4 framework 252:9 frankly 35:12 124:12 237:5,13 freaked 165:15 free 23:3 231:14 290:4 290:7 291:6 346:21 358:16 359:5 freestanding 355:17 frequently 63:10 166:15 185:16 Friday 332:14 Friedman 1:19 19:3,4 76:13 77:11 145:15 146:17 149:3 152:2 161:21 184:10 196:12 347:16 381:16 friend 247:11 256:1 friends 70:16 147:8 229:6 230:14 284:5 front 11:12 20:12 59:11

67:15 77:21 116:22 G- 56:8 78:16 141:14 248:5 334:10 fulfills 287:1 full 47:1 108:17 156:11 243:12 244:11 259:9 259:22 298:10 347:3 394:19 fully 314:22 function 124:3,6 148:7 173:17 261:22 286:21 293:19 296:22 298:1 298:13,19,20 300:2 301:21,21 302:9 303:5 304:21 305:8 305:14,19 306:8,18 310:3,6 312:5,13 314:17 315:1,7 319:14 321:21 325:22 341:9 346:15 347:10 348:5 355:8 362:8 371:22 372:6 373:14 376:1,3,10 378:5,13 378:17 383:18 **functional** 4:11,13,14 4:16,17,18 18:7,9 30:19.20 40:2 126:20 153:22 170:13 242:13 286:4,14 287:11,17 299:4,7,10 302:11 303:17,17 306:10 307:1 317:13 318:11 321:20 341:6 355:13 362:4,6 364:17,22 365:7 367:15,16 368:3 371:20 372:15 378:15 380:5 381:6 382:3 384:13 functioning 192:4,5,6 298:22 304:5 305:15 307:5 functions 61:21 316:6 Fund 10:8 fundamental 309:5 fundamentally 246:6 funded 20:20 furious 62:12 furiously 91:10 further 18:6 26:4 72:4 73:19 85:7 92:6 99:12 109:10 115:9 145:17 175:14 193:7 406:15 future 44:8 69:8 176:3 261:17 271:21 290:20 317:8 340:1 fuzzy 37:6 G **G** 4:1

422 G-code 56:3,12 74:8

76:15 78:10,18 80:3 90:22 G-codes 55:9,12 77:17 78:19,20 79:1 G8730 56:2 gain 63:10 217:17 302:17 303:4,16,17 gains 378:15 **GALE** 2:8 game 33:5 34:1 117:8 236:18 317:16 350:17 Ganey 184:12 gap 43:17 85:9,10,14 98:12,19 99:15,19 126:22 186:4 192:14 199:18,19 200:14 202:7 203:17 204:14 205:8,20 207:3 243:7 252:18,19 253:1 254:17 255:9 319:1 321:11 322:16 374:12 374:16 375:1,3 384:22 391:21 394:7 400:11 gaps 41:3 155:4 164:5 202:7 203:16 255:7,9 322:19 325:15 385:3 385:3 garbage 347:8,8 Gary 3:12 102:10 gather 377:11 geared 306:8 geez 226:7 gender 51:11 253:2 263:17,20 general 2:4,4,15 6:16 8:6 10:21 14:15,21 21:9,19 46:10 60:8 91:3 105:19 137:11 140:2 141:1 160:10 165:3 168:6 171:9 173:4 177:6 236:13 245:17 263:21 289:8 289:10 292:7 296:7 308:18 313:5 330:5 374:7 383:4 generalizability 233:20 generalizable 238:2 generalize 104:12 generalized 327:6 337:16 395:9 generally 78:18,19 79:1 184:2 generated 270:1 343:19 386:16 genetic 39:4

			423
maniatriaian 00.47	50:40 00:0 44 70:4 40	400-0 004-4 000-47	
geriatrician 20:17	59:13 62:9,14 73:4,19	198:8 201:4 202:17	graduate 3:3 147:8
germane 163:3	76:12 86:12 90:16	202:17 206:11,12	grain 225:20
Gerontological 2:7	92:10 93:8 94:12	213:17 214:9,21	grant 18:5 20:4,9
getting 14:14 29:18	99:22 108:1 114:5	215:4,6,11 216:2	126:18
54:4 74:20 87:7,9,18	118:17,21 121:20	217:13 219:16 225:15	grantees 153:3
140:8 148:21 152:3,7	140:4,5,6 141:13	225:15 227:2,19	grants 9:9
154:6 164:3 169:15	142:19 147:14 162:13	228:18 234:20,20	granular 243:16 247:21
184:17 194:9 195:7	168:20 176:16 177:4	235:16 240:3,8	248:1
196:6 209:9 223:18	177:12 178:7 179:17	241:19 244:1 247:22	graphs 333:6
260:7,16,18 262:2	180:8 181:6,14	249:21 252:11 255:2	grapple 62:3
279:21 304:1 367:15	183:12,22 185:2	255:3 257:10,13	grata 302:20
393:11	187:20 201:3 210:18	258:22 259:6 260:19	gratuitously 367:9
Giff 250:5 259:14	222:14 227:2,4 232:9	260:20 261:4 265:7	gray 45:17 115:3
GIFFORD 3:5 236:2	232:10,13 233:2,5	265:12 266:20 282:9	great 12:22 88:16 131:3
238:3 241:2 242:9	239:1,6 240:16	282:11,12 283:17	136:18 144:22 146:19
245:7 248:16,21	246:13 255:2,3	284:14,15 289:17	149:4 154:10,11
250:13 251:11,14	258:10 260:4,13,14	291:13 292:6 297:16	168:5 174:7 183:21
253:16 259:5 263:19	261:10 267:5 271:3	299:18,20 301:11	186:1 207:18 218:4
264:5,8 265:15,21	273:6 281:20 283:3	302:15,19 303:11	219:15 223:16 237:16
266:15,19,22 267:12	289:10 291:20 292:10	312:2 321:19 329:16	243:8 268:18 273:16
268:20 271:18 272:4	294:2 299:17 314:20	334:14,16 335:1	274:11 285:19 299:6
275:1,4,9,16,21 276:7	332:2 336:4 338:5	336:9 344:22 349:3	310:8 320:8 343:14
276:19,22 277:8,12	349:18 350:7 355:18	349:15 350:16 354:6	356:19 366:1 368:11
278:10 279:3,13,17	358:19 359:11 374:7	360:8 364:22 369:14	381:21,22 388:13
280:9 281:2 282:8,18	381:9,15 382:15	374:5,17 375:10	392:21 393:14 403:11
282:21 284:9	392:2 401:1,8 408:11	378:8 381:20 382:9	greater 26:9 45:11
give 6:17 29:20 34:3	go-around 34:16	391:13 395:16,16,22	308:13 353:4
63:12 65:1 77:9 86:11	goal 74:21 90:20 91:6	396:11 398:4,13	GRECC 2:7
96:19 100:21 134:11	138:11 142:12 246:14	400:11 406:16,19,22	Green 3:6 78:6,9,9,18
167:22 181:11 182:16		406:22	
	304:5 305:17 364:22		82:6 85:19,19 93:14
182:21 211:10 217:2	goals 26:12 41:15	gold 298:8	93:14 105:8
219:21 221:20 222:13	55:20 172:6	good 6:3 7:5,10,15,19	grew 13:6
226:15 227:5 230:12	goes 69:20 119:20	8:1 10:19 15:3 16:7	gross 364:17
234:6,7,9 237:21	219:3 332:13 349:9	16:18 17:8,16 18:19	ground 6:1 46:12
243:2 273:8 295:19	381:2 394:11 396:4	19:20 21:8 32:7 60:13	group 2:3 27:20,21
308:1 327:7 355:5	going 5:22 6:12 8:7,14	61:15 75:4,17 82:19	28:11 101:19 108:7
393:12	19:10 22:17 26:7	83:13 90:7 109:2	108:12 110:12 125:14
given 11:11 75:16 79:7	27:12 29:18 52:5	110:11 125:10 131:4	137:1 159:18 161:6
108:20 163:12 188:5	53:10,12 54:3 59:1	132:21 134:21 146:20	192:16 204:11,22
213:11 216:6 280:4	64:4,21,22 65:19	172:19 174:10 183:6	205:1,2 220:9,20
319:17 328:5 337:7	73:14,21 82:9,11	199:11 201:18 207:19	221:3 228:20 232:5
351:6,11,13 353:6	86:12 87:13 88:5,7,19	215:15 216:19,21	241:6 246:9 268:7
361:10 371:16	89:15 90:3 92:8,14,16	217:11 219:15 228:8	284:22 285:7 299:22
gives 296:4,11 307:6	94:4,8,15 98:11	229:7 230:10,10	308:12 338:10,11,13
giving 177:5 226:6	110:16,21,22 111:3,5	231:2 232:10 244:22	372:21 377:6
317:7 353:9	111:6,7,19 117:1,11	244:22 245:2,2	grouped 308:10
glaring 70:10	119:19 124:14,14	248:12 251:19 260:14	grouping 181:1 227:21
glass 108:17	125:2 128:22 131:18	279:11 285:21,22	groupings 180:22
global 127:22 158:1	136:22 144:21 149:15	287:4 295:14,20	181:6
163:8 164:1 165:6	149:20,21 150:7,9	296:4,5,12,15 309:2	groups 13:11 135:13
169:1,10 176:8	151:7,19 152:11,15	309:17 318:7 325:12	136:2 164:14 177:9
183:13 191:20 201:12	156:5 158:1,18	325:13 332:21 338:2	202:10 203:19 205:5
201:15 203:13,16	161:11 166:13 168:6	340:22 345:11 349:17	206:21 241:8 245:8
204:4 207:3,13	168:9,10,12,13	363:18 369:4 370:9	255:12 284:17 322:22
219:19 220:9,20	175:20 180:21,22	372:14 376:12,16	340:3 345:13 385:6
go 6:17 7:2,3 8:15 9:21	182:16 184:6 185:3	383:8	grow 214:9,14 232:2
10:12 22:21 32:1,2	189:17,22 190:17	gotten 44:19 164:15	growth 26:15
34:5 45:22 46:6 53:10	194:5,8 196:18 198:3	172:10 224:20 232:5	guardians 274:22 275:2
			gaa. a.a.io 21 1.22 21 0.2
11			

275:3,5,11,12 guess 64:12 66:11 73:20 79:11 81:4,15 82:2 84:17 108:15 110:15 111:19 112:9 122:6 125:14 134:22 137:5,17 142:10,10 154:22 159:5 161:19 169:12 170:5 178:18 184:10 196:9 197:13 200:1 227:1 241:18 249:8,15,18 250:11 256:21 275:11 278:2 294:10 297:14 316:11 331:7 350:21 351:4 358:22 373:5 393:22 405:15 guessed 258:5 guessing 231:11 guest 23:18 guidance 213:10 277:2 359:22 397:1 guide 346:9 358:2,17 guideline 90:6 guidelines 9:3 57:14,16 89:4 guilty 83:8 174:16 gulp 134:1 gut 295:8 quys 52:1 78:6 157:19 227:5 231:10 н half 106:22 108:12,17 108:17 179:2 215:12 319:4 321:14 330:11 330:12 331:2,2 335:14 407:7,14 halves 337:15 Hammersmith 2:15 5:14 6:16 8:5,6 19:10 19:18 20:14 21:2,6 22:3 Hampshire 218:20 hand 149:12 158:8 176:13 190:6 208:18 216:4 220:4,5 237:19 262:6 266:14 361:20 361:22 362:3 380:16 handed 278:6 handful 250:15 280:10 393:3 handicapped 140:14 handle 300:7,8 332:3 handled 157:3 happen 47:7 73:21 82:12 180:18,19 189:22 255:4 294:9

344:18 405:21 happened 33:12 80:4 157:1 190:3 192:4 happening 42:2 72:5 81:12,12 89:16 179:1 242:1 271:16 306:16 happens 34:20 179:20 180:1 292:17,19 378:11 391:2,21 happily 10:9 happy 11:9 22:1 226:15 335:7,22 399:18 hard 36:11 51:20 92:12 142:17 222:18 228:8 308:14 321:2 380:11 harkens 375:17 harm 38:22 82:11 197:14 harmonization 41:7,10 121:7 hate 148:9 155:18 253:12 Haves 3:7 403:7,8 404:11 405:2 HCAHPS 166:6 **HCBS** 126:14 127:6 131:2 132:11.15.17 140:12 141:10,18 144:6 157:22 184:20 191:11,21 214:1,7 head 10:21 107:16 heading 22:18 heads 190:14 health 1:16 2:6,7 3:3,5 3:8,11 13:3,7,20 16:20 17:6 19:7 20:17 21:11 28:15 65:16 76:16 77:14 78:4 88:1 113:15 114:3 125:14 125:22 139:10 159:17 159:21 160:8 184:19 193:20 198:11,17 254:6 291:17 301:6 318:14 384:15 392:7 392:8 health-related 40:1,16 healthcare 2:2 11:12,15 12:12,21 13:17 16:2 18:3 74:8 75:9 141:4 141:8 185:9 198:18 254:7 301:17 318:15 384:16 HealthPartners 1:13 HealthSouth 1:15 17:19 hear 43:10 45:16 59:6,8 65:7,9 66:1 78:7 125:11 127:2 213:21 234:16 285:15,17

Neal R. Gross and Co., Inc.

Washington DC

311:22 heard 8:7 69:22 114:2 149:13 152:13 183:8 197:4 224:19 390:16 394:12 397:4 404:11 hearing 81:6,20 87:20 92:9 235:9 359:8,15 399:13 heart 400:21 heavily 194:3 245:1 354:16 held 227:12 242:10,15 263:22 350:6 399:3,5 **HELEN** 2:14 help 14:19 47:2,5 53:10 84:13 88:12 98:6 101:11,21 112:22 151:3 158:19 168:22 172:5 187:6 190:18 190:19 196:15 218:3 225:18,21 226:3,21 237:12 238:1 279:4 310:12 334:11,15,16 351:6 361:1 376:10 382:10.10 helped 14:7 226:18 279:4 354:11 helper 382:5 helpful 97:12 110:20 144:6 165:9 184:13 186:7 222:12 223:19 321:10,17 351:16,22 394:9,16 396:18 408:6 helpfulness 215:19,21 helping 376:6 helps 73:8 78:13 84:14 311:21 348:13 hesitant 355:4 hey 73:15 hi 8:5 12:7 13:1 15:14 19:13 20:16 53:20 59:6 202:13 285:17 297:7 403:8 high 45:13 62:7 94:17 94:19 95:7,16 99:16 99:19 100:16,20 104:4,9,13 105:4 106:7,8,12 107:3 114:15,22 115:6,13 115:17 116:1 117:19 118:2 188:1,10,14 190:3 202:18 203:7 203:20 204:2,15,19 205:9,13,21 206:2,12 206:16 220:10,16 221:4,7,15 222:3,7 255:12,18 264:16,21

269:9.13 270:3.7.18 270:22 320:2 323:1,6 328:13 339:5,10 342:16,21 343:21 344:5 354:21 356:11 362:22 363:5 385:7 385:11,17,21 386:8 386:13,18 387:2,8,14 higher 33:11 63:11 80:12 144:3 239:4 240:19 250:10 309:9 345:21 347:19 349:10 highest 258:8 266:18 highlights 402:1 highly 104:8 105:13 250:4 257:10 258:18 354:21 355:7 388:21 hip 314:6 hire 144:12 172:8 hired 141:21 historically 152:16 history 82:15,16 113:1 122:19 317:1 367:11 hit 54:14 407:22 hitting 200:17 hodgepodge 143:14 144:2 hold 95:11 145:1 232:20 239:13 259:12 331:11 343:12 374:5 396:14.21 403:22 home 4:7 5:16 10:7 12:17 17:11,15 32:16 69:6 125:3 126:14 127:9,11,17 128:3,6 134:14 139:10,14 140:6 143:8,11 144:6 144:13 146:8 147:1,4 148:15 152:7 159:17 159:21 162:13 171:14 179:3 184:17 196:15 229:15,16 233:5,21 236:16,21 250:3,13 253:17 256:10 280:22 282:8,13,14 283:2 301:6,17 369:21 371:14 381:10,20 407:15 homelessness 28:14 homemaker 158:11,21 160:8 homemakers 141:17,21 142:16 145:19 159:18 homes 282:7 honesty 32:7 honor 11:2 hope 6:20 46:14 53:9 76:20 77:2 114:12

hopeful 302:13 hopefully 23:17 29:13 34:14 74:7 hoping 317:20 horrible 217:20 hospice 17:11 241:3 hospital 1:13 10:8 11:1 12:9 15:6,18 19:1 38:20 114:8 140:5 185:2 240:18 287:18 292:18,20 300:5 306:5 377:2 379:19 380:22 Hospital/Massachus... 2:4 hospitals 14:20 38:21 351:17 hostage 227:12 hostile 297:12 hotel 408:11 hour 131:6 285:4 hours 146:1,7 180:14 180:15 191:18,18 196:19 382:5,11,12 housekeeping 23:10 Hoy 1:20 15:20,20 373:20 374:2.5.8.11 375:13 huge 63:7 80:21 190:8 hundreds 258:7 husband 407:11 hypothesis 266:6 L i.e 49:10 56:20 **ICC** 325:7,9,19 327:15 330:5,14,18 331:14 331:15,18 371:4 ICCs 234:9 355:3 384:1 idea 9:14 63:2 111:21 135:5 177:14 266:8 ideally 131:5 identical 272:20,20 298:11 identified 29:14 36:18 121:1 127:15 317:18 identify 24:22 160:6 305:15 325:14 362:5 identifying 160:9 ignore 331:21 II 79:3 illnesses 58:11 immediate 163:12 impact 39:12 57:21 60:3 81:21 232:22 248:2 271:14,18 287:1 315:19 316:20 400:1

impacted 89:9 impacting 27:14 38:2 impacts 70:16 impairment 152:8 236:4,11 293:20 308:12 338:13 impairments 280:7 **implement** 63:4 148:2 implementation 57:3 234:1 345:8 implemented 55:5 270:2 343:20 386:17 implementing 88:8 271:14 implication 183:2,4 implications 183:17 importance 79:7 90:14 113:2 128:3 198:10 202:6 203:15 204:13 322:18 375:20 376:6 important 13:13 28:16 32:20 44:13 58:18 67:1 69:19 71:22 79:9 89:22 97:5 99:9 107:19 113:11 114:2 142:11 145:1 148:19 150:14 171:11 175:6 179:6 182:20 194:12 195:22 208:22 209:4 210:14 216:16 224:10 228:3 230:4 231:19 233:4,11 234:15,17 243:6 247:8 278:17 292:3 302:9 309:18 312:6.11 344:12 350:11 359:15 367:17 368:9 importantly 62:6 improve 26:12 58:18 76:19 142:18 172:13 302:16 305:2 310:2 317:7 321:20,22 354:9,13 376:16 378:4 380:4 improved 44:3 71:18 73:2 83:21 84:1 303:9 improvement 14:8 26:11 48:13 57:11,20 89:8 98:12 112:6 128:15 142:13 165:19 188:4 223:8 246:16 246:19 247:1 270:15 302:11,11,12 304:21 308:8 362:7,19 367:16 371:20 372:1 379:14 387:6 improvements 242:13 307:4 362:1 376:4

improving 11:4 107:12 124:6 301:20 308:5 362:9 imprudent 250:22 in-depth 42:14 in-person 10:1 21:22 33:15 194:15 211:19 334:4 inadvertent 309:7 inappropriate 224:18 262:22 inappropriately 242:17 395:17 incent 49:12 incenting 396:2 incentivize 85:2 **incidence** 213:16 inclarity 334:18 include 37:17,22 38:6 57:16 77:21 93:9 109:19 113:12 122:12 123:7 136:3 141:2 152:11 161:6 227:19 320:10 341:21 371:2 383:6,9 389:1 included 14:5 38:10.11 57:12 72:21 153:10 257:22 275:11 297:11 321:7 324:12 325:5 357:22 384:1,5 399:3 includes 12:15 56:11 57:1 123:10 298:22 362:18 including 27:2 37:15 93:10 126:4 127:21 127:22 129:7 152:9 168:7 220:8 221:1,14 222:2 264:14 269:4 269:22 339:4 342:11 343:18 385:15 386:4 inclusive 45:14 364:6 income 28:11 inconsistent 89:11 353:20.22 incorporate 231:6 incorporated 253:19 322:10 incorrect 27:7 increase 58:5.8 66:6 217:18 347:18 increased 57:5 64:14 297:18 347:20 increasing 74:22 76:17 incremental 373:18 indefinitely 233:7 independent 102:22 264:6 277:7,9,13,18 376:7,11

independently 276:18 367:20 379:13 indicate 78:12 260:2 276:8 indicated 56:15 123:14 129:5 281:7 296:19 299:5.8 indicates 55:13 indicating 267:17 indication 81:13 120:10 120:11 192:16 332:22 indicator 308:13 indicators 341:7 individual 8:20 27:12 48:6 50:1,11 128:2 134:13 158:20 160:10 162:11,12 163:17 183:16 218:2 224:2 258:21 273:6 276:5 278:22 301:19 351:9 380:3 individualized 170:17 individuals 66:21 117:5 136:2 147:7,11 148:7 184:22 200:18 237:10 276:12 279:8 302:16 industry 288:11 294:6 361:12 infancy 370:21 inferences 27:8 influence 276:14 influenced 194:3 information 8:13 23:19 30:6 52:21 67:14 68:2 68:3.6 98:11 104:22 117:20 118:4 120:8 120:21 121:3 126:9 128:6 129:9 130:1 142:22 144:6 170:18 170:19,20 171:6 172:12 176:10,17 177:22 181:11,17 210:17 223:22 224:9 258:16 270:19 271:2 291:18 293:2 294:17 299:16,19,20 321:5 321:12 322:11 331:22 332:20 333:21 334:10 335:11 351:5,7,17,19 358:19,21 362:12 363:2,7 373:1,5 381:7 381:11,12 387:11,16 394:8,10,14 401:4,6 inherent 86:10 278:11 309:16 initial 54:22 85:8 164:22 170:15 248:4 274:4

initially 67:12 134:6 195:1 384:3 initiative 55:6 231:22 238:14 251:1 271:11 initiatives 150:6 injuries 58:11 136:1 injury 12:20 136:13,14 147:10 171:17 219:7 380:1.1 inpatient 12:15 286:18 301:5 306:4 314:14 345:8,22 379:8 input 14:16 41:7 46:18 224:6 247:1 inputs 274:7 insight 117:15 **Insights** 3:2,10,14 53:17 54:19 56:11 120:22 121:2 instance 291:18 298:16 325:15 335:13 365:10 389:11 instances 185:19 405:9 Institute 3:12 20:9 57:11 58:1 Institute/Quality 3:2.14 institutes 3:10 126:1 297:12 institution 139:16 282:19 institution-based 171:16 institutional 127:18 instructions 6:17 instrument 35:12 51:21 133:14 165:12 166:18 166:19 167:12 184:4 230:1 259:20,22 260:1 285:2 287:17 288:16 289:3,16,19 290:3,5 306:21 307:15 315:6 316:9 348:16 353:3 358:1 instruments 17:21 30:21 31:4 32:13 231:7 244:17 249:17 259:1,3,4 298:2,12 insufficient 59:21 62:2 67:22 79:11 89:1,19 90:1 94:10,19,20 95:8 95:14,16 96:4,16 97:2 98:1 99:17,21 106:8 106:10,14 114:17 115:2,14,19 117:20 118:4,18 202:19 203:9,21 204:4,17,21 205:10,15,22 206:14 206:18 220:12,17,18

221:5,9,17 222:5,9 255:15,20 264:18 265:1 269:10,15 270:4,9,19 271:2 323:3,8 339:7,12 342:18 343:1 344:2,6 363:2,6 385:9,13,18 386:1,10,14,20 387:3 387:10,15 insurance 28:14 insure 85:2 insuring 62:21 integrated 16:21 129:15 244:17 integration 13:20 integrity 290:2,5 intellectual 135:19 intend 169:20 170:4 intended 50:2 91:2 113:6 122:22 123:13 169:20 170:5 250:2 315:6 intending 128:14 intense 14:5 348:10 intensities 313:20 intensity 240:19 314:11 316:18 352:17 intensive 372:5 intensively 230:2 intent 56:16 66:15 151:6 intentions 165:4,5 inter 338:18 345:11 354:17 inter-217:4 inter-class 323:13 324:22 325:18 inter-facility 359:16 inter-rater 103:2 interchangeable 311:4 interdisciplinary 346:19 interest 4:3 6:14,18 8:12 9:14,17 15:13 16:5,17 17:13 18:18 19:2,9 20:20 21:18 65:5,5 129:3 171:4 346:19 interested 9:8 167:2.6 235:9 245:5 310:10 341:9 379:3,9 interesting 22:6,7 61:3 164:13 279:17 375:13 407:5 interests 11:3 **interim** 311:2 interior 165:18 internal 32:9 165:12

360:14 internally 31:6 51:8 296:17 321:8 **interplay** 37:8,12 **interpret** 89:1 104:5 234:14 261:15 321:12 337:21 351:16 interpretation 30:8 33:6 83:10 103:20 336:13 404:3 interpreting 33:10 81:15 interquartile 189:12 252:19 interrupt 31:15 110:8 interunit 256:10 interval 234:7 intervention 76:19.22 77:1 89:8,9 117:11 198:19 254:7 310:7 318:16 384:17 interventions 55:19,22 92:17 intra 337:17 354:16,20 intra-item 324:20 intra-rater 234:8 intraclass 102:6 217:14 222:22 256:5,22 395:7 397:14 intraunit 256:5 intravenous 377:3 intrinsic 341:8 introduce 53:19 65:2 125:16,21 126:8 introduction 4:3.4 60:18 123:15 125:8 175:11 introductions 6:13,15 7:2 invest 346:17 357:19 invested 231:6 investment 345:16 involved 9:15 13:12 52:6 164:22 224:11 225:6 392:17 involvement 345:9 IRF 240:19 291:14 301:22 302:2 311:3 313:13 315:11 320:10 333:22 352:4,20 357:7,8 373:8 378:7 383:7 **IRFs** 288:14 290:20 291:12 320:14 371:8 377:18 391:9,13 398:14 Irvine 1:22 18:4 issue 38:18 47:18 63:8

70:20 79:10 88:6,7 101:5,22 105:6 110:16,16,21 118:18 151:8 159:3 161:17 190:14 214:20 215:7 215:14 226:21 240:8 278:9,13 301:11 337:8,20,21 343:6 346:2 352:15 354:4,7 360:10 368:6 395:7 395:20,21 396:13 400:20 issues 10:11 12:1,2 23:10 32:8 42:13 63:15 69:22 71:1 73:22 87:20 91:18 101:12 121:12,13 150:10 154:20 161:8 176:22 177:7 180:17 217:5 297:8 312:20 315:3 338:3 364:1 370:11 394:21 it'll 242:6 item 49:19 50:11 161:3 161:8,16,18 187:10 187:11 218:2 234:22 235:2 257:16 258:17 260:3,6 269:16 297:17 300:1 303:8,9 311:16 319:15 333:12 354:20 items 48:3,6 50:1,9 51:16,21 128:2 133:16 160:2 163:17 165:6.6 167:11.15 169:10 182:2,3 186:13 187:2 188:5 188:18 208:11 209:19 209:22 216:4,10,11 216:17 217:1 223:4 229:19 235:1,3 243:13,14,16 247:20 248:10,11,14 250:5 257:12,12,15,17,22 258:15,17,19,21 259:2,17,19 260:16 262:3 267:20 273:6 287:22 288:10 293:19 294:17,18 298:14,19 298:20 299:1,4,16 306:19 307:10 314:18 326:15 327:18,22 329:8 331:16 347:4 iterative 258:6 IUR 217:9 **IURs** 217:9,11 J

