NATIONAL QUALITY FORUM

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VALUE SET HARMONIZATION COMMITTEE

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TUESDAY APRIL 21, 2015

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The Committee met at the National Quality Forum, 9th Floor Conference Room, 1030 15th Street, N.W., Washington, D.C., at 8:38 a.m., Zahid Butt and Michael Lieberman, Co-Chairs, presiding.

PRESENT:

ZAHID BUTT, MD, FACG, Co-Chair MICHAEL LIEBERMAN, MD, MS, Co-Chair HOWARD BREGMAN, MD, MS, Epic CHENGJIAN CHE, MD, Booz Allen Hamilton CHRISTOPHER CHUTE, MD, DrPH, Johns Hopkins University CYNTHIA CULLEN, MS, MBA, PMP, Mathematica Policy Research YAN HERAS, PhD, Lantana Consulting WENDY HOFNER, RN, NextGen Health Care MATT HUMPHREY, Telligen RUTE MARTINS, MS, The Joint Commission ROBERT McCLURE, MD, MD Partners MARJORIE RALLINS, DPM, Physician Consortium for Performance Improvement JOSEPH SCHNEIDER, MD, MBA, FAAP, Baylor Scott & White Health ANN SMITH, RN, BSN, MSHA, National Committee for Quality Assurance NANCY WALKER, MHA, RHIA, Trinity Health

HELEN BURSTIN, MD, MPH, FACP, Chief Scientific

Officer

JASON GOLDWATER, MA, MPA, Senior Director ANN HAMMERSMITH, JD, General Counsel SHARON HIBAY, RN, DNP, Senior Director ANN PHILLIPS, MHA, Project Analyst KATHRYN STREETER, MS, Senior Project Manager MARCIA WILSON, PhD, MBA, Senior Vice President, Quality Measurement

ALSO PRESENT:

KEVIN LARSEN, MD, Medical Director, Meaningful Use, Office of the National Coordinator of Health IT, Department of Health and Human Services

JULIA SKAPIK, MD, MPH, Medical Officer, Office of the National Coordinator for Health IT, Department of Health and Human Services

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1	P-R-O-C-E-E-D-I-N-G-S
2	8:38 a.m.
3	MR. GOLDWATER: Okay, so why don't we
4	go ahead and begin? I know there are a couple of
5	people that are supposed to be here that have not
6	arrived yet, so we will do our best to catch them
7	up when they are here. Hopefully, they will be
8	here shortly. Apparently, as I told you before,
9	I heard the traffic is nightmarish, so that might
10	be causing some particular delays, but we don't
11	want to wait any further.
12	So on behalf of the National Quality
13	Forum, I want to welcome all of you to this very
14	important and, hopefully, a very, as much as
15	value sets can be, entertaining discussion over
16	the next eight hours. My name is Jason
17	Goldwater. I'm the Senior Director here at the
18	National Quality Forum overseeing the Value Set
19	Harmonization Project.
20	And I really do want to take a few
21	moments to thank all of you for attending this
22	morning and into this afternoon. I realize a lot

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of you came from places as long as the West Coast, and then some of you came from Howard County and it probably took you the same amount of time to get here, from what I understand, just about.

6 We have a pretty full agenda ahead of 7 us today. There's a lot of issues to discuss, so 8 I want to turn it over to my colleague, Katie 9 Streeter, who is the Senior Project Manager and 10 basically runs the day-to-day operations of this 11 contract, to sort of go over the agenda. Katie?

12 MS. STREETER: Thank you. Good 13 morning, everyone. We'll be starting off today by doing introductions. The staff will introduce 14 15 ourselves, and then our General Counsel, Ann 16 Hammersmith, will lead the Committee introductions, and we'll be going through a 17 18 disclosure of interests exercise.

We'll then be talking about ground
rules for today's meeting and setting the stage,
our expectations. The Committee will then first
dive into our first discussion about Prevailing

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1	Issues in Value Set Harmonization. We'll then be
2	discussing the benefits of value set
3	harmonization: what are we looking to get out of
4	this project?
5	Staff will then summarize an exercise
6	we performed, a preliminary analysis for value
7	set selection. The Committee will then be
8	talking about developing a criteria for value set
9	harmonization before we break for lunch at 12:30.
10	We'll then be talking about developing and
11	testing a process for value set harmonization.
12	And, lastly, we will break for public
13	comment. I would like to remind everyone that
14	this meeting is open to the public, so we may
15	have members, NQF members, and members of the
16	public listening in. And then we will adjourn by
17	4:00.
18	And just a reminder, the restrooms are
19	out past the main conference area past the
20	elevators on the right. We will be trying to
21	stick to our break and lunch time as best as we
22	can. So we have two breaks at 10:45 and 3:30.

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1	Lunch will be served at 12:30, and we plan on
2	taking a 30-minute break then.
3	And if you have any issues connecting
4	to Wi-Fi, we do have I believe we have signs
5	around here on the table that lists the log-in
6	and password, or you can send me an email if you
7	have any issues and we can have our IT people
8	help you out. Ann?
9	MS. HAMMERSMITH: Thank you, Katie.
10	I see a few familiar faces, so some of you may be
11	familiar with this part of the meeting. But I
12	will go over it with you, and then we will go
13	around the table and we'll have you disclose.
14	The Value Set Harmonization meeting,
15	it's not a CDP project, it's not a MAP project.
16	It is other, which we mean affectionately. But
17	we still have to do disclosures of interests. My
18	understanding is that all of you are subject
19	matter experts, so you got our long form where we
20	asked you details about your professional
21	activities.
22	So what we will be looking for you to
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disclose today is if you were involved in 1 2 anything that directly relates to the subject matter before the Committee. Just because you 3 disclose does not mean you are biased or that you 4 have a conflict. Part of the reason we do this 5 is to be open, to be transparent, so that all of 6 7 you can know where each other are coming from and also so that the public will know where you are 8 9 coming from.

We are particularly interested in your disclosure of grants, research activities, or speaking engagements, but only if it relates to the subject matter before the Committee. Please don't summarize your CV. Just keep your disclosure to the subject matter before the Committee.

I want to remind you of two things
before we disclose. You sit as an individual on
this committee. You're not representing your
employer. You're not representing anyone who may
have nominated you to serve on the Committee.
In addition, I want to remind you

that, unlike many conflict of interest processes, 1 2 we're not just interested in disclosures of monetary interests. Because of the nature of the 3 work that we do and that all of you will do in 4 this committee meeting, we're also interested in 5 activities, again, that directly relate to the 6 7 subject matter before the Committee.

And you may not have been paid for 8 9 them. You may have sat on a committee for your 10 professional society that's relevant to the topic 11 today. You know, just because money hasn't 12 changed hands doesn't mean that it shouldn't be 13 disclosed.