11	1		1
Jackson 3:8 125:22	263:16 264:3,6,9	379:5,18 380:11	260:18 261:10,12
130:12,16,18,21	265:5,14,17 266:10	381:2 392:9 395:11	266:4,9,19 267:7,7
131:1 133:12,16	266:17,20 321:18	kinds 30:12 132:13	271:21 277:2,4 278:3
135:15,17,22 136:8	322:6 326:5 327:17	148:12 161:14 190:22	278:8 281:15 282:21
136:14,17,20 137:21	327:22 328:3,8,11,15	243:17 327:4,12	292:18 293:17 294:4
138:13,15,18 139:8	328:21 329:4 331:8	334:19 378:21 407:16	294:9 295:5,5,10,16
139:13,22 140:21	331:20 333:18 334:11	Kirsten 2:20 7:11 14:2	295:20 296:4,13
141:16 142:1,5 143:1	334:14 336:21 337:14	14:12 98:10	297:15,22 298:6,10
146:9 151:18 152:14	353:11 355:20 394:19	knock 235:22	298:16 299:1 304:8,9
153:21 158:5 160:1,6	397:14	know 6:4 8:18 12:13	304:14,22 305:12,14
160:15,18,20 162:9	kappa 101:20 102:20	22:21 25:17 26:11	306:16 307:9,19
166:17 168:1 184:20 196:21 213:20	103:3 Karen 33:12	27:12 28:16 31:11	308:13 311:11,18
James 3:11 238:7 239:9	Katherine 1:13 15:4	33:8 34:5 38:1 43:6 44:2,18 45:14 47:1,4	312:4,9,11,14,22 313:12,12,15,18,21
263:8	157:18 186:2 208:4	49:11 50:13 51:18	313:22 314:10,15
Jane 3:10 53:18,20 65:1	Katherine's 189:11	52:17 59:10 60:3	316:3,14 320:12,22
66:2 91:8	KATHLEEN 3:4	61:16 63:10 67:11	321:14 322:10 324:18
JD 2:9,15	Kathy 286:10	69:20 70:5 71:2 72:16	325:14 328:6 330:10
Jean 126:4	Keck 2:10 15:16,18	73:5,19 77:15,16,17	330:22 331:2,14
Jennifer 1:16 13:2	keep 44:13 47:2,4 84:21	78:5,13 79:4,17 81:8	332:11,13,18 334:2
80:16 84:12 90:9	99:11 124:15 134:21	81:22 85:20 86:9 87:5	334:17 335:8,11,13
162:17 168:18 174:13	169:9 170:20 229:8	88:2,10,21 89:7,12,14	335:16,19 336:4,8,11
356:20	309:18 361:4	89:15 90:4,9,10 92:13	336:12,17 337:1,8,9
Jennifer's 360:9	keeping 47:7 281:9	96:1 97:3 99:9 101:16	338:10 340:15,17
Jewish 2:6	kept 192:13 293:21	104:13 107:13,20	344:14,16 345:2,20
Jimmo 301:12 309:1,22	Kerry 3:9 125:11	108:16 109:15,15,16	346:9,15,18 347:1,9
Joan 241:5	key 287:20	110:9 111:9,11 112:3	347:14 349:12 351:12
job 47:3 82:1 379:4 joined 64:22 199:9	kick 42:11 47:12 235:7 kiddo 69:17	112:4 116:16 117:5 119:15 120:8 122:5,8	351:15,17 354:2,21 355:1,2,4 356:13
joining 6:6 126:4	kidney 13:11	127:13 132:3 133:15	358:3 361:13 364:17
joint 17:13 19:16 73:12	kids 148:9,17,20	133:21 134:5,13	364:19,21 365:13
87:12	kind 11:10,13 14:14	135:4,5 136:4 143:5	368:13 371:6,8,22
joke 61:20	29:11 37:14 39:7	143:19 144:5,14	372:2,3,9,11,14 373:6
journey 14:5	48:10 51:9,20 65:3	145:15,22 146:6	373:15 374:13,13,14
judgment 71:12 77:5	70:2 74:10 79:15,16	148:4,4 150:5 151:13	374:19 375:6,9,10,12
jump 7:13 43:4 184:8	87:20 89:12,14 90:6,8	152:11 155:9 156:16	376:12 377:2 378:18
jump 7:13 43:4 184:8 356:10	87:20 89:12,14 90:6,8 90:10 92:19 104:12	152:11 155:9 156:16 158:10 161:7,11	376:12 377:2 378:18 379:21 380:5,9 382:4
jump 7:13 43:4 184:8 356:10 jumping 193:8	87:20 89:12,14 90:6,8 90:10 92:19 104:12 109:7,21 111:2,12	152:11 155:9 156:16 158:10 161:7,11 164:13 165:8 168:7	376:12 377:2 378:18 379:21 380:5,9 382:4 382:9 383:1,8,13,22
jump 7:13 43:4 184:8 356:10 jumping 193:8 June 1:6 5:4	87:20 89:12,14 90:6,8 90:10 92:19 104:12 109:7,21 111:2,12 120:13,16 131:18	152:11 155:9 156:16 158:10 161:7,11 164:13 165:8 168:7 168:15 169:7 171:3,5	376:12 377:2 378:18 379:21 380:5,9 382:4 382:9 383:1,8,13,22 388:13,15,16,18,20
jump 7:13 43:4 184:8 356:10 jumping 193:8 June 1:6 5:4 jurisdiction 132:11	87:20 89:12,14 90:6,8 90:10 92:19 104:12 109:7,21 111:2,12 120:13,16 131:18 145:5 148:2 151:16	152:11 155:9 156:16 158:10 161:7,11 164:13 165:8 168:7 168:15 169:7 171:3,5 176:8,20 179:7,10	376:12 377:2 378:18 379:21 380:5,9 382:4 382:9 383:1,8,13,22 388:13,15,16,18,20 388:22 389:9 390:20
jump 7:13 43:4 184:8 356:10 jumping 193:8 June 1:6 5:4	87:20 89:12,14 90:6,8 90:10 92:19 104:12 109:7,21 111:2,12 120:13,16 131:18 145:5 148:2 151:16 151:22 159:2 161:13	152:11 155:9 156:16 158:10 161:7,11 164:13 165:8 168:7 168:15 169:7 171:3,5 176:8,20 179:7,10 180:20 181:3 182:4	376:12 377:2 378:18 379:21 380:5,9 382:4 382:9 383:1,8,13,22 388:13,15,16,18,20 388:22 389:9 390:20 390:21,22 391:7,10
jump 7:13 43:4 184:8 356:10 jumping 193:8 June 1:6 5:4 jurisdiction 132:11	87:20 89:12,14 90:6,8 90:10 92:19 104:12 109:7,21 111:2,12 120:13,16 131:18 145:5 148:2 151:16 151:22 159:2 161:13 162:4,15 163:10,18	152:11 155:9 156:16 158:10 161:7,11 164:13 165:8 168:7 168:15 169:7 171:3,5 176:8,20 179:7,10 180:20 181:3 182:4 182:10,13 183:8,17	376:12 377:2 378:18 379:21 380:5,9 382:4 382:9 383:1,8,13,22 388:13,15,16,18,20 388:22 389:9 390:20 390:21,22 391:7,10 392:3,6,7,9,19 393:2
jump 7:13 43:4 184:8 356:10 jumping 193:8 June 1:6 5:4 jurisdiction 132:11 justified 69:3 K	87:20 89:12,14 90:6,8 90:10 92:19 104:12 109:7,21 111:2,12 120:13,16 131:18 145:5 148:2 151:16 151:22 159:2 161:13 162:4,15 163:10,18 166:1 171:21 173:1	152:11 155:9 156:16 158:10 161:7,11 164:13 165:8 168:7 168:15 169:7 171:3,5 176:8,20 179:7,10 180:20 181:3 182:4 182:10,13 183:8,17 185:1 187:2,19	376:12 377:2 378:18 379:21 380:5,9 382:4 382:9 383:1,8,13,22 388:13,15,16,18,20 388:22 389:9 390:20 390:21,22 391:7,10 392:3,6,7,9,19 393:2 393:3,5 394:12,22
jump 7:13 43:4 184:8 356:10 jumping 193:8 June 1:6 5:4 jurisdiction 132:11 justified 69:3	87:20 89:12,14 90:6,8 90:10 92:19 104:12 109:7,21 111:2,12 120:13,16 131:18 145:5 148:2 151:16 151:22 159:2 161:13 162:4,15 163:10,18	152:11 155:9 156:16 158:10 161:7,11 164:13 165:8 168:7 168:15 169:7 171:3,5 176:8,20 179:7,10 180:20 181:3 182:4 182:10,13 183:8,17	376:12 377:2 378:18 379:21 380:5,9 382:4 382:9 383:1,8,13,22 388:13,15,16,18,20 388:22 389:9 390:20 390:21,22 391:7,10 392:3,6,7,9,19 393:2
jump 7:13 43:4 184:8 356:10 jumping 193:8 June 1:6 5:4 jurisdiction 132:11 justified 69:3 <u>K</u> K 408:10,10	87:20 89:12,14 90:6,8 90:10 92:19 104:12 109:7,21 111:2,12 120:13,16 131:18 145:5 148:2 151:16 151:22 159:2 161:13 162:4,15 163:10,18 166:1 171:21 173:1 174:13,14 176:6	152:11 155:9 156:16 158:10 161:7,11 164:13 165:8 168:7 168:15 169:7 171:3,5 176:8,20 179:7,10 180:20 181:3 182:4 182:10,13 183:8,17 185:1 187:2,19 188:11,15 189:6,15	376:12 377:2 378:18 379:21 380:5,9 382:4 382:9 383:1,8,13,22 388:13,15,16,18,20 388:22 389:9 390:20 390:21,22 391:7,10 392:3,6,7,9,19 393:2 393:3,5 394:12,22 396:1 398:11,22 399:17 401:14 403:22 405:15,22 406:20
jump 7:13 43:4 184:8 356:10 jumping 193:8 June 1:6 5:4 jurisdiction 132:11 justified 69:3 <u>K</u> K 408:10,10 Kaiser 1:19 19:7 Kaplan 1:21 18:1,1 31:14,19 32:1 47:17	87:20 89:12,14 90:6,8 90:10 92:19 104:12 109:7,21 111:2,12 120:13,16 131:18 145:5 148:2 151:16 151:22 159:2 161:13 162:4,15 163:10,18 166:1 171:21 173:1 174:13,14 176:6 180:1 183:22 184:8 185:22 187:10 188:4 190:1,4,9,13 196:6,9	152:11 155:9 156:16 158:10 161:7,11 164:13 165:8 168:7 168:15 169:7 171:3,5 176:8,20 179:7,10 180:20 181:3 182:4 182:10,13 183:8,17 185:1 187:2,19 188:11,15 189:6,15 189:17 190:9,11 191:9 192:1,11 193:7 194:5 195:18 197:14	376:12 377:2 378:18 379:21 380:5,9 382:4 382:9 383:1,8,13,22 388:13,15,16,18,20 388:22 389:9 390:20 390:21,22 391:7,10 392:3,6,7,9,19 393:2 393:3,5 394:12,22 396:1 398:11,22 399:17 401:14 403:22 405:15,22 406:20 knowing 60:10 86:19
jump 7:13 43:4 184:8 356:10 jumping 193:8 June 1:6 5:4 jurisdiction 132:11 justified 69:3 <u>K</u> K 408:10,10 Kaiser 1:19 19:7 Kaplan 1:21 18:1,1 31:14,19 32:1 47:17 48:15,21 49:3,9,15,18	87:20 89:12,14 90:6,8 90:10 92:19 104:12 109:7,21 111:2,12 120:13,16 131:18 145:5 148:2 151:16 151:22 159:2 161:13 162:4,15 163:10,18 166:1 171:21 173:1 174:13,14 176:6 180:1 183:22 184:8 185:22 187:10 188:4 190:1,4,9,13 196:6,9 197:9 200:9 201:9	152:11 155:9 156:16 158:10 161:7,11 164:13 165:8 168:7 168:15 169:7 171:3,5 176:8,20 179:7,10 180:20 181:3 182:4 182:10,13 183:8,17 185:1 187:2,19 188:11,15 189:6,15 189:17 190:9,11 191:9 192:1,11 193:7 194:5 195:18 197:14 197:19,22 200:19	376:12 377:2 378:18 379:21 380:5,9 382:4 382:9 383:1,8,13,22 388:13,15,16,18,20 388:22 389:9 390:20 390:21,22 391:7,10 392:3,6,7,9,19 393:2 393:3,5 394:12,22 396:1 398:11,22 399:17 401:14 403:22 405:15,22 406:20 knowing 60:10 86:19 146:5 344:13
jump 7:13 43:4 184:8 356:10 jumping 193:8 June 1:6 5:4 jurisdiction 132:11 justified 69:3 <u>K</u> K 408:10,10 Kaiser 1:19 19:7 Kaplan 1:21 18:1,1 31:14,19 32:1 47:17 48:15,21 49:3,9,15,18 87:18 101:4,11 102:3	87:20 89:12,14 90:6,8 90:10 92:19 104:12 109:7,21 111:2,12 120:13,16 131:18 145:5 148:2 151:16 151:22 159:2 161:13 162:4,15 163:10,18 166:1 171:21 173:1 174:13,14 176:6 180:1 183:22 184:8 185:22 187:10 188:4 190:1,4,9,13 196:6,9 197:9 200:9 201:9 223:10 226:1 227:14	152:11 155:9 156:16 158:10 161:7,11 164:13 165:8 168:7 168:15 169:7 171:3,5 176:8,20 179:7,10 180:20 181:3 182:4 182:10,13 183:8,17 185:1 187:2,19 188:11,15 189:6,15 189:17 190:9,11 191:9 192:1,11 193:7 194:5 195:18 197:14 197:19,22 200:19 201:7 208:22 209:10	376:12 377:2 378:18 379:21 380:5,9 382:4 382:9 383:1,8,13,22 388:13,15,16,18,20 388:22 389:9 390:20 390:21,22 391:7,10 392:3,6,7,9,19 393:2 393:3,5 394:12,22 396:1 398:11,22 399:17 401:14 403:22 405:15,22 406:20 knowing 60:10 86:19 146:5 344:13 knowledge 288:12
jump 7:13 43:4 184:8 356:10 jumping 193:8 June 1:6 5:4 jurisdiction 132:11 justified 69:3 <u>K</u> K 408:10,10 Kaiser 1:19 19:7 Kaplan 1:21 18:1,1 31:14,19 32:1 47:17 48:15,21 49:3,9,15,18 87:18 101:4,11 102:3 103:5,15 110:15	87:20 89:12,14 90:6,8 90:10 92:19 104:12 109:7,21 111:2,12 120:13,16 131:18 145:5 148:2 151:16 151:22 159:2 161:13 162:4,15 163:10,18 166:1 171:21 173:1 174:13,14 176:6 180:1 183:22 184:8 185:22 187:10 188:4 190:1,4,9,13 196:6,9 197:9 200:9 201:9 223:10 226:1 227:14 230:3,20 231:17	152:11 155:9 156:16 158:10 161:7,11 164:13 165:8 168:7 168:15 169:7 171:3,5 176:8,20 179:7,10 180:20 181:3 182:4 182:10,13 183:8,17 185:1 187:2,19 188:11,15 189:6,15 189:17 190:9,11 191:9 192:1,11 193:7 194:5 195:18 197:14 197:19,22 200:19 201:7 208:22 209:10 211:11,20 214:20	376:12 377:2 378:18 379:21 380:5,9 382:4 382:9 383:1,8,13,22 388:13,15,16,18,20 388:22 389:9 390:20 390:21,22 391:7,10 392:3,6,7,9,19 393:2 393:3,5 394:12,22 396:1 398:11,22 399:17 401:14 403:22 405:15,22 406:20 knowing 60:10 86:19 146:5 344:13 knowledge 288:12 330:5
jump 7:13 43:4 184:8 356:10 jumping 193:8 June 1:6 5:4 jurisdiction 132:11 justified 69:3 <u>K</u> K 408:10,10 Kaiser 1:19 19:7 Kaplan 1:21 18:1,1 31:14,19 32:1 47:17 48:15,21 49:3,9,15,18 87:18 101:4,11 102:3 103:5,15 110:15 116:11,15 149:7	87:20 89:12,14 90:6,8 90:10 92:19 104:12 109:7,21 111:2,12 120:13,16 131:18 145:5 148:2 151:16 151:22 159:2 161:13 162:4,15 163:10,18 166:1 171:21 173:1 174:13,14 176:6 180:1 183:22 184:8 185:22 187:10 188:4 190:1,4,9,13 196:6,9 197:9 200:9 201:9 223:10 226:1 227:14 230:3,20 231:17 235:18 252:13 257:21	152:11 155:9 156:16 158:10 161:7,11 164:13 165:8 168:7 168:15 169:7 171:3,5 176:8,20 179:7,10 180:20 181:3 182:4 182:10,13 183:8,17 185:1 187:2,19 188:11,15 189:6,15 189:17 190:9,11 191:9 192:1,11 193:7 194:5 195:18 197:14 197:19,22 200:19 201:7 208:22 209:10 211:11,20 214:20 215:6 216:8 217:9,12	376:12 377:2 378:18 379:21 380:5,9 382:4 382:9 383:1,8,13,22 388:13,15,16,18,20 388:22 389:9 390:20 390:21,22 391:7,10 392:3,6,7,9,19 393:2 393:3,5 394:12,22 396:1 398:11,22 399:17 401:14 403:22 405:15,22 406:20 knowing 60:10 86:19 146:5 344:13 knowledge 288:12 330:5 known 28:9 287:17
jump 7:13 43:4 184:8 356:10 jumping 193:8 June 1:6 5:4 jurisdiction 132:11 justified 69:3 <u>K</u> K 408:10,10 Kaiser 1:19 19:7 Kaplan 1:21 18:1,1 31:14,19 32:1 47:17 48:15,21 49:3,9,15,18 87:18 101:4,11 102:3 103:5,15 110:15 116:11,15 149:7 151:4,10 161:1	87:20 89:12,14 90:6,8 90:10 92:19 104:12 109:7,21 111:2,12 120:13,16 131:18 145:5 148:2 151:16 151:22 159:2 161:13 162:4,15 163:10,18 166:1 171:21 173:1 174:13,14 176:6 180:1 183:22 184:8 185:22 187:10 188:4 190:1,4,9,13 196:6,9 197:9 200:9 201:9 223:10 226:1 227:14 230:3,20 231:17 235:18 252:13 257:21 261:10 263:10 266:15	152:11 155:9 156:16 158:10 161:7,11 164:13 165:8 168:7 168:15 169:7 171:3,5 176:8,20 179:7,10 180:20 181:3 182:4 182:10,13 183:8,17 185:1 187:2,19 188:11,15 189:6,15 189:17 190:9,11 191:9 192:1,11 193:7 194:5 195:18 197:14 197:19,22 200:19 201:7 208:22 209:10 211:11,20 214:20 215:6 216:8 217:9,12 218:9 220:2 223:9	376:12 377:2 378:18 379:21 380:5,9 382:4 382:9 383:1,8,13,22 388:13,15,16,18,20 388:22 389:9 390:20 390:21,22 391:7,10 392:3,6,7,9,19 393:2 393:3,5 394:12,22 396:1 398:11,22 399:17 401:14 403:22 405:15,22 406:20 knowing 60:10 86:19 146:5 344:13 knowledge 288:12 330:5 known 28:9 287:17 310:5
jump 7:13 43:4 184:8 356:10 jumping 193:8 June 1:6 5:4 jurisdiction 132:11 justified 69:3 <u>K</u> K 408:10,10 Kaiser 1:19 19:7 Kaplan 1:21 18:1,1 31:14,19 32:1 47:17 48:15,21 49:3,9,15,18 87:18 101:4,11 102:3 103:5,15 110:15 116:11,15 149:7 151:4,10 161:1 179:17 187:6,9	$\begin{array}{c} 87:20\ 89:12,14\ 90:6,8\\ 90:10\ 92:19\ 104:12\\ 109:7,21\ 111:2,12\\ 120:13,16\ 131:18\\ 145:5\ 148:2\ 151:16\\ 151:22\ 159:2\ 161:13\\ 162:4,15\ 163:10,18\\ 166:1\ 171:21\ 173:1\\ 174:13,14\ 176:6\\ 180:1\ 183:22\ 184:8\\ 185:22\ 187:10\ 188:4\\ 190:1,4,9,13\ 196:6,9\\ 197:9\ 200:9\ 201:9\\ 223:10\ 226:1\ 227:14\\ 230:3,20\ 231:17\\ 235:18\ 252:13\ 257:21\\ 261:10\ 263:10\ 266:15\\ 305:8\ 327:6,7\ 329:18\\ \end{array}$	$\begin{array}{c} 152:11\ 155:9\ 156:16\\ 158:10\ 161:7,11\\ 164:13\ 165:8\ 168:7\\ 168:15\ 169:7\ 171:3,5\\ 176:8,20\ 179:7,10\\ 180:20\ 181:3\ 182:4\\ 182:10,13\ 183:8,17\\ 185:1\ 187:2,19\\ 188:11,15\ 189:6,15\\ 189:17\ 190:9,11\\ 191:9\ 192:1,11\ 193:7\\ 194:5\ 195:18\ 197:14\\ 197:19,22\ 200:19\\ 201:7\ 208:22\ 209:10\\ 211:11,20\ 214:20\\ 215:6\ 216:8\ 217:9,12\\ 218:9\ 220:2\ 223:9\\ 225:16,22\ 226:5,10\\ \end{array}$	376:12 377:2 378:18 379:21 380:5,9 382:4 382:9 383:1,8,13,22 388:13,15,16,18,20 388:22 389:9 390:20 390:21,22 391:7,10 392:3,6,7,9,19 393:2 393:3,5 394:12,22 396:1 398:11,22 399:17 401:14 403:22 405:15,22 406:20 knowing 60:10 86:19 146:5 344:13 knowledge 288:12 330:5 known 28:9 287:17
jump 7:13 43:4 184:8 356:10 jumping 193:8 June 1:6 5:4 jurisdiction 132:11 justified 69:3 <u>K</u> K 408:10,10 Kaiser 1:19 19:7 Kaplan 1:21 18:1,1 31:14,19 32:1 47:17 48:15,21 49:3,9,15,18 87:18 101:4,11 102:3 103:5,15 110:15 116:11,15 149:7 151:4,10 161:1 179:17 187:6,9 189:10 200:16 214:17	$\begin{array}{c} 87:20\ 89:12,14\ 90:6,8\\ 90:10\ 92:19\ 104:12\\ 109:7,21\ 111:2,12\\ 120:13,16\ 131:18\\ 145:5\ 148:2\ 151:16\\ 151:22\ 159:2\ 161:13\\ 162:4,15\ 163:10,18\\ 166:1\ 171:21\ 173:1\\ 174:13,14\ 176:6\\ 180:1\ 183:22\ 184:8\\ 185:22\ 187:10\ 188:4\\ 190:1,4,9,13\ 196:6,9\\ 197:9\ 200:9\ 201:9\\ 223:10\ 226:1\ 227:14\\ 230:3,20\ 231:17\\ 235:18\ 252:13\ 257:21\\ 261:10\ 263:10\ 266:15\\ 305:8\ 327:6,7\ 329:18\\ 331:21\ 334:8\ 336:4\\ \end{array}$	$\begin{array}{c} 152:11 \ 155:9 \ 156:16\\ 158:10 \ 161:7,11\\ 164:13 \ 165:8 \ 168:7\\ 168:15 \ 169:7 \ 171:3,5\\ 176:8,20 \ 179:7,10\\ 180:20 \ 181:3 \ 182:4\\ 182:10,13 \ 183:8,17\\ 185:1 \ 187:2,19\\ 188:11,15 \ 189:6,15\\ 189:17 \ 190:9,11\\ 191:9 \ 192:1,11 \ 193:7\\ 194:5 \ 195:18 \ 197:14\\ 197:19,22 \ 200:19\\ 201:7 \ 208:22 \ 209:10\\ 211:11,20 \ 214:20\\ 215:6 \ 216:8 \ 217:9,12\\ 218:9 \ 220:2 \ 223:9\\ 225:16,22 \ 226:5,10\\ 227:13 \ 229:13 \ 231:8\\ \end{array}$	376:12 377:2 378:18 379:21 380:5,9 382:4 382:9 383:1,8,13,22 388:13,15,16,18,20 388:22 389:9 390:20 390:21,22 391:7,10 392:3,6,7,9,19 393:2 393:3,5 394:12,22 396:1 398:11,22 399:17 401:14 403:22 405:15,22 406:20 knowing 60:10 86:19 146:5 344:13 knowledge 288:12 330:5 known 28:9 287:17 310:5
jump 7:13 43:4 184:8 356:10 jumping 193:8 June 1:6 5:4 jurisdiction 132:11 justified 69:3 K K 408:10,10 Kaiser 1:19 19:7 Kaplan 1:21 18:1,1 31:14,19 32:1 47:17 48:15,21 49:3,9,15,18 87:18 101:4,11 102:3 103:5,15 110:15 116:11,15 149:7 151:4,10 161:1 179:17 187:6,9 189:10 200:16 214:17 222:22 225:14 226:17	$\begin{array}{c} 87:20\ 89:12,14\ 90:6,8\\ 90:10\ 92:19\ 104:12\\ 109:7,21\ 111:2,12\\ 120:13,16\ 131:18\\ 145:5\ 148:2\ 151:16\\ 151:22\ 159:2\ 161:13\\ 162:4,15\ 163:10,18\\ 166:1\ 171:21\ 173:1\\ 174:13,14\ 176:6\\ 180:1\ 183:22\ 184:8\\ 185:22\ 187:10\ 188:4\\ 190:1,4,9,13\ 196:6,9\\ 197:9\ 200:9\ 201:9\\ 223:10\ 226:1\ 227:14\\ 230:3,20\ 231:17\\ 235:18\ 252:13\ 257:21\\ 261:10\ 263:10\ 266:15\\ 305:8\ 327:6,7\ 329:18\\ 331:21\ 334:8\ 336:4\\ 336:18,21\ 337:2\\ \end{array}$	$\begin{array}{c} 152:11\ 155:9\ 156:16\\ 158:10\ 161:7,11\\ 164:13\ 165:8\ 168:7\\ 168:15\ 169:7\ 171:3,5\\ 176:8,20\ 179:7,10\\ 180:20\ 181:3\ 182:4\\ 182:10,13\ 183:8,17\\ 185:1\ 187:2,19\\ 188:11,15\ 189:6,15\\ 189:17\ 190:9,11\\ 191:9\ 192:1,11\ 193:7\\ 194:5\ 195:18\ 197:14\\ 197:19,22\ 200:19\\ 201:7\ 208:22\ 209:10\\ 211:11,20\ 214:20\\ 215:6\ 216:8\ 217:9,12\\ 218:9\ 220:2\ 223:9\\ 225:16,22\ 226:5,10\\ 227:13\ 229:13\ 231:8\\ 231:14\ 235:21\ 236:12\\ \end{array}$	376:12 377:2 378:18 379:21 380:5,9 382:4 382:9 383:1,8,13,22 388:13,15,16,18,20 388:22 389:9 390:20 390:21,22 391:7,10 392:3,6,7,9,19 393:2 393:3,5 394:12,22 396:1 398:11,22 399:17 401:14 403:22 405:15,22 406:20 knowing 60:10 86:19 146:5 344:13 knowledge 288:12 330:5 known 28:9 287:17 310:5 knows 77:18 <u>L</u>
jump 7:13 43:4 184:8 356:10 jumping 193:8 June 1:6 5:4 jurisdiction 132:11 justified 69:3 <u>K</u> K 408:10,10 Kaiser 1:19 19:7 Kaplan 1:21 18:1,1 31:14,19 32:1 47:17 48:15,21 49:3,9,15,18 87:18 101:4,11 102:3 103:5,15 110:15 116:11,15 149:7 151:4,10 161:1 179:17 187:6,9 189:10 200:16 214:17	$\begin{array}{c} 87:20\ 89:12,14\ 90:6,8\\ 90:10\ 92:19\ 104:12\\ 109:7,21\ 111:2,12\\ 120:13,16\ 131:18\\ 145:5\ 148:2\ 151:16\\ 151:22\ 159:2\ 161:13\\ 162:4,15\ 163:10,18\\ 166:1\ 171:21\ 173:1\\ 174:13,14\ 176:6\\ 180:1\ 183:22\ 184:8\\ 185:22\ 187:10\ 188:4\\ 190:1,4,9,13\ 196:6,9\\ 197:9\ 200:9\ 201:9\\ 223:10\ 226:1\ 227:14\\ 230:3,20\ 231:17\\ 235:18\ 252:13\ 257:21\\ 261:10\ 263:10\ 266:15\\ 305:8\ 327:6,7\ 329:18\\ 331:21\ 334:8\ 336:4\\ \end{array}$	$\begin{array}{c} 152:11 \ 155:9 \ 156:16\\ 158:10 \ 161:7,11\\ 164:13 \ 165:8 \ 168:7\\ 168:15 \ 169:7 \ 171:3,5\\ 176:8,20 \ 179:7,10\\ 180:20 \ 181:3 \ 182:4\\ 182:10,13 \ 183:8,17\\ 185:1 \ 187:2,19\\ 188:11,15 \ 189:6,15\\ 189:17 \ 190:9,11\\ 191:9 \ 192:1,11 \ 193:7\\ 194:5 \ 195:18 \ 197:14\\ 197:19,22 \ 200:19\\ 201:7 \ 208:22 \ 209:10\\ 211:11,20 \ 214:20\\ 215:6 \ 216:8 \ 217:9,12\\ 218:9 \ 220:2 \ 223:9\\ 225:16,22 \ 226:5,10\\ 227:13 \ 229:13 \ 231:8\\ \end{array}$	376:12 377:2 378:18 379:21 380:5,9 382:4 382:9 383:1,8,13,22 388:13,15,16,18,20 388:22 389:9 390:20 390:21,22 391:7,10 392:3,6,7,9,19 393:2 393:3,5 394:12,22 396:1 398:11,22 399:17 401:14 403:22 405:15,22 406:20 knowing 60:10 86:19 146:5 344:13 knowledge 288:12 330:5 known 28:9 287:17 310:5 knows 77:18
jump 7:13 43:4 184:8 356:10 jumping 193:8 June 1:6 5:4 jurisdiction 132:11 justified 69:3 K K 408:10,10 Kaiser 1:19 19:7 Kaplan 1:21 18:1,1 31:14,19 32:1 47:17 48:15,21 49:3,9,15,18 87:18 101:4,11 102:3 103:5,15 110:15 116:11,15 149:7 151:4,10 161:1 179:17 187:6,9 189:10 200:16 214:17 222:22 225:14 226:17 233:15 237:14 252:5	$\begin{array}{c} 87:20\ 89:12,14\ 90:6,8\\ 90:10\ 92:19\ 104:12\\ 109:7,21\ 111:2,12\\ 120:13,16\ 131:18\\ 145:5\ 148:2\ 151:16\\ 151:22\ 159:2\ 161:13\\ 162:4,15\ 163:10,18\\ 166:1\ 171:21\ 173:1\\ 174:13,14\ 176:6\\ 180:1\ 183:22\ 184:8\\ 185:22\ 187:10\ 188:4\\ 190:1,4,9,13\ 196:6,9\\ 197:9\ 200:9\ 201:9\\ 223:10\ 226:1\ 227:14\\ 230:3,20\ 231:17\\ 235:18\ 252:13\ 257:21\\ 261:10\ 263:10\ 266:15\\ 305:8\ 327:6,7\ 329:18\\ 331:21\ 334:8\ 336:4\\ 336:18,21\ 337:2\\ 344:17\ 353:21\ 356:3\end{array}$	$\begin{array}{c} 152:11 \ 155:9 \ 156:16\\ 158:10 \ 161:7,11\\ 164:13 \ 165:8 \ 168:7\\ 168:15 \ 169:7 \ 171:3,5\\ 176:8,20 \ 179:7,10\\ 180:20 \ 181:3 \ 182:4\\ 182:10,13 \ 183:8,17\\ 185:1 \ 187:2,19\\ 188:11,15 \ 189:6,15\\ 189:17 \ 190:9,11\\ 191:9 \ 192:1,11 \ 193:7\\ 194:5 \ 195:18 \ 197:14\\ 197:19,22 \ 200:19\\ 201:7 \ 208:22 \ 209:10\\ 211:11,20 \ 214:20\\ 215:6 \ 216:8 \ 217:9,12\\ 218:9 \ 220:2 \ 223:9\\ 225:16,22 \ 226:5,10\\ 227:13 \ 229:13 \ 231:8\\ 231:14 \ 235:21 \ 236:12\\ 237:16 \ 238:4,5\\ \end{array}$	376:12 377:2 378:18 379:21 380:5,9 382:4 382:9 383:1,8,13,22 388:13,15,16,18,20 388:22 389:9 390:20 390:21,22 391:7,10 392:3,6,7,9,19 393:2 393:3,5 394:12,22 396:1 398:11,22 399:17 401:14 403:22 405:15,22 406:20 knowing 60:10 86:19 146:5 344:13 knowledge 288:12 330:5 known 28:9 287:17 310:5 knows 77:18 <u>L</u> L's 86:14

lady 400:7 laid 338:3 Lake 14:1 Lakes 15:22 land 109:7 language 28:14 280:7 305:12 languages 280:8 laptop 44:16 large 91:20 208:16 229:18,22 248:22 340:19 366:20 larger 212:14 213:2 215:2 229:22 230:1 298:5 352:12 391:2 391:17 largest 144:11 lastly 288:13 late 6:7 65:8 323:19 latent 307:15 laundry 235:19 law 301:15,15 lawyer 11:14 **LCSW** 1:15 lead 17:1 42:8,9 52:7 54:1 59:5 85:3 98:13 99:4 100:1 125:5 131:19 137:11 145:5 146:15 154:13 232:4 273:9 289:14 372:17 374:8 376:3 leading 243:16 347:17 leads 86:20 130:4 370:8 lean 43:9 learning 345:10 leave 22:12 24:1 401:4 407:8,9,11 leaves 347:20 leaving 229:2,4 led 89:7 Lee 1:9,12 10:2 24:22 38:16 69:15 86:16 106:19 109:13 119:16 125:5 132:1 154:3 189:9 191:4 208:1 212:3 224:14 343:3 344:8 Lee's 350:5 left 29:6 196:9 307:8 356:3 400:7 legal 275:1 legitimate 261:6 Lego 70:5 Legos 70:5 legs 11:10 leisure 367:22 Len 17:9 125:6 137:15 142:8 145:4 158:7,19

182:22 208:1 289:12 LENARD 2:5 length 253:22 296:13 296:15 310:21 347:18 348:2,3 352:6,16 lengthy 253:11 let's 44:11 95:21 125:14 133:6 143:20 173:22 175:18 178:7 181:3 182:20 183:22,22 206:10 207:19,21 211:4 227:14 259:17 316:14 318:1 343:15 368:16 370:5 405:18 letting 192:9 level 35:10 51:16 55:11 57:10 79:21 80:12 81:1 101:17,19,21 102:4,5 103:10,13 110:17 124:7 130:10 130:13,15,16 133:2,3 133:5,9 135:7 136:7,8 144:10 146:12 160:13 160:16 183:9 215:16 218:2 223:20,21 234:9.10 237:1 240:19 241:4 256:6 256:12,17,18,22 260:9 261:9,14 267:18 277:3 278:5 303:7,8,13,14 310:1 320:21 321:4 324:17 325:1,7,20 329:6,14 329:16 330:21,21 333:12 334:10,21 335:10,11 336:6 337:1,3,3 348:10,18 348:22,22 349:15 351:9 352:10,11,17 355:21 356:1,4,6 357:5,19 371:3,17,18 373:16 375:5 379:7,8 394:9 395:1,2,5,11,14 397:5,15 399:21 400:10,20 levels 144:3 145:21 310:17 311:4 313:19 315:2 365:6 372:12 leverage 317:7 376:16 liability 273:22 license 288:16 licensed 76:16 Lida 3:9 125:10,11 127:4 life 11:13 40:2,16 57:22 58:19 60:9 127:12 241:4 lifesaving 58:10

lifted 161:9 light 25:19 87:6,12,13 179:7 **liked** 147:20 252:9,12 likelihood 304:4 Likert 245:10 247:6 limit 182:17 233:19 limitations 208:11 limited 237:20 374:14 limiting 383:13 Linda 2:1 12:7 54:1 59:13 60:14,22 63:22 92:7 93:2 99:5,6 103:21 117:8 122:10 135:4,11 166:10 181:20 191:5 193:15 227:17 253:4 269:18 282:4 290:11 308:18 338:6 344:11 347:13 356:20 358:13 382:15 line 24:9,13 89:18 112:20 126:3 196:10 199:8 228:15,16 229:11 242:20 287:11 347:12 383:12 392:19 403:3 lines 68:13 107:21 173:10 223:17 244:5 354:3 365:11 388:4 linked 113:21 252:10 Lisa 2:2,8 13:22 65:2,8 69:14 80:21 86:13 92:7 116:22 175:20 223:12 254:19 273:12 273:12,13,13,16 320:17 347:13 351:3 362:15 394:5 397:7 400:21 list 29:3 54:16 77:21 78:2 91:20 154:22 159:7 218:7 235:19 listed 101:18 103:6 listen 165:10 184:13 listened 273:17 listening 8:18 80:20 215:20 LISW 1:17 lit 24:14 **literacy** 28:15,15 literature 60:1 61:13 68:12 83:12 188:12 252:13,14 310:13 388:22 395:4,10 396:16 litmus 394:4 little 6:7 8:7 10:17 37:6 45:7 49:20 50:4 53:10 54:5,15 59:11 60:9

61:12.21 65:22 66:12 72:15 74:19 77:9 79:18 87:19 94:1 98:17 107:3,3 114:7 123:1 127:3 166:14 168:14 175:8,19 181:22 187:22 193:8 213:7 219:1 224:5 226:14 227:10 230:21 232:5 234:3 239:21 240:3 243:10,18,21 248:7 250:1 275:7 276:15 278:8 282:22 321:2 343:14 360:9 363:22 366:21 374:21 388:11 393:12 394:13 live 127:11 135:4 367:19 lived 5:9 living 17:3 148:10 251:16 282:13 Liz 21:6,8 86:14 119:6 125:6 load 376:19 loaded 156:5 **lobby** 23:14 lobbyist 11:14 location 301:2 355:9 log 23:18 logic 348:12 353:7 376:2 logistics 7:1 long 4:10,11,16,17,19 5:8 8:11 52:2 124:9 129:18 137:19,22 138:4,19 139:12,13 139:16 141:1,2,9 165:1 180:4 182:7,22 210:18 224:1 229:3,4 230:8,8 233:7 250:16 263:13 273:19 274:20 276:2,16 278:4 282:18 284:21 286:15 295:19 296:6.14 307:3 317:1 336:2 367:11 368:3 370:2 370:19 376:20 377:2 384:14 long-term 12:16 17:3 214:11 373:7 longer 27:18 40:22 41:1 225:1 244:2 347:17 367:14 404:5 look 21:3,4 25:18 34:14 36:14 40:13 41:3 44:9 46:21 58:22 68:17 101:15 108:16 124:3 133:8 144:9 146:2

150:19.20 151:13 121:2.11 122:11 405:7 Mammoth 15:21 155:4 189:11 190:6 124:10 132:19 134:22 Lucas 3:10 53:18,20,20 manage 87:5 193:7,13 210:12 143:14 144:19 150:3 66:3 77:19 91:13 managed 137:19,22 150:9 152:6 162:3 138:4,19 139:2 216:14,14 217:13,15 lump 131:17 163:14 217:19 223:12 237:16 168:1 175:12 190:16 lumping 245:2 140:16,17,22 141:1 238:18 257:4 259:7 192:16 209:2,6 lunch 23:15 168:9,11 147:3,13 214:11 260:14 263:8,14 210:12 211:12 238:6 172:22 173:22 174:2 management 17:10,19 295:17,18 296:17 238:6,7 241:2 243:14 174:8 18:12 57:14 60:11 303:8,10 304:13 249:15 251:17 252:15 69:1 73:2 79:8 87:15 Μ 260:19 277:3 285:9 240:15 309:11,12,13 315:6 316:17 319:17 322:7 297:9 299:16 317:2 **MA** 2:1,2,5 manager 2:20,22 7:11 330:12 338:13 351:11 326:10,13,14,16,18 ma'am 173:13 388:5 7:17 19:6 53:21 352:6,10,16 366:13 326:21 327:2 328:17 158:12 215:20 403:4 372:10 391:10 407:1 328:22 329:9,13,15 machines 65:21 managers 194:19 **MACPAC** 129:9 looked 68:12 72:2 335:8 337:2,9 352:19 manages 16:11 134:6 251:2 276:2,4 managing 73:17 148:14 354:11 359:15 360:3 **MACRA** 93:18 276:11 301:10 330:16 367:19 381:19 382:9 Madonna 19:1 mandated 287:18 334:19 365:20 366:10 382:10 394:13 Mae 5:14,15,17 288:13 mandatory 86:7,8 looking 5:18 6:21 26:5 lots 12:21 54:14 87:7,7 Maggie 3:5 287:12 28:18 29:8,9,10 30:10 321:18 manipulate 354:8 293:12 294:9 295:12 31:2 36:4 38:8 39:7 Louisiana 129:8 329:21 332:6 333:7 manner 398:14 39:22 50:1,5 70:1,2 love 10:10 64:4 223:22 manual 62:16 353:8 335:2 366:17 71:17 72:9 75:11 239:4 256:17 353:18 mail 134:8 211:12,18 398:8 76:11 80:3,6 87:1 375:3 398:16 manuals 290:22 277:15 279:11 283:1 low 57:10 63:15 68:15 88:14 89:3 90:14 283:2 map 244:1 251:3 91:10 92:12 95:3 68:19 79:18 94:18.20 mailed 279:10 March 39:22 281:4 117:21 119:4 139:6 95:8 99:17,20 106:7,9 mailing 282:6 marching 315:19 144:15 147:21 155:22 106:13 109:2,8,15 main 65:15 293:9 297:7 marginally 132:19 158:11 168:4 170:8 112:15 114:16 115:1 marital 28:15 297:14 183:2 192:13 198:3 115:14,18 117:20 maintain 290:2 301:20 mark 127:16 199:5 203:4.22 118:3 202:19 203:8 310:4 346:14 378:10 market 231:8,9,14 215:16 219:9 220:13 203:21 204:3,17,20 maintained 290:6 marks 7:12 222:18 223:14 254:11 205:10,14,22 206:13 maintaining 281:9 marrying 81:2 260:9 264:19 268:21 206:17 216:3 220:11 maintenance 25:8,13 Maryland 12:6 218:18 220:17 221:4,8,16 270:20 272:15 279:22 40:5,11 54:20 59:15 mask 27:5 37:10,11 284:2 295:21 312:12 222:4,8 234:2 235:14 59:16 100:7 302:9 masking 37:18 Mass 21:9,19 314:16 315:1 318:18 238:22 255:14,19 303:5 304:4 305:14 320:19 323:4 326:6 264:17,22 269:10,14 305:18 372:3 Massachusetts 2:4 327:19 331:15 333:17 270:4,8,19 271:1 major 177:13 232:16 129:7 135:5 136:13 339:8 343:5 349:11 293:4 320:1 323:3,7 364:1 253:20 379:21 382:19 352:14 366:12,22 330:18 339:6,11 majority 94:10 104:15 master 346:10,13 368:21 375:8 378:18 342:18,22 344:1,6 341:12 378:11 357:12 match 122:14 237:22 383:18 384:6 385:19 356:9,14 363:1,6 making 6:5 26:13 27:7 390:21 392:15 394:9 48:8 81:21 84:6 matched 80:4 385:8,12,18,22 386:9 395:12 402:7,14 386:14,19 387:3,10 104:10 108:11 148:15 material 52:14 193:10 210:12,21 398:13 looks 90:19 91:13,16 387:15 156:20 196:7 236:8 92:1 101:20 115:8 lower 104:3 349:10 276:13 309:8 310:13 materials 37:4 67:21 235:5 292:1 329:5 371:18 350:7 378:15 68:1 179:1 224:6 Mallery 3:10 126:1 337:1 359:18 363:3 lowest 373:16 288:11 346:8 358:2 lose 40:21 257:13 279:7 LTAC 306:11 320:11 150:13 151:3,9 153:6 373:10,11 399:1 matter 9:7,10,17,19 406:20 345:15 370:12 375:14 153:13,17 167:11,21 losing 40:19 196:16 379:7 383:5,12,15,22 169:8 170:7 186:12 97:7 108:15 124:20 225:19 257:15 391:1 404:7 162:1 174:4 192:3 186:19,22 187:8 LTACs 320:15 345:21 216:1 246:1,20 **lost** 232:6,6 188:13 194:14,19,22 lot 6:20 11:14,17 25:6 357:19 370:16,16 281:17 284:11 335:9 195:6,13,17 210:2,8 30:1,5,6,7 33:14 375:22 377:18 378:14 211:15 212:16 218:22 346:20 404:16 408:14 36:12 38:18 52:17,21 matters 143:15 379:16,19 382:18 219:5,14 225:2 87:9 110:10 114:10 390:16 391:15 399:15 226:10 227:22 matures 124:2

			430
maximum 187:13	41:12 42:4 43:16,19	206.2 4 0 207.17	11.1 5 16 20 12.5 7
MCO's 140:19	44:5 45:19,22 46:2,15	286:3,4,8 287:17 289:14,15 292:1,4,14	41:4,5,16,20 42:5,7 42:10,15 43:12 44:3
MCOs 129:10 139:1	44.5 45.19,22 46.2,15 47:15,21 48:1,7 49:22	294:14 295:10 298:7	
MD 1:12,13,14 2:4,6,8	50:5,12 51:10,19 52:7		45:11 46:13 48:2,6,13 50:6,8,8 51:22 52:3
		298:17,21 299:9,15	
2:10,14 3:2,4,5,6	53:13,14 54:18,22	300:7 301:1 302:5	52:13 53:5 54:17,18
MD/DO 113:7,12	56:7,10,16,21 57:4	303:7,10 306:8	55:3 65:6,13 85:22
MDS 236:15 297:11	58:17 59:15,16 60:1,2	307:15,18 308:7	86:2,3,8 89:11,12
298:12 299:1 341:5	61:4,19 63:4,9 64:16	309:8,10 315:16	93:13 105:12 109:19 111:1 112:11,16
mean 9:13 31:14 51:4 73:4 79:9 83:16 85:20	64:18 65:12,16 66:5	318:2,11 319:15	,
	66:19,20 67:4,5,18	320:13 321:7 322:18 322:18 329:8 330:13	113:13,16,18 114:10
85:21 88:17 92:14 93:9 108:3,9 142:12	69:4,9,10 70:2,10	330:21 336:14,16,22	121:1,3,5,16 123:1 125:4 126:13,22
144:15 151:4 153:19	71:18 72:2,9,19,22 73:19 74:21 75:2,4,22	339:3 340:10 342:9	125.4 126.13,22
156:11 157:18 159:21	75:22 77:8 78:11 81:6	342:10 343:18 344:17	128:13 129:4 130:8
163:19 169:12 170:1	81:9,17,21 82:3,4	344:19 346:17 347:3	131:8 137:2 138:6,22
176:4 177:8 178:5	83:11 84:4,5,19,21	347:9 348:9 349:16	142:18 146:10 154:15
182:7 183:7 185:22	85:1,4,12,15,17 86:7	349:19 353:13,16	155:8 156:1,14,16,17
186:8 187:4,11,11	86:10 87:15 88:9,21	354:5 355:6 359:4,22	157:9,14,15 158:2
188:15 189:6 200:19	89:15,17 90:6,13,21	360:13,14,15 362:18	161:3,9,16,19 163:9,9
201:2 213:8,16 225:4	94:2,16 95:9,12 96:3	363:13 364:5,5,6,7,11	163:19,20 164:2,14
225:5 226:11 238:18	96:22 97:4,5,9,22	364:12 365:2 366:5	165:20 169:1,2
244:8 245:11 246:18	98:4,11 99:2,15,19	367:18 368:19 369:10	172:16 174:10 179:5
250:2 256:10 261:8	100:8,15,18,18 101:8	369:17 372:18,22	179:12 180:12 181:13
263:20 276:22 277:16	103:2,4 104:5 105:6	377:17,22 378:5,9	182:19 183:10,12,13
278:2,8 279:11	105:15 106:6,11,14	381:12 382:1 383:17	183:16 184:12 186:12
292:15 299:14 300:18	107:8,12 109:4,17	384:13 385:14 386:3	188:8,10 189:14
310:22 312:4,17	111:1,17,18,22 113:1	386:15 387:5,19	190:1,12 191:2,8,11
319:13 321:15 322:12	113:7,9,14 114:15,21	393:19 394:22 396:21	194:5 197:2 201:5,15
333:19 334:7 335:2,6	115:2,4,12,16,19	400:1,2,3 402:5,13	201:15,15,16,19
336:3 337:1 348:14	116:5 117:18 118:1,5	403:15 405:7 406:3	202:11 203:11 207:2
358:15 361:13,19	118:7,14 119:5,10,10	measure's 41:8 287:20	207:3,4,5,13,14
375:2 379:11,14	119:12,20 120:12,20	measured 100:17 130:9	209:16 211:17,20
380:16 382:15 390:19	120:21 121:9 122:3,3	240:13 306:18 316:6	213:4 216:4 217:6,18
392:7 398:19 399:10	122:19,21 123:11,19	316:8,8 349:12 372:8	226:4,11 228:20
404:1 405:8,13,14	124:2,10 125:2,8	376:1 379:1	229:8,10,15,21 230:4
406:7	131:15 133:4 145:21	measurement 2:17	230:4,7,22 242:10
meaning 40:11 61:9	146:2 156:9,10,11	7:22 8:3 17:4 18:3,9	243:6 251:19,20
382:11	157:5,16 161:22	21:12 26:12 47:19	252:21 262:13 271:10
meaningful 108:1 111:3	164:21,22 174:21	48:18 53:1 57:19	271:13 272:19 274:21
111:4,7 189:20 191:3	177:12,15 180:7,11	121:8 126:22 127:6	280:21 284:16 286:14
209:22 269:7 342:13	186:9,13 192:12	130:9 142:12 159:3	286:17 287:7,15,21
386:6 391:5	196:2 198:10 199:14	193:1 231:18 232:1	288:7,9,21 289:2
means 24:14 45:13,17	199:16 202:6,17 202:15 204:14 207:6	243:7 253:7 261:15	293:14 297:9,15,17
61:13 62:6 87:1 96:8 96:20,21 97:2,7	203:15 204:14 207:6 207:20 208:9 209:12	286:21 287:5 302:15 306:10 315:20 317:6	297:20 298:4,9 300:4 301:11 303:3,16
109:18 186:5,19	209:13,14 210:19	317:16 362:4 365:7	304:6,17 305:13
189:18 235:17 325:20	216:5 226:4 229:1,22	371:22 375:19 378:22	309:6 310:10 312:2
406:8	230:1,13,18,21	measurements 316:15	316:1,5,22 317:3,6,13
meant 62:22 63:1 92:20	231:15 232:15 233:5	378:16	324:11 330:8,17
103:9 340:10	233:11 242:3 245:20	measures 4:5,7,9,15,20	331:11 334:1,3 336:7
measure 4:10,10,11	246:6,15 250:19	15:8 18:14 20:5,7,10	337:2 340:12 341:3,5
11:19 12:3 17:6 18:7	252:10 254:4,5,21	20:11 25:11,13,14,18	341:6 343:5 344:11
21:20 25:9 26:5,16,17	255:8 256:7 259:7,12	27:3,17,21 29:21 30:4	345:4 349:6,7 350:9
27:12,14 28:4 30:2	264:14 269:22 270:14	30:12,14,16,20 32:14	350:13 351:1 353:3
32:3,15,22 33:1,17	272:9,12,22 273:3,18	34:1,5,7 35:22 36:14	360:20 361:6,7,16
34:2,7,11,15 35:5	273:19,22 274:5,6	36:17,18,19,21,22	366:15 367:10 370:3
36:7,15 38:2 39:5,7	275:8 280:19 282:1	38:20 39:19,21 40:1,8	370:21 371:2 372:19
39:10,16 40:5,6 41:9	283:10,21 285:10	40:8,10,16,18,21 41:3	381:2,4,17 383:6,8,14

			431
284:5 202:44 48 20	400.40 400.40 407.40	402:40 404:40 20	202-2 44 200-5 45 40
384:5 392:14,18,20	136:16 166:13 167:19	193:19 194:18,20	383:3,11 389:5,15,19
393:1 396:8,9,12	181:21 182:9 193:19	195:5,11,15 196:1,12	390:9,15 393:6 394:7
397:4 398:10 399:7	194:18,20 195:5,11	197:12,18 199:22	394:19 397:14,18
400:9,14 401:18	195:15 227:18 228:5	200:16 202:13 203:1	398:1,6,7 399:21
404:1,4,4,7	253:5,20 267:9,13	208:7 210:6,10,20	401:17 404:12 405:6
measuring 55:20 75:17	282:5,15,19 283:5	211:3,6 214:17 218:5	405:17,20 406:7,11
111:21 113:22 121:10	290:12 291:4,8,17	219:4,10 222:22	408:3
133:1,2 140:18	308:19 310:15 311:19	223:2,13 224:15	members 6:9 10:14
158:20 159:9 165:14	312:7,22 313:6	225:14 226:17 227:18	13:12 53:6 76:10 95:1
298:13 312:3 314:17	320:10,16 338:7,17	228:5 232:11 233:15	152:10 194:21 195:8
347:7,10 367:15	348:8 356:22 357:3,5	237:14 239:17,20	198:22 224:1 241:13
373:14 377:21 378:17	357:9,14,17 358:4,7	240:2,7 241:18	268:4 282:10 346:4
381:14	358:10 382:17 383:3	242:22 243:4 244:20	360:2 397:6 407:22
mechanics 54:5	383:11 398:7 399:21	249:7 251:10,12,21	membership 41:14
mechanism 120:2	member 4:8,21 11:7	252:5,8 253:5,20	46:18 252:2 263:22
median 108:9	12:7 13:1,22 15:3,14	254:20 256:3,12,21	memory 237:3
Medicaid 3:7,9 126:14	15:20,21 16:7,18 17:8	257:7 260:8 261:7,19	mental 13:7
127:10 128:5 132:9	17:16 18:1,19 19:3,13	262:7,10 263:6,16	mention 109:14 116:3,8
138:12,15 139:3	19:20 20:16 21:3,8	264:3,6,9 265:5,14,17	120:16 280:21 313:2
140:11,16,17,22	31:14,19 32:1 37:6,20	266:10,17,20 267:9	319:4 351:19
147:4 162:5 171:14	38:14 47:17 48:15,21	267:13,15 268:18	mentioned 9:14 43:1
179:2 196:15	49:3,9,15,18 59:6,10	271:6 272:3 273:15	64:11,13 83:20
medical 1:15,18 3:2,12	60:16 61:1 63:6 64:4	274:6,7,8,12,20 275:3	111:10 123:16 154:4
3:13 14:9 16:10 18:22	64:9,22 65:7 66:11	275:6,10,18,22 276:1	162:3 175:11 177:22
18:22 19:4,21,22	67:21 69:15 72:14	276:4,10,21 277:6,10	180:18 257:5 281:10
31:21 53:17 56:21	74:4 76:13 77:11	278:2,6,7,12 279:9,15	352:5 353:6 399:22
58:19 61:18 102:22	78:15 79:7 80:7,9,12	280:4,18 281:5 282:5	mere 376:15
132:19 308:15 310:6	80:17 83:7 84:14,17	282:15,19 283:5	merely 78:17
315:3,4 341:6	86:16 87:18 90:18	285:17,21 289:13	mess 260:20
medically 14:5 373:15	92:8 93:3 96:7,12,18	290:7,9,12 291:4,8,17	messed 266:14
377:1,7	97:11,15,17 98:22	291:21 292:13 293:6	met 1:8 140:3 143:16
Medicare 3:6,9 85:21	99:5,7 100:5,12 101:4	297:7 299:12,14	146:11 148:2 192:18
113:21 271:13 288:14	101:11 102:3 103:5	300:3,14,17 301:9	230:20
301:15,15 309:19	103:15,21 104:15,21	304:14 305:4 308:3	method 31:17 279:22
medication 63:12 77:7	105:3,7,21 106:4,16	308:19 310:15 311:19	296:10
87:3 217:10	106:19 107:20 109:12	312:7,22 313:6,10,15	methodology 37:16
medicine 1:17,22 2:8	110:7,15 112:8 115:5	313:18 314:21 318:4	288:1 361:21
2:11 11:1 15:6,16,16	116:1,11,15 117:1,16	320:10,16,18 321:9	methods 15:10 17:14
18:2,5,21 20:18 58:1	118:10 121:18,22	321:18 322:6 326:5	211:7 299:21
65:10,11 93:4,17	122:11,17 123:9,13	327:17,22 328:3,8,11	metric 250:21 251:8
287:10	123:20 124:1 134:9	328:15,21 329:4	286:22 288:5
MedPAC 299:2	134:17 135:6,9,12	331:8,20 333:18	metrics 21:1 242:14
meet 25:16 74:21	136:6,12,16 137:16	334:11,14 336:21	310:22
403:14 408:12	138:8,14,17 139:5,9	337:14 338:7,17	Metropolitan 2:5
meeting 6:21 20:3,13	139:18 140:7 142:10	339:16,19 340:16	MGH 21:21
21:22 22:14 23:1,4,8	143:3 145:8,15	341:13,16,21 342:3	mic 43:9 65:22 135:8,11
23:21 25:8 33:15	146:17,22 149:3,7	345:6 347:16 348:8	306:16
52:15 53:9 54:11	151:4,10 152:2 154:3	350:4 351:4 352:2,9	microphone 24:17
180:15 181:14 192:10	154:10 155:18 156:4	353:11 355:20 356:22	173:12 285:12 287:4
249:16 334:4 389:10	156:6 158:9 161:1,21	357:3,5,9,14,17 358:4	323:17 327:16
396:3,3,22	162:19 163:2,5	358:7,10,11 359:13	microphones 24:5,14
meetings 24:2 30:6,7	166:13 167:19 168:16	360:10 364:4 365:8	mid 356:13
mega-complex 5:12	168:20 169:19 171:8	365:18 366:1,4 367:8	million 335:14,15
Melillo 2:1 12:7,7 54:2	173:7 174:16,18	370:7,10 371:10	millions 232:18
63:6 93:3 99:5,7	175:21 178:18 179:17	372:16 373:20 374:2	mimic 227:8
103:21 104:15,21	181:21 182:9 183:1	374:5,8,11 375:13	mind 47:7 99:11 109:8
105:3,7,21 122:11	184:10 186:3,18,21	376:22 377:15 379:15	114:9 116:7 176:2
135:6,9,12 136:6,12	187:6,9,21 189:10	380:18 381:16 382:17	207:20 223:6 229:14
		002.17	
u			

337:15 371:22 372:7 379:18 mindful 310:11 minds 309:19 mine 146:17 311:1 312:1 319:2 376:19 minimal 148:8 244:15 279:2 minimally 234:15,17 **minimum** 187:12,14 219:13 229:21 238:16 259:11 Minneapolis-St 16:19 Minnesota 16:20 17:4 218:20 minor 236:5 minus 187:14 minute 95:11 125:7 167:22 216:2 403:22 minutes 42:4 112:20 124:16 126:10 168:14 172:21 173:22 174:1 174:2 182:19,21 286:9 363:11 407:1 **minutiae** 391:3 MIPS 93:18 mis-dropped 258:12 misleading 164:21 219:1 misread 276:3 misreading 276:11 missed 22:4 208:18 210:12 224:8 320:18 403:1 missing 29:14,15 269:8 292:9,22 293:7 294:7 294:10,13,19 339:17 342:15 369:3 386:8 387:22 misspeaking 366:18 misunderstanding 331:4 mitigate 148:3 mix 211:22 302:21 308:5,10,11 355:15 mixed 60:9 92:9 **mixture** 244:19 **MJHS** 17:10 MLTSS 138:2 139:3 141:6,7 mobility 4:13,18 285:1 364:5,7,11,16,21 mode 212:1 model 355:12,18 modeling 319:11 moderate 45:13 94:18 94:20 95:7,13 99:16 99:20 106:7,9,13

109:6.8 114:16.22 115:13,18 117:19 118:2 202:19 203:8 203:21 204:3,16,20 205:9,13,21 206:4,13 206:17 220:11,16 221:4,8,16 222:4,8 237:2 255:13,19 264:17,22 269:9,14 270:3,8,18,22 323:2,7 339:6,10 342:17,22 343:22 344:5 363:1,5 385:8,12,17,22 386:9 386:13,18 387:2,9,14 modest 265:10 modifications 293:18 379:14 modified 72:8 modify 305:22 mom 69:16 mom's 382:9 moment 44:11 401:5 Momentum 1:16 13:3 **MONDAY** 1:5 monitor 88:1 159:11,19 monitored 60:5 monitoring 60:4 83:14 83:15 84:6,7 116:13 month 38:18 234:7 292:14 295:13,17 296:3,14,21 months 22:21 57:2 178:12,16 224:21 389:7 morning 6:3,13 7:5,10 7:15,19 8:1,15 10:19 15:3 16:7,18 17:8,16 18:19 19:20 21:8 50:14 54:9,16 116:19 125:10 193:9 401:13 407:3 morphed 132:18 Morrise 2:2 13:22,22 69:15 92:8 117:1 146:22 273:12 274:8 278:12 339:16,19 Mort 2:4 21:7,8,9 86:16 125:6 210:6,20 211:3 motion 176:5 177:2.11 178:19 180:6 224:15 389:13 motor 4:14,16 285:1 305:8 364:5,5,15 384:13 move 79:19 91:7 95:14 95:19,21 96:22 98:8 100:1 101:3 122:2,9 145:6 151:22 170:2

174:11 175:6 176:15 179:11,20 207:9,19 207:21 242:19 249:6 251:22 264:11 317:22 319:1 323:9 376:13 378:20 396:10 moves 72:22 moving 98:5 150:15 153:4 201:9 209:10 209:12 213:2,5,6 214:6 254:15 255:21 273:3 370:1 376:8 384:22 401:3 **MPA** 1:16 MPH 1:12,21 2:4,6,14 2:16,21,22 3:2,5,12 MQF 272:10 muddy 166:14 MULLER 3:11 229:7 239:10,16,19 240:1,6 242:5 244:8 250:1 253:12 256:8 258:2 262:9,14 265:13,16 284:7 **multi-** 49:18 multi-dimensionality 235:8 multi-item 48:2.5 49:22 50:2 multi-stakeholder 41:14 multidimensional 225:18 226:22 multiple 20:21 25:10 131:1 142:15 149:14 149:18 150:2 151:12 269:8 342:14 386:7 multiplied 189:18 **multiply** 187:15 Munthali 2:16 8:1,2 177:10 must-pass 181:7 **mutating** 321:22 mute 19:14 23:20 24:8 Ν N 4:1 **N.W** 1:9 name 7:19 10:20 11:7 16:7 17:8,16 19:3 names 157:15 256:18 Nancy 112:18 narcotic 87:10 116:4 narcotics 73:11 narrow 108:18 189:12 382:20 383:18 narrowing 194:11 national 1:1,8 2:3 10:4

17:18 126:17 129:17 231:17 246:9 251:1 253:18 288:18 351:13 352:10 361:18 394:20 nationally 87:13 nationwide 138:3 nature 356:18 Navigation 19:6 NCQA 38:5 nearly 5:5 296:13 375:7 Nebraska 1:14 18:22 19:2 necessarily 38:9 100:7 107:11 111:6 197:21 261:2 302:16 necessary 27:7 61:8 153:5 need 14:15 21:21 23:12 23:21 24:18 27:11 41:4 44:9 65:4 70:3 70:10,17 82:4 90:13 97:13 114:18 119:6 121:7,8 137:17 140:5 144:20 146:2 147:18 151:22 154:14 165:19 172:6 174:11 178:22 191:19 192:7 216:22 217:1,7,10 219:12,20 227:3,4 248:13 273:5 294:17 314:17 356:21 359:21 361:4.11 363:21 367:1 373:15 378:20 381:7,21 382:9 400:18 401:1,9 401:16 402:16 needed 71:3 184:2,2 185:21 244:11 251:4 262:12 381:9 needing 226:3 needs 11:5 14:7,16 27:13 36:1 47:6 75:13 81:22 143:16 146:5 146:11 148:1 155:6,9 155:17 156:22 164:4 175:8 183:14 190:7 192:10,15,17 201:6 201:13,16 205:1,3,7 207:5,14 217:6 218:1 221:11,15 222:3 230:19 289:22 311:13 332:19 negative 270:17 362:21 387:7 negatively 57:21 neither 52:8 **nesting** 149:15 net 38:21 39:1 network 2:1 12:11,15

23:18 39:1 Neuro-Qol 20:5 382:22 383:10,16 neutral 315:20 Nevada 129:8 never 12:2 92:14 95:10 399:17 154:19 186:14 187:3 NIH 20:4 195:2 197:20 207:20 Ninety-five 133:22 224:17 337:15 nevermind 267:13 397:7 noise 102:16 260:19 Nevertheless 192:13 new 1:19 5:10,16 10:6,6 262:3 10:7,14 15:20 17:9 19:8,17 25:11,12,21 nominated 9:1 26:2 29:7 40:8 54:12 non 138:2 302:20 58:15 61:18 64:22 113:6 157:16 174:17 218:20 309:11 311:20 317:11 352:21 360:10 370:13 non-opioid 87:11 377:10,10 393:8 non-pharmacological 398:10 399:15 407:22 76:18,22 newness 394:4 non-physician 55:2 **NG** 14:6 113:7 nice 144:9 non-physicians 77:14 nicely 230:6 non-profits 13:15 NICHOLAS 3:3 non-proxies 195:19 Nick 228:11 229:11.13 nonprofit 10:8 244:8 245:8.13 247:9 nonsignificant 265:11 248:17 251:6 256:8 Northwest 19:8 Northwestern 1:16 258:3 284:9 Nicole 1:19 19:3 76:11 19:22 125:6 145:4,14 notably 208:10 146:14 149:5 151:21 notation 224:8 161:20 169:18 184:9 note 11:6 62:18 104:1 196:11 208:2 347:13 Nicole's 347:14 Niewczyk 3:12 287:3 noted 28:19 85:10 290:21 291:7,10 292:12 293:11 294:20 notes 31:10 57:18 295:12 296:9,16 127:5 297:21 300:11,16,21 noteworthy 372:9 303:2 305:3,11 notice 108:2 374:11 306:14 307:22 308:11 noticed 322:2 311:7 312:5,8 313:4 noting 57:7 86:20 313:14,17 314:4 187:22 366:15 319:7,22 320:7,12 notoriously 161:3 321:6 322:2,8 324:6 226:19 324:10 327:14,21 novice 80:18 328:2,7,10,12,20 **NPI** 103:14 329:2,18,21 335:6 NQE 126:17 128:21 NQF 2:12 4:8,21 7:11 338:12 340:7,22 341:15,19 342:1,5 346:7 347:22 354:14 356:8 357:4,6,11,16 357:21 358:6,8 361:12 364:15 365:17 56:7 127:2 156:9 365:19 366:2,16 367:2 368:10 370:18 371:19 373:6 375:2

378:3 379:11 381:22 388:12 390:19 392:16 394:17 397:9 398:18 nodding 107:15 264:11 nomenclaturally 35:19 non-76:15 87:10 113:3 non-distinction 107:14 155:3 228:3 235:11 263:17 271:7 407:9 127:20 128:18 209:4 7:21 23:5 25:17 27:1 27:15 30:10 32:9 33:4 33:10 34:19 35:9 38:3 46:1,17 52:11 54:20 217:20 261:4 281:4 286:18 315:18 331:9 360:12 361:3 396:5

397:18 404:20 **NQF's** 8:6 309:3 number 6:4 18:13 40:18 54:13 57:3 61:2 62:5 62:7 63:10,12 64:13 66:4 84:19 88:10 91:14 96:20 121:1 123:7 127:13 147:7 154:22 164:12 173:15 181:4 201:1 205:5 206:12,13,13 212:8,9 212:13,14 213:15 217:3,4 218:7,17 220:10,11,11 221:4,4 221:4,5,15,16,16,16 222:3,4,4,5 235:14 254:8,9 255:12,13,13 255:14 257:14 259:7 259:11 262:2 264:16 264:16,17,18 266:11 270:3 272:13,14 273:10 279:18 281:19 282:1 283:22.22 295:20,22 302:6 304:16 306:19 318:17 318:18 323:1,2,2,3 339:5,5,6,7 342:16,17 342:17,18 343:21,22 344:1,1 349:7 362:22 362:22 363:1,2,14,15 368:20,20 369:10,11 371:6 375:9 382:5 384:18,19 385:7,7,8,9 385:16,17,17,18 386:8,9,9,18,18,19 387:8,9,9,10,20,21 388:7 391:21 397:6 402:13,13,14 403:6 numbers 51:14 95:11 122:15 157:15 202:14 212:11,18 219:18 222:17 259:11 340:19 374:12 377:12 391:14 numerator 56:1 nurse 1:18 19:16 77:22 348:19 nurses 345:14 346:21 nursing 4:12,13,14 12:17 17:12 19:15 32:16 229:14,16 231:9 232:17,17 233:5,6,21 236:16,21 249:12 250:3,13 253:17 256:10 280:22 283:2 284:20 286:4 286:15 292:5 299:3 301:16,19 303:19 314:13 315:12 316:4

318:12 319:9 324:13 325:3 338:15 341:2 345:10 348:19 359:19 373:8 nuts 52:22

0

obesity 58:8 objectives 74:6 obligations 406:21 oblique 226:20 235:7 observe 403:10 obtain 83:5 obtaining 82:15 243:5 obvious 80:19 131:7 188:2 308:15 364:10 obviously 26:11 29:18 35:1,20 86:3 104:17 105:12 184:3 197:19 206:5 209:2 232:16 233:4,10 272:20 276:12 336:5 351:8 367:10 368:5 occupation 28:12 occupational 66:22 113:4.8 occur 23:2 356:17 occurring 57:1 **October** 39:22 odd 248:18 offensive 241:14 offer 112:22 166:15 286:13 361:7 offered 280:7,9 289:21 offering 290:4 office 12:5 66:15 129:17 192:20 Officer 2:14 53:17 oftentimes 308:14 Ogungbemi 2:18 7:19 7:20 oh 5:15 17:6 79:15 106:3 109:12 135:12 168:17 179:16 186:22 187:1 198:14 256:16 267:13,14 285:17 297:7 300:21 308:18 313:14 316:13 317:18 328:15 338:5 343:13 347:12 356:21 362:14 362:15 389:15 Ohio 1:17 16:9 okay 5:16 20:14 21:2,6 22:3,12 37:20 38:14 39:17 46:10 49:15 59:7,10 65:7,9 77:13 80:7,18 95:4 96:2 97:17 99:13 100:12

102:3 104:15,21 105:21 106:4,4,10,16 107:20 114:20 115:14 117:21 118:11,12 119:2,3 123:9,20 125:1,11,14 127:4 130:7,17,19,22 131:3 131:3 132:5 135:18 135:21 136:6,12,18 137:5,10 138:17 139:9 141:13 142:7,8 145:14 146:19,20 149:2 151:2 153:12 153:15 154:1,10,11 154:21 155:1,13 156:5 158:4 160:14 160:21 161:20 168:3 168:18 169:17 171:7 173:6,8,20,21 174:1 182:17,20,21,22 183:21 184:1 186:21 187:8 191:4 192:4,5,6 193:14 194:18,20 195:11,21 197:1,10 199:10,18,19 200:16 201:3,14,18 202:5 203:3,11,12,14 204:10,13,18,22 205:11,16 206:10,20 207:7,15,18,19,20 210:20 211:4 219:5 219:15,21 220:4,6,13 220:14,19,20,21,22 221:10 222:10 224:13 228:5,6,7,9,14 232:8 240:1 251:21 254:3 254:15 255:8,16,21 264:9,12 267:14 268:22 269:3,11 270:12 272:7 276:10 276:21 282:15 283:5 283:8,17 285:19 286:2,10 287:4 290:9 301:9 308:17,20 313:6,9 317:21 318:7 318:7,10,19 319:7,21 320:6,8,16 321:16 322:16 323:9 324:9 338:17,20 339:2,13 342:8 343:2,9 344:7,9 353:22 356:19,21 357:9,14 358:10,15 359:13 362:13,15,16 363:3,8,15,18 365:18 368:16,17 369:4,4,15 369:18 374:2,10 384:19 385:2 393:9 394:1 398:6 402:2,18

405:18 406:1,11 407:13 old 10:8 87:22 214:18 279:11 older 56:22 194:2 264:3 293:16 once 24:16 184:22 246:21 258:19 297:20 379:2 oncology 83:19 91:4 one's 250:14 388:10 one-by-one 184:1 193:2 one-on-one 382:5 ones 104:17 114:4 137:6 148:11 155:15 223:7 258:1 275:20 278:4 319:3 363:10 364:9 379:17,18 onward 152:21 open 24:9 94:21 99:14 106:3,5 114:14 117:17 118:13 120:13 137:15 173:5,10 174:15 198:8,9,20 199:3 201:20,22 202:2,5,12 203:15 220:7,12 221:1,12 228:15,16 254:10 255:8 256:1 264:14 265:3 269:4.21 270:13 272:11 281:21 283:9,19 306:11 322:17 339:3 342:9 343:17 362:17 363:12 368:18 369:8 370:4 388:3 402:6 403:2 opening 318:11 operating 315:18 operations 286:11 **Operator** 173:10,13,18 199:7,9 228:11,13,16 285:15 388:3,5 403:2 403:4 405:3 opiates 77:7 opinion 22:18 23:2 42:17 46:21 152:11 247:19 248:2 opinions 209:7 opioid 57:13,16 79:8 87:6,10 opioids 88:10 opportunities 121:7 opportunity 26:10 54:9 54:20 68:2 95:20 98:12 116:12 119:22 120:3 122:14 130:1 174:19 242:15 243:3 273:10 367:9 403:10

406:9 opposed 91:3 127:18 162:21 164:9 248:1 348:19 380:14 389:22 400:14 opposite 190:9 266:21 328:16 opposition 178:19 optimal 111:15 202:9 203:18 223:18 255:11 322:20 385:5 optimistic 350:2 optimizing 196:20 option 94:17,17,19 95:6 96:4,5,13,16,17 99:15 99:16,16,17 106:6,7,8 106:9,9 114:15,16,16 114:17 115:12,13,13 115:14,16 117:18,19 117:19,20 118:15,15 170:1,10,13 171:5 177:20 178:5 182:4 198:19,20 205:8,9,9 205:10,20,21,22,22 206:12,12,13,14 222:4,4,5 255:12,13 255:13,14 264:15,16 264:17,17 272:13,14 282:1 283:21,22 318:17,17 323:1,1,2,3 339:5,5,6,7 342:16,16 342:17,18 343:21,22 343:22 344:1 362:22 362:22 363:1,1,14,15 368:20,20 369:10,10 369:17,17 384:18,18 385:7,7,8,8,16,17,17 385:18 386:8,8,9,10 386:17,18,19,19 387:8,9,9,10,20,21 402:5,6,13,14 406:3,4 options 56:2 96:14 220:10 221:3,15 254:8 269:9 270:3,17 oral 8:15 order 43:15 83:5 124:15 213:3 261:14 301:20 325:4 357:17 359:7 397:20 401:8 orders 315:19 Oregon 19:8 129:7 organization 2:5 144:1 193:20 272:4 289:2 310:9 361:17 398:12 organizations 16:3,4 16:22 139:3 393:17 organized 143:20 organizing 143:10

orientation 42:1 original 107:5 120:21 123:18 originally 55:1 66:21 113:6 123:12 248:16 OT 348:18 outcome 15:8 30:4 34:22 35:5 36:6 65:13 68:10 70:19 71:18 73:1,20 74:21 75:2,12 82:19 86:20 99:8 122:2,3 196:2 198:11 198:17 232:15 254:6 262:13 318:15 384:16 388:17 outcomes 2:8 3:8 17:5 18:14 34:20 60:8 61:14 65:11 69:11 75:4 85:6 89:9 288:5 311:12 314:1,7,16 355:19 367:14,15 403:9 outliers 111:8 outpatient 93:10 301:6 301:17 305:16 outweigh 116:5.8 270:16 outweighed 362:20 387:7 over-speaking 213:10 overall 12:2 43:22 84:1 112:3,4 118:13 119:4 120:11 121:7,8 133:22 165:3,11,21 182:7 191:7 202:8 203:18 219:6 230:15 230:16 232:22 237:4 247:11 248:2 255:10 259:13 260:2 272:12 281:22 283:11,20 289:16 322:20 363:8 363:13 368:15,18 369:8,16 385:4 387:17 392:1 400:13 400:18 402:4,11 406:2 overarching 232:14 overlap 139:19 overreport 117:9 oversee 41:20 oversight 350:18 overuse 73:12 116:4 117:4 121:12 overview 25:3 42:4 127:8 owners 5:10 Ρ

p 325:10,19 366:22 P-R-O-C-E-E-D-I-N-G-S 5:1 **P.C** 2:10 **P.J** 408:12 **p.m** 174:3,5,6 284:12 284:13 408:15 Pace 33:12 package 125:3 127:21 130:8 132:13 154:15 155:11,17 162:10 174:9 212:18 packet 153:8 page 103:5 104:1 186:6 215:17 265:7,13,14 271:7 333:15 399:11 pager 323:15 pages 103:22 paid 78:16 141:21 pain 4:6 18:11 40:6 53:13 54:21 55:18 56:3,18 57:8,10,12,15 57:17,18,19,21 58:4,6 58:13,15 60:3,5 61:2 61:9,17 62:4,8,10,10 63:7,13,18 66:16,16 66:18,18 67:7 68:9 69:1,1,17 70:13,22 71:7,11,16,20,21 72:4 72:6,8,21 73:2,3,6,7,7 73:9,13,16,17,20 74:15 75:6,8,17 76:19 77:6,7 79:8,17,18 80:6,11 81:1,17 86:19 87:5,15,21 88:3 89:6 89:11,20 90:21 92:22 100:16,17,19 112:11 113:16,22 117:2,7,9 121:8,10,16 122:2,13 124:3,4,7 375:19 pain-free 124:5 painful 58:9 164:10 paired 70:19 palliative 15:17 61:1 83:19 89:16 91:5 panel 26:22 27:1,9,15 34:19 109:19 182:10 242:9 panels 35:13 Pap 78:21 paper 280:2 papers 357:7 paperwork 253:13 par 241:21 314:14 paragraph 326:20 parallels 230:21 parameters 131:14 314:4

parents 14:13 15:9 148:10 Parisi 2:5 17:8,9 137:16 138:8,14,17 139:5,9 139:18 140:7 142:10 145:8 155:18 156:4 158:9 183:1 289:13 290:7,9 parsimonious 229:9 246:14 250:10 parsing 141:10 part 12:11 28:4,21 32:8 39:13 40:22 51:1 67:1 69:2 77:12 80:4 84:10 98:6 101:5 109:5 123:17 128:20 129:19 135:2,18 138:5 139:3 152:17 162:22 167:12 167:14 184:4 185:6 185:12 195:7 196:21 197:5 202:12 219:11 238:3,4 263:21 271:10 288:14 290:17 298:5 301:1,7 340:5 353:8 390:8 part-time 10:6 partially 21:14 258:10 participant 133:18 185:15 participants 43:8 108:18 188:16 189:7 participate 21:14 93:20 127:11 344:22 participated 16:15 participating 21:5 22:2 47:9 108:10,13,14 125:17 128:19 190:4 352:9 participation 64:15,16 64:20 93:19 112:10 112:15 participatory 18:15 particular 39:11 40:21 45:10 71:10 72:19 83:11 84:3 86:9 96:9 131:15 132:10 154:14 158:7 160:9 172:7 210:16 245:6 249:14 254:18 303:20 particularly 9:7 10:13 52:6,22 134:7 317:19 346:2 364:2 372:20 372:20,21 407:20,21 partly 107:4 partner 16:2 Partners 1:20 2:1 12:12 16:2,20 partnership 2:3 10:4

14:19 41:8 **Partridge** 1:9,12 5:3,15 10:2,2 38:15,16 47:16 50:13 52:4 53:22 59:3 59:8 60:14,20 63:21 64:2,6 65:19 66:9 69:14 72:12 74:3 76:9 78:14 79:6 80:15 84:12,16 85:18 86:12 87:17 90:15 91:8 92:5 93:2,22 96:10 98:5 99:3,6,12 100:22 101:10 105:5,22 106:17 107:15 109:10 109:20 110:14 114:12 115:8,21 116:10,14 116:17 118:6,11,16 119:2 121:20 122:10 122:16 123:21 124:8 131:22 132:3,6 133:15,19 134:16,19 135:8,10,16,21 136:18,22 140:8 141:12,20 142:3,7 154:16 155:2.14 158:18 160:4 177:1 179:14 191:6 193:6 201:12,21 212:5 213:13 228:17 232:4 233:14 235:18 242:19 243:1 249:5 251:22 252:7 253:3,14 254:2 254:15 255:1,21 262:5 264:10 265:2 268:22 269:16 270:10 271:3 272:7,18 274:17 280:3,17 281:16 282:3 283:6 283:12,17 284:5 323:22 343:4,10 344:9 346:1 360:8 369:21 370:9 373:19 373:22 374:3,6,10 376:18 377:8 380:7 382:13 384:10,22 388:9 389:12,18,21 390:10 394:5,18 397:3,11 400:6 401:7 402:2 405:5,18 406:15 407:14 parts 85:21 152:1 pass 43:19,19 45:21 100:21 119:18 152:5 178:8 206:20 207:6 393:19 passed 90:1 118:19 119:11,12 181:7,14 183:16 206:21 207:4

207:5 268:15 357:12 403:14,20 passes 43:20 106:15 115:3,4 118:5 177:12 199:16 205:1,17 339:13 passing 346:13 passion 13:19 paths 90:3 patient 1:20 2:2 12:10 13:6,9,11,18 14:1,8,8 14:16,18,20,22 15:11 16:11 19:6 28:8 30:17 49:4 55:14 61:21 62:22 63:16 66:17 72:3 76:21 79:14,17 82:15 101:21 122:12 164:2 200:14 215:16 224:6 229:5 232:15 234:9 236:8 237:21 260:9 262:13 275:14 275:17,18 293:22 294:21 300:7 303:9 303:13,20 304:11,12 305:19,21 306:6 309:8 310:19 311:2 312:9 315:4 322:4 324:16 325:4,22 326:14,16,18,22 328:1,4 329:6,10,11 329:16 335:10 336:22 337:3,3 345:14 351:9 355:21 356:3 357:5 364:20 371:3 372:6 372:21 375:6 376:7 376:10,13 378:9,12 378:19 381:2,4,5,15 382:3 391:12 patient's 60:6 72:5 200:6,11 305:22 306:22 307:7 315:7 319:14 348:5 355:13 patient- 34:19 patient-centric 99:8 patient-oriented 20:11 patient-reported 15:8 17:5 18:14 30:4 34:22 35:5 196:2 197:20 patiently 154:2 273:8 patients 2:3 14:19 16:9 16:13 39:14 40:17 58:12 60:13 63:9,17 67:3,8 69:11 73:8 75:17,19 80:22 82:12 83:16 91:4 139:10 169:22 196:13 200:4 218:8 224:1,3 225:5 230:3 233:21 242:7

	I	I	I
249:11 280:6 292:5	264:3 267:20 273:8	108:4 110:9 171:12	personally 70:4
292:15,17,20 293:1	276:15,16 295:18	perception 57:18 200:5	persons 127:10 312:6
293:15 295:21,22	302:21 305:1,9	200:6	377:1
303:4 304:8 308:4	309:20 310:1 316:16	perfect 306:21	perspective 11:16 99:8
310:20 311:14 312:20	317:18 350:19 361:20	perfectly 393:2	122:7 143:5,15 144:7
317:11 320:1 324:14	367:18 368:2 380:1	perform 67:5 105:13	159:2
324:16 326:9 327:3	396:2,2 405:16	259:9 314:8 324:22	perspectives 27:4
327:10,18,19,20	406:17	349:6,8	pertinent 309:1
328:18 329:6,10,12	people's 338:4 362:2	performance 20:7,10	pestered 52:20
330:11 339:22 341:19	percent 45:9,12 46:4	20:11 26:10,15 27:3	Peter 2:9 11:7 38:15
342:1,3 347:19	66:6,6 90:19 91:16,17	30:4 32:22 33:17 34:2	
352:18 355:16 357:7			66:9 78:14 79:6 171:7 178:17 180:21 190:15
	95:6,7,7,8 98:1,2	34:6,7,11,15 36:7	
357:7 362:8 371:3,11	99:19,20,20,21 102:8	43:17 49:7 67:10,16	191:9 224:13 232:8,9
371:17 372:8 373:14	102:13 103:7,16	84:4 85:11,12,13	271:5 274:19 286:7
376:21 377:7 378:15	104:2,11 105:17	98:12,18 99:15,18	299:11 364:3 367:7
381:9,19 384:4	106:12,12,13,13	100:15,18,18 102:15	377:14 380:7 391:19
patients' 13:13	108:3,4,9,20,20	103:4 104:1,8,9,13	405:5
patterns 133:13 168:2	109:16 112:6 114:22	109:19 112:4,9 128:6	Peter's 233:16 262:5
322:4	114:22 115:1,1,17,17	140:19 143:21 155:4	308:4
Paul 16:19	115:18,18 118:1,2,3,3	186:4 192:14 199:18	PFCC 16:2,3 41:20
Paulette 3:12 287:3	119:9,10 127:16	199:19 202:7,7,9	pharmacologic 87:11
331:6 335:2	199:14,15 203:7,8,8,9	203:16,16,18 204:14	phase 1:3 29:22 30:1
Paulette's 392:3	204:2,2,3,3,7,19,19	205:8,20 207:3 255:9	31:13 33:9,12,19
pause 46:8 220:1	204:20,20 205:12,13	255:11 319:1 321:11	36:22 40:12 45:10
228:10	205:14,14 206:2,4,5	322:16,19,21 325:14	49:11 52:17 156:14
pay 159:19 162:5	206:16,16,17,17	351:7 354:9 380:13	333:3,22 384:4 390:8
348:15	214:2,3,3 220:16,16	385:3,5 395:1 403:15	390:9,11 399:7
payers 127:6 309:20	220:16,17,17 221:7,8	404:16	401:20
paying 185:12	221:8,8 222:7,8,8,8	performed 55:11 56:18	PhD 1:13,18,21 3:3,8,9
payment 288:14 348:6	230:22 234:8 238:10	71:17 78:12,13	3:10,12
350:10,17 351:2	239:7 254:13,13	performers 190:4	Philadelphia 1:14 15:7
400:3	255:18,18,19,19	257:20	phone 6:8,10 9:22
pays 144:16	259:20,21,21 260:4,5	performing 51:19	19:11,12 22:4 23:20
PCORI 16:16 18:6 20:8	264:21,21,22,22	105:11 112:2 356:9	24:7,9 29:5 38:16
pediatric 10:10 70:15	269:13,14,14,15	356:10,12 374:17	43:4 45:3 47:9 54:4
157:1 293:17 340:11	270:7,7,8,8,22,22	period 27:16,22 57:2	86:13 93:7 94:17 95:1
pediatrician 75:15 76:7	271:1,1 272:17,17	157:12 177:17 178:1	118:9 124:19 125:7
pediatrics 10:22 157:3	283:15,16 284:4,4	178:8,13,14 181:18	173:6 185:7 189:4
PEM 355:11	293:3 294:8,11	225:1 233:7 296:14	211:18 228:12 368:22
penalizing 396:1	318:20,21 321:1	296:21 390:6 392:12	phoneline 173:19
penalty 49:11	323:6,7,7,8 339:10,10	periodic 345:18	PHQ-9 35:8
pending 129:14	339:11,11 342:21,21	perioperative 18:11	physical 18:21 66:22
Pennsylvania 3:10,14	342:22 343:1 344:4,5	Permanente 1:19 19:7	92:1,22 93:4,10,16
15:5 129:7	344:5,6 363:4,5,5,6	perplexing 151:16,17	113:4,8,20 123:16
people 6:6 19:11 39:11	363:16,17 369:7,7,12	person 1:3 16:11 21:14	132:20 136:5 154:17
50:1 58:11 60:3 73:5	369:13,19,19 371:13	39:19 47:10 122:18	155:7 181:4 197:14
81:11 105:12 108:6,7	382:21 383:2 384:20	128:11,11 144:13	201:13,16 205:17
108:10 109:16 110:10	384:21 385:11,12,12	146:1,6 189:3 194:1,3	207:5 287:10 298:19
110:12 117:8 122:4	385:13,21,21,22	194:4 211:9 240:4,16	298:22 315:7
132:14 135:19 136:1	386:1,12,13,13,14	262:16 282:11 288:19	physically 135:19
136:4 139:14 141:18	387:1,2,2,3,13,14,14	310:5 330:21 331:16	140:13 298:19
144:16 148:15 159:10	387:15 388:1,2 402:9	349:5 361:2 379:2	physician 55:6,7 62:15
161:14 166:22 173:6	402:9,20,20 406:5,6	person's 146:11	66:15 67:5 79:15,15
184:15 188:17 192:2	percentage 36:8 95:16	persona 302:20	92:20 114:9 122:20
192:17 196:3 197:11	98:20 105:14 108:6	personal 60:10 160:7	123:3 345:10 394:21
208:3,10,20 209:8	186:11 208:16 295:6	162:12,12 172:9	395:1,5
233:5 236:3,6,18	percentages 375:11	191:18 216:9	physicians 2:4 17:2
241:10,13 242:2	percentile 104:3 108:3	personalized 259:7	49:13 62:11,19 93:16
			+0.10 02.11,19 30.10
11	'		'