So with that, let's start the 14 15 disclosures. Tell us your name, tell us who 16 you're with, and if you have anything to disclose. And, Dr. Tcheng, I will call on you at 17 18 the end of the disclosure. So let's start with 19 the co-chairs. Dr. Lieberman? 20 CO-CHAIR LIEBERMAN: Hi, I'm Mike I'm the Acting Chief Health 21 Lieberman.

Information Officer at OHSU, Oregon Health and

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Science University. I have no significant
 disclosures.

3 CO-CHAIR BUTT: Good morning. I'm 4 Zahid Butt, CEO of Medisolv. We are a quality 5 measurement software vendor. We do use value 6 sets in many of our applications. I do not have 7 any other disclosures to make.

8 MEMBER HUMPHREY: Matt Humphrey. I
9 work as a Solutions Delivery Manager at Telligen.
10 Nothing to disclose.

11 MEMBER CHUTE: Chris Chute, Bloomberg 12 Distinguished Professor of Health Informatics at 13 Hopkins, also Chief Health Research Information 14 Officer at Hopkins. My disclosures are I chair 15 the ICD-11 Committee for the World Health 16 Organization. I also sit on the Joint SNOMED ICD 17 Harmonization Committee.

MEMBER SMITH: Anne Smith. I'm
Director of Measure Validation at NCQA, National
Committee for Quality Assurance. And we develop
value sets for quality, for our quality measures.
MEMBER CULLEN: Cynthia Cullen,

Mathematica Policy Research. We're a social policy research firm. We do clinical quality measure development and develop and use value sets.

5 MEMBER McCLURE: Rob McClure. I'm 6 deeply involved in this subject matter. I'm a 7 consultant to ONC, involved in helping to do 8 value set harmonization and value set evaluation 9 for the quality measures.

I'm a consultant to the National 10 11 Library of Medicine in the development of the VSAC, which is used to house and support the 12 13 creation of value sets around all of those I've been doing value set development 14 things. 15 work for a long time. I'm a co-chair at HL-7, 16 Vocabulary Workgroup at HL-7, and involved in the development of the standard that defines how 17 18 value sets are defined.

19 MEMBER HERAS: My name is Yan Heras. 20 I'm an independent consultant, and I'm actually 21 currently working on leading the QRDA 22 implementation guide work for CMS, so that

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involves some value set and also participating in 2 the eMeasure development for hospital side. So that's my disclosure. 3

MEMBER SCHNEIDER: Joe Schneider. I'm 4 Chief Medical Information Officer of the North 5 Texas Division of Baylor Scott and White Health, 6 7 the old Baylor. I'm a practicing pediatrician at UT Southwestern. My disclosure probably comes in 8 9 as I chair the Practice Management Council at the Texas Medical Association, which is on the record 10 11 as opposing ICD-10.

Good morning, this is 12 MEMBER WALKER: 13 Nancy Walker. I'm the Director of the Quality Health Record at Trinity Health, and I use the 14 value sets in evaluating our eMeasures for all 15 16 the facilities that we have.

MEMBER HOFNER: Hello, my name is 17 18 Wendy Hofner. I'm with NextGen Health Care. Ι 19 am currently the Director of Meaningful Use 20 Services, and we use value sets within our 21 quality measure program. I do not have any disclosures. 22

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MEMBER RALLINS: Good morning, I'm 1 2 Marjorie Rallins with AMA-PCPI. Of course, we develop measures, we conduct measure testing and 3 develop value sets in developing specifications. 4 I also sit on the Content Standards Committee 5 that reports into the HIT standards work ----6 7 The Content Standards Workgroup that excuse me. reports into HIT Standards Committee of ONC. 8 9 MEMBER CHE: My name is Chengjian Che, 10 I go by Cheng. So I work for Booz Allen 11 Hamilton. I used to be an EH measure developer, so I was developing the value sets. Now I'm the 12 13 value set user. Nothing to disclose. 14 MEMBER BREGMAN: Howard Bregman, 15 Director of Clinical Informatics at Epic, the 16 electronic health record vendor. And I have nothing to disclose. 17 18 MEMBER MARTINS: Rute Martins with the 19 Joint Commission, wherein we develop eCQM, so we 20 develop value sets. We're also an eCOM receiver. No conflicts to disclose. 21 22 MS. HAMMERSMITH: Okay, thank you.

And, Dr. Tcheng, are you on the phone? Dr.
 Tcheng? Okay, guess not. Any other Committee
 members on the phone? No, okay.

Thank you for the disclosures. Before 4 I leave today, I want to remind you that we look 5 to you to help us make the conflict of interest 6 7 process work. Part of what that means, in addition to disclosing, is that if you're in the 8 9 meeting and you think you have a conflict or if you think one of your Committee members has a 10 conflict or is behaving in a biased manner, we 11 12 ask you to speak up.

13 You can do it in real-time. If you don't want to do it that way, you can approach 14 15 your co-chairs who will work with NQF staff or 16 you can work with NQF staff directly. What we don't want is for you to sit there thinking, oh, 17 18 maybe I have a conflict, or I know that so-and-so 19 is up to their eyeballs in something and they may 20 be biased. We really want you to tell us in realtime. 21

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So with that, do you have any

questions, comments? Okay, thank you.

2	MR. GOLDWATER: Okay. Thank you all
3	very much for your introductions. So we'll take
4	a few moments and introduce ourselves since we'll
5	be with you today and for the remainder of this
6	contract, which will extend into next year.
7	So as I mentioned before, my name is
8	Jason Goldwater. I'm a Senior Director here at
9	NQF. I've been involved in health IT for about
10	20 years now, starting with the HIPAA X12
11	transaction set standards, when those were
12	implemented.
13	I spent a good portion of my career at
14	CMS. Actually, it was HCFA when I first started,
15	if we can all remember back to those good old
16	days. And spent a lot of time with the Office of
17	Clinical Standards and Quality, which apparently
18	has now also been changed to the Center for
19	Clinical Standards and Quality, working on a lot
20	of software for manual record extraction for
21	quality measures, including the CMS abstraction
22	reporting tool which I think Matt Humphrey, who

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is here, is now taking over those duties. 1 2 So I have a long relationship with value sets, standards. I've attended and 3 participated in SNOMED groups, HL7 standards, 4 X12/HL7 harmonization, which was a lot of fun. 5 And also spent a lot of time working with ONC on 6 7 a variety of projects, including the SHARP projects, as Chris may remember, where I was the 8 9 PI investigating and doing an evaluation of 10 those. Katie? 11 12 MS. STREETER: Thank you. Hi, I'm 13 Katie Streeter. I'm Senior Project Manager here at our Quality Measurement Department at National 14 15 Ouality Forum. I've been here for about four and 16 a half years. I've worked primarily on many different consensus development projects for the 17 18 endorsement of performance measures. And more 19 recently, I've started to become more involved in 20 the health IT-related projects. Hi, I'm Ann Phillips. 21 MS. PHILLIPS: 22 I'm a Project Analyst here at NQF. I work on

most of the health IT projects with NQF. 1 I 2 started with transition of the QDM. I work with I work on HIT patient safety and with 3 eMeasures. the Value Set Harmonization Project. I've been 4 here about a year and a half. 5 DR. HIBAY: Good morning. I'm Sharon 6 7 I'm one of the Senior Directors here at Hibay. NOF. I want to welcome everyone, it's nice to 8

put some names and faces together that I've been working with for a long time.

Il I've been in the measurement space since before 2000. And probably my greatest, or most relevant work, with the value sets is working with lots of you on the Meaningful Use 2 measures, retooling -- actually, back to Meaningful Use 1 measures.

17 So I worked as a contractor with CMS 18 -- with PQRS, Meaningful Use, ACO measures. In 19 addition, I've worked very intimately with ICD-20 10, ICD-9, SNOMED. I think we're all saying the 21 same sort of stuff. And then after I did a stint 22 with CMS contracting, I was Director of

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Performance Measures with the American Board of 1 2 Internal Medicine where I oversaw about 1300 different measures for their inventory. 3 So I'm very happy to be here and share 4 5 and build this process with everyone. MR. GOLDWATER: Okay. So I want to 6 7 take just a few moments to set the stage for -oh, sorry Marcia. I forgot. 8 9 DR. WILSON: Hi, I'm Marcia Wilson, I'm forgettable Senior Vice President of Quality 10 11 Measure, and I oversee the measure endorsement and measure selection processes. 12 Thank you. 13 MR. GOLDWATER: It should also be noted Marcia is my boss. We know how my 14 15 performance review will go at the end of the 16 Thank you, Sharon, for pointing that out. year. I do want to take a few moments to set 17 the stage because we do have a fairly packed 18 19 agenda, and we only want to keep you all here for 20 a day. So setting up some ground rules and 21 22 some logistics. So first and foremost, I realize

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this is an all-day discussion on value sets. So 1 2 the coffee is plentiful and it is behind me. Feel free to get some whenever you need to. 3 We understand, in working with value 4 sets, terminology is incredibly important. 5 All of you are experts in various terminologies and 6 7 have used them significantly throughout most of your career, I would assume. But we don't want 8 9 to be spending a lot of time discussing the ins 10 and outs of terminology. It's important, but we 11 really need to work on building a consensus to this group on how we will do value set 12 13 harmonization. We want to work towards the defined 14 15 meeting objectives. That is the wish of our 16 client who is funding this project, who will be here, I'm assuming, at some point. And we will 17 18 talk about what those meeting objectives are as 19 we move throughout the presentation. The staff here, Katie and Ann, will 20 maintain a list of important but out-of-scope 21 22 parking lot issues that will be tackled at future

meetings.

2	Please know that we are recording this
3	meeting, as is standard process for every NQF
4	meeting. So please speak into your microphone
5	when you have something to say. If during the
6	course of our discussion, you want to pipe in,
7	chime in, whatever the case may be, just turn
8	your placard to this, and I will call on you.
9	I would ask that when you are making
10	comments, please keep them as succinct as
11	possible. I realize we all have a lot to say,
12	but we do also have a lot to get through in the
13	next eight hours. So I want to make sure we try
14	to get everything done so that we are proceeding
15	along as we need to, both for our client and for
16	the purpose of this project.
17	Members of the public will have the
18	opportunity to provide comments throughout the
19	meeting. Verbal remarks should be brief, and any
20	details should be submitted to the staff.
21	So I don't know I'm assuming there
22	are people here who know a lot about NQF, but I

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1	don't know if everybody knows everything
2	what NQF does. So I want to turn this over to
3	Ann just to give you all a brief description of
4	what NQF does.
5	MS. PHILLIPS: The National Quality
6	Forum is a private, nonprofit, voluntary,
7	consensus standard-setting organization. The NQF
8	operates under a three-part mission to improve
9	the quality of American healthcare.
10	Our aim is to build consensus on
11	national priorities and goals for performance
12	improvement and working in partnerships in order
13	to achieve them, endorsing national standards for
14	measuring and publicly reporting on performance
15	and promoting the attainment of national goals
16	through education and outreach program.
17	Our membership is broken up into eight
18	councils: consumer, health plan, health
19	professionals, provider organizations, public and
20	community health agencies, purchasers, quality
21	measurement research and improvement, supplier
22	and industry.

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1	MR. GOLDWATER: So I want to now take,
2	again, a few moments and describe for you the
3	project. I know we had an orientation for all of
4	you where we went over just sort of the basic
5	highlights of what we were charged to do, but I
6	want to get a little bit more specific because I
7	think that will help guide the discussion.
8	NQF is defining value set
9	harmonization as the process by which unnecessary
10	or unjustifiable variance will be eliminated from
11	common value sets and electronic clinical quality
12	measures by the reconciliation and integration of
13	competing and/or overlapping value sets.
14	Under your guidance, we are looking to
15	develop and pilot test a harmonization approval
16	process to promote consistency and accuracy in
17	eCQM value sets. These harmonized value sets
18	will also provide a basis of gap analysis and for
19	examination of face validity of future value
20	sets. It will also offer guidance on how
21	approved value set status should be integrated
22	into our endorsement process of electronic

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clinical quality measures.

2	The project is going to address the
3	following issues: what are the harmonization
4	criteria for value sets used in eCQM development
5	and when is it applicable? Will measure
6	developers, and there are quite a few of you
7	here, be mandated to demonstrate they have
8	actively utilized the Value Set Authorization
9	Center, or the VSAC for short, harmonize value
10	sets in eCQM development, and what components of
11	this process apply to the review and approval of
12	newly-submitted value sets and how should that
13	process be structured?
14	We will address what the role of value
15	set authors and stewards in responding to
16	recommendations for changes or additions to value
17	sets. How are these recommendations for
18	additions or changes in the value set content
19	integrated into the existing VSAC catalog, and

20 then how does this process and approval integrate 21 with or impact our overall measure endorsement

22 process?

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The deliverables that we are 1 2 responsible for from now through the end of the contract: a harmonization process for resolving 3 missing, duplicate, competing, or otherwise 4 problematic value sets; ground rules for measure 5 developers on the use of endorsed harmonized 6 7 value sets to build measures; and then guidance on policies and procedures for coordinating this 8 9 harmonization work with the VSAC. 10 So as you can see, fairly easy things. 11 It should be a very short meeting. Our time line and milestones. 12 So 13 we're meeting today, and we will, hopefully, come up with a process that we will then start to 14 15 pilot with our technical expert panel. We will 16 identify test measures, a couple of them, to use this process on. We will develop and draft the 17 18 harmonization approval process, and then we'll do 19 an iterative test and report back to you the 20 results of that. The Committee charge. The Committee, 21 22 your committee, will provide guidance in the

development of this process and provide input on the identification of variance in value sets, criteria for evaluating variance in value sets, and an iterative pilot process for resolving this variance.