107:9 113:4 347:1 pick 105:12 161:2 257:22 259:10 267:1 **picked** 10:6 229:22 242:6 picking 250:6 399:14 picture 359:18 piece 70:19 120:14 188:21 236:4 piecemeal 156:12 piggybacks 358:12 Pittsburgh 3:3 229:12 268:5 place 13:5 15:21 53:8 85:14 89:21 112:14 320:6 placed 26:9 places 42:16 277:3 320:6 380:3 plan 55:16,20,21 56:5 56:10,14,19,20 60:4 62:10,16 71:19,22 72:7,10,20 73:1 74:15 75:7 76:18,21 77:2,5 81:3 82:16 86:20,22 89:7.21 100:19 117:3 117:14 129:11,19 150:18,21 151:1 176:20 180:4,17 305:22 planning 128:12 271:9 plans 84:7 171:2 191:16 281:13 392:7 392:8 plate 388:10 play 197:22 249:19 308:12 plays 109:17 please 7:4 43:4 95:1 96:8 135:16 145:1 173:14 202:15 239:15 304:19 306:12 368:13 388:4,6 390:1 403:3,5 pleased 54:19 286:13 pleasure 5:21 11:2 plug 339:22 plus 45:13 72:20 95:13 185:17 306:15,17 PM&R 93:15 **PMs** 30:13 pneumonia 309:14 376:14 point 20:6 22:14 23:12 24:20 44:17 45:19 57:7,10 61:19 71:6 86:6 87:16 92:18 107:19 117:4 118:19 132:8,14 137:5 138:9

142:11 146:22 150:14 150:19 152:20 156:8 160:22 161:1 162:20 169:15 175:20 178:20 184:7 186:11 192:7 195:7 197:3 201:2 202:21 214:16,19 222:20 245:10,10,19 246:12 247:18 249:7 267:17 269:19 271:21 272:2 274:16 277:15 307:6 310:14 311:5 314:15 349:3 359:1 370:12 pointed 109:3 111:17 112:1 127:1 250:6 pointing 107:22 points 146:15 194:8 222:16,18 246:14 252:20 301:1 331:1 339:14 371:4 policy 13:14,18 33:4 348:2 politic 241:20 **pool** 391:15 poor 61:16 230:10 242:6 244:21 245:18 **pop** 22:20 popping 152:19 population 56:22 70:14 70:15.16 76:1 91:7 104:14 127:8 137:18 140:13,20,22 145:9 145:18 152:3,12 179:3 189:5 202:10 203:19 208:16 210:15 210:16 213:17 215:12 224:9 237:17 253:7,9 255:12 278:11 279:16 280:4 295:6 303:14 306:7 322:21 340:11 385:6 populations 63:16 93:12 171:17 222:17 286:16,20 293:18 303:21 305:19 316:17 322:5 383:5 portfolio 36:17 39:18 39:20 40:14 41:1,3,20 portion 112:2 141:7,11 215:13 231:8 Portland 19:8 posed 168:21 posit 164:7 position 122:7 **positive** 55:17 56:4 245:1,4 252:6 265:18 possibility 38:21 90:8

155:3 174:9 217:12 217:21 possible 188:1 222:13 289:9 349:20 397:10 397:11 399:19 possibly 174:20 217:17 374:7,11 post 5:9,19 21:22 181:18 227:15 382:21 post- 20:11 249:17 301:4 post-acute 17:11,20 20:10 140:1 249:14 249:19,21 251:13 286:21 288:2,4 300:6 306:14 307:2,9 310:18 311:9 370:22 371:21 372:8 379:3 post-comment 120:1 post-meeting 183:20 post-operative 18:11 potential 116:3,6,9 121:12 134:12 190:19 282:16 310:11 315:15 396:8 potentially 148:1 151:17 155:17 156:17 161:9 184:15 347:17 400:3 Powers 2:9 PQRS 55:9 93:15 105:9 113:3,17,18 123:6,18 practical 79:14 352:3 practicality 63:3 practice 17:2 60:13 67:2 71:13 83:14,15 83:22 84:2,6,8,18 85:10 114:9 practices 16:3 67:6 83:1,2 91:1,3,3 92:20 107:9,10 110:19 practicing 93:16 practitioners 77:22 pre 382:21 pre-75 383:2 pre-specify 234:13 pre-specifying 234:15 precise 220:8 221:1,14 222:2 264:15 339:4 385.15 precision 215:15 217:18 218:3 225:19 257:14 predicted 124:9 predictive 317:14 355:7 355:7.8 388:19 prefer 179:11 241:3 preferable 254:1

preliminary 28:6,21 131:6 premature 181:22 premier 379:18 premise 243:5 preparation 52:15 53:9 prepared 110:4 preponderance 266:7 prescribed 88:9,10 prescribing 57:13,16 prescriptions 57:9 87:10,11 present 1:11 3:1,22 8:17 28:8 presentation 44:8 289:5 presented 43:16 44:6 120:22 153:8 186:4,6 209:11 330:7 373:2 presenter 54:14 president 2:16 8:2 17:10 21:10 presiding 1:10 press 45:1 173:15 184:12 388:6 403:5 pressure 267:10 309:12 317:12 376:14 pressuring 122:1 presumably 133:5 208:15 229:3 presumption 365:12 pretty 91:20,22 110:11 120:11 134:1 184:12 189:15,15 213:15 216:3 217:11.11 228:19 236:20 237:2 238:8 245:1 296:4 315:19 316:20 322:9 325:11 326:2 329:7 334:20 356:14 367:4 390:4 394:15 407:5 prevent 208:12 218:1 301:21 Prevention 58:3 previous 163:17 249:8 330:7 366:5 367:22 370:12 383:22 previously 58:12 64:10 363:19 368:16 primarily 115:7 186:16 377:17 primary 13:20 17:1 59:12 184:7,18 185:1 207:22 208:8 250:22 282:11 285:8 286:6 289:6 291:20 297:5 302:10 319:2 339:15 364:2

prime 180:11,12 principal 5:16 printed 323:21 prior 26:22 28:8 53:4 54:11 188:12 273:21 281:4 372:10 403:18 privately 147:12 **PRO** 198:12,17 318:15 **PRO-** 30:12 **PRO-M** 35:4 **PRO-PM** 30:18 32:19 33:1 34:21 35:10 100:14 PRO-PMs 30:3,21 33:11 407:21 probably 37:9 50:15 52:22 69:21 86:5 108:8 109:1,7 116:2 124:10 186:1 214:22 226:14 228:19 229:14 239:6 257:19 267:22 268:19 272:1 279:2 299:9 308:15 313:9 315:17 337:20 341:11 345:14 358:12 365:4 392:8 403:16 problem 104:10 110:21 151:16,17 190:9 237:11 251:17 303:1 327:3 329:14 331:8 377:12 problematic 217:5 problems 6:5 189:13 190:11 242:17 315:4 procedurally 174:18 proceed 99:13 114:13 304:16 process 4:4 25:14,21 31:8 35:6 41:13 42:1 44:12 53:3 54:12 56:16 69:10 72:22 75:5 81:8,9 83:11 90:5 99:10 122:3 156:8 195:10 196:22 198:18 227:11 228:8 254:7 258:13 272:6 287:6 318:16 384:17 389:11 391:20 392:2 392:17 401:8,15 407:22 processes 75:3 procrastinated 52:2 productivity 57:22 products 314:3 professional 8:14 56:13,17 231:13 professionals 55:10 57:4,6 67:13,17 91:15

123:8.11 professor 10:21 15:4 15:15 18:2,20 19:14 19:21 20:18 65:9 profiles 237:22 profit 289:1 program 16:8 55:8 61:5 79:2 86:1,3 93:18 108:6 113:3,18 114:6 123:4,6,18 130:12,14 130:16 132:15,17,21 133:3,9,17 134:10 136:7,8 137:19 138:12,20,20 139:4 139:21 140:2,12,16 140:18 141:6,17,18 144:11,11 149:11,17 150:6,8,11 151:8 159:2 160:15 161:12 161:14,15 162:10 170:3 172:5,7,10 184:21 190:22 192:19 193:21 213:6 219:8 271:14 355:12 program- 85:20 programs 15:17 16:1 55:4 86:4 125:14 128:7 131:2,2 132:11 133:6 136:11,15 138:2,5,15 141:2 143:11,14,17 149:16 149:18 150:2,4 156:15 158:1 172:1,2 172:4,14 179:2 188:16 212:7,13,20 212:21 213:9,12 214:8,9,13,14 215:1,2 215:12 281:14 305:17 progress 58:10 270:15 362:20 387:6 progressing 152:18 progression 319:13 prohibit 208:12 prohibited 27:18 project 2:18,19,20,22 4:4 6:12 7:8,9,11,16 7:20 39:21 41:16,18 53:21,21 112:21 129:17 157:1 175:11 projected 381:9 projects 14:18 16:15 **PROM** 35:7,8,8,10 **PROMIS** 20:4 promise 407:10 pronounce 54:3 properly 316:12,17 properties 31:4 342:10 396:11

property 5:11 prophecy 216:15 217:2 223:15 226:2 257:13 260:15 proportion 48:22 102:7 233:20 proposed 93:17 316:8 pros 174:19 175:17 384:16 protect 305:5 protecting 365:14 protection 309:17 protocol 57:13 71:10 373:7 protocols 68:22 69:2 proud 315:22 317:4 prove 82:18 394:2 proved 36:8 proven 338:10 provide 31:12 41:7 42:3 56:8 68:2 110:4 120:4 171:14 180:9,16 232:18 242:15 277:3 288:3 301:17 320:20 320:22,22 322:13 355:4.10 379:22 380:4 384:8 389:7 392:6 393:5 397:18 399:18 404:21 provided 68:3,5,11 72:1 77:6 101:20 102:7.14 121:2 141:9 163:22 233:9 240:10,12 252:10 253:1 261:9 287:8 313:21 321:12 404:6 provider 17:11,20 61:2 64:13 72:4 76:16 86:9 87:2 101:15,17 102:4 102:5,9,14 103:6,10 103:13,18 134:13,14 141:14,15 144:10,15 147:13 159:6 204:12 241:11 276:13 309:10 providers 14:11 55:3 64:14 66:5 73:5 74:13 77:20 85:11,16 90:20 91:18,19,20 98:20 103:8,13 104:11 122:22 123:4 128:7 130:20 147:12 148:14 161:15 169:22 185:10 191:22 194:16 202:9 203:19 223:21 255:11 322:21 350:15 378:4 381:6 385:5 provides 56:1 290:17 381:6,11

providing 33:16 42:12 97:8 111:9 142:16 208:13 243:22 365:6 provision 146:12 provoking 403:12 proxies 152:16,19 153:5,11 195:19 200:2 proxy 41:14 46:17 153:7,16 193:11 209:3,7,13 222:18 237:10 psychologists 78:1 113:5 psychometric 31:4 47:22 396:11 psychometrics 323:10 PT 3:7 public 3:3 4:8,21 8:17 46:1,7 53:4 58:14 88:1 95:21 119:20,21 119:22 120:5 128:15 157:12 168:8 173:5,9 173:10,14,19 178:14 181:15 183:18 198:4 239:5 253:17 271:8.9 288:12 289:17.21 290:1 360:18 388:4,7 390:6 392:13 401:9 402:22 403:3 405:4 406:13 publically 360:21 publications 307:20 publicly 169:21 170:14 170:16 238:19 published 57:15 317:2 317:10 354:16 357:6 358:17 382:2 388:22 389:2 pull 108:8 120:4 137:6 154:4,14 155:10 156:19 225:3,7 390:22 394:15 pulled 121:11 137:14 154:17 191:15 240:22 324:16 335:20 pulling 73:12 164:9 purchased 289:18 348:11 pure 239:1 purpose 8:16 47:19 48:18 77:8 85:1 310:3 317:5 362:5 purposes 48:19 169:13 170:21 218:13 246:15 246:16,19 344:14 381:14 pursue 280:12

			435
		10 5	000.40
push 277:4	156:7 157:18 158:9	queue 43:5	330:12
pushback 30:7	161:22 162:18 163:3	quick 46:12 47:17	range 63:22 67:17
pushed 36:5 238:13	163:6,15 167:1	60:17 76:13 201:17	188:1 212:19 214:5
pushing 31:12 36:11	168:21 169:19 170:8	212:5 257:7 262:7	252:19 340:14 388:21
put 23:11 43:2,5 62:5	174:17 175:3,4 183:6	271:6 306:2	ranges 189:12 193:4
70:4 116:12 165:2	185:22 186:3 189:11	quickly 63:11 171:8	372:15
166:8 175:5 184:7	189:16 191:9 197:13	225:8 313:10 335:4	rank 355:19
224:18 246:19 247:12	200:1,21 202:21	382:17	ranking 246:3
247:12 258:20 268:14	203:2 210:3 211:6	Quinnonez 2:19 7:5,7	rare 356:8
307:13 309:2 315:20	212:4,6 215:11	94:15 95:3 96:2,15	Rasch 319:11
319:12 324:3 339:21	216:13 217:3,4	97:20 99:14 106:2,5	rate 109:15 112:4
345:6 363:21 371:10	237:15 244:7 246:20	114:14,20 115:11	230:15,16,17,19
406:17	257:8 258:2 261:1,6	117:17 118:12 119:3	234:2,4 237:20
putting 89:21 167:15	265:6,6 271:4 272:8	119:8 198:8 199:1,4	238:15,17 239:4,8
228:1 281:13 290:1	289:16 295:15 297:8	199:12 202:5,16	248:12 250:11 340:17
Pyles 2:9	303:3 306:11 308:4	203:4,14 204:8,13	340:20 351:12
	309:5 319:2 334:8	205:2,7,19 206:4,7,9	rated 67:22 68:18 347:4
Q	337:5 339:16 341:1	219:21 220:6,22	rater 345:12 354:17,17
QI 360:14	341:22 350:12,21	221:12 222:1 254:3	rates 58:4 67:10,16
qualify 79:20 146:6	351:5 354:1,15	255:7 264:13 269:3	237:11,13,15 238:22
quality 1:1,8 2:16 3:10	359:10,14 366:6	269:21 270:13 272:11	242:12
7:21 8:2 12:1,8 17:10	375:19,20 376:16,19	281:21 283:8,13,19	rating 61:16,18 128:1
21:1,10,12 40:1,16	377:14,16 380:8	318:10 322:17 338:21	165:6 183:13 219:19
48:8,13 49:6 53:17	381:17,22 391:19,20	339:2 342:8 343:17	220:20 246:5 307:10
54:19 55:3,6,7,10	396:20 399:8,16	362:17 363:12 368:17	322:3 345:11 347:2
56:1,11 57:10,22	400:8 401:8	384:12 385:2 402:3	372:12
58:18 60:9 68:15,19	questionable 120:17	402:18 406:1	ratings 158:2 163:8
74:20 78:11,12 79:2,3	questioned 261:11	quite 47:1 100:20	164:1 165:3,11,21
81:6,8,14 85:1,3,5,22	questioning 79:16	102:19 151:7 188:1	169:1,10 203:13,16
86:4 90:13 93:6,12	questionnaire 241:13	188:14 209:6 213:17	204:5 220:10 325:22
120:22 121:2 122:21	253:19	236:22 295:15 298:14	ratio 351:13
123:1,3 126:13,17	questions 22:9,11	343:10 364:8 374:7	rational 254:5
127:4,6 128:15	25:22 28:5,20 29:4,6	392:18	rationale 38:12 75:18
163:20 191:10 223:8	33:4 42:19,20 46:9	quorum 45:8,10	198:10,16 318:14
231:22 241:22 242:2	47:14 51:7 52:1,21	quoted 371:12	384:15
246:16,18 247:1	53:5 54:15 59:1 66:13	4	Ravers 331:16
251:1 271:10 286:14	69:16 76:10,14 80:16	R	re- 49:11 119:22 405:12
288:18 291:14 302:5			
	88:18 92:6 120:13	race 39:4 262:20.21	
302:14 309:6.8.9	88:18 92:6 120:13 122:13 124:11 133:22	race 39:4 262:20,21 263:1	405:18
302:14 309:6,8,9 310:10 317:6,7,14,15	122:13 124:11 133:22	263:1	405:18 re-admissions 292:20
310:10 317:6,7,14,15	122:13 124:11 133:22 134:4 142:9 146:16	263:1 raise 24:21 155:11	405:18 re-admissions 292:20 re-discussion 120:6
310:10 317:6,7,14,15 322:1 332:22 341:9	122:13 124:11 133:22 134:4 142:9 146:16 154:5 155:6 160:2	263:1 raise 24:21 155:11 197:15 241:20 292:10	405:18 re-admissions 292:20 re-discussion 120:6 re-do 332:2
310:10 317:6,7,14,15 322:1 332:22 341:9 347:9 350:9 354:10	122:13 124:11 133:22 134:4 142:9 146:16 154:5 155:6 160:2 167:4,20 168:7 173:4	263:1 raise 24:21 155:11 197:15 241:20 292:10 301:12 309:5 349:17	405:18 re-admissions 292:20 re-discussion 120:6 re-do 332:2 re-endorse 82:3
310:10 317:6,7,14,15 322:1 332:22 341:9 347:9 350:9 354:10 354:13 359:3,22	122:13 124:11 133:22 134:4 142:9 146:16 154:5 155:6 160:2 167:4,20 168:7 173:4 174:22 175:13 184:11	263:1 raise 24:21 155:11 197:15 241:20 292:10 301:12 309:5 349:17 350:12 354:7 397:5	405:18 re-admissions 292:20 re-discussion 120:6 re-do 332:2 re-endorse 82:3 re-vote 120:9,10 178:16
310:10 317:6,7,14,15 322:1 332:22 341:9 347:9 350:9 354:10 354:13 359:3,22 361:9,15 376:17	122:13 124:11 133:22 134:4 142:9 146:16 154:5 155:6 160:2 167:4,20 168:7 173:4 174:22 175:13 184:11 197:7 199:19 224:7	263:1 raise 24:21 155:11 197:15 241:20 292:10 301:12 309:5 349:17 350:12 354:7 397:5 raised 53:6 69:5 301:11	405:18 re-admissions 292:20 re-discussion 120:6 re-do 332:2 re-endorse 82:3 re-vote 120:9,10 178:16 181:18 206:11 222:1
310:10 317:6,7,14,15 322:1 332:22 341:9 347:9 350:9 354:10 354:13 359:3,22 361:9,15 376:17 383:4,11	122:13 124:11 133:22 134:4 142:9 146:16 154:5 155:6 160:2 167:4,20 168:7 173:4 174:22 175:13 184:11 197:7 199:19 224:7 227:19 230:12 231:7	263:1 raise 24:21 155:11 197:15 241:20 292:10 301:12 309:5 349:17 350:12 354:7 397:5 raised 53:6 69:5 301:11 304:18 344:11 360:10	405:18 re-admissions 292:20 re-discussion 120:6 re-do 332:2 re-endorse 82:3 re-vote 120:9,10 178:16 181:18 206:11 222:1 369:14 392:13 405:1
310:10 317:6,7,14,15 322:1 332:22 341:9 347:9 350:9 354:10 354:13 359:3,22 361:9,15 376:17 383:4,11 quantifies 382:10	122:13 124:11 133:22 134:4 142:9 146:16 154:5 155:6 160:2 167:4,20 168:7 173:4 174:22 175:13 184:11 197:7 199:19 224:7 227:19 230:12 231:7 232:21 233:17,17	263:1 raise 24:21 155:11 197:15 241:20 292:10 301:12 309:5 349:17 350:12 354:7 397:5 raised 53:6 69:5 301:11 304:18 344:11 360:10 360:11 370:11 394:22	405:18 re-admissions 292:20 re-discussion 120:6 re-do 332:2 re-endorse 82:3 re-vote 120:9,10 178:16 181:18 206:11 222:1 369:14 392:13 405:1 405:16,17 406:10
310:10 317:6,7,14,15 322:1 332:22 341:9 347:9 350:9 354:10 354:13 359:3,22 361:9,15 376:17 383:4,11 quantifies 382:10 quarrel 313:11	122:13 124:11 133:22 134:4 142:9 146:16 154:5 155:6 160:2 167:4,20 168:7 173:4 174:22 175:13 184:11 197:7 199:19 224:7 227:19 230:12 231:7 232:21 233:17,17 239:11 241:7,10	263:1 raise 24:21 155:11 197:15 241:20 292:10 301:12 309:5 349:17 350:12 354:7 397:5 raised 53:6 69:5 301:11 304:18 344:11 360:10 360:11 370:11 394:22 407:16	405:18 re-admissions 292:20 re-discussion 120:6 re-do 332:2 re-endorse 82:3 re-vote 120:9,10 178:16 181:18 206:11 222:1 369:14 392:13 405:1 405:16,17 406:10 reach 118:19 237:18
310:10 317:6,7,14,15 322:1 332:22 341:9 347:9 350:9 354:10 354:13 359:3,22 361:9,15 376:17 383:4,11 quantifies 382:10 quarrel 313:11 quarter 296:17 335:15	122:13 124:11 133:22 134:4 142:9 146:16 154:5 155:6 160:2 167:4,20 168:7 173:4 174:22 175:13 184:11 197:7 199:19 224:7 227:19 230:12 231:7 232:21 233:17,17 239:11 241:7,10 243:21 244:3,4,12,18	263:1 raise 24:21 155:11 197:15 241:20 292:10 301:12 309:5 349:17 350:12 354:7 397:5 raised 53:6 69:5 301:11 304:18 344:11 360:10 360:11 370:11 394:22 407:16 raises 215:10 354:4	405:18 re-admissions 292:20 re-discussion 120:6 re-do 332:2 re-endorse 82:3 re-vote 120:9,10 178:16 181:18 206:11 222:1 369:14 392:13 405:1 405:16,17 406:10 reach 118:19 237:18 361:14
310:10 317:6,7,14,15 322:1 332:22 341:9 347:9 350:9 354:10 354:13 359:3,22 361:9,15 376:17 383:4,11 quantifies 382:10 quarrel 313:11 quarter 296:17 335:15 356:9,11	122:13 124:11 133:22 134:4 142:9 146:16 154:5 155:6 160:2 167:4,20 168:7 173:4 174:22 175:13 184:11 197:7 199:19 224:7 227:19 230:12 231:7 232:21 233:17,17 239:11 241:7,10 243:21 244:3,4,12,18 246:13,21 247:5,22	263:1 raise 24:21 155:11 197:15 241:20 292:10 301:12 309:5 349:17 350:12 354:7 397:5 raised 53:6 69:5 301:11 304:18 344:11 360:10 360:11 370:11 394:22 407:16 raises 215:10 354:4 raising 51:1 174:17	405:18 re-admissions 292:20 re-discussion 120:6 re-do 332:2 re-endorse 82:3 re-vote 120:9,10 178:16 181:18 206:11 222:1 369:14 392:13 405:1 405:16,17 406:10 reach 118:19 237:18 361:14 reached 45:16 46:3,9
310:10 317:6,7,14,15 322:1 332:22 341:9 347:9 350:9 354:10 354:13 359:3,22 361:9,15 376:17 383:4,11 quantifies 382:10 quarrel 313:11 quarter 296:17 335:15 356:9,11 quarterly 296:18	122:13 124:11 133:22 134:4 142:9 146:16 154:5 155:6 160:2 167:4,20 168:7 173:4 174:22 175:13 184:11 197:7 199:19 224:7 227:19 230:12 231:7 232:21 233:17,17 239:11 241:7,10 243:21 244:3,4,12,18 246:13,21 247:5,22 248:1,5,18 249:2,2	263:1 raise 24:21 155:11 197:15 241:20 292:10 301:12 309:5 349:17 350:12 354:7 397:5 raised 53:6 69:5 301:11 304:18 344:11 360:10 360:11 370:11 394:22 407:16 raises 215:10 354:4 raising 51:1 174:17 197:3 345:3	405:18 re-admissions 292:20 re-discussion 120:6 re-do 332:2 re-endorse 82:3 re-vote 120:9,10 178:16 181:18 206:11 222:1 369:14 392:13 405:1 405:16,17 406:10 reach 118:19 237:18 361:14 reached 45:16 46:3,9 95:18 119:17 181:13
310:10 317:6,7,14,15 322:1 332:22 341:9 347:9 350:9 354:10 354:13 359:3,22 361:9,15 376:17 383:4,11 quantifies 382:10 quarrel 313:11 quarter 296:17 335:15 356:9,11 quarterly 296:18 question 24:20 32:7	122:13 124:11 133:22 134:4 142:9 146:16 154:5 155:6 160:2 167:4,20 168:7 173:4 174:22 175:13 184:11 197:7 199:19 224:7 227:19 230:12 231:7 232:21 233:17,17 239:11 241:7,10 243:21 244:3,4,12,18 246:13,21 247:5,22 248:1,5,18 249:2,2 252:1 262:11 267:21	263:1 raise 24:21 155:11 197:15 241:20 292:10 301:12 309:5 349:17 350:12 354:7 397:5 raised 53:6 69:5 301:11 304:18 344:11 360:10 360:11 370:11 394:22 407:16 raises 215:10 354:4 raising 51:1 174:17 197:3 345:3 ran 325:17	405:18 re-admissions 292:20 re-discussion 120:6 re-do 332:2 re-endorse 82:3 re-vote 120:9,10 178:16 181:18 206:11 222:1 369:14 392:13 405:1 405:16,17 406:10 reach 118:19 237:18 361:14 reached 45:16 46:3,9 95:18 119:17 181:13 204:7 207:4,12 281:6
310:10 317:6,7,14,15 322:1 332:22 341:9 347:9 350:9 354:10 354:13 359:3,22 361:9,15 376:17 383:4,11 quantifies 382:10 quarrel 313:11 quarter 296:17 335:15 356:9,11 quarterly 296:18 question 24:20 32:7 67:9,11 75:16 77:9,16	122:13 124:11 133:22 134:4 142:9 146:16 154:5 155:6 160:2 167:4,20 168:7 173:4 174:22 175:13 184:11 197:7 199:19 224:7 227:19 230:12 231:7 232:21 233:17,17 239:11 241:7,10 243:21 244:3,4,12,18 246:13,21 247:5,22 248:1,5,18 249:2,2 252:1 262:11 267:21 268:10 287:5,6,14	263:1 raise 24:21 155:11 197:15 241:20 292:10 301:12 309:5 349:17 350:12 354:7 397:5 raised 53:6 69:5 301:11 304:18 344:11 360:10 360:11 370:11 394:22 407:16 raises 215:10 354:4 raising 51:1 174:17 197:3 345:3 ran 325:17 RAND 2:7 20:19	405:18 re-admissions 292:20 re-discussion 120:6 re-do 332:2 re-endorse 82:3 re-vote 120:9,10 178:16 181:18 206:11 222:1 369:14 392:13 405:1 405:16,17 406:10 reach 118:19 237:18 361:14 reached 45:16 46:3,9 95:18 119:17 181:13 204:7 207:4,12 281:6 391:22 401:15 404:9
310:10 317:6,7,14,15 322:1 332:22 341:9 347:9 350:9 354:10 354:13 359:3,22 361:9,15 376:17 383:4,11 quartifies 382:10 quarrel 313:11 quarter 296:17 335:15 356:9,11 quarterly 296:18 question 24:20 32:7 67:9,11 75:16 77:9,16 78:5 80:10,20 82:2,6	122:13 124:11 133:22 134:4 142:9 146:16 154:5 155:6 160:2 167:4,20 168:7 173:4 174:22 175:13 184:11 197:7 199:19 224:7 227:19 230:12 231:7 232:21 233:17,17 239:11 241:7,10 243:21 244:3,4,12,18 246:13,21 247:5,22 248:1,5,18 249:2,2 252:1 262:11 267:21 268:10 287:5,6,14 288:22 292:6,7 293:9	263:1 raise 24:21 155:11 197:15 241:20 292:10 301:12 309:5 349:17 350:12 354:7 397:5 raised 53:6 69:5 301:11 304:18 344:11 360:10 360:11 370:11 394:22 407:16 raises 215:10 354:4 raising 51:1 174:17 197:3 345:3 ran 325:17 RAND 2:7 20:19 random 80:9 188:15	405:18 re-admissions 292:20 re-discussion 120:6 re-do 332:2 re-endorse 82:3 re-vote 120:9,10 178:16 181:18 206:11 222:1 369:14 392:13 405:1 405:16,17 406:10 reach 118:19 237:18 361:14 reached 45:16 46:3,9 95:18 119:17 181:13 204:7 207:4,12 281:6 391:22 401:15 404:9 reaction 267:1
310:10 317:6,7,14,15 322:1 332:22 341:9 347:9 350:9 354:10 354:13 359:3,22 361:9,15 376:17 383:4,11 quartifies 382:10 quarrel 313:11 quarter 296:17 335:15 356:9,11 quarterly 296:18 question 24:20 32:7 67:9,11 75:16 77:9,16 78:5 80:10,20 82:2,6 84:18 88:16 90:10,18	122:13 124:11 133:22 134:4 142:9 146:16 154:5 155:6 160:2 167:4,20 168:7 173:4 174:22 175:13 184:11 197:7 199:19 224:7 227:19 230:12 231:7 232:21 233:17,17 239:11 241:7,10 243:21 244:3,4,12,18 246:13,21 247:5,22 248:1,5,18 249:2,2 252:1 262:11 267:21 268:10 287:5,6,14 288:22 292:6,7 293:9 293:12 310:16 311:14	263:1 raise 24:21 155:11 197:15 241:20 292:10 301:12 309:5 349:17 350:12 354:7 397:5 raised 53:6 69:5 301:11 304:18 344:11 360:10 360:11 370:11 394:22 407:16 raises 215:10 354:4 raising 51:1 174:17 197:3 345:3 ran 325:17 RAND 2:7 20:19 random 80:9 188:15 215:7 324:15 325:2	405:18 re-admissions 292:20 re-discussion 120:6 re-do 332:2 re-endorse 82:3 re-vote 120:9,10 178:16 181:18 206:11 222:1 369:14 392:13 405:1 405:16,17 406:10 reach 118:19 237:18 361:14 reached 45:16 46:3,9 95:18 119:17 181:13 204:7 207:4,12 281:6 391:22 401:15 404:9 reaction 267:1 read 53:2,8 64:12 86:21
310:10 317:6,7,14,15 322:1 332:22 341:9 347:9 350:9 354:10 354:13 359:3,22 361:9,15 376:17 383:4,11 quartifies 382:10 quarrel 313:11 quarter 296:17 335:15 356:9,11 quarterly 296:18 question 24:20 32:7 67:9,11 75:16 77:9,16 78:5 80:10,20 82:2,6 84:18 88:16 90:10,18 91:11 100:3 102:11	122:13 124:11 133:22 134:4 142:9 146:16 154:5 155:6 160:2 167:4,20 168:7 173:4 174:22 175:13 184:11 197:7 199:19 224:7 227:19 230:12 231:7 232:21 233:17,17 239:11 241:7,10 243:21 244:3,4,12,18 246:13,21 247:5,22 248:1,5,18 249:2,2 252:1 262:11 267:21 268:10 287:5,6,14 288:22 292:6,7 293:9 293:12 310:16 311:14 323:11 334:5 349:17	263:1 raise 24:21 155:11 197:15 241:20 292:10 301:12 309:5 349:17 350:12 354:7 397:5 raised 53:6 69:5 301:11 304:18 344:11 360:10 360:11 370:11 394:22 407:16 raises 215:10 354:4 raising 51:1 174:17 197:3 345:3 ran 325:17 RAND 2:7 20:19 random 80:9 188:15 215:7 324:15 325:2 331:1,2	405:18 re-admissions 292:20 re-discussion 120:6 re-do 332:2 re-endorse 82:3 re-vote 120:9,10 178:16 181:18 206:11 222:1 369:14 392:13 405:1 405:16,17 406:10 reach 118:19 237:18 361:14 reached 45:16 46:3,9 95:18 119:17 181:13 204:7 207:4,12 281:6 391:22 401:15 404:9 reaction 267:1 read 53:2,8 64:12 86:21 155:4 178:22 221:7
310:10 317:6,7,14,15 322:1 332:22 341:9 347:9 350:9 354:10 354:13 359:3,22 361:9,15 376:17 383:4,11 quartifies 382:10 quarrel 313:11 quarter 296:17 335:15 356:9,11 quarterly 296:18 question 24:20 32:7 67:9,11 75:16 77:9,16 78:5 80:10,20 82:2,6 84:18 88:16 90:10,18 91:11 100:3 102:11 102:19 108:22 109:22	$\begin{array}{c} 122:13 \ 124:11 \ 133:22\\ 134:4 \ 142:9 \ 146:16\\ 154:5 \ 155:6 \ 160:2\\ 167:4,20 \ 168:7 \ 173:4\\ 174:22 \ 175:13 \ 184:11\\ 197:7 \ 199:19 \ 224:7\\ 227:19 \ 230:12 \ 231:7\\ 232:21 \ 233:17,17\\ 239:11 \ 241:7,10\\ 243:21 \ 244:3,4,12,18\\ 246:13,21 \ 247:5,22\\ 248:1,5,18 \ 249:2,2\\ 252:1 \ 262:11 \ 267:21\\ 268:10 \ 287:5,6,14\\ 288:22 \ 292:6,7 \ 293:9\\ 293:12 \ 310:16 \ 311:14\\ 323:11 \ 334:5 \ 349:17\\ 353:2 \ 358:12 \ 360:7\\ \end{array}$	263:1 raise 24:21 155:11 197:15 241:20 292:10 301:12 309:5 349:17 350:12 354:7 397:5 raised 53:6 69:5 301:11 304:18 344:11 360:10 360:11 370:11 394:22 407:16 raises 215:10 354:4 raising 51:1 174:17 197:3 345:3 ran 325:17 RAND 2:7 20:19 random 80:9 188:15 215:7 324:15 325:2 331:1,2 randomization 215:7	405:18 re-admissions 292:20 re-discussion 120:6 re-do 332:2 re-endorse 82:3 re-vote 120:9,10 178:16 181:18 206:11 222:1 369:14 392:13 405:1 405:16,17 406:10 reach 118:19 237:18 361:14 reached 45:16 46:3,9 95:18 119:17 181:13 204:7 207:4,12 281:6 391:22 401:15 404:9 reaction 267:1 read 53:2,8 64:12 86:21 155:4 178:22 221:7 222:7 254:13 255:18
310:10 317:6,7,14,15 322:1 332:22 341:9 347:9 350:9 354:10 354:13 359:3,22 361:9,15 376:17 383:4,11 quartifies 382:10 quarrel 313:11 quarter 296:17 335:15 356:9,11 quarterly 296:18 question 24:20 32:7 67:9,11 75:16 77:9,16 78:5 80:10,20 82:2,6 84:18 88:16 90:10,18 91:11 100:3 102:11 102:19 108:22 109:22 112:8 117:14 132:22	$\begin{array}{c} 122:13 \ 124:11 \ 133:22\\ 134:4 \ 142:9 \ 146:16\\ 154:5 \ 155:6 \ 160:2\\ 167:4,20 \ 168:7 \ 173:4\\ 174:22 \ 175:13 \ 184:11\\ 197:7 \ 199:19 \ 224:7\\ 227:19 \ 230:12 \ 231:7\\ 232:21 \ 233:17,17\\ 239:11 \ 241:7,10\\ 243:21 \ 244:3,4,12,18\\ 246:13,21 \ 247:5,22\\ 248:1,5,18 \ 249:2,2\\ 252:1 \ 262:11 \ 267:21\\ 268:10 \ 287:5,6,14\\ 288:22 \ 292:6,7 \ 293:9\\ 293:12 \ 310:16 \ 311:14\\ 323:11 \ 334:5 \ 349:17\\ 353:2 \ 358:12 \ 360:7\\ 376:3 \ 381:18 \ 399:9\\ \end{array}$	263:1 raise 24:21 155:11 197:15 241:20 292:10 301:12 309:5 349:17 350:12 354:7 397:5 raised 53:6 69:5 301:11 304:18 344:11 360:10 360:11 370:11 394:22 407:16 raises 215:10 354:4 raising 51:1 174:17 197:3 345:3 ran 325:17 RAND 2:7 20:19 random 80:9 188:15 215:7 324:15 325:2 331:1,2 randomization 215:7 randomized 84:2	405:18 re-admissions 292:20 re-discussion 120:6 re-do 332:2 re-endorse 82:3 re-vote 120:9,10 178:16 181:18 206:11 222:1 369:14 392:13 405:1 405:16,17 406:10 reach 118:19 237:18 361:14 reached 45:16 46:3,9 95:18 119:17 181:13 204:7 207:4,12 281:6 391:22 401:15 404:9 reaction 267:1 read 53:2,8 64:12 86:21 155:4 178:22 221:7 222:7 254:13 255:18 269:13 275:7 283:15
310:10 317:6,7,14,15 322:1 332:22 341:9 347:9 350:9 354:10 354:13 359:3,22 361:9,15 376:17 383:4,11 quartifies 382:10 quarrel 313:11 quarter 296:17 335:15 356:9,11 quarterly 296:18 question 24:20 32:7 67:9,11 75:16 77:9,16 78:5 80:10,20 82:2,6 84:18 88:16 90:10,18 91:11 100:3 102:11 102:19 108:22 109:22	$\begin{array}{c} 122:13 \ 124:11 \ 133:22\\ 134:4 \ 142:9 \ 146:16\\ 154:5 \ 155:6 \ 160:2\\ 167:4,20 \ 168:7 \ 173:4\\ 174:22 \ 175:13 \ 184:11\\ 197:7 \ 199:19 \ 224:7\\ 227:19 \ 230:12 \ 231:7\\ 232:21 \ 233:17,17\\ 239:11 \ 241:7,10\\ 243:21 \ 244:3,4,12,18\\ 246:13,21 \ 247:5,22\\ 248:1,5,18 \ 249:2,2\\ 252:1 \ 262:11 \ 267:21\\ 268:10 \ 287:5,6,14\\ 288:22 \ 292:6,7 \ 293:9\\ 293:12 \ 310:16 \ 311:14\\ 323:11 \ 334:5 \ 349:17\\ 353:2 \ 358:12 \ 360:7\\ \end{array}$	263:1 raise 24:21 155:11 197:15 241:20 292:10 301:12 309:5 349:17 350:12 354:7 397:5 raised 53:6 69:5 301:11 304:18 344:11 360:10 360:11 370:11 394:22 407:16 raises 215:10 354:4 raising 51:1 174:17 197:3 345:3 ran 325:17 RAND 2:7 20:19 random 80:9 188:15 215:7 324:15 325:2 331:1,2 randomization 215:7	405:18 re-admissions 292:20 re-discussion 120:6 re-do 332:2 re-endorse 82:3 re-vote 120:9,10 178:16 181:18 206:11 222:1 369:14 392:13 405:1 405:16,17 406:10 reach 118:19 237:18 361:14 reached 45:16 46:3,9 95:18 119:17 181:13 204:7 207:4,12 281:6 391:22 401:15 404:9 reaction 267:1 read 53:2,8 64:12 86:21 155:4 178:22 221:7 222:7 254:13 255:18

reading 133:11 142:21 267:18 268:10 274:10 274:13 278:14 readmissions 240:8 265:8 300:4,8 readmitted 240:18 292:17 300:20 372:4 ready 40:12 94:14 101:1,2 105:22 114:13 172:21 180:11 180:12 220:3 249:5 253:14 255:7 264:10 269:1,20 272:16 288:21 317:22 338:21 338:22 360:21 362:13 377:13 384:10 386:2 real 63:4 79:13 147:18 172:1 194:6 196:8 232:21 262:7 271:6 306:2 327:10 realistic 398:11 reality 95:17 realize 73:15 108:13 278:21 realizing 401:14 really 7:13 11:22 12:1 14:16 26:13 30:5,9 31:1,20 32:7,20 33:19 33:21 36:4,11 38:2 42:15 45:18 46:18 47:4 54:10 60:16 62:3 62:5,7,15 63:15 68:13 69:17,18,18 70:4,17 71:9 72:17 79:10,21 82:3 85:5 86:1 87:1.4 88:3 90:8 99:9 108:8 108:21 110:20 111:3 111:8,9,15 122:1 137:13 138:10 142:11 144:14,20 147:20 148:19 151:13 158:22 161:16 163:20 164:2 166:4,21 168:13 171:8,21 172:12 178:20 179:6 192:1,2 192:14,21 194:11,11 206:3 210:13,15 215:6,18 216:16,19 222:18 223:19 228:8 229:9 232:12 234:14 236:5,7,7,12 238:13 238:22 243:6 244:19 246:4,17 247:8 248:6 250:6 251:7 252:8,12 252:13 257:10 258:17 260:13 262:14 266:9 268:1 275:13 277:16 280:11 292:3 294:18