And I should note here that we do have 6 7 two co-chairs, Dr. Lieberman and Dr. Butt, who have graciously agreed, we did not force them 8 9 against their will, to be co-chairs of this 10 committee. And so they are going to help us steer this discussion. I think all of you know 11 them and know them well, so they have significant 12 13 and extensive expertise in this area. And we asked them to be the co-chairs to help facilitate 14 15 this. They also are very familiar with NQF and 16 have worked with us in the past.

17 The ground rules for today is to 18 identify the basic issues surrounding value sets 19 and devise methods to potentially correct these 20 problems. The focus is a proposed solution, 21 which is very important to our clients, which is 22 Office of the National Coordinator, CMS, and NLM.

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It is vital that by the time we get to 4:00, we construct a proposed methodology. We actually were thinking about we were going to hold you here and not let you go back home until we have one, but I thought that was a bit extreme, quite honestly.

7 The co-chairs are here to facilitate 8 the session, identify additional information that 9 might be useful to the Committee, and help keep 10 the project on track.

11 So let's begin our discussion. So I 12 want to first of all, again, I know a lot of you 13 know a good deal about value sets, but we do want 14 to have just a basic, even understanding of the 15 life cycle of a value set. So I'm going to turn 16 it to Ann to walk you through this.

MS. PHILLIPS: Okay. This was new to
me, but I asked the NLM exactly how a value set
is published in the VSAC, and it starts
conceptualization, which happens outside of the
VSAC.

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The author creates a new value set,

and that value set is drafted. Then the author submits the value set for a steward's approval, and that steward can be within the organization 3 or in an outside organization. And that steward 4 will review the proposed value set, and, at that point, the steward can reject it, and the author 7 has to redraft it or abandon it, or the steward approved it.

9 Once the approved value set is approved in the VSAC, it's ready to publish. 10 Now proposed value sets and draft value sets are 11 12 listed in the VSAC. They are not publicly 13 accessible, but if you have authoring privileges, you can see that there are many draft and 14 15 proposed value sets that have not been approved 16 and are not published.

However, once the value set is 17 18 approved, it is ready to publish. And publishing 19 is as simple as pressing a button, and your value set will appear as a published value set after 20 midnight on the day that you press the publish 21 22 button.

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The VSAC publishes a value set, and it 1 2 doesn't undergo any kind of updates unless it's associated with an eCQM. Every January/February, 3 that process begins and is completed by May. 4 And those are the value sets in eCQMs that are used 5 in federal programs. Currently there are no 6 7 other programs that require that value sets be reviewed yearly, only the eCQMs used in federal 8 9 programs. So once the value set hits that, hits 10 11 the VSAC, unless it's looked at in a federal 12 program, it's going to stay, unless someone 13 outside of the Value Set Center initiates some kind of update. 14 MR. GOLDWATER: So before we start the 15 16 discussion, somebody new has entered the room. And she is our Chief Science Officer, so I do 17 want her to introduce herself. While you have a 18 19 mouthful of food, it's not excuse. So feel free. 20 DR. BURSTIN: That was the worst possible timing, as well as the worst possible --21 22 you don't realize how hard it is to eat a hard-

boiled egg while somebody calls on you. 1 Good morning, everybody. I'm Helen 2 I'm the Chief Scientific Officer. Burstin. 3 Thanks to so many of you for coming back. We've 4 had many of you on prior committees, and thanks 5 to all of our new folks, as well. 6 7 We're really excited about this new work and continuing to sort of push the field 8 9 forward and sort of building these key building blocks of eMeasures. So delighted. 10 11 Apologies for being late. My 84 year old mother decided to have chest pain at 8:00, 12 13 and the daughter doctor is usually pretty critical to those discussions. She's fine. 14 15 So anyway, thanks so much and looking 16 forward to the day. 17 MR. GOLDWATER: Okay. So I want to 18 start the discussion, and I'm also going to let Michael and Zahid lead this, as well. So again, 19 20 leveraging all of your expertise and knowledge, can you discuss with us what you believe the 21 22 major issues around value sets are and have been?

Dr. Chute?

2	MEMBER CHUTE: Well, I'm still a
3	pointy-headed academic. Now it's on tape. I
4	guess I want to center around something that I
5	thought you missed in your overarching goals and
6	scope, and I would articulate that as shared
7	principles for value set generation and use that
8	would engender harmonization out of the box.
9	And you know, I'm naive in this space,
10	as many of you know. But I'm curious if, for
11	example for quality metrics, there is a principle
12	that all value sets would be drawn from a
13	parsimonious, non-overlapping, specified set of
14	terminologies and classifications.
15	The obvious candidate are the
16	meaningful use suspects that, for example, if
17	you're going to specify a medication, thou shalt
18	an RxNorm code, thou shalt not use NDC, thou
19	shalt not use NDF or whatever may be in fashion.
20	But one would pick a the principle would
21	articulate what is the domain from which any and
22	all value sets would derive.

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I submit that if such a principle is 1 2 not in place, if organizations, communities, whatever, are free to derive value sets from any 3 terminology they choose, or worse, make their own 4 pizzas, we will never be able to achieve any 5 meaningful harmonization. 6 7 MR. GOLDWATER: Dr. Rallins? So I wanted to build MEMBER RALLINS: 8 9 on Dr. Chute's comments. And Chris, there are 10 some principles that the value sets that are in 11 federal programs were developed against, and that happened in 2011. But I do -- you know, I do 12 13 agree with you that you've got to have a set of principles to build from. 14 15 In addition to that, those guidelines 16 that the measure developers are using -- when the Standards Committee developed those guidelines, 17 18 it was the intent on what you should report 19 quality measures with, not how you actually 20 capture that. So that's a -- you know, I think that's an important distinction to keep in mind. 21 22 CO-CHAIR LIEBERMAN: So could I ask a

question? So what is the current state of affairs in that manner? Does the VSAC ---- they do have a set of terminologies that they currently use and it's limited, isn't that correct? To the terminologies you referred to as part of meaningful use.

7 MEMBER RALLINS: Well, they were -those are the ---- for the measures that are in 8 9 meaningful use, those are the guidelines that we follow. And they're developed in accordance with 10 11 the -- I don't want to get into too much technical detail, but we've took the data 12 13 elements in the categories that are used for the quality data model and developed recommendations 14 15 against those.

MR. GOLDWATER: So I want to point out, and we are probably -- we are going to talk about this a little later. So we took on some pre-work analysis with the help of NLM before we met today, in order to see if we were able to identify within meaningful use a couple of measures, whether there was overlapping value

sets and whether there were similar concepts being expressed in different ways.

And there were a number of them. Particularly in depression measures, we found there to be significant degrees of overlap and similar concepts being represented. And in particular, we found there to be a lot of overlap between SNOMED and ICD-9 and ICD-10.