295:4,17 296:22 302:1 305:17 306:3,7 306:9 308:14 311:11 313:5,10,12 320:2 321:10,11 328:13 330:6 331:17 332:14 336:15 351:21 355:21 356:16 364:16 367:13 367:17,18 368:2,4,9 370:13,14 374:19 375:11 377:11 390:2 393:6,7,13,14 394:3,4 394:8 395:19 403:12 408:6 realm 191:11 193:7 348:7 realms 193:16 realtime 23:3 reason 61:12 70:9,10 73:7 166:21 175:15 208:14 216:1 241:17 245:17 247:2 289:22 reasonable 263:4 274:3 reasonably 245:12 reasons 40:19 176:8 **Rebecca** 1:15 54:2 59:13 recall 8:10 237:4 recap 222:15 receive 41:18 63:13 129:13 145:11 162:14 185:1,9 230:17 received 44:18 52:14 54:22 113:10 131:7 188:22 243:12 receiving 127:10 140:1 185:3 196:4 recipient 147:1 162:7 recognition 304:20 recognize 25:5 52:13 54:13 68:7 69:4,12 71:20 recollection 334:2 recommend 137:13 201:15 204:12 211:22 219:19 247:10 272:8 281:18 407:20 recommendation 45:22 69:6 73:13 89:4 118:13 119:5,13 207:4,13 223:14 272:9,12 273:17 274:3 281:22 283:10 283:20 368:18 369:9 387:18 390:13 400:19 401:10 402:4,12 recommendations 41:5 41:7,9 44:7 128:1

163:9 164:1 165:3 169:2 180:9 183:14 201:13 204:11,15 221:3 222:14 360:13 recommended 27:15 36:16 37:1 45:11 46:4 46:7 72:19 156:10 247:3 334:3 404:8 recommending 118:21 213:2,5 230:14 271:4 reconfigure 335:21 reconsider 120:1 178:10,10 reconsideration 95:20 178:15 183:19 record 17:6 31:21 56:21 102:22 124:21 174:5 282:12 284:12 401:2 408:15 records 53:3 113:16 308:16 recreation 379:5 recreational 367:22 **recuse** 21:22 recused 46:16 reduce 58:19 74:7.11 reduces 76:18 reducing 74:21 reduction 257:8,9 redundancy 250:7 redundant 364:8,13 **Reed** 2:20 7:10,11 164:17,20 165:17 166:3 reexamined 265:22 referral 87:3 referrals 305:21 referring 135:14 refinements 353:9 reflected 116:20 reflective 91:6 reflects 284:17 refuse 294:20 refused 309:14 regard 100:14 107:7 407:20 regarding 48:10 280:18 regardless 288:2 307:19 regards 67:9 68:6 regional 19:5 352:10 regions 143:22 registered 45:2 registry 102:17 113:13 113:19 **regular** 69:17 rehab 91:17 93:17 140:5 287:18 290:13

301:5 302:11 306:5 340:15 345:8 348:10 348:11 rehabilitation 2:1 11:16 11:18 12:2,9,15,16 18:21 19:1 20:9 93:5 233:9 286:18 304:2 379:19,22 380:4 rehabilitative 314:12 rehospitalization 242:12 267:12 reimbursable 78:20 reimbursement 78:22 93:20 reiterate 163:16 347:12 353:1 relate 380:19 related 4:20 13:18 20:2 36:13,14,18 37:2 38:20 107:4 120:17 120:19 121:2,4,16 126:22 184:3 199:20 209:18 228:20 260:22 275:13 280:20 287:5 287:7 288:22 323:11 370:2 388:14 400:2.3 relates 112:9 208:9 209:5 298:11 relating 155:6,8 relation 41:2 relationship 29:12,13 55:13 61:15,21 73:16 198:11,17 254:6 257:21 318:14 353:12 384:15 relationships 29:10 **relative** 246:3 relatively 174:2 182:12 323:19 356:12 relegated 61:19 relevant 9:5,6,10,16,19 18:16,16 107:2 275:12 343:6 368:5 reliability 33:2 35:11,14 36:9 43:17 51:1,5,17 100:3,15,20 101:5,7 101:17,19 102:5,16 103:2,4 106:3,6,11,14 106:15 107:1 109:2 150:10 161:7 167:18 173:1 207:22 208:2 209:18 211:7 213:4 215:10,19 216:21 217:5 219:17 220:8 221:1,11,13 222:2 234:6,8 248:22 256:1 256:5 264:14 323:10 324:12 334:21 339:3

ng 5:20 55:4,6,7 57:2,4 66:5 5:17 86:1,4 98:21 99:10 2,16,18 105:11 4,17 111:18 2 113:16,18,21 122:21 123:3 6 148:17 198:4 223:9 238:16 6,19 239:6 17 271:8,9 9 291:2,5,14 9 360:14,18 0 366:13 66:18 170:17 8 296:18 299:2 ories 335:9 ory 357:13,22 9 383:21 ent 8:22,22 19 48:3 49:6 4 ntation 110:1 ntatives 52:19 ented 32:3 3 324:18 enting 215:5 ents 231:12 43:7 113:11 1 181:16 336:2 0 403:17 ed 157:6 291:3 1 **s** 129:8 86:1,2 90:22 128:5 131:8,11 9 277:6 288:9 6,19,20 293:18 0 344:15 345:16 8 365:10,11 4 d 84:20,21 93:6 290:15 294:14 5,18 313:13,16 9 331:5 349:16 365:9 ment 90:5 1 351:1 396:22 ments 193:5 4 s 131:12 277:18 3 301:16 345:9 duled 40:11 h 2:7,8 3:11 9:9

15:12 16:14 21:11 58:3 65:12 68:12 74:5 82:8 126:1 200:10 287:3,16 311:20,20 317:2 356:22 381:3 researcher 15:7 20:17 20:20 65:17 researchers 16:13 129:9 resident 4:10 229:3 230:8 236:16 243:5 273:19 282:13 304:12 residential 5:12 residents 256:19 268:4 268:5 282:12 304:1,3 resolved 404:14 resonating 49:20 resource 57:22 resources 305:21 393:17 respect 39:15 47:20 140:19 170:21 192:15 216:9 241:15 265:8 364:4 respectable 371:6 375:6 388:21 respectfully 388:13 respiratory 377:4 respond 41:17,19 195:8 226:11 235:20 268:10 274:22 280:22 responded 188:8,17 respondent 229:5 respondents 167:17 188:19 193:10 212:8 212:9 213:16 responding 354:10 response 72:8 109:15 234:2,3 237:11,13,15 237:20 238:11,14,17 238:22 239:4,8 244:21 245:4,6,9 248:12 250:11 321:22 340:17,20 responses 53:7 92:10 110:2 153:9 194:9 200:9,12 231:1 235:9 245:2 responsibilities 17:1 21:16 47:20 responsible 185:12 responsive 354:7 responsiveness 240:14 rest 40:7 182:10 236:5 244:4 252:2 384:7 401:12 restaurant 408:9 restoration 302:7

367:16 368:4 restorative 91:17 303:22 304:11 restricted 364:21 restrictions 172:10 restrooms 23:13 restructure 335:18 resubmit 40:20 369:15 resubmitted 332:7 333:4,8 result 58:5,16 72:6 75:7 96:1 197:21 369:12 resulted 323:12 resulting 81:14 results 97:22 102:20 128:15 153:7 205:12 206:16 210:17 211:10 220:15 221:7,19 222:7 237:8 243:19 254:13 255:18 264:20 269:13 270:7,21 272:16 283:15 284:3 293:8 318:20 323:6 326:20 331:19 337:20 339:9 342:21 344:4 351:10.13.14 352:11 363:4,16 369:6,19 384:20 385:11,21 386:12 387:1,13 388:1 394:10 400:15 402:9,19 406:14 resumed 124:21 174:5 284:12 Retained 3:4 retest 234:6 retested 101:9 rethought 407:20 retired 10:3 retraining 345:18 retrospective 82:22 return 367:20,22 379:4 returned 218:7,9,18 reverse 258:13 review 25:9 29:3 40:11 40:12 42:14 56:11 59:20 80:2 82:22 84:5 88:22 99:1 109:5 123:2 182:3 252:13 252:14 267:4 289:13 340:5 345:7 reviewed 46:13 65:6 89:17 291:22 reviewer 59:13 70:8 319:2 reviewers 103:1 297:5 364:2 reviewing 52:3 59:16 reviews 83:18

revoting 95:21 rewrite 267:6 **REZEK** 3:12 102:12 103:12,19 104:7,19 104:22 Rheumatology 65:10 right 6:2 7:13 22:5 23:14,19 34:12 35:18 37:7 38:9 42:5 54:8 75:14 76:11 90:17 92:5,7 101:1 105:8 106:2 107:13 110:6 115:11 116:21.22 125:6 133:19 134:5 142:1 143:6,13 150:14 151:9 153:17 155:16 156:2,3 159:21 160:5,13,17 160:19 161:19 162:22 163:1,4 165:16,22 166:10 174:7 179:10 186:20 187:1 191:9 193:6 195:5,13 200:22 201:17 202:4 203:12 206:7,8,9,19 207:21 212:19 213:18 214:2 219:10 220:20 222:11 228:17 232:8 235:20 238:9,13 239:16 242:21 250:14 250:20 257:4 261:3.5 262:8 268:21 279:11 280:1,9 281:15 285:11 292:10 296:6 296:11 298:8 300:14 303:7 311:18 313:1 314:5,11 318:22 321:13 330:1 331:13 332:8,17 333:6 336:20 341:1 343:15 353:20,22 360:22 365:9,9 370:17 375:15 390:8,14 392:10 396:5.21 398:3 400:5 401:10 404:8,17,19 407:4 rights 13:13 288:15 291:15 rigor 348:11,22 rigorous 349:10 **risk** 37:8,11,11,16,22 38:5,11 39:6,8 58:13 82:12 262:8,12 263:10,12,18,19 264:2 269:6 288:1 309:9,12,16 313:22 342:12 376:14 386:5 RN 1:18 2:5 3:13

road 244:1 280:13 344:18 robust 130:5 216:18 217:11 393:14 395:4 395:10 rock 322:7 role 16:10 41:11 roll 129:11 141:5 rolling 31:8 room 1:8 10:13 24:4 59:12 60:21 66:1 76:11 80:16 112:6 118:9 126:6 173:11 188:3 283:4 rotation 226:20 rotations 226:19 235:7 rough 306:22 roughly 384:3 391:11 round 108:5 128:22 153:2 170:15 171:1 213:9,11 225:11 246:12 261:5,6 rounds 210:4,7,8 229:19,19 244:10,11 **routine** 79:16 **row** 11:12 royalty-free 288:16 361:8 **rule** 31:1 128:9,10 214:7 382:21 383:2 398:19 rules 6:1 46:12 101:13 277:1 332:18 398:20 run 15:17 131:18 140:12 159:1,13 172:4 325:7 397:20 397:21 398:2 S safety 21:10 38:21 39:1 154:18 155:7 181:4 201:13,16 205:18,20 206:11 207:5 216:9 Saliba 2:6 20:15,16,16 21:3 96:7,12,18 97:11 97:15,17 143:3,3 199:7 242:22 243:4 244:20 267:15 268:18 276:1,10,21 277:6,10 278:2 285:21 Salida 236:14 Salt 14:1 Sam 18:19 134:8 218:4 314:20 345:3,4 376:19 sample 102:21 123:2

216:22 219:7 223:18 234:18 237:11 238:2 241:1 249:1 260:17 280:11 324:15,15 325:2 335:20 390:20 391:7,17 395:18 398:16 samples 277:19 374:20 375:4,6 391:8 sampling 188:7,14 214:20 215:3,7 218:11 219:12 223:19 Sampsel 2:21 6:3,11 23:9 24:11 31:18,22 32:5 37:14,21 48:9,20 49:2,8,14,16 50:3 51:3 64:21 88:16 94:6 95:10 96:21 98:8 99:22 100:9 101:2,6 102:1 119:1,14 156:13 157:17 176:4 177:8 178:4 180:5 182:6 183:7 201:2 207:1,8,16 225:13 227:1 228:11,14 239:13 261:7 332:4,9 332:11 333:7,10,15 333:19 335:1 336:3 337:12 340:4,9 391:19 397:21 399:6 401:11,19 402:21 403:21 404:19 405:12 406:8.13 Samuel 1:14 394:12 Samuel's 372:17 Sarah 2:21 5:22 6:11 40:5 43:1 50:13 70:1 88:12 94:3 98:5 116:11 118:11 155:12 155:19 177:1,22 179:18 197:3 206:21 217:21 261:3 281:17 331:20 390:2 396:6 Sarah's 264:11 sat 388:15 satisfaction 83:21 111:20 122:12 144:3 164:2 231:5,9,18 233:1 236:12 238:19 243:6,15 245:17 246:2 250:22 252:20 258:16 259:13 260:3 263:13 271:19 272:1 satisfactions 236:21 satisfactorily 56:2 satisfied 233:12 240:5 247:11 262:16 263:1 264:4.4

saw 90:15 175:19 saying 52:10 59:15 73:6,15 82:4 90:7 107:18 156:9 166:2,3 177:14 187:1 226:7 258:11 273:4 311:22 329:2,6,11 330:3 331:7 336:13 360:21 361:2 394:1 400:15 401:22 says 29:12 79:17 102:8 152:4 271:6,7 305:7 316:13 326:13,21 341:22 358:20 360:4 scale 61:18 63:10,13 69:20,21,22 70:1,3,5 71:8 127:22 160:9 161:22 163:13 175:1 183:12,13 184:12 186:15,16 187:14 201:4,12,14,18 202:11,21 203:11 207:2 230:11 244:21 245:6 246:5 259:9,10 307:10 353:18.19 368:7 372:12 380:21 scaled 163:19 scales 61:16 165:8 215:15,18 245:9,10 247:6 scenario 79:14 279:5 scenes 384:8 schedule 47:13 scheduled 124:13 school 1:17,22 2:8,10 3:3 10:22 15:5,16,18 18:5 19:15,22 37:17 65:10 schools 37:15 38:4 science 69:13 **Sciences** 19:22 scientific 2:14 100:2 220:7 221:13 239:14 255:22 342:9 scope 57:5 163:13 score 4:12,13,14,16,17 4:19 102:15 103:4 133:7,8 141:15,16 187:14 236:14 248:13 259:18,21 260:1 261:15 283:10 284:22 285:1,1 286:5 300:19 303:6,10 318:12 319:10 347:19 348:13 351:11 361:22 365:21 382:4 384:14 398:14 scores 104:8 188:1,10 188:14 208:13 233:1

185:18 188:15 191:15

213:2,6 214:21 215:9

243:17 246:2.22 263:10 273:4,4 274:3 274:4 294:1 320:21 321:3 349:10,11,12 scoring 244:2 276:14 322:4 398:15 screen 23:19 96:13 198:15 201:11 285:11 324:4 screened 188:19 screening 55:16 57:9 90:21 91:7 152:5 188:18,20 screwed 266:13 scribe 278:16 script 400:7 scripting 196:17 scroll 98:10 **SDS** 26:21 27:2,4,14,15 27:17 28:7,13 37:7,16 38:6,10 49:5 se 33:7 117:4 132:12 searched 263:8,10 seasoned 148:21 seat 11:12 Sebelius 301:13 309:1 second 20:1 48:1 50:5 65:1 94:17 106:7,8 143:4 163:16 168:12 204:16 205:9,21 206:10 219:22 221:20 234:5 235:20 239:18 252:11 273:5 274:5 359:14 369:15 389:10 Secondly 288:7 seconds 154:9 168:14 section 10:21 88:20 120:5,20 145:3 313:9 see 7:7 28:18 39:10,16 44:4,22 46:8 64:8 73:18 91:11 94:9 110:7,8 111:3 114:7 116:20 120:6 122:9 122:14 123:21 147:22 155:15 156:15 162:6 166:16 171:22 172:16 173:22 176:18 180:10 194:7.8 199:9 211:5 211:18 217:16 218:14 219:10 223:22 227:14 238:1 239:4 241:3 254:19 258:11 260:15 261:17 262:5 263:10 267:20 274:8 278:17 298:7 299:6 303:8 305:18 307:4 316:5 319:17 320:1,14 326:2,8,10,11 327:13

328:5.13.16.17.18.20 328:22 329:1 331:19 335:3 349:1 352:12 352:15 356:16 359:1 362:14 371:19 373:17 375:10 378:12 388:20 392:5 394:1 398:8,8 398:16,19 seeing 30:12,13 124:17 143:18 176:9,11 236:6 243:11 304:4 308:8 324:17 326:12 327:20 329:17 367:8 seek 46:2 seeking 117:10 seen 29:7 40:14 95:10 266:22 350:8 374:22 segment 140:20 390:10 select 67:5 144:13 159:10 selected 56:12 123:2 selecting 144:17 self 4:11,17 284:22 292:2 318:12 346:10 348:18,20 364:16 365:1.4 370:6 372:18 self-209:13 298:17 self-care 286:5 298:18 298:21 325:9,19 self-report 209:11 222:20 self-reported 18:7 72:6 sell 5:10 send 237:6 sending 241:12 Senior 2:21,22 6:11 7:16 21:9 sense 84:20 111:20 143:10 151:5 159:1 187:17 189:7 227:7 231:14 236:6 237:21 250:2 256:4 258:18 263:15 327:12 330:15 346:3 393:11 sensing 196:6 sensitive 303:3 338:11 sensitivity 371:16 372:14 sent 8:11 300:5 sentence 10:16 62:15 separate 70:20 71:1 131:8,12,12,13 136:10 137:14 141:6 154:18 155:15 157:7 157:8,14,15 161:17 165:17 166:5,8 181:2 183:10 184:18 201:3 209:16 309:18 320:15

340:9 364:9 separately 102:18 154:5 155:10 157:11 183:10 227:10 separating 158:7 series 40:1,15 serious 231:13 serve 9:1 46:17 362:5 served 139:15 141:8.19 service 1:18 9:5 10:4 19:17 126:13 146:12 152:7 184:18 193:21 196:14,16 198:19 200:7,12 254:8 318:16 383:12 384:17 services 3:7,9 4:7 20:17 21:11 65:16 74:8 78:21 125:3 126:15 127:10,11,17 127:18 128:4,7 129:18 137:22 138:5 138:19 139:14,16 140:1 141:1,3,9 143:8 143:12,12 144:7 145:11 147:5,9,14,16 147:19 148:5 159:14 162:1,2,5,8,10,14 163:21,21 166:14,15 169:22 171:15,16 179:4 185:1 188:22 196:4 214:11 216:1 290:18 291:2.2 301:18 310:20 314:12 358:9 379:22 serving 8:4 45:9 127:9 141:17,19 282:17 **SES** 28:10 37:7,16 263:8 set 32:14 42:5 98:9 114:10 156:9,11 159:3 163:8 166:5 193:1 194:4 195:12 203:13 229:9,19,21 237:1 242:14 244:11 244:15 247:5 263:4 287:22 300:3 301:10 330:12 335:10,12 337:14 370:1 374:13 374:13 377:17,22 393:15,16 sets 137:3 203:12 207:12 219:17,19 313:3 316:21 325:6 330:22 setting 60:4 143:11 236:13,14 249:14,20 288:2,17 300:6,9 302:2,3 306:7,9 345:8

348:10 352:21 370:13 370:22 393:2,8,13 394:4 settings 17:21 233:10 249:21 297:13 314:18 316:2,10 345:16 348:15 377:22 391:8 393:19 settlement 301:13 302:1 seven 7:12 10:13 127:22 372:12,13 severe 237:2 share 130:1 315:14 shared 30:6 40:2 48:8 170:18 271:19 Sharon 1:17 16:8 273:12 280:17 sheet 53:2 232:6 Shepherd 379:20 Sherrie 1:21 18:1 33:18 47:16 48:9 50:19 85:18 87:17 101:10 107:21 109:3 110:14 116:10 149:5 160:21 179:16 189:8 199:21 200:15 212:4 213:19 214:15 232:7 233:14 246:13 252:4 254:16 256:2 261:11 265:3 266:9 321:17 326:4 332:13 333:16 334:7 335:3 336:12 353:10 394:6,18 398:5 407:17 Sherrie's 179:14 223:14 **shift** 127:14 **short** 4:10 126:10 139:11 180:3 229:2,9 229:16 230:7,18 237:3 249:11 252:4 253:8 254:4 268:4 269:18 274:21 276:15 292:14 367:13 shortened 348:2 shorter 181:17 250:9 348:3 shot 109:22 show 26:13 212:17 303:11 322:7 333:13 337:21 349:13 376:12 399:1 showed 252:16 showing 66:3 96:13 104:2 223:2 243:19 257:1 shown 241:6 shows 212:18 218:17

325:12 shrink 257:14 260:17 **shrinking** 374:12,16 375:1,3 sickle 70:17 side 54:6 88:19 sides 68:16 sign 305:20 signal 102:16 229:22 242:8 250:7 significant 67:7 155:5 211:16 233:1 235:13 235:15 354:22 366:11 376:4 377:12 379:22 380:12 391:4 significantly 70:16 signs 266:12 silly 191:19 similar 89:17 156:13 157:5 184:12 259:2 274:1,14 285:3 340:2 363:19 370:11 377:21 399:9 401:17,22 simple 361:19 **simplify** 293:21 simply 290:2 Simultaneous 105:2 143:2 293:5 295:1 296:8 313:7 324:2 329:20 334:13 341:18 357:2 sincerely 129:22 single 34:14 48:4 62:22 161:3,8,16,18 235:6 sit 8:19 17:13 380:11 site 5:9 54:6 309:14 315:20 361:16 362:1 370:20 sites 288:4,9 316:7 384:5 sitting 42:5 52:19,19 312:10 situation 171:13 situations 82:8 six 56:8 81:10 245:16 245:20 284:15 316:5 321:19 371:4 380:9 380:13 382:18 383:20 383:21 384:7 387:19 390:16 391:16 394:2 size 83:13 135:2 189:17 212:11 213:2,6 214:8 214:13,21 215:9 217:1 223:18 234:18 249:1 280:11 390:20 395:18 398:16 sizes 260:17 skew 111:2

skewed 104:8 110:20 252:18 skilled 4:12,13,14 12:17 17:12 231:9 232:17 232:17 233:6 249:12 284:19 286:4,14 292:5 299:2 301:16 301:18,18 303:19 314:13 315:11 316:4 318:12 319:9 324:13 325:3 338:15 341:2 359:19 373:8 **skip** 133:13 168:2,2 skipped 347:12 sleeve 11:11 slide 26:18 28:22 29:16 32:6 33:7 34:16 36:12 37:4,5 40:4,7,17 41:10,21 43:13 44:10 45:6 46:11 **slight** 372:1 375:10 slightly 169:14 255:3 330:19 **slip** 143:4 slow 310:4.7 small 16:1 83:22 105:14 108:6,7 111:6 112:2 212:9 213:15,17 215:13 219:12 231:11 233:20 262:2,21 294:8 295:9 306:19 373:17 375:4 377:12 377:22 smaller 212:13,21,21 212:22 215:1 232:5 295:22 297:1 391:15 smallest 370:20 smears 78:21 smoothly 53:11 SNF 240:10,12 241:21 242:5 253:7 282:9 302:3,18,20 306:11 311:3 313:16 314:5 319:3 343:5 345:15 357:7 378:7 379:8 404:4 **SNFs** 231:18 239:7 251:11 271:11 280:10 296:5,10 302:4 345:21 357:18 371:9 377:18 383:20,21 social 14:3 17:17 19:21 77:22 113:5 159:13 sociodemographic 26:21 28:13 262:19 socioeconomic 28:11 366:9 soft 127:3 360:19

software 348:12 solid 191:10 322:7 **some-odd** 391:13 somebody 24:6,12,19 38:10 59:12 62:6 63:3 140:15 229:2 278:16 309:14 316:13 347:5 351:19 405:15 somebody's 300:2 someday 340:12 someone's 278:5 **somewhat** 169:9 313:11 340:2 345:21 360:19 367:13 Somplasky 3:13 112:18 112:19 soon 129:1 281:14 sores 309:12 sorry 19:13 60:14 76:11 80:17 92:7 95:10 96:12,16 109:13 110:8 116:22 135:12 146:21 148:20 152:2 153:20 157:7 168:17 177:1 179:16 186:22 198:13 202:2 210:8 225:14 228:7.21 249:6 255:1,5 269:1 299:13 308:18 333:2 338:5,8 343:7 347:12 347:13,16 356:21 360:7 362:14 382:15 383:22 400:20 sort 5:18 61:8 62:15 88:3 91:2 104:8.10 143:6 144:1 145:5 149:15 151:5 165:2 165:10,14 167:17 182:13 185:21 188:20 189:6 190:2 191:15 195:6 215:7 216:8 231:15 232:2 238:14 241:12 242:16 244:18 250:5,9 259:10 263:3 276:17 289:9 295:18 296:1 309:22 311:7 315:15 320:22 331:18 341:20 346:20 348:1 361:21 364:17 sorts 361:15 sound 54:5 65:21 107:14 182:21 240:3 404:13 sounded 149:10 296:3 sounds 177:14 180:4 394:14 404:14 source 129:12 137:3 sources 103:11 270:1

343:19 386:16 Southern 2:11 space 11:18 144:21 **Spanish** 210:5 sparse 253:9 Spaulding 2:1 12:9,11 12:14 379:21 speak 22:19 24:16,20 25:1 43:2,6 112:14 178:18 244:9 285:16 295:13 297:21 324:6 329:22 366:17 374:19 374:21 speaking 9:8 11:21 47:13 78:18,19 79:1 85:9 105:2 112:20 143:2 293:5 295:1 296:8 313:7 324:2 329:20 334:13 341:18 357:2 393:22 Spearman- 257:12 260:14 Spearman-Brown 216:15 217:2 223:15 226:2 **spec** 103:2 special 11:5 45:5 specialist 185:2 specialties 93:5 specific 60:1 66:20 67:12,14 72:18 77:17 80:6 83:11 85:21 86:2 86:2 144:15 147:15 163:20 197:12 318:2 322:13 339:14 **specifically** 30:3,9 46:2 70:13 78:3 86:8 88:19 89:3 91:12 100:3 123:15 217:6 218:6 254:17 273:11 316:3 specification 55:22 324:13 specifications 26:6 44:6 51:7 56:7 86:22 100:4,10 208:9 209:5 209:9 220:8 221:2,14 222:2 264:15 269:4,8 292:8 339:4 342:11 342:14 385:16 386:4 386:7 specifics 289:11 specified 178:1 specify 349:4,7 specifying 71:6 77:3 specs 101:5 spectrum 351:14 spending 127:14,17 spent 38:18 249:15

spinal 380:1 **spirit** 197:2 spiritual 229:16 split 157:7,13 236:7 284:16 325:5,5 splitting 168:7 202:2 337:15 spread 338:19 square 388:20 389:1 stability 234:19,21 354:16 373:15 stable 214:22 215:8 322:7 356:13 staff 2:12 6:14 23:6,6 28:17 30:5 34:9 41:15 45:4,16 47:3 52:11 59:20 67:22 88:22,22 109:5 142:16 158:10 160:8 165:9,9 180:14 184:13 186:7 193:22 215:19,19 230:16 240:14 278:6,7 344:13,15,21 345:10 345:10,17,19 349:5 389:8 397:18 398:9 404:20 408:5 staffing 253:10 stage 316:11 stakeholder 15:11 stakeholders 46:19 stand 23:13 41:13 288:21 standard 33:11 48:17 82:17 84:22 90:11 132:16 189:14.19 190:8 192:22 231:17 247:5 250:20 263:12 294:5 298:8 331:11 350:6 396:4 standardization 286:20 standardized 55:15 56:5,13,19 62:18 236:17 249:17 251:5 251:8 287:22 311:13 standards 17:14 47:22 399:4 403:15 standing 41:12 53:6 361:3 standpoint 239:2 stands 290:12 294:19 star 173:15 230:21 271:21,22 388:6 403:5 stare 200:19 staring 111:13 start 5:22 6:13 7:3,4 9:20 52:2,10 59:14 60:17 82:7 98:14

100:2 131:21 132:2 149:5 154:12 183:22 184:6,8 192:7 198:3 262:4 273:13,14 284:14 285:10 286:3 289:8 317:22 318:1 330:2 370:5 380:17 391:1 started 7:14 13:7,10 27:19 229:18 250:21 starting 73:5,6 98:13 129:1 182:18 252:3 372:3 396:10 state 1:17 14:3 16:9 28:15 128:5 130:10 130:12,14,16 131:2 132:9 133:2,2,4,6,8 134:10,15 135:3,13 136:7,8 138:14,18 140:11 142:4 143:6 143:10 144:16 145:22 147:11,22 149:22 150:3,3,8,12,17,21 151:8,14 153:3 157:22 159:7,9,12,15 170:2 192:20 219:9 253:21 351:13 state's 133:7 149:10 150:5,21 stated 261:18 299:2 statement 50:17 313:12 states 128:14,19 129:1 129:5 134:22 136:9 141:5 143:19 149:14 149:14,16,18 150:12 150:16,19 151:1,10 151:12,15 157:19,21 158:3 159:5 161:2 167:14 170:9,10,11 170:17,19 171:3,22 172:4,5,13,15,17 185:11 191:12 219:3 238:18,21 239:5 253:16,18 301:14 stating 22:17 305:13 statistical 320:5 366:20 statistically 354:22 366:10 391:4 statistician 167:10 statistics 108:21 213:21 status 18:8,9 28:11 30:19,20 40:2 46:3,9 307:1,7 321:20 367:17 368:4 380:5 382:3 stay 4:10,10,11 229:2,3 229:4 230:8,8,8,18

233:6.7 249:11 250:16 252:4 254:4 268:4 276:2,15,16 278:4 282:18 292:15 296:15 310:21 311:3 348:2,3 352:7,16 356:14 357:18 377:2 staying 47:13 124:19 stays 296:13 347:18 step 35:1,2 41:18 55:19 62:21 72:22 73:19 92:15 191:6 196:8 239:11 267:22 273:7 383:1 Stephen 1:20 15:20 373:19 steps 34:21 130:4 378:19 steward 53:14 Stille 1:9,12 10:19,20 67:20 72:13 75:15,21 76:6 78:8 107:17 109:21 125:1 127:3 130:7,14,17,19,22 131:3 132:1,5 135:11 137:10 142:8 144:22 145:14 146:14.19 149:2,4 151:2,21 153:12,15,18 154:1,8 154:11,21 155:13,16 156:3 158:4,6,16 160:11,17,19,21 161:18 162:17 163:1 163:4 164:11,19 165:16,22 166:10 168:3,18 169:17 171:7 172:19 173:8 173:21 174:7 175:18 178:17 179:13,16 181:20 182:11 183:5 183:21 185:20 187:18 189:8 191:4 193:3,14 195:21 196:11 197:1 197:17 198:5 199:2 199:17 200:15,22 201:8,14 202:1,20 203:3,10 204:6,10,22 205:4,16 206:3,6,8,19 207:7,15,18 211:1,4 212:3 213:19 214:15 218:4 219:15 220:2 220:19 221:10 222:10 223:5 224:13 227:17 228:6 284:14 285:13 286:2 289:4 290:11 291:19 297:4 299:11 305:6 306:1 307:11 308:2,17,20 313:8

314:20 317:21 318:6 318:22 319:21 320:4 320:8,17 321:13 322:15 323:9,18 324:3,9 326:4 338:2 338:20,22 339:13,18 339:21 340:13 342:6 343:2,9,13 344:7 347:11 351:3 353:10 356:19 362:13 363:8 363:18 366:3 367:6 368:11 398:4 407:13 stock 172:1 stop 46:5 137:7 276:8 367:13 390:2 stops 43:20 374:13 story 225:9,12 straight 338:1 strange 5:17 strapping 234:14 **Strategies** 1:16 13:3 strategy 15:22 38:11 stratification 269:7 366:8 386:6 stratifications 342:13 stratified 338:9 stratify 38:6 304:13 322:8 stratifying 305:9 streaming 24:8,13 street 1:9 54:7 408:10 stress 382:1 stresses 381:19 stretch 369:21 strikes 196:7 strong 215:6,18 252:22 257:21 265:17 306:4 317:1 325:21 327:10 354:20 362:6 stronger 75:13 strongest 188:3 265:18 267:3 strongly 154:13 158:7 struck 105:3 structure 165:18 198:18 254:7 318:16 384:17 structured 39:8 182:12 struggle 190:18 struggled 33:20 191:12 struggling 111:12 351:15 356:6 396:13 397:2 student 14:3 studied 360:20 studies 68:14,16 82:9 83:3,17 382:2 study 60:3 68:9 69:8

71:15 81:22 82:10.13 82:14,17,20,21 83:4 83:18 117:12 306:17 346:10 371:12 studying 14:3 62:4 273:9 stuff 98:21 145:6 191:15 225:4 237:18 241:5 289:11 stunned 193:9 style 18:15 sub 157:15 sub-domains 364:19 sub-groupings 136:4 sub-questions 199:18 subcontractor 14:17,17 140:10 **subgroup** 108:19 subject 9:6,10,16,19 subjects 225:17 226:4 260:12 submission 28:19 32:15 34:15 50:7 103:22 114:5 296:19 307:13 391:11 submissions 17:6 20:3 25:10 28:5,18 31:13 227:9 398:21 submit 93:6 95:1 96:6 283:4 291:13 340:11 342:2,4 368:22 369:2 390:7 submitted 36:21 42:13 44:9 50:8 66:4 91:14 114:5 127:20 173:17 281:3 289:2 293:3 298:4 323:12,15 332:7 333:3 371:2 384:4 392:22 403:18 404:22 **submitting** 45:3,4,6 90:20 123:5 351:8 358:22 subscale 165:18 subscales 165:7 subscriber 358:5,14 359:7 subscribers 286:12 290:18 373:12 391:13 subscribing 291:1 371:7 373:9 subsequent 248:22 372:11 subsequently 324:21 subset 335:19 336:10 substantially 311:1 substitute 61:17 subtract 187:11

successfully 350:1 suddenly 309:8 359:3 suffer 93:20 suffering 87:21 88:5 sufficient 61:8 174:22 suggest 90:4 92:9 147:10 175:16 374:22 suggested 27:2 117:9 149:13 180:21 330:4 330:9 331:18 suggesting 84:8 176:9 389:13 390:15 suggestion 183:11 201:5 223:16 309:2 397:12 suggestions 44:3 177:5 suggests 58:4 103:7 188:2 209:1 397:8 suitability 44:1 118:14 119:4 182:8 272:13 281:22 283:11,20 363:9,13 368:15,19 369:9,16 387:18 402:4,12 406:2 suitable 120:12 summarize 324:8 summary 42:12 116:18 243:13,14,21 summative 243:17 244:3 super 321:17 supervising 144:18 supplement 166:19,20 167:8.8 **supplied** 159:7 333:22 334:5 383:20 **supply** 159:19 388:13 supplying 192:10 support 38:12 60:2 67:19 83:13 97:4 148:8 176:14 210:19 233:16 235:2 247:4 272:5 381:21 397:13 supported 97:10 supporting 226:8 supportive 127:10 supports 61:13 90:12 129:19 138:1,5,20 139:17 141:2,3,10 176:13 198:11,16 214:12 235:5 254:5 318:14 384:15 suppose 12:13 supposed 48:3,7,17,21 49:6,10,13 84:5 148:16 182:18 200:20 360:17 374:15 396:9 sure 8:10 33:5 34:11

36:6 43:9 48:11 62:14 76:6 77:13 86:4 91:8 91:21 98:8 103:15 108:11 135:6,13 148:15 155:3 157:4 158:13 163:2 165:13 177:13 186:5 191:13 197:17 208:19 212:16 224:10 228:9.15 235:19 236:8 239:19 265:22 275:19 276:13 277:19 279:7 285:13 292:12 295:9 298:16 310:13 311:21 316:12 324:9 332:19 340:15 343:11 350:7 363:22 377:9 380:6 389:15 400:22 surely 59:1 surface 177:6 surgeries 14:6 surgical 58:12 surprised 213:14 surprising 188:5 surrounding 57:8 survey 17:14 31:16 49:21 50:9.11.19 51:14,16,18,21 133:10 137:4 152:4 160:3 167:14 184:21 185:8,13 194:10,15 194:16 195:3,4,10 196:22 211:7 212:1 228:2 231:13 236:7 238:7 241:5.12 243:12 244:2 249:4 249:13,19 250:3,4,10 253:21 276:5 277:14 278:16 279:10,18 281:9,10 282:20 283:1 surveyed 166:22 218:9 218:10 surveys 30:17 32:13 122:12 134:13 184:15 184:16 185:3,14 189:3 211:9,9 218:7,9 218:18 231:10 243:15 245:15 248:6 249:9 253:11 263:13 276:18 suspect 5:6 67:15 suspected 28:9 Suter 2:8 65:7,8 175:21 223:13 254:20 273:13 273:15,16 320:18 321:9 340:16 341:13 341:16,21 342:3 351:4 372:16 394:7

397:7 Sutter 2:9 Suzanne 2:22 7:16 24:11 37:4 94:7 157:2 157:2 333:2 390:2 Sven 3:2 53:16 swallow 14:4 swallowing 383:7 swing 73:14 switch 228:18 symptom 40:3,3 60:8 symptoms 58:9 60:5 83:14 84:1,6 syndromes 58:15 system 2:2,6 11:12 12:12,21 14:9,15 55:8 117:8 184:19 223:9 236:18 288:15 294:15 295:4 350:18 352:9 systematic 127:5 143:22 systematically 143:20 242:6 263:1 systems 11:4 57:11 114:3 125:12 127:7 143:21 291:18 Т **T-score** 186:18 TA 398:2 table 9:21 13:5 42:6 46:19 52:20 64:7 90:16 123:22 187:19 199:20 212:17 218:6 218:17,21,22 219:11 224:16,18 225:1 265:6 338:3 360:11 tackle 235:21 taq 52:5 take 39:9 44:7 52:7,9 68:8 69:6 70:3 84:17 92:16 94:3,14 95:13 118:6 124:2,13,14 125:9 133:5 134:1 148:11 168:6,8,12 187:2,10 196:19 235:17 264:1 284:10 286:8 306:9 309:13 358:17 367:9 372:7 377:17 378:19 390:11 400:18 401:9 407:12 taken 30:5 272:21 308:9 takes 224:1 336:2 355:12 talk 6:22 8:7 13:9 35:21 36:19 37:2 41:11 44:11 50:16 65:20

68:1 80:5 88:20.21 94:11 102:1 137:1,6 145:2 149:6 155:11 157:3 172:22 174:14 176:17 181:1 183:11 193:15 208:1,5 213:7 225:10 228:19 245:13 247:10 313:8 324:4 389:10,17,19 talked 29:4,17 41:22 74:5 131:4 155:20 199:20 238:6,6,20 241:2 267:2 269:17 289:10 344:10 379:4 talking 28:14 30:16 31:20 32:10 34:17,19 35:7 45:7 48:12,16 50:18 51:8,14 59:21 79:22,22 81:5 83:18 85:20 89:13 100:2 107:7 133:9 134:8,18 134:20 135:1 141:7 148:21 158:22 162:15 162:20 163:8,18 167:13 172:20 173:2 187:19 249:16 259:20 267:11 280:5 296:5.6 296:9 298:17 316:3 317:22 355:21 361:4 380:19 393:16,18 397:16 talks 359:22 tallying 206:22 tape 24:2 tapped 105:15 target 210:15,16 targeting 208:17 TBI 218:13 219:8 **TCPI** 14:19 **TCU** 17:3 teach 381:8 team 7:17 52:5 77:18 125:17 400:9 teased 175:8 technical 202:3 231:4 239:10 346:3 397:19 398:2 technically 51:4,15 100:9 121:4 167:13 technician 349:6 technicians 345:15 technique 378:17,22 techniques 58:10 315:21 tee 98:6 **TEFT** 126:19 128:18,22 129:20 153:1,2,19 170:10,11,12,22

teleconference 3:22 telephone 134:8 211:9 211:13 tell 22:22 38:3 68:4 73:9 81:20 86:9 94:4,12 146:10 148:9 167:21 186:8 216:22 293:2 302:22 317:16 321:2 321:11 352:3 366:10 370:14 tells 81:10 165:18 281:17 temperature 5:5 ten 132:9 133:6 157:8,8 157:14,14 231:5,12 245:10 375:9 tenant 5:16 tend 105:12 117:6 141:13 143:21 243:15 257:11 295:16 296:1 tended 39:2 377:20 tends 114:10 253:9 282:22 Teno's 241:5 tent 80:18 179:14 tents 175:20 tenure 38:17 term 4:16,17,19 49:21 129:18 137:19,22 138:4,19 139:12,13 139:16 141:1,3,9 180:3,4 233:7 237:3 263:13 273:19 284:21 286:15 289:21 292:14 296:6 307:3 347:7 367:14 368:3 370:2 370:19 376:20 377:6 384:14 terms 69:11 76:14 87:16 88:1,9 107:12 108:15 117:13 145:10 158:15 188:14,16 189:2 196:3 200:1,6 215:15 243:22 253:10 273:20 278:3 293:14 294:7,13 297:19 299:1,7 306:22 310:19,20,21 312:13 322:3,4 340:19 348:6 350:22 351:10,22 355:8,8 365:5 367:2 368:3,14 370:18 371:11 380:21 382:4 382:8 389:2 393:4 terrible 217:9 terribly 192:21,21 test 102:5 103:1,10 128:21 167:9 195:20

213:1 234:6 251:18 266:11 267:18,22 268:1,15 392:8,8 394:4 tested 35:11 36:9 39:14 50:21,22 101:16 102:17 166:22 175:2 175:8 211:7 212:7 230:2 245:19 251:16 279:13 354:18 400:6 testing 26:2,8 29:11 34:5 56:11 101:8 126:19,21 129:2 138:6 152:14 153:21 170:12 193:7 209:19 210:3,4,18 212:6 220:9 221:2,14 222:3 223:3 225:5 234:7 235:4 241:9 243:19 245:9 246:12 247:18 248:4 261:14 264:15 267:19 268:3,6,16 269:5 273:22 287:7 339:4 340:18 342:12 366:20 385:16 386:5 tests 152:19 thank 6:4 8:4 12:22 16:17 17:6 19:18 20:14 21:2,6 22:3,5 23:8 24:10 38:14 52:10 53:22 54:8 58:21 59:2,3 63:6 74:4 86:16 95:2 97:11 97:12,14 105:21 114:12 119:7 122:15 124:7,19 129:21 130:6,7 136:19 137:16 140:7 145:13 146:20 168:5 170:7 194:18 198:14 199:1 203:2 207:19 211:13 213:18 228:7 251:21 253:3 268:19 273:15 275:22 284:5,7,10 285:18,19 286:1,10 288:18 289:3,4 290:10 293:10,11 307:11 315:13 317:21 339:20 358:10 394:17 402:17 403:9 405:2 thanks 13:21 15:2 16:6 23:9,9 69:15 80:13 144:22 149:1,4 173:7 211:3 218:4 272:3 284:9 285:22 289:5 291:21 320:9 351:4 352:1 368:11 Theberge 2:22 7:15,16

24:6 37:5 39:17 94:22 97:13,16,18 114:18 119:6 157:4 173:9,16 173:20 198:21 199:6 199:10 221:21 285:14 285:19 286:1 388:3 402:16 403:2 408:9 theoretical 187:12,13 187:14 Theoretically 360:16 theory 75:10 **Therapeutic** 3:7 403:9 therapist 113:20 therapists 66:22,22 92:22 113:4,5,8,8 123:16 345:15 346:22 therapy 92:1 93:11 301:17,18 345:9 377:3,3,4 they'd 361:13 373:11 thing 22:13 45:1 48:2 49:12,19 61:2 62:22 71:14 80:1,18 90:7 92:18 94:8 109:13,13 117:11 120:15 161:20 163:10 169:4 171:1 173:2 184:6 185:22 209:17 214:6 223:5 224:4 225:14 231:3 231:19 233:11 234:5 234:12 235:2 244:18 244:20 246:4 252:12 258:22 259:5 274:11 274:13 279:6 305:8 312:3 327:5 329:3,7 329:11 338:6 346:7 353:2 359:6 things 6:15 7:1 9:4 18:16 23:2 28:2 39:4 39:9 44:4 47:17 51:12 58:17 71:5 89:14 131:18,20 132:13 142:20 150:5 151:11 151:12 161:2 163:14 178:22 182:14,15 186:7 190:7,10,22 197:10 208:1 209:2 214:18 225:2,20 226:1,19 232:12 234:13 238:5 240:13 242:1 244:6,12,19 252:11 257:10 261:4 267:8 277:20 289:10 293:21 295:17 296:17 297:9 299:16 308:14 312:13 315:12 332:5 349:18 352:14,18 353:5 364:12 367:18

			448
200.2 270.45 277.5	200.40 240.0 0 42	404.47 405.0 47.00	404.47 400.47 400.0
368:2 376:15 377:5	309:18 310:8,9,12	401:17 405:6,17,20	181:17 182:17 190:3
378:21 379:1,4,6,10	311:9,11 314:17	406:7,11 408:3	193:22 214:10,14
392:9,11 403:11	315:17,22 316:20	Thomas' 308:22	225:1 227:5 229:4
407:17	317:5,15,22 321:9	thought 37:15,17 38:4	232:2 233:2,8 249:15
think 11:8 12:4 13:5	323:20 329:2,19,22	52:22 60:17 62:1 75:5	251:8 259:6 268:7
16:4 22:14,15,17,21	332:4,7,13,18 333:1,8	113:10 116:7 134:6	281:14 288:20 296:5
24:7 25:6 28:16 32:6	333:10,20 334:7,22	140:9 145:1,2 182:9	296:12 301:9 313:1
33:8,18 36:1,16 37:9	336:3 338:1,2,3,22	223:15 236:22 238:10	332:18 345:4 346:17
39:2,10 47:11 50:14	339:16,19 340:4	262:15 266:1 268:11	353:6 356:14 360:11
50:19 51:5 53:1 59:22	343:6,11 344:17	274:10 331:6 377:9	361:3,3 369:2,3
61:11,14 62:3 63:22	345:20 346:1 347:13	389:16 403:12	382:14 388:5,8 389:5
67:10 69:18 70:9,20	347:14 348:17 349:1	thoughts 71:3 179:13	390:3,4,11 392:18
71:3 72:13,16,19,22	349:2,6,20 350:11,11	184:11 188:7 208:2	403:4 405:3 407:6
73:17,18 74:1 75:21	352:21 354:2,2	thousand 248:6	408:1
82:5 86:5 87:3,18	356:20 360:8,18	threats 36:10 269:5	timeframe 295:20 296:3
88:17 90:3,4,9 92:6	362:10 363:21 367:17	278:4	timeline 180:17
92:11 94:2 95:14	368:4,12 370:10,15	three 22:21 34:18 42:4	times 54:13 189:19
98:16 100:6 102:12	370:16 371:15 375:3	94:18,20 99:16 106:7	258:7 302:6 393:3
103:19 104:9 105:5	375:4,22 376:1,9,15	114:16 115:13 117:19	405:21 408:4
106:22 107:2,18,21	377:14 380:7 381:13	117:21 125:7 135:1	tiny 50:16 212:15
109:5 111:11 114:9	382:19 389:2 390:11	187:4 191:17 210:6,8	269:18 345:5
115:10 116:4,8,18	392:3,10 393:7,10	215:18 216:9 219:17	tipping 109:8
117:13 118:16 120:10	394:16 396:5 397:3	228:20 229:8 230:7	tires 235:7
120:18 121:10,15	399:13,16 400:4	230:16 243:20 244:3	title 157:16
122:4,6 125:6 132:17	401:13,15 403:16	246:21 249:1 253:18	to-date 14:6
134:3 136:3 137:1,3	407:7,15	255:14 259:1,3,17	today 5:22 7:12,14 11:6
143:9 144:4,5,8,19	thinking 48:22 81:4	264:17 269:10 270:4	13:5 21:4,15 25:4
145:2 146:17 148:19	98:15 108:16 141:14	270:18 272:19 283:14	26:5 35:22 42:2 44:7
150:13,18 151:22	145:17 164:8 174:14	284:19,20,21 286:9	44:9 50:6 54:17 130:2
154:3,16 155:21	177:18,19 184:14	316:5 323:2 339:6	227:4 287:2 288:20
156:7 157:18,19	187:17 197:5,8 219:8	342:17 344:1 353:2	290:20 298:5 312:10
158:5,19,21 164:14	227:20 245:21 271:22	368:21 370:3 375:9	363:19 375:18 389:6
168:19 169:3,9,11,13	274:13 275:13 354:3	382:19 385:19 392:8	405:9,21 407:6,17
171:9 172:13 174:22	376:6	402:7 404:3.8	toilet 378:20
175:2,7,13,19 178:19	third 11:8 52:12 106:9	threshold 79:13 319:18	toileting 217:7
178:22 180:2 182:6	204:16 205:9,21	thrilled 12:19	tomorrow 21:20 35:21
183:7 185:11 186:1	273:5 274:5 288:9	throes 87:4	36:1 41:2 407:3
187:6 189:2,4,11	405:6	throw 340:5	ton 322:10
190:14 193:15 194:10	Thirty 337:12	thrown 218:19	tongue 228:21 240:3
196:4 197:9,18,22	Thirty-nine 406:5	thumbprint 326:8	tool 32:17,18 33:1,16
199:10,20 200:2,10	Thomas 2:9 11:7,8 37:6	327:10 328:18	35:6,12,15,18 50:18
201:8 202:1 208:7,21	37:20 38:14 66:11	tied 228:22	50:21 51:15 55:15
209:3,9 210:11,18	67:21 78:15 79:7 80:7	tight 189:15 326:15	56:5,13,19 71:7,11
211:16 212:16,19	80:9,12 168:16 171:8	328:17	72:1,18,18 80:6 83:1
213:14 219:2 223:17	178:18 196:1 224:15	time 11:8 20:1 23:1	83:2 137:4 155:21
225:10 226:14 227:2	232:11 239:17,20	24:16 25:18 26:12	156:2 196:20 290:14
227:4,11,22 228:2,18	240:2,7 241:18 262:7	30:19 32:21 35:13,17	297:17 298:5 302:15
228:21 232:7 236:5	262:10 263:6 271:6	38:18 42:18 44:16	306:10,17 344:13
236:13 241:6 242:5	272:3 274:20 275:3,6	47:3,4,13 52:12,16	346:13,19 358:15
242:16 243:8 244:13	275:10,18,22 279:9	57:19,20 60:2 64:17	359:4,17
246:11 247:20 252:22	279:15 286:7 299:12	67:18 69:4 72:6 73:21	tool-based 29:21 30:13
254:16 259:14 261:7	300:3,14,17 301:9	75:9 76:3 94:3 97:19	30:16 33:1 34:4
262:18,20 267:21	304:14 305:4 313:10	100:11 108:11 121:14	Toolbox 20:5
268:6,20 273:16,20	313:15,18 318:4	124:16 125:20 127:19	tools 30:19,20 32:13
274:2,15,17 283:6	364:4 365:8,18 366:1	128:20 129:6,14	33:7 75:17 126:20
285:9 292:3 293:9	367:8 377:15 379:15	134:2 168:12 170:8	133:20 153:22 170:13
295:16,22 298:17	389:5,15,19 390:9,15	173:13,18 175:17	231:22 298:13 299:17
307:20,22 309:2,16	397:18 398:1,6	173.13,18 175.17	299:21 304:22 350:14
507.20,22 505.2,10	097.10.090.1,0	177.17 100.12,12	233.21 304.22 330.14
II			

350:15,20 358:1 top 112:14 219:11 246:5 252:22 257:20 341:5 top-223:8 topic 68:20 82:14 topics 13:18 tossing 79:10 total 61:17 212:7 218:18 235:1 257:16 257:21 382:4 totally 140:9 356:4 touch 11:22 touched 254:16 touchscreen-based 18:8 tough 110:22 tracheotomy 14:6 tracing 355:3 track 44:13 tracking 72:5 trademark 129:13 152:15 traditionally 376:1 train 345:17 381:7 trained 38:5 194:16 195:3 344:13.21 350:19,20 training 17:18 288:11 290:21 345:1 346:9 349:15 350:5,8,13 353:8 357:10,20 358:1,17 398:8 399:1 trait 307:15 transcriber 24:3 transfer 376:7 transfers 300:8 transform 186:15 187:5 transformation 125:13 187:10,16 Transforming 58:2 translate 51:9 120:13 121:13 274:3 translating 279:6 transmitted 295:3 transparency 8:16 9:15 270:15 362:19 387:5 traumatic 12:20 147:9 219:7 treat 57:21 treated 314:7 treatment 28:9,10 55:21 56:20 57:9 58:19 60:4 71:1,19,22 72:7,7,10 74:15 75:7 75:8 77:3,5 82:16 84:7 89:21 100:19 304:12

treatments 58:15 tremendous 11:11 52:13 172:15 247:1 tremendously 171:11 trend 348:1 374:21 trending 88:18 375:14 trends 374:15 trepidation 54:16 trial 26:21 27:16,22 trials 84:3 tried 31:11 62:17 63:4 349:19 391:7 trigger 167:3 trivial 395:20 trouble 66:12 74:19 262:4 327:11 328:11 329:17 troubling 328:13 true 70:14 73:17 296:15 315:14 truly 288:5 314:16 332:21 trunk 278:18 trusting 73:20 Truven 3:8 125:22 trv 47:2 65:21 125:15 131:5 158:19 202:3 206:10 247:16 293:12 297:21 310:17 321:19 349:18 352:2 354:8,9 368:8 376:10 389:8 393:5 407:4,6 trying 25:3 35:2 61:4 62:4,9 79:12 87:4 91:19 134:10 138:9 143:7 145:10 151:5 156:18 163:14 164:4 164:6 169:3 190:13 190:15 222:15 223:11 241:20 249:17,18 257:4 258:14 259:2,6 259:8 277:4 302:13 306:8 311:5 332:14 336:4 392:4 393:18 tube 14:6 312:16 379:12 turn 6:15 24:17 42:6 53:12 130:3,3 131:19 157:19,21 229:6 239:8 391:3 turned 159:16 245:22 335:4 turning 79:10 turnover 345:19 turns 52:9 Twenty- 214:1 twice 299:19 **two** 10:16 11:10 12:5

18:16 24:15 27:4 37:13,14 38:3 42:4 47:17 52:5 66:13 71:1 76:13 87:19,20 94:19 96:5,17,20 99:16 102:22 103:11 114:16 115:13 117:19 118:15 126:10 141:5 158:10 178:12,16 180:16 182:19 184:8 187:4 191:8 203:22 208:3 209:15 210:3 216:4,4 217:4 220:14 224:21 230:15 250:8 254:9 254:11 255:5,13 264:16 269:9,11 270:3,5,18,20 272:14 272:15 283:22 284:2 284:17 285:7 286:19 294:11 300:15,16 303:20 313:9 316:6 318:18,18 323:2,15 325:6 330:22,22 339:6 342:17 343:22 344:2 353:2 356:15 358:11 360:7 364:3.8 364:14,18 368:21 369:3 370:3 380:14 382:12 386:21 389:7 400:8,13,16 401:2,5 402:14 405:15 408:4 two-and-a-half 191:18 two-year 27:16 type 31:2,3 57:6 67:13 71:4 82:22 113:7 185:8 333:21 350:18 352:17 355:16 types 86:3 91:1,19 163:21 172:14 194:9 311:14 314:18 349:21 typical 5:4 294:5 typically 24:18 35:6 51:10 120:17 131:2 134:19 136:15 138:16 139:15 140:10 142:1 142:2 162:9 184:20 209:6 211:18 376:21 typo 266:2 U U.S 279:11 **UCLA** 20:18 **UCLA/JH** 2:6 **UDF** 296:2

286:11,12 336:7,19 370:1,14 392:12 400:9 404:21 406:9 ulcers 267:10 317:12 376:14 ultimately 151:6 233:12 350:16 umbrella 163:15 unable 14:4 112:19 276:6 unaddressed 401:5 unanimously 191:22 unbelievably 408:6 uncertainty 87:14 unclarity 334:18 unclear 158:12 237:2 243:10,18 403:13,19 uncomfortable 156:20 166:4 337:7 378:1 under- 117:6 121:12 218:12 under-assessment 70:12 under-detected 88:4 under-detection 87:21 under-evaluated 88:3 under-represented 81:1 under-treatment 70:13 undergo 357:10 undergoing 179:3 underlying 186:13 underneath 192:8 understand 5:11 14:7 23:21 27:11 61:7 76:8 82:2 86:6 87:5 101:21 103:16 113:1 134:10 138:10 142:4 156:7 168:22 169:15 186:5 186:9,17 190:19 226:3 241:20 282:6 293:17 295:5 297:22 303:19 314:22 315:8 330:6 331:12 332:15 347:6 351:7 359:5 373:4 388:17 understandability 223:4 understanding 31:3 36:2 58:14 66:12 83:8 85:3 93:4 144:21 187:21 190:21 209:20 223:17,20 267:17,18 306:2 331:15 338:4 366:6 379:16 389:22 404:2 understood 209:21 268:12 303:15

UDS 290:17 295:17

UDSMR 3:4,5,12 11:19

11:21 284:16 286:5

350:6 352:9

			450
	00:40 40:00 40:4 50:0		
undertook 272:5	26:16 43:22 48:1 50:2	validity 33:2 35:11,15	various 30:20 142:16
undue 58:20	57:22 63:17,19 69:1	36:10,10 43:18 51:1,5	196:5 310:17 352:12
unethical 82:20	71:7,11 77:4 87:10	51:18 64:11 106:16	365:6
unexpectedly 21:17	88:5,13,18 91:2 92:21	106:18 107:2,3,8,8,12	vary 246:10 310:22
unfairly 395:17	115:7,21 116:16	111:14 114:13,15,21	vehicles 279:20
unfortunately 311:8	117:14,18 118:1,4	115:2 158:17 167:18	vendor 185:13 195:4
unified 138:19 143:7	119:11 121:13 128:13	172:22 215:10 223:10	249:3 277:9,19 283:1
uniform 231:17 236:15	128:14 129:6 135:11	235:4,10,13 248:22	vendors 194:17 231:5
uniformity 290:3,6	145:3 156:10 165:20	251:18,20 265:10	238:7,21 244:16
unintended 88:8 116:3	165:22 167:15 169:20	269:2,4 273:22 278:4	247:3 251:6 277:13
116:13 270:17 310:11	170:4,6 172:13 173:1	298:8 339:14,14	279:19
362:21 387:7	182:14 190:20 228:3	340:18 342:7,10	vent 383:7
unintentionally 38:22	270:14 277:7,8	349:13 353:13 386:2	ventilator 371:12,13
unique 249:22 288:10	279:22 288:12,14	386:3,4 388:15,16,18	377:4
unit 49:7 101:18 130:9	289:16,19,20 290:22	388:19 389:4 391:22	venture 377:10
149:9 189:20 217:5	291:3,11,15 299:20	395:13,14 400:12	venue 291:8 301:5
217:16 223:1 256:11	307:2 315:16 316:4	404:15	307:9,16,18 311:17
256:13,18 257:2	341:3 344:13 346:13	valuable 57:19 81:17	311:17 314:7 361:8
306:5 337:5 355:17	347:7 351:7 352:3	81:18 172:12 380:16	378:18 384:4
356:2 395:6,7	354:1,5 358:1,6,16	valuation 18:4 359:3	venues 307:2 311:15
United 10:7	359:17 360:1,2,5,6	value 80:21 169:4 175:3	312:19,21 371:21
units 217:15 256:20	361:7,21 362:16,18	175:4,12 325:10,19	372:10
345:22	365:1,3,7 370:13,21	351:16 359:8 362:10	verbal 210:21
university 1:14,16,17	373:4,11 376:5	values 194:6 299:7	verified 197:21 198:2
1:21 2:11 3:3 10:22	380:21 387:4 392:1	319:17 320:14 366:22	Vermont 193:20
15:5 16:9 18:4,21	396:1,10 398:13	388:20	versa 52:8 144:1
19:15 229:12 289:1	399:13 400:1 404:5	Van 2:10 15:14,15 54:2	version 209:14 280:2
unmet 146:5 155:6,9,17	useful 144:5 172:17	54:3 61:1	versus 48:14,19 49:21
164:4 183:14 190:7	223:11 340:3 361:16	variability 144:20 146:7	74:22 88:5 103:10
192:15 201:6,13,16	373:3 381:12 382:7	188:11 190:21 217:8	150:11 151:11 155:22
205:1,3,7 207:5,14	396:18	257:2 260:20 265:2	190:22 197:3 211:18
217:6,7,10 218:1	users 17:20 172:8,18	269:1 325:13 327:13	217:16 226:20 260:10
219:20 221:11,15	297:19 305:16 350:7	328:4 329:1,16,17	293:20 301:12 309:1
222:3	uses 55:9 396:7,8	338:19 391:14 392:22	315:11 375:9 382:11
unnecessary 58:19	USMDR 344:11 406:17	variable 262:3 265:7,9	391:15
88:4	USPSTF 89:4	304:10	Verville 2:10
unreliable 161:4 353:14	usual 339:22	variables 194:13	vet 159:20
353:15,17	usually 54:14 165:11	235:13 355:18	viable 307:17
unusual 252:20 353:16	166:6 186:14 187:3,9	variance 101:15 102:7	vice 2:16 8:2 17:9 18:2
353:20	353:14 356:12 376:22	102:13 103:6,8,13,16	21:9 52:8 144:1
updated 76:2	Utah 14:1,3 147:4 159:4	103:18 161:13 260:10	view 60:10 296:15
updates 26:6	utility 190:19 372:6	260:11 328:3	349:3 382:14
upper 278:18	373:13	variation 49:1 102:9	Virginia 3:2,12,13 13:4
usability 26:16 43:21	utilization 69:9 74:7,12	104:1 149:19 150:4,8	visit 66:15 72:3
88:6,13,19 115:21	74:13 75:10	150:9,12 151:14	Visiting 1:18 19:16
117:13,18 118:1,4	utilizations 375:14	172:3,15 191:1 202:8	visits 57:1
119:11 134:4 145:3	utilize 69:3 83:1,2	203:17 252:15 255:10	visual 110:1 280:6
145:17 146:18 173:1	287:22 288:16 296:1	257:15 261:22 262:1	vital 148:5
182:14 239:1 270:11	utilized 56:14 85:15	322:20 326:17,19,22	VNA 135:3
270:11,14 343:8,12	utilizing 85:12 295:10	327:2,8 328:9 329:5	voice 236:8,9
344:7 351:5 353:13		329:10 379:17 380:13	volume 399:11
362:16,18 372:20	V	385:4	voluntarily 128:14
380:19 387:4 392:1	VA 2:7 20:18	variations 143:18	170:9 341:3
394:8 395:22 399:13	vaccine 309:15	326:16 349:1,21	voluntary 64:15 67:4
400:12	valid 52:1 109:4 208:13	varied 234:18	84:19 85:4 105:6
usable 35:12 349:20	353:15,17 354:12	varies 326:1	108:5,18 109:17
354:12	validation 80:5 165:6	variety 298:2 324:18	110:22 111:17 112:10
use 12:21 15:9 20:5	165:11,12	varimax 226:20 235:7	113:18 122:21 151:20
	I	I	I

			451
	I	I	I
190:2,2,4 365:9	203:6,22 204:1,18	255:16 269:11 270:5	357:22 374:16 388:6
volunteer 10:4 367:9	205:11 206:1,15	283:13 344:2 386:21	389:3
vote 43:12 44:5,16,21	220:14,14 221:6,18	waiver 136:14,15 138:2	wanting 106:21
44:22 45:2 85:9 94:3	222:6 254:11,12	141:18,19 147:2,15	wants 24:20 25:1 60:21
94:8 95:15 96:9 97:14	255:17 264:20 269:12	147:17 148:14 172:2	192:11
97:15,18 99:13 100:7	269:12 270:5,6,20,20	214:8,9	warning 305:20
101:6 106:1 114:13	272:15,16,21 273:2	waivers 147:8 148:12	wary 366:21
114:19 115:15 118:7	283:14,14 284:2,2	149:1 214:1	washing 361:20,22
118:20 119:16 120:6	318:18,19 323:4	walk 358:13 379:9	362:3
131:13 168:10 174:9	339:8 342:19 344:2,3	walks 66:14	Washington 1:9 5:4,9
176:12,13,19 177:2	363:3,15 368:22	wall 200:17	10:5 12:6
177:10 178:6 180:5	369:1,4,5,5,11,15,18	want 6:8,19 7:3 10:12	wasn't 103:9 142:21
182:8,8,15 183:19	384:19 385:10,19,20	22:10,12,20 23:4 25:2	145:9 153:10 155:5
197:8 198:6,9 199:5	386:11,21,22 387:12	26:9,14 28:1 31:10	157:7 195:14,19,20
201:4,6,6 202:6 203:5	387:22 401:2 402:7,8	33:5 34:1,7 35:20	208:19 224:10 258:16
203:11 205:21 207:11	402:9,15,18 406:4	42:20 46:18,22 48:10	259:8 260:6,7 293:2
219:16 220:4,5	voting 26:4 43:15 44:12	49:22 52:10 59:4,4	308:8 377:9 389:15
221:22 255:16 264:19	44:20 45:12 94:4,12	60:15 78:21 93:9	405:10
269:1,20 270:6 274:4	94:13,16,21 95:4,5	98:10,16 99:4 107:6	watching 5:19 93:22
274:18 281:17,18,20	96:2 97:21 98:3 99:14	109:18 112:22 117:10	water 94:7 166:14
282:3 283:9,15,16	99:18 101:4 106:2,5	120:3,9 137:6 140:21	way 5:8 24:19,22 39:2
318:7,20 322:16	106:11 114:14,20	143:9 146:22 152:12	45:19 48:11 62:9,14
323:4 336:18 338:5	115:12,15 117:17,22	154:6 155:14 161:6	62:21 66:1 81:12
338:21 339:1,8 342:7	118:12 119:9 131:12	164:20 165:13,20	94:12 107:8 108:16
343:15,21 362:14	131:13 137:14 158:15	170:19 176:16,18	110:4 111:10 122:5
377:13 384:11 386:2	181:9 183:9,12 198:9	178:10 180:7,10,19	139:21 144:4,20
387:22 400:19 401:10	198:12,20 199:13	186:5 192:12 195:15	164:7,22 165:1,1
402:16 405:8,13,14	201:20,21 202:12,17	197:15,15 202:3	167:1 168:5 169:21
405:19 406:2	202:18 203:6,14	208:1 210:20,21	172:11 178:21 182:2
voted 95:6 98:1,2	204:1,18 205:11	218:5 227:6 232:9,9	194:6,9,12 195:7
106:12,12,13,14	206:1,15 220:6,12,15	232:13,14 235:21	210:18 216:6 233:1
114:22,22 115:1,1,17	220:22 221:6,12,18 222:6,11 227:3 254:4	238:16 239:11 244:7 247:9 261:13,17	236:10,17 241:16
115:17,18,19 118:2,2 118:3,3 119:9,10	254:8,9,11,12,21	263:22 273:8,11,13	242:4 245:22 251:5 258:9 259:15,16
157:10 181:4 199:15	255:5,8,17 264:11,13	274:15 275:19 280:12	266:8 268:9,17 276:7
203:7 204:3,4 205:13	264:20 269:3,12,21	281:7 290:2 294:11	276:19 277:16 280:1
205:13,14,14 254:13	270:6,13,21 272:11	302:20 309:13 313:2	291:12 294:5 295:4
254:14 255:18,19,19	281:21 283:14,19,21	322:11,14 326:8,9,11	295:17 302:14 305:1
255:20 264:21,21,22	283:22 284:3 318:11	328:13,16,17,17,22	308:9 311:13 319:19
269:13,14,14,15	318:19 322:17 323:5	332:3 334:22 335:7	319:22 330:1 333:11
270:7,8,22,22 271:1	339:2,5,9 342:8,19	335:22 344:21 346:16	334:15,18 360:5,6
272:17,17 284:4,4	343:17,21,22 344:3	346:17 347:8,9 353:1	365:13 396:2 397:16
323:6,7,7,8 339:10,10	362:17 363:4,12,14	355:5,20 360:19	397:16 398:3 400:22
339:11,11 342:21,22	363:14,16 368:17	361:1,5 364:11,12	ways 245:20 246:7
342:22 343:1 344:5,5	369:4,6,8,11,18	365:3,15,16 375:20	298:3 322:9 349:9
344:6,6 363:5,5,6,6	384:12,19 385:2,10	383:19 391:17 392:5	350:17 360:3
363:17,17 369:7,7,20	385:14,20 386:3,11	393:5 395:15 399:3	we'll 6:6,14,15,22 9:21
384:20,21 385:11,12	386:22 387:4,8,9,12	399:18,20 401:4	36:19 37:2 39:22
385:12,13,21,22,22	387:17 388:1 402:3,6	403:9 405:16,16	40:19 41:1 42:8,11,18
386:1,12,13,13,14	402:8,11,19 404:10	407:19 408:3,11	43:3,5,11,21 44:18
387:1,2,2,3,13,14,14	406:4	wanted 8:3 12:18 29:20	45:5 52:9 59:14,16
387:15 388:2,2	vulnerable 237:17	86:17 120:15 133:4	66:1 80:5 94:9,11,11
402:20,20 406:5,6	317:19	146:15 163:2 168:20	95:18 98:8 99:22
votes 44:15,18 45:3,6		170:20 194:7 218:14	125:7 131:13 134:3
94:9 95:2,4,5 96:6	W	229:9 266:8 279:7	137:14 145:6 146:20
99:17 106:10 117:21	wait 154:7,8 197:16	280:19 290:9 295:19	149:5 154:11 168:8
117:22 119:4,8 181:2	waiting 86:14 115:15	308:21 314:21 315:9	183:11 198:6 201:17
183:10 199:13 201:17	154:2 208:4,5,5	331:10 344:16 357:21	207:8,9,11,16 221:19
	l	l	l