9 And so going back to what Dr. Chute 10 was saying, which is if we are not sort of 11 developing a pre-standard process and criteria and putting constraints immediately on the 12 13 development of value sets, how are we going to sort of resolve that particular issue, which I 14 15 see as being somewhat pervasive and I don't know 16 of any way, at this point, to particularly get through that issue. 17

18 MEMBER MARTINS: So that's also part 19 of the guidelines is that there were identified 20 standard vocabularies, such as SNOMED for 21 diagnosis, but then transitional vocabularies 22 were identified. So that overlap is actually

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built in, which is interesting.

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2 There were ICD-9 and ICD-10 codes initially in the HITSP specifications, but 3 there's a huge outcry from the field that these 4 are the codes that we have. This is structured 5 information that we currently have. Why can't we 6 7 use these codes? It's included in their ongoing conversations every year about when to pull the 8 9 plug on ICD-9 and ICD-10 as transitional 10 terminologies for eCQMs. So that is part of the built-in variation. 11 I don't think anyone knows, at this 12 13 point, how that affects the standardization of the reporting and how that affects potentially 14 15 the measure rates. So that's where it's coming 16 from. What I would say, in terms of the 17 18 issues for harmonization, knowing that we have a certain set of built-in variation and that there 19 20 are principles around which vocabularies should be used in value sets, is that, you know, just as 21 22 providers want clinical decision support, measure

developers need decision support, as well. 1 2 And having this information available on, is the value set that I'm creating already 3 overlapping with ten other value sets that 4 already exist? Having ---- trusting, really, 5 that the value sets that already exist do meet 6 7 quality standards. Otherwise, we're just going to be developing the same value set. And we 8 9 trust that the value set that's already there makes sense and we should be using it. 10 So that's what I would say is a big 11 issue in the harmonization is trusting value sets 12 13 that are already there for re-use and being able -- having tools to help us to identify where 14 15 overlap may exist, as opposed to doing it 16 manually. MR. GOLDWATER: Dr. Chute? 17 18 MEMBER CHUTE: As one of the founders 19 of the Common Ontology effort between SNOMED and 20 ICD, I can speak with some authority on this notion of overlap and semantic dissonance. 21 22 To put it mildly, as long as we have

1	these interim terminologies and built-in overlap,
2	the goal of harmonization is elusive, and indeed,
3	impossible. So if that is to persist, we might
4	as well go home.
5	I think there are workarounds. I have
6	been sometimes accused of being pragmatic. And I
7	think the workarounds are the following: that we
8	should propose that value sets be defined in a
9	canonical form with a single set of
10	terminologies.
11	One has to acknowledge that we live in
12	a real world and that data is not necessarily
13	connected collected in raw SNOMED form, and I
14	get that. Thus it is perfectly acceptable to
15	designate what I would characterize as quality
16	metric surrogates, and they would not be the same
17	as the quality metrics, but they would be
18	surrogates and reported as such. And those
19	surrogates would involve mapping of usual
20	suspects to the canonical defined form.
21	For example, one might define a
22	quality metric in terms of SNOMED. Organizations

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like Kaiser might actually report in that quality 1 2 metric form. Other organizations, mere mortals, might still have ICD codes as their exclusive 3 modality of diagnostic designation. 4 It's important to recognize that the 5 quality metric that they would report is a 6 7 It is not identical to the quality surrogate. metric that is canonically defined. It is 8 9 impossible to, given the state of the art today and given the many, many mappings that are 10 implicit between and among, for example, 11 diagnostic terminologies, it is not correct to 12 13 say that you can have a mapping and that it is the same quality metric. It is a different 14 15 quality metric. 16 So we do have somebody MR. GOLDWATER: else who has entered the building, who also 17 18 happens to be one of our clients. So I'm going 19 to have Julia introduce herself, and then I have 20 you a comment. DR. SKAPIK: Julia Skapik from ONC. 21 22 I'm a Medical Officer, and I've worked for the

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past several years on setting up the VSAC and trying to improve the processes around value sets.

I really appreciate Dr. Chute's 4 I would say that we do consider 5 comments there. it the goal of this project to catalog and 6 7 understand what best practices and recommendations around value sets in general are, 8 9 particularly in a case like this where it potentially limits your ability to harmonize when 10 there are multiple terminologies involved. 11 And I would encourage you not to all go home, but 12 13 rather to include that as part of your recommendations in your report. 14 15 MR. GOLDWATER: Zahid? 16 CO-CHAIR BUTT: So yes, so I'm very encouraged to have plenty of pragmatists at the 17 18 table. But I think we sort of -- you know, as 19 you said, in terms of the pragmatism, we sort of 20 come from the practical side of things where the eCQMs have to be implemented today and generate 21 22 results that are meaningful.

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The only thing that I would like to 1 2 just mention at this point is that, potentially within the eCOMs, there are separate use cases in 3 which a certain level of overlap perhaps is 4 acceptable, in terms of perhaps defining an 5 inpatient population where a precision in 6 7 complete alignment may not be necessary on a oneto-one basis. But perhaps in certain portions of 8 9 the same eCQM where there is a more precise use 10 case, that might be more applicable in terms of, you know, whether you're defining a certain 11 effect or a negation principle. 12

13 There might be, within the eCQM, certain use cases where there is a very precise 14 15 definition necessary and perhaps a singular 16 terminology is needed. Whereas in certain use cases it may be that, if you're defining a large 17 18 population of a certain type of thrombotic stroke 19 or hemorrhagic stroke, it may not be as -- the 20 precision of the mapping may not be as required. It's just another idea to sort of 21

think about while we transition from these

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various terminologies into a future state. 1 2 MR. GOLDWATER: Dr. Che? MEMBER CHE: So when we talk about a 3 trust -- we have to take into consideration of, 4 you know, how this value set has been vetted or 5 You know, when we develop a set, 6 tested. 7 sometimes it would just come from the ideal concept. If we look at SNOMED CT, we'd say, yes, 8 9 this concept probably will represent this kind of new idea. But has this been verified, tested in 10 11 EHR or in reality? So maybe some pieces may seem, in this value set definition -- has this 12 13 been tested and vetted? MR. GOLDWATER: Dr. Rallins? 14 15 MEMBER RALLINS: I just wanted to go 16 back again, as a member of the workgroup that developed the recommendations that the measure 17 18 developers are using to develop value sets, Dr. 19 Chute, I can assure you there was passionate 20 debate about using a single ontology-based 21 vocabulary. 22 Yes, I know. MEMBER CHUTE: I was

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part of that debate.

2	MEMBER RALLINS: Right, right. And we
3	learned in that, on that, of course, because we
4	wanted ontology-based vocabularies that could
5	actually capture clinical detail, but we also
6	looked at where organizations actually were in
7	their maturation, or their path towards using
8	ontology-based vocabularies. Hence, we ended, we
9	landed on transition vocabularies, which, you
10	know, can be described as administrative ICD-9,
11	10, etcetera.
12	But those recommendations also had
13	expiration dates for the transition vocabularies,
14	and I think we should contemplate that. I don't
15	know, Dr. Skapik, if ONC is contemplating the
16	expiration dates on those recommendations for the
17	value sets.
18	DR. SKAPIK: So thanks, Marjorie. I
19	think you know that I brought this up for some
20	time, and I don't think that there's been, you
21	know, the level of consideration in terms of what
22	to do about value sets. I think that expertise

in this room is really ideally poised, especially 1 as external stakeholders, to provide us with 2 comments and advice on that specific topic. 3 As you know, the recommendations made 4 by the Standards Committee were not in any way 5 codified in a rule, or any other kind of 6 7 It was merely a list of language. recommendations. So I think we're at a point 8 9 where ONC and CMS and HHS, overall could make a decision either way. I think that, if there's a 10 11 strong sense from a group of broad experts that one path is better than another, that a more 12 13 forceful case might be made back to the Standards Committee, and also to the federal government 14 15 itself, to make that change. 16 MR. GOLDWATER: Dr. Chute and then Dr. Rallins. 17 18 MEMBER CHUTE: Sorry for going out of 19 sequence, but, having been a member of the HIT 20 Standards Committee at that time, I would point out, just as a bit of history, that in the 21 22 Meaningful Use 1 specification, the

recommendations from the Standards Committee were for single terminology. Those recommendations were overridden by ONC and HHS, and that's how we ended up with the dual system, should we say. 4 But it should be made on record that the Standards Committee advocated a single 7 terminology.

DR. SKAPIK: Sure. And I would say 8 9 that, you know, although the Standards Committee 10 had reluctantly endorsed the use of transitional 11 terminologies, they did say that a year into Meaningful Use 3 they expected those to be 12 13 expiring.

So I would say that that's around now, 14 15 although it's a little bit nebulous given delays 16 in the execution of stage 3, that that should probably be undertaken. I don't think it 17 18 necessarily requires any actual modifications to 19 the rule language, or to an actual rule for us to 20 execute on that, and I think it is a technically sound approach and something that probably, even 21 22 if ONC and CMS were to change that approach, they

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probably wanted to feel confident that this is the right time to do that. So any evidence that would support that would probably be useful.

MR. GOLDWATER: Dr. McClure? 4 MEMBER McCLURE: This is really a 5 question of process. I have my bias, I don't 6 7 doubt that, but I'd ask the chairs to consider, part of what we're talking about is questions on 8 9 how a value set should be created. And those 10 obviously have an impact of what we do in the context of harmonization. 11

And so I wonder, you know, at the risk 12 13 of being chained into the room, that we consider -- before we try and figure out how to do 14 15 harmonization, we think about this committee 16 would have some work before it to have recommendations on how value sets should be 17 18 created from the beginning. Dr. Chute raised 19 that as his very first point. So I'm asking if 20 the chairs believe that that's something that this committee should fully address in some way 21 22 first, before it does the other.

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1 MR. GOLDWATER: I'll let the chairs 2 answer that first, and then we'll get some 3 responses.

CO-CHAIR LIEBERMAN: Well, I think 4 that's in the scope. And we talk a lot about the 5 charge being how we harmonize existing value 6 7 sets, but part of that was in the process of how you develop a new value set, and how that gets 8 9 approved and brought in, especially in light of if there are already existing value sets that 10 11 need to, that would need to be taken under consideration before you agree to create a new 12 13 So I would say that that is within scope in one. 14 general. 15 MR. GOLDWATER: Ms. Martins and Dr.

16 Heras.

MEMBER MARTINS: So back to the question of the vocabularies that are co-existing right now with the eCQMs, we know that that creates problems in terms of the reporting when we don't have a single canonical form of the measures. But let's just assume for a minute

1	that ICD-9 has been taken on
2	(Telephonic interference)
3	MEMBER MARTINS: that visit. The
4	data is still not being captured in SNOMED
5	(Telephonic interference)
6	MEMBER MARTINS: so the mapping
7	still exists. The overlap would exist, but it
8	would be across a number of unknown local
9	proprietary/non-proprietary vocabularies. So I
10	would argue that we're always going to have
11	surrogates, unless the data is being captured in
12	these standard vocabularies at the point of
13	entry, really. So we're always going to have
14	that overlap.
15	And then the other thought here, in
16	terms of the ICD-9 and ICD-10, one important
17	thing to remember is that, and this is always a
18	problem because these measures have a history,
19	most of these measures, and they were developed
20	using ICD-10 and ICD-9 measures, original
21	vocabulary tested against ICD-9 to capture
22	certain populations. And to this day, I still

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don't know whether using SNOMED will have the 2 same effect. So that's something that is, I think, really critical as we move to different 3 vocabularies, to see that the measures retain the 4 properties that we would like them to retain when 5 we use these different vocabularies. 6

7 MR. GOLDWATER: Dr. Heras? MEMBER HERAS: Yes, so for major 8 9 issues around value sets, from my experience, I see a value measure -- and so one area it's 10 11 really looking at different measures, so they're developed by different developers. And sometimes 12 13 they don't look at what others are developed. So I think how you create a value set, the process 14 really needs to be -- so I echo the doctor's 15 16 So we need some process for how we comments. gather value sets. 17

18 And the second one that we talk about 19 is the existing overlapping terminologies that we 20 said for diagnoses. We need to have ICD-9, ICD-10, and SNOMED. So this is something that we 21 have to go for, and this is the measures that 22

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we're having to use. I think just the mapping -because during the development process we do the mapping. Sometimes, we usually start out from, like, ICD-9 from, you know, the paper measure manual when we create the mapping, but we don't document that mapping anywhere.

7 So I think that process, you know, part of the development that we should capture 8 9 that and at least, you know, as that one step 10 forwards, we can -- during the eCQM we had three different value sets within the grouping. 11 At least we can provide that level of mapping. 12 Ι 13 know, still, when you implement this, people still have to map their local codes or whatever 14 15 codes they have to the value set.

So a third one that I see is really from the, at the value sets in the measure and to the reporting standards and how that, you know, the mismatch there, you know, from where -according to the reporting standards, it requires something different than, you know, the value sets being used in the eCQM. So that's the three

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major issues that I see.