228:18 229:6 229:6 281:20 407:2 window 295:13 265:13 14:10 25:56 311:11 31:38 340:11 285:29:47 301.9 315:33:10 295:328:13 33:110 333:3 363:9 389:17 315:33:10:20 255:29:56:21 255:29:56:21 393:5 406:10 we'we 5:18 14:10 25:56 winder 30:16:10 we're 6:12 8:14:10:20 253: 255: 251:13 52:00 68:5 73:15 wonder 50:45:10:62 write 278:13 309:3 317:9 357: 19 38:8 1317:70 1372: 168:4 monderin 56:41:79:12 write 778:12 36:20 46:5 77.49 38:8 138:31 49:20 179:8 18:18 91:56:10 41:47:15 21:16:12:12 271:12 22:16:30:11 36:20 46:5 67:4.7.8 29:21 31:11 422:11 29:43:11:73:33:10 336:19 393:12 word 39:6 66:16 78:15 36:20 46:5 67:4.7.8 29:21 31:16 32:11:10 26:11 94:11:15:14 26:13:18:22:16:12 271:12 22:16:30:11 336:19 393:13 36:31 11:16:14:16:14 377:11 38:01:54:05:20 371:13:16:24:17:23:22:16:22:23:16 271:12:22:16:22:23:16 271:12:22:16:22:23:16 36:15:11:16:16:13:16:11:16:14:16:16:14:11:16:16:14:16:16:14:16:16:14:16:16:14:16:16:14:16:16:14:16:16:14:16:16:14:16:16:14:16:16:14:16:16:14:16:16:14:16:16:14:16:16:14:16:16:14:16:16:13:16:11:16:16:14:16:16:14:16:16:16:16:14:16:16:15:16:16:14	<u>.</u>			452
2854 286:2 289:10 we've 5:18 14:10 25:5.6 winter 39:21 2853 24:17 30:1.9 365:12 19 30:0.8 331:13 38:3 40:11 28:5 29:4.7 30:1.9 315:34:10 36:5.11 28:5 29:4.7 30:1.9 365:12 19 30:0.8 25:3 26:5 28:1.13 95:10 110:4 114:2 worder 50:15 106:2.0 winter 39:21 wirte 278:13 39:1:0 29:9.10,7 30:12,13 120:7 121:11 1228 worder 50:15 106:2.0 wirte 278:13 39:1:0 36:7,19 38:7 137:7,10 137:2 168:4 worder 50:15 106:2.0 wirte 278:13 39:1:0 36:12,19 30:0.3 120:7 121:1 1228:14 worder 50:15 106:2.0 wirte 278:13 39:1:0 36:12,19 30:0.3 120:7 121:1 1228:14 worder 50:15 106:2.0 wirte 78:13 39:1:0 31:51 48:10,12 729:16 120:7 1229:14 34:5.7 120:7 1229:14 34:5.7 120:7 1229:14 34:5.7 31:13 14:13:16:15 137:17 weaknesse 9:12 word 360:1 25:12 31:13 34:3 31:13 14:11:13:16 173:17 weaknesse 9:12 worder 17:17 19:12 136:16 16:16 17 11:13:14:13:16:14:14 135:15 31:16:16 129:12 14:22 133:20 14:12 16:17 12:21 14:12 16:17 12:21 11:13:13:18:14:14:16 14:10 16:11:22 197		407.0		
311:11 313:8 340:11 333:5 406:10 28:5 29:4,17 30:19 31:5 341:0 36:5,11 40:10 42:2 44:19 32:5 20:63:5 73:15 wish 9:18 42:19 43:2,4 25:19 45:14 31:5,14 16:20 35:20 68:5 73:15 365:12,19 380:8 wrap 190:13,15 wrap 190:13,1				
33:13 363:9 389:17 393:5 406:10 31:5 34:10 36:5,11 40:10 42:24:419 25:41:9 408:11 wrap103 31:22 wrap103 31:22 wifter 30:10 52:20 68:5 73:15 95:10 110:4 114:2 wonder 60:15 106:20 wonder 60:7 40:14 wrap103 31:22 33:7,19 35:7,19 38:7 13:7.10 137:2 168:4 wonder 60:15 106:20 wonder 60:7 40:14 writtig 178:13 30:6 49:13 25:20 68:5 73:15 178:20 79:11 122 120:7 12:11 122:5 wonder 60:15 106:20 31:7,19 35:7,19 38:7 137:7,10 137:2 168:4 wonder 60:15 106:20 writtig 178:13 30:14 75:11 77:33 251:16,17 261:12 300:19 340:19 340:19 340:13 wroth 93:66 8:16 78:15 30:14 75:711 76:10 77:71 39:71:13 34:9 347:22 word 80:12 word 72:21 11:15 14:3 37:13 44:9 347:2 37:11 34:9 347:22 word 80:12 word 72:21 11:15 14:3 37:14 78:11,16 94:4 37:11 34:9 347:22 word 80:22 word 72:21 11:15 14:3 37:14 78:14/11 11:10 weakness 69:12 25:12 31:13 34:13 Y 172:19 19:13:14 weakness 69:12 25:12 21:12 23:12 Y 40:12 19:17 70:14 11:10 weakness 69:12 weakness 69:12 Y 41:12:11 11:16:16:17 weakness 6				
393:5:406:10 40:10:42:24:19 withdrawn 281:33 wrap 6:15:264.4 wrap 6:15:264.4 299:91.0:17:30:12:13 120:71:11:1298.1 women 10:5:264.4 women 50:5:16:02.0 write 9:78:18:309:3 395:6:40:13:00:27:01:12:25:16 120:71:21:11:1298.1 women 50:15:10:62.0 write 9:78:13:309:3 395:6:40:13:00:27:01:12:25:16 131:7:10:137:2:1684.1 9:15:10:45:18:86.6 write 9:12:12:22:16:300:17 71:9:9,10:12:27:9:16 225:4:10:22:6:1 230:19:30:19:30:122 wrod 30:02 wrod 30:02 81:5:4:4:22:34:4 269:17:279:13:28:5:3 word 30:02 word 30:02 35:15:316:19:349:13 85:20:8:5:87:4:7,8 339:17:344:9:347:22 word 30:02 word 30:02 35:15:316:19:349:13 91:21:92:11:16:94:4 337:13:44:9:347:22 word 30:02 14:12:16:17:59:21 14:12:16:17:59:21 111:13:11:13:11:13:14:13:16:15 406:17 weaknesses 6:12 25:12:13:34:13 24:10:19:17:22:14:12 111:13:12:11:11:13:11:13:11:13:11:13:11:				
were 6:12 8:14 16:20 52:20 68:5 73:15 women 10:5 264:4 write 278:18 309:3 28:3 26:5 28:1,13 95:10 110:4 114:2 95:10 110:4 114:2 wonder 50:15 106:20 write 178:13 120:178:18:18 31:7, 9 35:7, 19 38:8 13:7, 10 137:2 168:4 yonder 50:15 106:20 wonder 50:15 106:20 write 178:13 20:12 31:5, 14 42:3 84:4 225:4, 10:22:6 yonder 50:22 word s0:6 write 116:19 147:15 31:5, 14 42:3 84:4 269:17 279:13 285:3 word s0:6 80:2 80:5 87:4, 78 289:2 317:18 302:10 word s0:6 68:16 78:15 353:18, 19 39:6 91:21 92:11, 16 94:4 39:17:13 380:15 40:5:20 word s0:6 68:16 78:15 353:18, 19 39:6 X X 91:21 92:11, 16 94:4 39:17:13 380:15 40:5:20 16:12 19:7 20:22 23:1 353:18, 19 39:6 X 127:9 129:19 131:18 weakness 69:12 25:13 13:13 43:13 36:13 46:21 12:0 Y Y 20:12 141:10 14:3:18 14:41 weakness 69:12 weakness 69:12 25:19 126:7.11 Y Y 20:12 145:10 19:15 40:13 weakness 69:12 weakness 69:12 yeakness 69:12 Y 12:19:17:13:14 Y				
25:3 26:5 28:1,13 29:9,017 30:12,13 31:7,9 35:7,19 38:8 31:7,9 35:7,19 38:8 31:7,10 137:2 168:4 77:19,9,10,12 72:9,16 50:21 59:21 70:171:6 183:8 199:20 213:11 73:14 75:11 77:33 81:5,14 82:3 84:4 85:02 86:5 87:4,7.8 85:02 86:5 87:4,7.8 85:02 86:5 87:4,7.8 85:02 86:5 87:4,7.8 85:02 86:5 87:4,7.8 95:3,4 107:7 111:12 37:11 380:15 40:52 91:21 92:11,16 94:4 37:11 380:15 40:52 91:21 92:11 11:15 117:21 119:3,19 weaknesses 61:12 92:13 18 62:11,20 111:13 11:15 117:21 119:3,19 weaknesses 61:12 92:13 18 62:11,20 115:22 156:18 157:21 116:51:11:13 11:15 116:11 91:12,15 116:11 91:12,15 116:11 91:12,15 116:11 91:11:13 11:15 116:11 91:13,151 116:11 91:13,151 116:11 91:12,15 116:11 91:12,15 116:11 91:12,15 116:11 91:12,15 116:11 91:12,15 116:11 91:12,15 117:21 117:21 112 117:11 115:15 117:21 117:21 117:21 112:15 116:11 91:17 117:21 112:15 116:11 91:17 117:21 112:15 117:21 117:21 117:11 115:11 117:21 117:21 117:11 117:11 117:21 117:21 117:11 117:11 117:21 117:21 117:11 117:11 117:21 117:21 117:11 117:11 117:11 117:11 117:11 117:11 117:11 117:11 117:11 117:11 117:11 117:20 117:11 117:11 117:20 117:11 117:11 117:20 117:11 117:11 117:20 117:11 117:11 117:20 117:11 117:20 117:11 117:20 117:11 117:21 117:11 117:20 117:11 117:	393:5 406:10	40:10 42:2 44:19	withdrawn 281:3	wrapping 351:22
299,10,17 301:79 327,19 381 31:79 371:79 </td <td>we're 6:12 8:14 16:20</td> <td>52:20 68:5 73:15</td> <td>women 10:5 264:4</td> <td>write 278:18 309:3</td>	we're 6:12 8:14 16:20	52:20 68:5 73:15	women 10:5 264:4	write 278:18 309:3
299,10,17 301:79 327,19 381 31:79 371:79 </td <td>25:3 26:5 28:1,13</td> <td>95:10 110:4 114:2</td> <td>wonder 50:15 106:20</td> <td>writeups 304:16</td>	25:3 26:5 28:1,13	95:10 110:4 114:2	wonder 50:15 106:20	writeups 304:16
317,935-7,1938:8 1317,10137:2186:4 wondering 64:17.9:12 with 116:19147:15 396.491:350:6,10.14 178:20179:81818 91:5104:5188:6 210:21226:14345:7 71:39,010,127:29.16 225:4,10232:6 271:12292:16300:17 265:167:306:3 85:20.865 87:47,8 289:217:781322:10 word 360:2 word 360:2 335:18,1936:6 87:18 88:19 90:14 337:1344:937:22 word 360:2 286:13 353:18,1936:6 97:21 92:11.16 944 337:1344:937:22 word 360:2 286:13 353:18,1936:6 97:21 92:11.16 944 339:12;148 530:8 word 360:2 286:13 353:18,1936:6 97:21 92:19 131:18 weaknesse 61:12 word 360:2 241:15,1944:8 353:18,1936:6 117:21 19:3.19 weaknesse 61:12 word 360:2 241:15,1944:8 352:13,184 114:12 0141:12.15 weaknesse 61:12 word 360:2 241:15,1944:8 352:13,184 52:11,20 114:12 014:112.17 weaknesse 61:12 362:13,267:11334:13 361:1936:11494:114 Yeat 12:10 114:12 014:17:2.15 weaknesse 61:12 125:19126:7.11 Yeat 13:10:13:16:12:10:17:10:112		120:7 121:11 129:8	wondered 5:7 40:14	
39:6 49:13 60:5 10,18 178:20 179:8 181:8 91:5 104/5 188:6 20:21 226:14 345:7 50:21 50:21 70:171:6 183:8 199:20 213:11 196:16 211:12 235:16 20:01 235:16 71:39,10,12 72:9,16 225:16,17 261:12 300:19 340:19 373:1 words 36:02 words 96:6 68:16 78:15 81:5,14 82:3 84:4 269:17 729:13 232:10 words 96:6 68:16 78:15 286:13 words 36:6 87:15 286:13 91:21 92:11,11:12 37:11 340:15 405:20 14:12,16,17 15:9,21 16:11 29:42:12 Y Y 91:31 103:11 11:12 weakness 69:12 weakness 69:12 words 33:7 y2:11 31:16 44:14 Y Y Y 204:12 Y 416:17:10 183:6 147:21 119:31 14:11 143:11 14:12 weakness 69:12 weakness 69:12 weakness 69:12 weakness 69:12 y2:13:18 62:11,20 Y Y Y 204:12 Y 416:17:10 183:6 145:10 19:154:15 weakness 69:12 Y Y 416:17:10 183:6 145:10 19:154:154 Weakness 69:12 weakness 69:12 weakness 69:12 <t< td=""><td></td><td></td><td></td><td></td></t<>				
50:21 59:21 70: 171:6 183:8 199:20 213:11 196:16 211:12 235:16 wrong 38:9 54:3 73:14 71:9,9,10,12 72:9,16 255:4,10 232:6 271:12 292:16 300:17 300:19 340:19 373:1 81:54 48:2:3 84:4 269:17 279:13 285:3 word 360:2 word 360:2 353:18,19 396:6 85:20 86:5 87:4,7,8 289:2 317:18 322:10 337:1 344:9 347:22 word 360:2 word 360:2 91:21 92:19 131:11 377:1 344:9 347:22 286:13 word 360:2 16:12 19:7 20:22 23:5 91:21 92:19 131:16 377:11 380:15 406:17 16:12 19:7 20:22 23:5 word 360:2 16:12 19:7 20:22 23:5 117:21 119:3,19 weaknesse 69:12 weakness 69:12 weakness 69:12 weakness 69:12 yda1 61:16,16 141:10 143:18 144:14 weaming 73:5.6 125:13 16 82:11.20 Y 240:12 Y 156:13 167:12,15 webinar 21:67:13 389:8 398:5 404:17 177:17 Y 125:13 13:12 Y 166:11,18 167:12,15 webiste 371:13 389:8 398:5 404:17 178:177:10 183:6 178:177 Y 128:13 192:21 174:16 177:10 183:6 178:177 128:13 192:21 178:178:178:178:178:			0	
71:9.9.10.12 72:9.16 225:4.10 232:6 271:12 292:16 300:17 146*13 265:8.12,19 73:14 75:11 77:3.3 251:16,17 261:12 300:19 340:19 373:1 uord 360:2 uord 360:2 315:15 316:19 349:14 86:520 86:8 74.7.8 289:2 317:18 322:10 uord 90:6 68:16 78:15 286:13 353:18,19 396:6 91:21 92:11,16 94:4 349:12,18 350:8 377:14 344:9 347:2 266:17 77:15 286:13 X 91:21 92:11 11:13 114:13 115:15 ueakness 69:12 25:12 31:13 34:13 Y 14:12,16,17 15:9,21 117:13 119:19 13:16 ueakness 69:12 25:12 31:13 34:13 Y 20:12 27 125:19 216:71 19 15:40:20 weakness 69:12 25:12 31:18 62:11,20 Y 20:12 27 136:13 19:15 12:13 ueakness 69:12 weakness 69:12 25:13 18 62:11,20 Y 20:12 27 136:15 19:15 15:12 weakness 69:12 weakness 69:12 25:13 18 62:11,20 Y 20:13 22:13 136:15 19:15:15 173:17 weakness 69:12 weakness 69:12 26:17 27:12 129:17 10:17:17 129:17:17 129:17:17 129:17:17 129:17:17:17 129:17:17:17:17				
7:14 75:11 77:3.3 251:16.17 261:12 300:19 340:19 373:1 266:1 267:5 306:3 81:5,14 82:3 84:4 269:17 279:13 285:3 word 360:2 word 300:2 97:18 88:19 90:14 337:1 344:9 347:22 word 360:2 word 360:2 91:21 92:19 131:16 349:12 18 350:8 work 7:21 11:15 14:3 353:16.19 349:18 177:21 119:3,19 weakness 69:12 work 7:21 11:15 14:3 X 134:71 380:10 41:6 weakness 69:12 25:13.18 62:11.20 Y 141:10 143:18 144:14 wear 11:10 weakness 69:12 yeah 32:5 67:22 155:22 156:18 157:21 wearing 73:5.6 125:19 126:7.11 yeah 32:5 67:22 155:22 156:18 157:21 weaking 33:7 webinar 24:7 43:8 45:3 175:5 245:14 304:6 165:11 162:15,20 webinar 24:7 43:8 45:3 175:5 245:14 304:6 178:17 7 166:11,18 167:12,15 webinar 24:7 43:8 45:3 175:5 245:14 304:6 178:17 7:19 176:10 177:5,19 week 81:016 191:8 33:15 404:20 191:7 133:19 245:11 180:12 122 18:21 worker 77:14 78:1,4 183:10 33:12:20 188:10 33:12:20 171:17 weighed 39				
81:5,14.82:3 84:4 269:17 279:13 28:3 word 360:2 315:15 316:19 349:18 85:20 86:5 87:4,7.8 289:2 317:18 322:10 word 9:6 68:16 78:15 353:18,19 396:6 91:21 92:11,16 94:4 337:1 344:9 347:22 28:13 word 9:6 68:16 78:15 353:18,19 396:6 91:21 92:11,16 94:4 349:12,18 350:8 word 7:21 11:15 14:3 X 91:34 71 33:10 117:21 119:3,19 weaknesse 69:12 25:12 31:13 34:13 X 127:9 129:19 13:11:8 weaknesses 69:12 25:12 31:13 44:13 Y 204:12 145:10,19 154:6 wearing 73:5.6 125:19 126:7.11 Yada 161:16,16 145:10,19 154:6 wearing 73:5.6 125:19 126:7.11 Yeak 28:6 55:10 166:11,18 167:12,15 week 71:13 389:8 99:5 40:417 Year 28: 65:10 166:11,18 167:12,15 week 71:13 389:8 99:5 40:417 Year 28: 15:15 21:31 166:17,11 week 71:12 392:12 worker 77:14 78:1,40:12 78:11 797.19 170:6 177:11,13,21 week 71:13 38:93:95:40:17 38:19 367:12 34:12 177:1 38:20 390:13 176:17 177:51 week 71:12 392:12 worker 77:14 78:1,4 179:17 39:19:24:11				
85:20 86:5 87:47.8 2289:2 317:18 322:10 words 9:6 68:16 78:15 353:18,19 396:6 87:18 88:19 90:14 349:12,18 350:8 work 7:21 11:15 14:3 X 95:34 107:7 111:12 377:11 380:15 405:20 14:12 16:7,17 15:9,21 X X 140:12 19:17 20:412 117:21 119:3,19 weaknesse 69:12 25:12 31:13 34:13 Y Y 204:12 134:71 38:10 141:6 weakness 69:12 yata 161:16,16 Yate:19 126:7,11 Yate:28,8 65:10 145:10,19 154:6 wearing 73:5,6 125:19 126:7,11 Yate:28,8 65:10 Yate:28,8 65:10 145:10,19 154:6 wearing 73:5,6 125:19 126:7,11 Yate:28,8 65:10 Yate:28,8 65:10 156:21 56:18 157:21 Webinar 24:7 43:8 45:3 175:5 245:14 304:6 188:13 195:15 213:13 166:11,18 167:12,15 webist 371:13 389:8 398:5 404:17 Yate:28:16 7:22 176:10 177:5,19 weeks 180:16 191:8 34:10 130:20 147:3 389:20 390:13 176:10 177:5,19 weighed 245:1 160:7 180:19 184:22 232:19 176:10 177:5,19 weighed 245:1 160:7 138:18 185:19 199:6,10,12 201:4 weighed 24				
87:18 88:19 90:14 337:1 34:49 347:22 268:13 91:21 92:11,16 94:4 349:12,18 350:8 work 7:21 11:15 14:3 95:3,4 107.7 111:12 377:11 380:15 405:20 14:12,16,17 15:9,21 117:21 119:3,19 weakness 69:12 25:13,18 62:11,20 14:10 143:18 144:14 weakness 69:12 25:13,18 62:11,20 14:10 143:18 144:14 weakness 69:12 25:13,18 62:11,20 14:10 143:18 144:14 weakness 69:12 weakness 69:12 25:13,18 62:11,20 145:10 13:15 144:14 weakness 69:12 weakness 69:12 25:13,18 62:11,20 145:10 13:16 144:16 weakness 69:12 weakness 69:12 25:13,18 62:11,20 145:10 13:15 146:15:15 Wearing 73:5,6 125:19 126:7,11 yeah 32:5 167:22 166:11,18 167:21 website 371:13 39:83 89:5 40:47 year 32:5 157:5 92:2 170:8 171:1,13,21 week 71:09 112 worker 77:14 76:17 year 32:61 67:3:4 81:10 180:12 122:18:18 323:13,15 404:20 34:10 130:20 147:3 389:20 390:13 160:17 172:03 122 week 78:01 69:18 34:10 130:20 147:3 389:20 390:13 190:61 172 20:34:22 <				
91:21 92:11, 16 94:4 349:12, 18 350:8 work 7:21 11:15 14:3 X 95:3, 4 107.7 111:12 377:11 380:15 405:20 14:12, 16, 17 15:9, 21 14:12, 16, 17 15:9, 21 111:13 114:13 115:15 406:17 14:12, 16, 17 15:9, 21 14:12, 16, 17 15:9, 21 127:9 129:19 131:18 weakness 69:12 25:12, 31:13 34:13 Y 1347: 138:10 141:6 weakness 69:12 25:12, 31:13 34:13 Y 141:10 143:18 144:14 wearing 383:7 52:13, 18 62:11, 20 Y 141:10 143:18 144:14 wearing 73:5, 6 125:19 126:7, 11 Yada 161:16, 16 144:10 143:18 144:14 wearing 73:5, 6 125:19 126:7, 11 Yada 161:16, 16 145:10 147:5, 20 wear 126:7 129:12, 16, 22 133:20 174:16 177:10 183:6 166:11, 18 167:12, 15 website 371:13 389:8 398:5 404:17 144:20 406:19 408:2 170:10 177:5, 19 week 7:12 392:12 worker 7:14 78:14 19:17 93:19 24:11 173:17 180:21, 22 182:18 333:15 40:20 worker 7:14 78:14 13:5 19:17 93:19 39:20 174:16 177:10 183:6 180:21, 22 18:218 333:15 98:72 week 7:12 39:21 </td <td></td> <td></td> <td></td> <td>353.18,19 390.0</td>				353.18,19 390.0
95:3,4 107:7 111:12 377:11 380:15 405:20 14:12,16,17 15:9,21 X 140:12 191:17 204:12 111:13 111:13 406:17 22:12 31:13 34:13 Y 127:9 129:19 131:18 weaknesses 177:15 36:2,22 41:15,19 44:8 Y 134:7 138:10 141:6 wearing 383:7 52:13,18 62:11,20 yaa 161:16,16 145:10,19 154:6 wearing 73:5,6 125:19 126:7,11 Yale 2:8,8 65:10 155:1 162:15,20 Weaver 126:7 129:12,16,22 133:20 174:16 177:10 183:6 166:11,18 167:12,15 webinar 24:7 43:8 45:3 175:5 245:14 304:6 188:13 195:15 213:13 166:11,18 167:12,15 webinar 24:7 43:8 45:3 175:5 245:14 304:6 188:13 195:15 213:13 166:11,18 167:12,15 webinar 24:7 43:8 45:3 175:5 245:14 304:6 188:13 195:15 213:13 166:11,18 167:12,17 webinar 24:7 43:8 45:3 175:5 245:14 304:12 176:10 177:5 92:2 176:10 177:5,19 week 810:16 191:8 32:113:14 201:4 404:20 406:19 408:2 178:11 797.19 170:6:17 120:34:22 weighted 245:1 worker 17:17 76:17 180:19 184:22 23:11 180:19 184:22 23:11 180:19 184:22 23:11 126:17 1203:12 </td <td></td> <td></td> <td></td> <td>Y</td>				Y
$ \begin{array}{ c c c c c c c c c c c c c c c c c c c$,		
117:21 119:3,19 weakness 69:12 25:12 31:13 34:13 Y 127:9 129:19 131:18 weaknesses 177:15 36:2,22 41:15,19 44:17,20 Yad 161:16,16 141:10 143:18 144:14 wearing 73:5,6 125:19 126:7,11 Yae 2:8,8 65:10 145:10,19 154:6 wearing 73:5,6 129:12,16,22 133:20 Yae 17:10 183:6 155:1 162:15,20 webinar 24:7 43:8 45:3 175:5 245:14 304:6 188:13 195:15 213:13 166:11,18 167:12,15 website 371:13 336:19 367:20 368:2 226:17 166:11,18 167:12,15 website 371:13 338:13 38:5 404:17 yeat 22:19 170:8 177:11,13,21 weekr 123 92:12 worked 12:3 14:12 17:4 180:19 184:22 232:19 170:10 177:5,19 weeks 180:16 191:8 34:10 130:20 147:3 389:2 390:13 187:18 190:13,15,17 weighted 245:1 100:7 389:2 0390:13 199:5,10,12 201:4 weighted 245:1 160:7 13:8 34:18 180:3 12:20 199:5,10,12 201:4 weighted 245:1 160:7 13:8 34:18 180:3 12:20 202:16,17 203:42,22 weighted 245:1 160:7 13:8 34:18 180:3 12:20 222:11 22:157 13:22				▲ 140.12 191:17 204:12
127:9 129:19 131:18 weaknesses 177:15 36:2,22 41:15,19 44:8 Y 204:12 134:7 138:10 141:6 weaknesses 177:15 36:2,22 41:15,19 44:8 Y 204:12 141:10 143:18 144:14 wearing 383:7 52:13,18 62:11,20 Yada 161:16,16 145:10,19 154:6 wearing 73:5,6 125:19 126:7,11 Yada 161:16,16 155:22 156:18 157:21 Weaver 126:7 129:12,16,22 133:20 174:16 177:10 183:6 168:16 165:13 173:17 38:98 398:5 404:17 year 28:1 57:5 92:2 168:16,91,01,01,21,13 Week 7:12 392:12 worked 12:3 14:12 17:4 180:19 184:22 232:19 176:10 177:5,19 weeks 180:16 191:8 34:10 130:20 147:3 294:10 296:14,21 180:21,22 182:18 323:3,15 404:20 191:7 193:19 245:11 389:20 390:13 199:5,10,12 201:4 weight 245:3 worker 17:17 76:17 13:8 34:18,18 55:5 202:16,17 203:4,22 weiltunderstood 210:1 13:6 30:11 52:6 121:9 13:6:13 13:8 3:48 10:3 12:20 226:12 269:11 270:5 124:21 157:13 174:5 171:18 172:11 177:20 13:4:21 191:22 272:1 236:12 269:11 270:5 124:21 157:13 174:5 171:18 13:18 13:8:18 13:8:3				
134:7 138:10 141:6 weaning 383:7 52:13,18 62:11,20 yada 161:16,16 141:10 143:18 144:14 wear 11:10 65:11 94:1 124:11 Yale 2:8,8 65:10 155:22 156:18 157:21 Weaver 126:7 125:19 126:7,11 Yale 2:8,8 65:10 155:22 156:18 157:21 Weaver 126:7 129:12,16,22 133:20 174:16 177:10 183:6 166:11,18 164:6 165:13 173:17 336:19 367:20 368:8 226:17 166:14,18 167:12,15 website 371:13 389:8 398:5 404:17 year 28:1 57:5 9:2 166:6,10,10,12,13 WeeFIM 340:10 404:20 406:19 408:2 178:1 179:7; 19 176:10 177:5,19 weighed 393:7 251:6 316:9 year's 62:11,19 335:13 187:18 190:13,15,17 weighed 245:1 160:7 389:20 390:13 199:5,10,12 201:4 weighed 245:1 160:7 13:8 34:18,18 55:5 202:16,17 203:4,22 weighed 393:7 125:6 11:9 :36:11 32:9 13:6 30:11 52:6 12:19 22:11 228:17 231:22 weighed 393:7 13:6 :0:11 52:6 12:19 23:11,9 33:13 206:10 213:5 220:13 61:9 8:3 109:8 125:1 113:5 125:9 13:6 :0:11 52:6 12:19 22:1				
141:10 143:18 144:14 wear 11:10 65:11 94:1 124:11 Yale 2:8,8 65:10 145:10,19 154:6 wearing 73:5,6 15:11 94:1 124:11 Yale 2:8,8 65:10 155:22 156:18 157:21 weaver 126:7 webinar 24:7 43:8 45:3 175:5 245:14 304:6 188:13 195:15 213:13 163:8 164:6 165:13 173:17 Webinar 24:7 43:8 45:3 175:5 245:14 304:6 188:13 195:15 213:13 166:11,18 167:12,15 webita 371:13 WeeFIM 340:10 389:8 389:5 404:17 year 28:1 57:5 92:2 176:10 177:5,19 week 712 392:12 worked 12:3 14:12 17:4 180:19 184:22 232:19 178:1 179:7,19 180:21,22 182:18 323:13,15 404:20 191:7 193:19 245:1 389:20 390:13 389:20 390:13 180:21,22 182:18 323:13,15 404:20 191:7 177 76:7 160:7 180:31 12:09 20:30:13 year 56:11,19 32:13 202:16,17 203:4,22 weighed 393:7 worker 17:17 76:17 10:13:5 10:3:11 32:19 13:5:13 16:3:13 12:20 202:16,17 203:4,22 weighed 245:1 worker 17:17 76:17 10:12:19 12:21:13 12:5:18 135:18 136:3 30:6:17 32:11 32:12 224:16 243:12 252:13 26:12 82:17 34:6 167:3,6,7,7 13:13 14:13 26:20 20:17 13:13 14:13 26:20 20:17 28:8:				
145:10,19154:6 wearing 73:5,6 125:19126:7,11 yeah 32:5167:22 155:12156:18157:21 Weaver 126:7 129:12,16,22133:20 174:16177:10183:6 163:8164:6165:13 173:17 336:19367:20368:8 326:17 166:11,18167:12,15 website 371:13 389:838:838:5404:17 yeah 32:5167:22 170:8171:1,13,21 website 371:13 389:838:5404:17 yeah 32:5167:22 170:8171:1,13,21 weeks 180:16191:8 34:10130:20147:3 39:6398:5404:17 186:1318,15,17 weighed 393:7 worket 12:314:1217:4 180:19184:2223:19 187:18190:13,15,17 weighted 245:1 weighted 245:1 39:0390:13 199:5,10,12 201:4 weighted 245:1 worker 17:17 76:17 year 56:8,1810:312:20 199:5,10,12 201:4 weighted 245:1 worker 77:14 78:1,4 13:5 202:16,17 203:44,22 weighted 245:1 t6:19:8:3 109:8 125:1 13:6 30:11 52:6 12:9 36:16:73:6,7.7 266:2 26:11 270:5 124:21 157:13 174:5 27:12,56:27:14 23:12 22:22:12 22:7:12 22:7:13 26:52 306:17 32:19 32:2:30:13 306:15 266:2 126:11 270:5 124:21 293:10 30:8:13 30:8:12 30:7:13 30:9:35:14 30:9:35:14 27:12,56		-		
$ \begin{array}{ c c c c c c c c c c c c c c c c c c c$				
158:1 162:15,20 webinar 24:7 43:8 45:3 175:5 245:14 304:6 188:13 195:15 213:13 163:8 164:6 165:13 173:17 336:19 367:20 368:8 226:17 166:11,18 167:17.13,21 website 371:13 389:8 398:5 404:17 404:20 406:19 408:2 178:1 179:7,19 170:8 171:1,13,21 week 712 392:12 worked 12:3 14:12 17:4 180:19 184:22 232:19 294:10 296:14,21 170:10 177:5,19 weeks 180:16 191:8 34:10 130:20 147:3 294:10 296:14,21 294:10 296:14,21 180:21,22 182:18 323:13,15 404:20 191:7 193:19 245:11 389:8 306:15 294:10 296:14,21 199:5,10,12 201:4 weighted 245:1 worker 17:17 76:17 year's 62:11,19 335:13 202:16,17 203:4,22 welcome 4:2 5:3,21 6:19 8:3 109:8 125:1 160:7 138: 34:18,18 55:5 202:16,17 203:4,22 well-understood 210:1 136:3 01:1 52:6 121:9 134:26 167:36,7,7 125:19 126:17 132:9 206:2 264:19 267:10 34:9 66:7 89:18 143:6 167:36,7,7 193:1 194:1 196:13 306:17 321:19 322:3 265:2 298:17 314:15 251:2 257:18 265:22 200:3 273:9 285:15 York 1:19 10:7 17:9 272:15,16 277:4		-	,	
163:8 164:6 165:13 166:11,18 167:12,15 168:6,910,10,12,13 170:8 171:1,13,21 170:8 171:1,13,21 180:21,22 182:18 180:21,22 182:18 180:21,22 182:18 180:21,22 182:18 180:21,22 182:18 180:21,22 182:18 180:21,22 182:18 180:21,22 182:18 180:21,22 182:18 180:21,22 20:13 199:5,10,12 201:4 222:11 228:17 231:22 236:7 238:13 242:10 226:7 238:13 242:10 226:12 24:12 25:20:13 266:2 264:19 267:10 266:2 264:19 267:10 277:21,516 277:4 279:21,22 281:15 277:21,516 316:9 38:22 277:15 298:17 314:16 266:5 236:11 270:5 277:21,519 336:11 322:4 329:2,4 331:4 323:4 329:2,4 331:4 323:4 329:2,4 331:4 323:4 329:2,4 331:4 336:12 336:2 386:3 336:12 336:2 386:3 336:12 336:2 386:3 336:12 336:2 386:3 336:12 336:2 386:3 336:12 337:19 336:13 336:2 336:3 336:12 336:13 337:19 337:13 356:14 336:6 336:6 336:6 336:12 337:19 336:12 336:12 336:3 336:12 336:12 336:3 336:12 336:12 336:3 336:12 336:12 336:3 336:12 336:12 336:3 336:6 336:6 336:6 336:12 337:12 336:13 336:2 338:22 349:11 355:19 356:1 347:15 380:12, 19 336:13 336:2 336:12 336:6 336:6 336:6 336:6 336:6 336:1 336:6 336:6 336:1 336:1 336:1 336:1 336:6 336:6 336:1 337:1 336:1 337.1				
166:11,18 167:12,15 website 371:13 389:8 398:5 404:17 year 28:1 57:5 92:2 170:8 171:1,13,21 week 7:12 392:12 worked 12:3 14:12 17:4 176:10 177:5,19 week 7:12 392:12 170:8 171:1,13,21 week 7:12 392:12 worked 12:3 14:12 17:4 180:19 184:22 232:19 180:21,22 182:18 323:13,15 404:20 191:7 193:19 245:11 389:2 0 390:13 187:18 190:13,15,17 weighted 245:1 weighted 245:1 160:7 year's 62:11,19 335:13 202:16,17 203:4,22 weighted 245:1 160:7 13:8 34:18,18 55:5 56:22 61:6 73:4 81:10 202:16,17 203:4,22 weighted 245:1 160:7 13:8 34:18,18 55:5 56:22 61:6 73:4 81:10 202:16,17 203:4,22 welcome 4:2 5:3,21 workers 77:14 78:1,4 13:5 56:22 61:6 73:4 81:10 202:16,17 203:4,22 well-understood 210:1 13:6 30:11 52:6 121:9 13:4:21 191:22 272:1 236:7 238:13 242:10 well-understood 210:1 13:6 167:3.6,7.7 350:9 353:4 268:2 269:10 34:9 66:7 89:18 143:6 167:3.6,7.7 350:9 353:4 279:21,22 281:15 251:2 257:18 265:22 200:3 273:9 285:15 306:17 303:13				
168:6,9,10,10,12,13 WeeFIM 340:10 404:20 406:19 408:2 178:1 179:7,19 170:8 171:1,13,21 weeks 180:16 191:8 34:10 130:20 147:3 34:10 130:20 147:3 180:21,22 182:18 323:13,15 404:20 191:7 193:19 245:11 389:20 390:13 196:6,18 198:2,21 weighed 393:7 yeighed 245:1 160:7 138:34:18,18 55:5 202:16,17 203:4,22 weighed 245:1 weiccme 4:2 5:3,21 workers 77:14 78:1,4 13:6 30:17:09 11:2 226:12 28:17 231:22 weil-understood 210:1 125:18 136:13 135:18 136:3 306:17 321:19 322:3 260:2 264:19 267:10 a4:9 66:7 89:18 143:6 167:3,6,7,7 193:1 194:1 196:13 36:6:17 321:19 322:3 272:15,16 277:4 191:16 243:20 250:17 124:21 157:13 174:5 171:18 172:11 177:20 193:1 194:1 196:13 285:21,22 296:9 307:8 311:3 408:15 works 126:7 303:13 works 126:7 303:13 young 148:21 194:2 34:10 336:9 338:2,4 331:4 Weer 16:21:3 73:12 Work 61:21.1,19 86:20 19:17 34:3 63:9 338:12,19 356:1 wide 191:1 36:6 36:6 36:22 36:14 366:15 37:12 284:13 385:12 366:12 wide 191:1 380:6 </td <td></td> <td></td> <td></td> <td></td>				
170:8 171:1,13,21 week 7:12 392:12 worked 12:3 14:12 17:4 180:19 184:22 232:19 170:8 171:1,13,21 week 7:12 392:12 worked 12:3 14:12 17:4 34:10 130:20 147:3 389:20 390:13 180:21,22 182:18 323:13,15 404:20 191:7 193:19 245:1 389:20 390:13 year's 62:11,19 335:13 196:6,18 198:2,21 weighed 393:7 weighed 245:1 160:7 year's 62:11,19 335:13 202:16,17 203:4,22 weighed 245:1 113:5 130:8 122:0 13:8 34:18,18 55:5 202:16,17 203:4,22 weighed 245:1 13:5 13:5 56:22 61:6 73:4 81:10 206:10 213:5 220:13 6:19 8:3 109:8 125:1 13:6 30:11 52:6 121:9 13:8 34:18,18 55:5 306:17 321:19 322:3 266:2 264:19 267:10 34:9 66:7 89:18 143:6 167:3,6,7,7 35:09 353:4 yellowish 5:19 272:15,16 277:4 191:16 243:20 250:17 193:1 194:1 196:13 30:61:7 321:19 322:3 285:21,22 296:9 307:8 31:3 408:15 worksheet 43:16 young 148:21 194:2 371:2 2318:7 321:8 Ween't 62:13 74:18 worksheet 33:14 366:15 19:17 323:4 329:2,4 331:4 Ween't 378:20 worksheet 33:14 366:15 20:19 20:15 256:12 371:12 356:19 356:1<				
176:10 177:5,19 180:21,22 182:18weeks 180:16 191:8 323:13,15 404:2034:10 130:20 147:3 191:7 193:19 245:11 251:6 316:9294:10 296:14,21 389:20 390:13187:18 190:13,15,17 199:5,10,12 201:4 202:16,17 203:4,22weighed 393:7 weighted 245:1 weighted 245:1311:7 193:19 245:11 251:6 316:9389:20 390:13 year's 62:11,19 335:13 year's 62:11,19 322:23 336:17 321:19 322:33 336:17 321:19 322:3 337:13 242:10 242:14 57:13 174:5 245:12 265:18 265:22 279:21,22 281:15 245:12 267:18 265:22 279:21,22 281:15 245:12 267:18 265:22 251:2 257:18 265:22 200:3 273:9 285:15 yorks heet 43:16 young 148:21 194:2 young 20:20 110:9,10 115:18 317:22 318:7 321:8 332:16 336:19 338:22 340:11 355:19 356:1 340:13 355:13 366:3 331:22 wheelchair 378:20 wheil 91:1 341:16 348:19 346:5 wider 279:21 341:13 385:2 386:3 380:2 340:11 3385:2 386:3 380:2294:10 206:4,21 380:12 199 341:13 385:2 386:3 380:2294:10 206:4,21 340:12 340:12 340:12 340:12294:12 340:12 340:12 340:12294:12 340:12 340:12 340:12 340:12 </td <td></td> <td></td> <td></td> <td></td>				
180:21,22 182:18 323:13,15 404:20 191:7 193:19 245:11 389:20 390:13 196:6,18 198:2,21 weighed 393:7 year's 62:11,19 335:13 199:5,10,12 201:4 weighted 245:1 160:7 202:16,17 203:4,22 welcome 4:2 5:3,21 worker 77:14 78:1,4 56:22 61:6 73:4 81:10 206:10 213:5 220:13 6:19 8:3 109:8 125:1 113:5 56:22 61:6 73:4 81:10 222:11 228:17 231:22 125:9 working 7:17 10:9 11:2 134:21 191:22 272:1 236:7 238:13 242:10 well-understood 210:1 13:6 30:11 52:6 121:9 288: 299:8 306:15 242:16 243:11 259:20 went 11:13 26:20 28:17 13:6 167:3,6,7,7 350:9 353:4 260:2 264:19 267:10 34:9 66:7 89:18 143:6 167:3,6,7,7 350:9 353:4 277:21,22 281:15 251:2 257:18 265:22 200:3 273:9 285:15 York 1:19 10:7 17:9 283:13 284:14,15 268:5 284:12 293:10 worksheet 43:16 young 148:21 194:2 315:1 316:3 317:19 39:2,10 195:1 373:12 worksheet 43:16 young 148:21 194:2 297:15 298:17 314:16 weren't 62:13 74:18 worksheet 43:16 young 148:21 194:2 323:4 329:2,4 331:4				
187:18 190:13,15,17 weighed 393:7 251:6 316:9 year's 62:11,19 335:13 196:6,18 198:2,21 weight 245:3 worker 17:17 76:17 138 34:18,18 55:5 202:16,17 203:4,22 weighted 245:1 160:7 138 34:18,18 55:5 202:16,17 203:4,22 weighted 245:1 160:7 13:8 34:18,18 55:5 202:16,17 203:4,22 weighted 245:1 worker 17:17 76:17 13:8 34:18,18 55:5 222:11 228:17 231:22 125:9 worker 17:10:9 11:2 13:6 30:11 52:6 121:9 13:6 30:11 52:6 121:9 242:16 243:11 259:20 well-understood 210:1 werking 7:17 10:9 11:2 13:6 30:11 52:6 121:9 28:8 299:8 306:15 242:16 243:11 270:5 124:21 157:13 174:5 143:6 167:3,6,7,7 350:9 353:4 99:8 306:15 279:21,22 28:115 251:2 257:18 265:22 20:3 273:9 285:15 York 1:19 10:7 17:9 285:21,22 296:9 307:8 311:3 408:15 works 126:7 303:13 90:17 33:19 315:1 316:3 317:19 89:2,10 195:1 373:12 works 166:13 378:20 works 166:11,19 86:20 349:11 355:19 356:1 sheez 87:22 whitle 244:12 380:6 110:9,10 115:18 326:3,4 370:1 3		weeks 180:16 191:8		294:10 296:14,21
196:6,18 198:2,21 199:5,10,12 201:4 202:16,17 203:4,22 202:16,17 203:4,22 202:11 228:17 231:22 222:11 228:17 231:22 226:12 257:18 265:22 226:22 264:19 267:10 226:22 264:19 267:10 226:22 264:19 267:10 226:22 264:19 267:10 226:22 264:19 267:10 226:22 264:19 267:10 2272:15,16 277:4 279:21,22 281:15 226:22 281:15 226:22 281:15 226:22 296:9 2307:8 311:3 408:15 232:12 257:18 265:22 200:3 273:9 285:15 200:3 273:9 285:16 200:3 273:9 285:15 200:3 273:9 285:15 200:3 273:9 285:15 200:3 273:9 285:15 200:3 273:9 285:16 200:3 273:9 285:15 200:3 273:9 285:15 200:3 273:9 285:16 200:3 273:9 285:15 200:3 273:9 285:15 200:3 273:9 285:16 200:3 273:9 285:16 200:3 273:9 285:15 200:3 273:9 285:16 200:3 273:9 285:16 200:3 273:9 285:15 200:3 273:9 285:16 200:3 273:9 285:17 200:3 273:9 285:16 200:3 273:9 285:16 200:3 273:9 285:16 200:3 273:9 285:17 220:17 21 220:17 22 220:11 13:6 300:11 220:12 20:12 20:12 20:12 20:11 21:11 21	180:21,22 182:18	323:13,15 404:20		389:20 390:13
199:5,10,12 201:4 202:16,17 203:4,22 206:10 213:5 220:13weighted 245:1 welcome 4:2 5:3,21 6:19 8:3 109:8 125:1160:7 workers 77:14 78:1,4 113:513:8 34:18,18 55:5 56:22 61:6 73:4 81:10 125:19 126:17 132:9220:11 228:17 231:22 236:7 238:13 242:10 242:16 243:11 259:20 242:16 243:11 259:20 242:16 243:11 259:20 242:16 243:11 259:20 266:2 264:19 267:10 272:15,16 277:4 279:21,22 281:15 266:2 264:19 267:10 242:16 243:20 250:17 279:21,22 281:15 251:2 257:18 265:22 283:13 248:14,15 297:15 298:17 314:16 315:1 316:3 317:19 317:22 318:7 321:8 323:4 329:2,4 331:4 323:4 329:2,4 331:4 332:16 336:9 338:22 336:9 338:22 374:15 380:12,19 381:13 385:2 386:3 386:21 393:18 396:9weighted 245:1 weighted 245:1 weighted 245:1 297:15 298:17 314:16 386:21 393:18 396:9160:7 weighted 245:1 weighted 245:1 weighted 245:1 113:5160:7 workers 77:14 78:1,4 113:5136:7 336:9 338:22 works 126:7 303:13 works 126:7 303:14 30:6 the provide 122 63:5 351:2 work 126:7 303:14 30:6 the provide 122 63:5 351:2 30:6 the provide 122 63:5 351:2 30:6 the provide 122 63:5 351:2 30:6 the provide 122 63:5 351:2 30:6<	187:18 190:13,15,17	weighed 393:7	251:6 316:9	year's 62:11,19 335:13
202:16,17 203:4,22 206:10 213:5 220:13 222:11 228:17 231:22welcome 4:2 5:3,21 6:19 8:3 109:8 125:1 125:9workers 77:14 78:1,4 113:556:22 61:6 73:4 81:10 125:19 126:17 132:9222:11 228:17 231:22 236:7 238:13 242:10 242:16 243:11 259:20 260:2 264:19 267:10well-understood 210:1 went 11:13 26:20 28:17 34:9 66:7 89:18workers 77:14 78:1,4 113:5156:2 61:6 73:4 81:10 125:19 126:17 132:9260:2 264:19 267:10 266:2 264:19 267:10a4:9 66:7 89:18 124:21 157:13 174:5124:21 157:13 174:5 124:21 157:13 174:5171:18 172:11 177:20 193:1 194:1 196:13 200:3 273:9 285:15 works 126:7 303:13 works 126:7 303:13306:17 321:19 322:3 350:9 353:4279:21,22 281:15 297:15 298:17 314:16 315:1 316:3 317:19 323:4 329:2,4 331:4268:5 284:12 293:10 89:2,10 195:1 373:12 Wexner 1:17 16:10 wheel chair 378:20 whittle 244:12 widel 91:1works 126:7 303:13 works 126:7 303:13 works 126:7 303:13 works 126:5 351:2yellowish 5:19 yesterday 6:5 York 1:19 10:7 17:9 19:17 young 148:21 194:2 younger 340:232:4 329:2,4 331:4 369:3,4 370:1 373:22 374:15 380:12,19ween't 62:13 74:18 89:2,10 195:1 373:12 wheez 87:22work 62:11,19 86:20 187:22 335:14 366:15 38:6zeore 187:1 200:11349:11 355:19 356:1 360:12,19wheelchair 378:20 whete 287:22world 've 399:2 111:6 148:3 165:14 111:6 148:3 165:14218:19 220:15 255:19 294:15 318:21 369:12 294:15 318:21 369:12374:15 380:12,19 381:13 385:2 386:3wider 279:21 willing 349:4 353:8111:6 148:3 165:14 111:6 148:3 165:14 111:6 148:3 165:14294:15 318:21 369:12 294:15 318:21 369:12<	196:6,18 198:2,21		worker 17:17 76:17	years 5:8,18 10:3 12:20
206:10 213:5 220:13 222:11 228:17 231:22 236:7 238:13 242:106:19 8:3 109:8 125:1 125:9113:5 working 7:17 10:9 11:2 136: 30:11 52:6 121:9 125:18 135:18 136:3 125:18 135:18 136:3 126:2 264:19 267:10125:19 126:17 132:9 134:9 66:7 89:18 143:6 167:3,6,7,7 1268:2 1269:11 270:5 272:15,16 277:4 279:21,22 281:15 283:13 284:14,15 285:21,22 296:9 307:8 311:3 408:15113:5 working 7:17 10:9 11:2 136: 30:11 52:6 121:9 125:18 135:18 136:3 136:3 306:17 321:19 322:3 306:17 321:19 322:3 306:17 321:19 322:3 191:16 243:20 250:17 193:1 194:1 196:13 200:3 273:9 285:15 Works 126:7 303:13 Worksheet 43:16 World 61:22 63:5 351:2 Work 1:19 10:7 17:9 19:17125:19 126:17 132:9 134:21 191:22 272:1 288:8 299:8 306:15 306:17 321:19 322:3 306:17 321:19 325:1279:21,22 281:15 283:13 284:14,15 297:15 298:17 314:16 317:22 318:7 321:8 322:16 336:9 338:22 349:11 355:19 356:1 356:6,6 360:2 367:14 369:3,4 370:1 373:22 381:13 385:2 386:3 388:121 385:2 386:3 388:21 393:18 396:9103:8 109:8 125:1 Widel 934:19 346:5 Wider 279:21 Widel 934:19 346:5113:5 World 61:22 63:5 351:2 Worlh 62:11,19 86:20 380:6 Would've 399:2 Would've 399:220:12 20:15 255:19 20:15 235:14 380:6111:10 381:13 385:2 386:3 386:21 393:18 396:9wider 279:21 Willing 349:4 353:8111:6 148:3 165:14 165:15 166:4,8218:19 220:15 255:19 20:15 255:19				13:8 34:18,18 55:5
$\begin{array}{c c c c c c c c c c c c c c c c c c c $			workers 77:14 78:1,4	56:22 61:6 73:4 81:10
236:7 238:13 242:10 242:16 243:11 259:20 260:2 264:19 267:10well-understood 210:1 went 11:13 26:20 28:17 34:9 66:7 89:1813:6 30:11 52:6 121:9 125:18 135:18 136:3 143:6 167:3,6,7,7 171:18 172:11 177:20 193:1 194:1 196:13 200:3 273:9 285:15288:8 299:8 306:15 306:17 321:19 322:3 305:9 353:4 yellowish 5:19 yesterday 6:5 York 1:19 10:7 17:9 193:1 194:1 196:13 200:3 273:9 285:15279:21,22 281:15 279:21,22 281:15 288:13 284:14,15 288:2 296:9 307:8 311:3 408:15 317:22 318:7 321:8 322:4 329:2,4 331:4 332:16 336:9 338:22 349:11 355:19 356:1 349:11 355:19 356:1 356:6,6 360:2 367:14 349:11 355:19 366:1 366:3,4 370:1 373:22 381:13 385:2 386:3 381:13 385:2 386:3 381:13 385:2 386:3 381:13 385:2 386:3 381:13 385:2 386:3well-understood 210:1 went 11:13 26:20 28:17 125:18 135:18 135:18 136:3 171:18 172:11 177:20 193:1 194:1 196:13 200:3 273:9 285:15 works 126:7 303:13 worksheet 43:16 world 61:22 63:5 351:2 worrying 73:11 356:1 worsened 309:11 317:11 317:11 317:11 317:11 317:11 317:11 317:11 317:11 317:11 317:11 317:11 317:11 317:11 317:12 317:12 317:11 317:11 317:11 317:11 317:11 317:11 317:11 317:12 317:12 317:11 317:11 317:11 317:11 317:11 317:12 317:12 317:12 317:13 317:13 317:14 317:11 317:14 317:15 317:14 317:14 317:15 317:14 317:11 317:15 317:14 317:11 317:11 317:12 317:14 317:11 317:11 317:12 317:14 317:11 317:11 317:12 317:12 317:14 317:11 317:11 317:11 317:12 317:14 317:11 317:15 317:14 317:11 317:15 317:14 317:11 317:11 317:11 317:11 317:11 317:12 317:12 317:12 317:12 317:13 <b< td=""><td>206:10 213:5 220:13</td><td>6:19 8:3 109:8 125:1</td><td>113:5</td><td>125:19 126:17 132:9</td></b<>	206:10 213:5 220:13	6:19 8:3 109:8 125:1	113:5	125:19 126:17 132:9
242:16 243:11 259:20 260:2 264:19 267:10 268:21 269:11 270:5 272:15,16 277:4went 11:13 26:20 28:17 34:9 66:7 89:18 124:21 157:13 174:5 191:16 243:20 250:17 251:2 257:18 265:22 283:13 284:14,15 285:21,22 296:9 307:8 311:3 408:15 315:1 316:3 317:19 317:22 318:7 321:8 315:1 316:3 317:19 317:22 318:7 321:8 322:4 329:2,4 331:4 332:16 336:9 338:22 349:11 355:19 356:1 356:6,6 360:2 367:14 369:3,4 370:1 373:22went 11:13 26:20 28:17 34:9 66:7 89:18 124:21 157:13 174:5 251:2 257:18 265:22 200:3 273:9 285:15 works 126:7 303:13 works 126:7 303:14 317:11 317:12 200:3 273:9 285:15 works 126:7 303:13 works 126:7 303:14 317:11 3204:12 2004:12 2004:12 2004:12 2004:12 2004:12 2004:12 2004:12 2004:12 2004:12 2004:12 2004:12 2004:12 2004:12 2004:12 2004:12 2004:12 2004:12 2004:12 20	222:11 228:17 231:22	125:9	working 7:17 10:9 11:2	134:21 191:22 272:1
260:2 264:19 267:1034:9 66:7 89:18143:6 167:3,6,7,7350:9 353:4268:21 269:11 270:5124:21 157:13 174:5171:18 172:11 177:20yellowish 5:19272:15,16 277:4191:16 243:20 250:17193:1 194:1 196:13yesterday 6:5279:21,22 281:15251:2 257:18 265:22200:3 273:9 285:15York 1:19 10:7 17:9283:13 284:14,15268:5 284:12 293:10works 126:7 303:1319:17285:21,22 296:9307:8 311:3 408:15works 126:7 303:1319:17297:15 298:17 314:16weren't 62:13 74:18worksheet 43:16young 148:21 194:2315:1 316:3 317:1989:2,10 195:1 373:12worsened 309:11younger 340:2317:22 318:7 321:8West 3:2,12,13worsened 309:11317:11323:4 329:2,4 331:4Wexner 1:17 16:10317:11Z349:11 355:19 356:1wheelchair 378:20worth 62:11,19 86:20187:22 335:14 366:15366:6,6 360:2 367:14whittle 244:12380:6110:9,10 115:18369:3,4 370:1 373:22wide 191:1would've 399:2118:2,3 204:19 206:4381:13 385:2 386:3wider 279:21111:6 148:3 165:14218:19 220:15 255:19381:13 385:2 386:3willing 349:4 353:8165:15 166:4,8294:15 318:21 369:12	236:7 238:13 242:10	well-understood 210:1	13:6 30:11 52:6 121:9	288:8 299:8 306:15
260:2 264:19 267:1034:9 66:7 89:18143:6 167:3,6,7,7350:9 353:4268:21 269:11 270:5124:21 157:13 174:5171:18 172:11 177:20yellowish 5:19272:15,16 277:4191:16 243:20 250:17193:1 194:1 196:13yesterday 6:5279:21,22 281:15251:2 257:18 265:22200:3 273:9 285:15York 1:19 10:7 17:9283:13 284:14,15268:5 284:12 293:10works 126:7 303:1319:17285:21,22 296:9307:8 311:3 408:15works 126:7 303:1319:17297:15 298:17 314:16weren't 62:13 74:18worksheet 43:16young 148:21 194:2315:1 316:3 317:1989:2,10 195:1 373:12worsened 309:11younger 340:2317:22 318:7 321:8West 3:2,12,13worsened 309:112323:4 329:2,4 331:4Wexner 1:17 16:10317:11Z349:11 355:19 356:1wheelchair 378:20worth 62:11,19 86:20110:9,10 115:18369:3,4 370:1 373:22wide 191:1would've 399:2110:9,10 115:18381:13 385:2 386:3wider 279:21111:6 148:3 165:14218:19 220:15 255:19381:13 385:2 386:3wider 279:21111:6 148:3 165:14294:15 318:21 369:12386:21 393:18 396:9willing 349:4 353:8165:15 166:4,8zone 45:17 115:3	242:16 243:11 259:20	went 11:13 26:20 28:17	125:18 135:18 136:3	
268:21 269:11 270:5124:21 157:13 174:5171:18 172:11 177:20yellowish 5:19272:15,16 277:4191:16 243:20 250:17193:1 194:1 196:13yesterday 6:5279:21,22 281:15251:2 257:18 265:22200:3 273:9 285:15York 1:19 10:7 17:9283:13 284:14,15268:5 284:12 293:10works 126:7 303:1319:17285:21,22 296:9307:8 311:3 408:15worksheet 43:16young 148:21 194:2297:15 298:17 314:16weren't 62:13 74:18world 61:22 63:5 351:2younger 340:2315:1 316:3 317:1989:2,10 195:1 373:12worsened 309:11317:11323:4 329:2,4 331:4Wexner 1:17 16:10317:11317:11323:4 329:2,4 331:4Wexner 1:17 16:10317:11200:3 273:9 235:14 366:15349:11 355:19 356:1wheez 87:22187:22 335:14 366:15200:3 273:9 20:11356:6,6 360:2 367:14wheez 87:22187:22 335:14 366:15200:11369:3,4 370:1 373:22wide 191:1would've 399:2110:9,10 115:18381:13 385:2 386:3wider 279:21111:6 148:3 165:14218:19 220:15 255:19381:13 385:2 386:3wider 279:21111:6 148:3 165:14294:15 318:21 369:12386:21 393:18 396:9willing 349:4 353:8165:15 166:4,8201:15:3	260:2 264:19 267:10	34:9 66:7 89:18		
272:15,16 277:4 279:21,22 281:15 283:13 284:14,15 285:21,22 296:9191:16 243:20 250:17 251:2 257:18 265:22 268:5 284:12 293:10 307:8 311:3 408:15193:1 194:1 196:13 200:3 273:9 285:15 works 126:7 303:13 worksheet 43:16 worksheet 43:16yesterday 6:5 York 1:19 10:7 17:9 19:17 young 148:21 194:2 young 148:21 194:2 young 148:21 194:2 young 248:21 194:2 young 148:21 194:2 young 148:21 194:2 young 248:21 194:2 young 148:21 194:2 young 240:2317:22 318:7 321:8 323:4 329:2,4 331:4 332:16 336:9 338:22 349:11 355:19 356:1 356:6,6 360:2 367:14 369:3,4 370:1 373:22 374:15 380:12,19 381:13 385:2 386:3 386:21 393:18 396:9West a:2,12,13 Wext at 117 16:10 wheel chair 378:20 wheel at 117 16:10 wheel at 117 16:10 wheel at 117 16:10 317:11 worsheed 309:11 317:11 worsheel 309:11 317:11 2204:12 230:11 356:14 380:6369:3,4 370:1 373:22 381:13 385:2 386:3 386:21 393:18 396:9widely 344:19 346:5 wider 279:21 willing 349:4 353:8105:15 166:4,8369:3,4 370:1 373:22 381:13 385:2 386:3 386:21 393:18 396:9willing 349:4 353:8105:15 166:4,8		124:21 157:13 174:5		
279:21,22 281:15251:2 257:18 265:22200:3 273:9 285:15York 1:19 10:7 17:9283:13 284:14,15268:5 284:12 293:10307:8 311:3 408:15works 126:7 303:1319:17285:21,22 296:9307:8 311:3 408:15worksheet 43:16young 148:21 194:2297:15 298:17 314:16weren't 62:13 74:18worksheet 43:16young 148:21 194:2315:1 316:3 317:1989:2,10 195:1 373:12worsened 309:11307:81 1356:1323:4 329:2,4 331:4Wext 3:2,12,13worsened 309:11317:11323:4 329:2,4 331:4Wexner 1:17 16:10317:112204:12349:11 355:19 356:1wheel chair 378:20worth 62:11,19 86:202-score 187:1356:6,6 360:2 367:14whittle 244:12380:6110:9,10 115:18369:3,4 370:1 373:22wide 191:1would've 399:2118:2,3 204:19 206:4381:13 385:2 386:3wider 279:21111:6 148:3 165:14218:19 220:15 255:19381:13 385:2 386:3willing 349:4 353:8165:15 166:4,8294:15 318:21 369:12	272:15,16 277:4			
283:13 284:14,15 285:21,22 296:9268:5 284:12 293:10 307:8 311:3 408:15works 126:7 303:13 worksheet 43:1619:17 young 148:21 194:2 younger 340:2297:15 298:17 314:16 315:1 316:3 317:19 317:22 318:7 321:8weren't 62:13 74:18 89:2,10 195:1 373:12worksheet 43:16 world 61:22 63:5 351:2 worrying 73:11 356:1 worsened 309:11young 148:21 194:2 younger 340:2323:4 329:2,4 331:4 332:16 336:9 338:22 349:11 355:19 356:1 356:6,6 360:2 367:14 369:3,4 370:1 373:22West 3:2,12,13 Wexner 1:17 16:10 wheel chair 378:20 whittle 244:12 whittle 244:12 whittle 244:12 380:6work 62:11,19 86:20 187:22 335:14 366:15 380:6Z 204:12 Z-score 187:1 zero 95:6 99:20,20 110:9,10 115:18 118:2,3 204:19 206:4 218:19 220:15 255:19 294:15 318:21 369:12 294:15 318:21 369:12381:13 385:2 386:3 386:21 393:18 396:9willing 349:4 353:8165:15 166:4,829:17 115:3				
285:21,22 296:9307:8 311:3 408:15worksheet 43:16young 148:21 194:2297:15 298:17 314:16weren't 62:13 74:18world 61:22 63:5 351:2younger 340:2315:1 316:3 317:1989:2,10 195:1 373:12worsened 309:11356:1323:4 329:2,4 331:4Wexner 1:17 16:10317:112204:12332:16 336:9 338:22wheelchair 378:20worth 62:11,19 86:20Z 204:12349:11 355:19 356:1wheez 87:22187:22 335:14 366:15Z core 187:1356:6,6 360:2 367:14whittle 244:12380:6110:9,10 115:18369:3,4 370:1 373:22wide 191:1would've 399:2118:2,3 204:19 206:4374:15 380:12,19widely 344:19 346:5wouldn't 32:1 64:3218:19 220:15 255:19381:13 385:2 386:3wider 279:21111:6 148:3 165:14294:15 318:21 369:12386:21 393:18 396:9willing 349:4 353:8165:15 166:4,8zone 45:17 115:3				
297:15 298:17 314:16 315:1 316:3 317:19 317:22 318:7 321:8weren't 62:13 74:18 89:2,10 195:1 373:12 West 3:2,12,13world 61:22 63:5 351:2 worrying 73:11 356:1 worsened 309:11younger 340:2323:4 329:2,4 331:4 332:16 336:9 338:22West 3:2,12,13 West are 1:17 16:10 wheelchair 378:20 349:11 355:19 356:1 356:6,6 360:2 367:14 369:3,4 370:1 373:22West 3:2,12,13 West 87:22world 61:22 63:5 351:2 worsened 309:11 317:11younger 340:2349:11 355:19 356:1 356:6,6 360:2 367:14 369:3,4 370:1 373:22West 87:22 whittle 244:12 wide 191:1 widely 344:19 346:5 wider 279:21world 61:22 63:5 351:2 worsened 309:11 317:11Z369:3,4 370:1 373:22 381:13 385:2 386:3 386:21 393:18 396:9wider 279:21 willing 349:4 353:8world 61:22 63:5 351:2 worsened 309:11 317:11 317:11Z204:12 204:12worth 62:11,19 86:20 187:22 335:14 366:15 380:6zero 95:6 99:20,20 110:9,10 115:18 218:19 200:4 218:19 220:15 255:19 294:15 318:21 369:12 294:15 318:21 369:12				
315:1 316:3 317:19 89:2,10 195:1 373:12 worrying 73:11 356:1 317:22 318:7 321:8 West 3:2,12,13 worsened 309:11 323:4 329:2,4 331:4 West 3:2,12,13 317:11 323:4 329:2,4 331:4 West 3:2,12,13 317:11 323:4 329:2,4 331:4 West 3:2,12,13 317:11 323:16 336:9 338:22 wheelchair 378:20 worth 62:11,19 86:20 349:11 355:19 356:1 wheez 87:22 187:22 335:14 366:15 356:6,6 360:2 367:14 whittle 244:12 380:6 369:3,4 370:1 373:22 wide 191:1 would've 399:2 374:15 380:12,19 widely 344:19 346:5 wouldn't 32:1 64:3 381:13 385:2 386:3 wider 279:21 111:6 148:3 165:14 386:21 393:18 396:9 willing 349:4 353:8 165:15 166:4,8				
317:22 318:7 321:8 West 3:2,12,13 worsened 309:11 Z 323:4 329:2,4 331:4 Wexner 1:17 16:10 317:11 204:12 332:16 336:9 338:22 wheelchair 378:20 worth 62:11,19 86:20 Z-score 187:1 349:11 355:19 356:1 wheez 87:22 187:22 335:14 366:15 Zero 95:6 99:20,20 369:3,4 370:1 373:22 wide 191:1 would've 399:2 110:9,10 115:18 369:3,4 370:1 373:22 widel 91:1 would've 399:2 118:2,3 204:19 206:4 374:15 380:12,19 widely 344:19 346:5 would't 32:1 64:3 218:19 220:15 255:19 381:13 385:2 386:3 wider 279:21 111:6 148:3 165:14 294:15 318:21 369:12 386:21 393:18 396:9 willing 349:4 353:8 165:15 166:4,8 zone 45:17 115:3				,
323:4 329:2,4 331:4Wexner 1:17 16:10317:11Z 204:12332:16 336:9 338:22wheelchair 378:20worth 62:11,19 86:20Z-score 187:1349:11 355:19 356:1wheez 87:22187:22 335:14 366:15Zero 95:6 99:20,20356:6,6 360:2 367:14whittle 244:12380:6110:9,10 115:18369:3,4 370:1 373:22wide 191:1would've 399:2118:2,3 204:19 206:4374:15 380:12,19widely 344:19 346:5wouldn't 32:1 64:3218:19 220:15 255:19381:13 385:2 386:3wider 279:21111:6 148:3 165:14294:15 318:21 369:12386:21 393:18 396:9willing 349:4 353:8165:15 166:4,8zone 45:17 115:3				Z
332:16 336:9 338:22 349:11 355:19 356:1 356:6,6 360:2 367:14wheelchair 378:20 wheez 87:22worth 62:11,19 86:20 187:22 335:14 366:15Z-score 187:1 zero 95:6 99:20,20 110:9,10 115:18369:3,4 370:1 373:22 374:15 380:12,19 381:13 385:2 386:3 386:21 393:18 396:9wheelchair 378:20 wheez 87:22worth 62:11,19 86:20 187:22 335:14 366:15 380:6Z-score 187:1 zero 95:6 99:20,20 110:9,10 115:18369:3,4 370:1 373:22 374:15 380:12,19 381:13 385:2 386:3 386:21 393:18 396:9widel 191:1 widely 344:19 346:5 wider 279:21would've 399:2 111:6 148:3 165:14 115:15 166:4,8Z-score 187:1 zero 95:6 99:20,20 110:9,10 115:18 294:15 318:21 369:12 294:15 318:21 369:12				
349:11 355:19 356:1 356:6,6 360:2 367:14 369:3,4 370:1 373:22 wheez 87:22 whittle 244:12 187:22 335:14 366:15 380:6 zero 95:6 99:20,20 110:9,10 115:18 369:3,4 370:1 373:22 374:15 380:12,19 wide 191:1 would've 399:2 118:2,3 204:19 206:4 374:15 380:12,19 widel 344:19 346:5 wouldn't 32:1 64:3 218:19 220:15 255:19 381:13 385:2 386:3 wider 279:21 111:6 148:3 165:14 294:15 318:21 369:12 386:21 393:18 396:9 willing 349:4 353:8 165:15 166:4,8 zone 45:17 115:3			-	
356:6,6 360:2 367:14 369:3,4 370:1 373:22whitle 244:12 wide 191:1380:6 would've 399:2110:9,10 115:18 18:2,3 204:19 206:4374:15 380:12,19 381:13 385:2 386:3 386:21 393:18 396:9widel y 344:19 346:5 wider 279:21would've 399:2 uould't 32:1 64:3 111:6 148:3 165:14 165:15 166:4,8110:9,10 115:18 18:2,3 204:19 206:4 294:15 318:21 369:12 294:15 318:21 369:12				
369:3,4 370:1 373:22 374:15 380:12,19wide 191:1 widely 344:19 346:5 wider 279:21would've 399:2 wouldn't 32:1 64:3 111:6 148:3 165:14 165:15 166:4,8118:2,3 204:19 206:4 218:19 220:15 255:19 294:15 318:21 369:12 zone 45:17 115:3				
374:15 380:12,19widely 344:19 346:5wouldn't 32:1 64:3218:19 220:15 255:19381:13 385:2 386:3wider 279:21111:6 148:3 165:14294:15 318:21 369:12386:21 393:18 396:9willing 349:4 353:8165:15 166:4,8zone 45:17 115:3				
381:13 385:2 386:3 386:21 393:18 396:9 wider 279:21 willing 349:4 353:8 111:6 148:3 165:14 165:15 166:4,8 294:15 318:21 369:12 zone 45:17 115:3				-
386:21 393:18 396:9 willing 349:4 353:8 165:15 166:4,8 zone 45:17 115:3				
330.11 330.4 402.11 WIII 220.9 195.15 230.17 250.2 291 2:10 15:14,15 54:3				
	390.11 390.4 402.11	WIII 220.9	190.10 200.17 200.2	∠yı 2.10 15:14,15 54:3
	I	I	I	I