2	MEMBER CHUTE: I think that's a nice
3	summary of the three major issues, but I do want
4	to address Ms. Martins' point, which is apt, and
5	that is that perhaps it's a fool's errand to
6	think that one would ever have a canonical metric
7	that is genuinely reported as data collected. I
8	appreciate that.
9	That begs the question of where really
10	lies most of the dissonance. I think, as a
11	practical matter, the mapping from laboratory
12	codes to LOINC is, if not an exact science, at
13	least acceptable for most purposes, certainly for
14	statistical aggregation and metric purposes.
15	Correspondingly, I think mappings from
16	proprietary drug codes to RxNorm are
17	correspondingly robust. I won't say reliable,
18	but adequate. So maybe obsession over that level
19	of micro dissonance at the source level to a
20	canonical designation may be tolerable.
21	The rub is really with the diagnostic
22	codes. And as I said, working with SNOMED on

what we call a common ontology, and here I'll
disclose my biases, as consistent with my
disclosures. ICD-11 is working very, very
assiduously to ensure that ICD-11 is defined in
terms of SNOMED semantics. The prior versions of
ICD have not done that.

7 Yet, that is the way virtually all of the diagnostic data is collected in this country 8 9 at this time, and it begs the question of whether 10 an exception to the meaningful use specification might be considered by NQF, at least for a period 11 of time until we have a more robust rendering, 12 13 and that is that the published canonical form of NQF metrics might be, gasp, ICD-10, anticipating 14 15 the ICD-10 conversion. I will go on record, by 16 the way, as saying I don't object to the ICD-10 conversion, although I think ICD-11 is going to 17 18 be better, but that's all right.

(Laughter)

20 MEMBER CHUTE: So, you know, the issue 21 of that principle, what do we designate as the 22 source terminologies for at least canonical

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metrics specification, I think, persists. What 1 2 I'm putting on the table is that to cut through the major source of the dissonance, which is 3 clearly in the diagnostic codes, that a 4 consideration and exception to the meaningful use 5 specification be considered explicitly to embrace 6 7 ICD-10 as the canonical form for quality metrics. MR. GOLDWATER: Zahid? 8 9 CO-CHAIR BUTT: So just to follow up on what Chris just said, I think that the way, 10 11 one way at least, as an overarching principle to at least consider here would be that perhaps 12 13 SNOMED and ICD-9, 10, or 11 could potentially live together in harmony. 14 15 The question is really how to 16 harmonize it, what is the principle as it pertains to eCQMs, because SNOMED, being the most 17 18 granular of clinical terminologies, in terms of 19 the diagnostic tests potentially are best suited 20 for the documentation by the clinicians, because that would get the closest to the concept in 21 22 their day-to-day documentation. And the ICD-9

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1	and 10 pretty much are at a slightly higher level
2	than that, and so, in that sense, I don't
3	consider them competing with each other, but one
4	feeding into the other.
5	And if that framework could be
6	formalized somehow, perhaps there would be less
7	potential problems where you are trying to
8	compete, as opposed to when you're trying to
9	harmonize these in a sort of a not
10	horizontally but more vertically, because the use
11	case for the ICD classification system is going
12	to persist probably forever, because I don't see
13	a day when you will be submitting your claims
14	with SNOMED diagnostic codes.
15	Probably wouldn't be needed, that
16	granularity wouldn't be needed, because they'll
17	still have to convert that back to some
18	classifier to make it relevant for what they need
19	to do, while the claims measures that CMS is
20	moving towards, outcomes measures, are all going
21	to be based on that data that's submitted through
22	that process.

So I think it would be best for us to find a way to formalize some sort of relationship which is implicit in the word harmonization because, otherwise, we would be saying that we need just a singular, everywhere, singular terminology.

7 MEMBER SCHNEIDER: As a person who has to implement these things, I find myself agreeing 8 9 with Dr. Chute. We've got SNOMED for this, ICD-10 10 for that. We're trying to do ICD-9. And from a practical standpoint, I can't do everything and 11 I can't be an expert in everything. And so while 12 13 there could be some sort of relationship of these things, I would say, from a physician and 14 15 possibly a hospital standpoint, asking to speak 16 one language and then those who want to convert it to something else can have a set of published 17 18 tables, as to here's how you convert from this to 19 that, and I understand that that's not easy. But 20 asking me to -- you know, we've got teams doing ICD-10, we've got teams doing SNOMED coding, and 21 22 it's just driving us crazy.

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So, please, let's get -- I think Dr. 1 2 Chute's concept of a single place where we're going, I guess I'm reminded of narrow gauge 3 The Illinois Central basically said, railways. 4 overnight, we're going to switch. They didn't 5 try to make all sorts of transition things. 6 It 7 was basically literally over the course of several days we went to our current gauge. 8 9 I think we have to set a direction and 10 say this is where we're going, and we're going by 11 this date. In between, we have what Dr. Chute 12 calls surrogates, and we have to recognize them 13 as such and accept them as such for those who can't get there. But after a certain date, 14 15 that's it. You are in standardsville. Thanks. 16 CO-CHAIR BUTT: Just to -- I, again, want to clarify what I said. I didn't imply that 17 18 the physician or the clinicians would have to 19 deal with two separate things. I think they are 20 having to do it today, and that's part of the I think that the framework I'm at least 21 problem. 22 suggesting for consideration is that the

physician would only deal with SNOMED, and that's all. There's no need for the physician then to also have to select the appropriate ICD-9 or 10. That could all be done through mapping.

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And it's a problem when something is 5 coded in 9 or 10 and you have to go backwards to 6 7 That's the bigger problem. SNOMED. But once something is coded in SNOMED, let's say by a 8 9 physician as part of their documentation, whether 10 that's selecting the SNOMED directly or it's mapping to the local term, and that's, I think, 11 what Chris was alluding to, once that's done by 12 13 the physician, then I think the physician should 14 be done really.

The next level of classification 15 16 that's needed for the use cases should happen potentially automatically and behind the scenes 17 18 and vetted by coding, and the physicians wouldn't 19 have to select two different code systems.

20 So some more things that DR. SKAPIK: came up when Dr. Chute was talking earlier was, 21 22 currently, we get a lot of questions from the

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community about what are the rules surrounding mapping, and the current answer that we give to people is it's expected that you can justify your mapping, but we haven't really provided people with any consistent or reliable or audit-based or audit sort of protective mappings.

7 And I agree that there are some cases in which mapping is much easier and not very 8 9 subjective. We have had reports from people in the field who have discovered that there are 10 11 vendors doing mapping that would be inconsistent with the intent of measures, and there are some 12 13 concerns about how do I know that I'm going to pass an audit and be able to keep any incentive 14 payment if there's not better guidance. 15

16 So I think that any guidance that the 17 Committee has about what the appropriate ways to 18 do mapping are, who should be responsible for 19 determining what appropriate mapping is, should 20 there be better resources? I mean, we know that 21 there are resources in existence that could 22 potentially help people, but they have not been

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endorsed by HHS in any way.