385:21 387:13 11:00 124:21	20 168:12,14,14 218:20 234:18 238:10 248:18	373:20 374:9 387:19
		388:9 400:8 402:5
11:10 124:17	260:11 288:8,10	2778 4:18 370:4 388:9
		400:8 402:13 406:3
		28 30:19,19 204:20
		270:7,22 371:13
		285 4:12
		203 4.12 29 115:1,17
		2967 4:7 50:6 125:2
		199:14 202:12
		2B2.3.J 265:7
		2b5 108:1
		200 100.1
		3
		3 1:3 104:1 189:18,19
		202:19 203:21 206:13
		220:11 221:4,16
		222:4 281:4 363:1
		385:8,18 386:9,19
		387:10 390:11
		3,000 214:3,4
	-	3,922 371:3
		3,984 324:14
		3.6 66:6
		3:03 284:13
		30 73:4 154:8 173:22
		214:2 296:20 325:4
		337:10 398:16
		300 85:22 138:1
		308 333:15,15
		309 333:15
		30s 148:22
		32 385:13,22
		33 95:7 264:21 269:13
	269:22 270:14 272:12	368 4:13,14
164:12 181:4 183:9		37 385:12 402:19
183:10 197:14 198:21	273:19 281:19 282:1	370 4:16
1915(c) 136:15 214:1	283:10	388 4:18,19
196 234:19	2616 4:11 229:4 273:10	39 204:3 205:13 206:17
1996 18:10	281:19 283:21	206:17,19,20 220:16
1A 318:1,9	262 219:6	255:18
1B 263:17	27 174:2 387:19	390 4:20
1st 10:3	273 4:10,11	
	2769 4:11 285:10 286:3	4
2	318:9,11 322:18	4 202:19 203:21 206:14
2 30:1 33:9,19 128:22	339:3 342:9 343:18	220:11 221:5,16
153:2 171:2 198:20	362:18 363:9,14	222:5 257:12 363:2
202:18 203:20 206:13	368:16 403:13,19,21	385:9,18 386:10,19
215:17 220:11 221:4	277 369:17	387:10
221:16 222:4 333:3	2774 4:13 363:19	4,000 371:3
333:22 362:22 363:15	368:14,19	40 45:14,15 46:4 204:7
368:20 369:11,17	2775 4:14 305:7 363:20	407:1
384:4,19 385:8,17	368:14 369:10	400 17:2 213:6 214:2,3
386:9,18 387:9,21	2776 4:16 370:3 373:20	219:13 223:18
401:20 402:6,14	374:1 384:11,13	403 4:21
406:4	385:15 386:3,15	41 103:5 214:3
0 000 400.40 040.0	387:5,20 400:17	10 00E-01 000-0
2,300 193:10 212:8 2:44 284:12	2777 4:17 370:4,5	42 385:21 388:2
	11:14 124:22 12 13:8 25:9,10 57:2 91:17 271:7 292:14 295:13,17 296:3,14 296:21 12:04 174:5 12:30 174:3 12:34 174:6 125 4:7 125-year 10:8 13 252:19 15 124:17 182:21 238:10 239:7 307:21 15-minute 193:17 150 212:19 15th 1:8 16 323:6 339:10 344:5 363:4,6,17 371:5 384:1 385:22 387:2 387:14 1600 408:10 16th 408:10 17 220:17 222:8 269:14 173 4:8 174 319:9 324:13 18 56:22 63:22 64:1 75:19 147:7 199:12 220:17 271:11 292:19 293:16 300:13 339:22 19 50:6,8 127:21 130:8 154:22 156:1,17 157:7,8 161:19 164:9 164:12 181:4 183:9 183:10 197:14 198:21 1915(c) 136:15 214:1 196 234:19 1996 18:10 1A 318:1,9 1B 263:17 1st 10:3 2 2 30:1 33:9,19 128:22 153:2 171:2 198:20 202:18 203:20 206:13 215:17 220:11 221:4 221:16 222:4 333:3 33:22 362:22 363:15 368:20 369:11,17 384:4,19 385:8,17 386:9,18 387:9,21 401:20 402:6,14	11:14 124:22 306:15,17 337:10 12 13:8 25:9,10 57:2 91:17 271:7 292:14 295:13,17 296:3,14 200 335:16 371:8 296:21 200 335:16 371:8 12:04 174:5 201 66:7 374:18 12:34 174:6 201 66:7 374:18 12:34 174:6 201 66:7 374:18 12:34 174:6 201 66:7 374:18 12:34 174:6 201 66:7 374:18 12:34 174:6 201 66:7 374:18 12:34 174:6 201 66:7 374:18 12:34 174:6 201 66:7 374:18 12:34 174:6 201 66:7 374:18 12:34 174:6 201 66:7 374:18 12:34 174:6 201 66:7 374:18 13:252:19 201 66:7 374:18 15:17:13:17 201 66:7 374:18 12:34 174:6 201 66:7 374:18 13:252:19 201 66:7 374:18 15:14:17 18:21 201 66:7 374:18 201 61:21:17 317:12 15:17:33:10 21:4:4 95:3 342:21 363:4,6,17 371:5 366:13,14 387:1 22:0:17 222:8 269:14 23 16:10 271:1 21:80:14 24 17:19:17 27:11:1 292:19 25 18:10

I	
43 95:8 99:19 44 220:16 264:21 45 14:6 173:22 47 339:10 387:14 402:9 48 118:1 180:14 <u>5</u> 5 4:2 106:13,13 115:18 119:9 201:1 323:7 342:22,22 5,000 375:7 384:3 391:11 5:23 408:15 50 91:16 127:16 171:12 205:12 269:13 50,000-plus 214:4 500 399:11 52 114:22 118:2 53 4:6 386:13 402:9 56 204:2 255:18 57 99:19 58 344:5 363:5 387:2 388:1 <u>6</u> 6 1:6 4:3 186:6 199:15 203:7 204:3,20 222:7 254:13 255:19 272:17 283:16 284:4 6:00 406:20 60 39:19 45:12,14,15 204:7 60.001 45:13 61 265:7,14 270:22 406:6 63 402:20 66 45:8 67 106:12 115:17 204:19 221:8 222:8 68 323:7 342:21 <u>7</u> 7 213:4 7.4 66:7	9 9,600 271:11 90.6 104:2 91 108:4 259:21 92 218:8,10 93.23 186:8 94 199:14,15 254:13 272:17 283:15 284:4 95 119:9 133:10 384:20 9th 1:8
63 402:20 66 45:8	
204:19 221:8 222:8	
· · · · · · · · · · · · · · · · · · ·	
8	
8 407:4 8:30 1:9 407:4 8:39 5:2 80 105:16	
80 105:16 800 335:17 391:12 800-plus 371:8 82 108:3 112:5	
84 259:20 260:4 363:16 86 260:4 89 109:16 259:20	
II	

CERTIFICATE

This is to certify that the foregoing transcript

In the matter of: Person and Family Centered Care

Before: NQF

Date: 06-06-16

Place: Washington, DC

was duly recorded and accurately transcribed under my direction; further, that said transcript is a true and accurate record of the proceedings.

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