2	That sort of guidance, I think, is
3	very helpful, and I think that, to Zahid's
4	comment, I think to say what is expected in terms
5	of roles, and relationships, and understanding
6	different terminologies is similarly helpful,
7	because it's very difficult I think for a lot of
8	implementers to train physicians on what to do
9	and, you know, nurses, anyone who is doing
10	coding, without some sort of more clear guidance
11	on that topic.
12	MR. GOLDWATER: Dr. Bregman and then
13	Dr. Rallins.
14	MEMBER BREGMAN: Well, let nothing I
15	say be interpreted to mean that I'm not in
16	support of having a single terminology for any
17	given value set. However, I'd like to invite us
18	to move on because, really, we're asked to
19	address what are the major issues around value
20	sets, and I don't think that various
21	terminologies is really deal-killer. I can
22	imagine if we were in Canada and we had two

official languages, no one could really argue that we need to just standardize and only speak one language. You have to live in a world of two languages.

So I would raise the other issues 5 around value sets, speaking practically, which is 6 7 that a single concept for one measure is not equal to the same concept of another measure. 8 9 And that, I think, is not so much the terminology but that is what is the real frustration for most 10 11 providers that are reporting on quality measures, which is that what is defined as a flu vaccine --12 13 and I just pick an example, probably not the best one but a very accessible example -- what is a 14 15 flu vaccine for one measure is not the same as a 16 flu vaccine in another measure.

17 And, therefore, when I administer a 18 flu vaccine, I may count for one, and yet another 19 one, which seems to have the same goal, it 20 doesn't count. And I think that, more than the 21 terminology issue, is really what we should try 22 to tackle: how do we get various measures to use

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the same value sets when, essentially -- the 1 2 initial description by Jason was not so much eliminate variation, eliminate unjustifiable 3 So if it's not justifiable, how do we variation. 4 5 get these in sync? MR. GOLDWATER: Dr. Rallins, do you 6 7 have a comment? I'll save that MEMBER RALLINS: 8 9 comment for later. MR. GOLDWATER: Dr. Schneider? 10 11 MEMBER SCHNEIDER: If you could go back to the little map of how value sets are 12 13 created. When I saw this, I saw this thing called the VSAC, and the very first box says 14 15 anybody can create a value set. And it reminds 16 me of the problems that we have of reports, in terms of my own organization. Anybody could ask 17 18 for a report, and we made every single report. 19 And so the process, if you have sort 20 of an uncontrolled process with multiple different possible standards at the very, very 21 22 beginning, you've got to narrow that down. Ι

mean, there needs to be, I would say and 1 2 probably, the VSAC is the way to do this nationally -- that would be a proposal -- is I 3 want to suggest that I'm going to create a value 4 set that would be a review process against other 5 value sets, a question of, boy, these seem very 6 7 similar. And if you don't pass that stage, it's a box in front of the actual creation, then you 8 9 don't even get to the ability to create a value 10 set. You can do one locally, if you want. 11 12 I mean, you can do whatever you want locally. 13 But you cannot create something without a prior stage that says, yes, this doesn't overlap with 14 15 anything else we're doing and it fits the 16 standards criteria of what we defined as necessary for this sort of thing. 17 18 MR. GOLDWATER: Dr. McClure? 19 MEMBER McCLURE: And so I want to lend 20 some support to Howard's comment about what we do So even though, and I still firmly believe 21 next. 22 I think that for us to accomplish a useful we're

going to have to say something about how good value sets are created, and we've spent a bunch of time talking about the terminologies that might be involved in that.

The issue that Howard gives of 5 consistency in terms of the meaning of an idea 6 7 that is referenced inside of a quality measure is a big issue for implementers, and particularly 8 9 The idea of, you know, if I say for providers. 10 these two quality measures both say there's -- if you've given a flu vaccine, it's important. 11 It might be you're out in one place and in in 12 13 another. But, in fact, the two value sets that are used by those two measures are different. 14

15 There's an issue in terms of 16 harmonization, and I think that's a whole 17 different set of things to discuss from, having 18 created a good value set, you can document that 19 you did create a good value set. I mean, they 20 certainly overlap.

21 So I do think that it's worthy, you 22 know, we have to set aside time for both of these

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things. And, you know, I can imagine a white board where one is for these are issues with regards to harmonization, and these are issues with regards to good quality practice in terms of creating value sets. So we just keep track of those as we go along.

Having been doing this for 30 years,
I know we can auger in in a lot of places, and
choosing terminologies, clearly, is one of those
and it's not a very productive spot to grow
fruit. So I don't know that I would spend much
more time on that.

13 I do want to say one more thing with regards to -- two pieces. One, in terms of the 14 15 VSAC, just to clarify, yes, it's true that anyone 16 could create a value set VSAC is not -- you know, it didn't create that opportunity. That's always 17 18 been true. But what we're talking about is not 19 only creating value sets but using value sets, 20 right? And so the fact that, in part, what this committee, I believe, should be doing is saying 21 22 here are how we identify high-quality value sets.

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The presumption would be that only high-quality value sets would end up being used, even though you may have less high-quality value sets in a So it doesn't require necessarily a change VSAC. in the VSAC. It means documenting how you can identify high-quality value sets and make sure they're used.

And the other thing, just back to this 8 9 issue of how do we identify. So two value sets 10 are named vaccines, or flu vaccines. Just because they're both named flu vaccines doesn't 11 necessarily mean they actually are intended to 12 13 fully encompass what every one of us would say that list of flu vaccines is. And so I think 14 15 part of, as we, again, start to capture 16 information that Committee members are going to bring you with regards to our final product, part 17 18 of what we need to do in the context of 19 harmonization is clarify how we get value set 20 authors and stewards to say exactly what they 21 mean.

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And through that process, we can then

better understand are these to be harmonized or should they actually be different and, therefore, communicate to users, no, the reason that these look different is that they have a purpose to be different.

MR. GOLDWATER: So before I call on 6 7 somebody else, let me just interject for two minutes here. I think that this has been a very 8 9 interesting discussion, and I think the issues that have been raised are fairly consistent with 10 the issues that we have found since we began this 11 project. And I think terminology is a 12 13 significant issue. It has been for a while. Ι mean, this is not anything that's new. 14

15 ICD codes have been consistently used 16 in billing since billing was accepted, and 17 SNOMED, you know, came in as a far more robust 18 clinical vocabulary. But replacing ICD-10 with 19 SNOMED, while perhaps desirable for those of us 20 that are informaticists, may not necessarily be 21 that feasible in the reality.

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I think the issues with value set

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harmonization, terminology is part of it. But I 1 2 think why we didn't want to spend a lot of time on this, although I think having the discussion 3 was interesting and needed, is that we're not 4 going to resolve that today. There's no way that 5 we're, in eight hours, going to resolve 6 7 terminology issues that have been persistent for the last 20 or 30 years. It's a very noble idea, 8 9 and worthwhile of a different discussion, but not 10 something that we're actually going to be able to 11 solve.

I think the issues that have been 12 13 raised, particularly around the ones that Dr. Bregman and Dr. McClure brought up, as well as 14 15 others, is what constitutes a good quality value 16 How do we assess whether that is a good set? quality value set, and how do we get authors and 17 18 stewards to conform to a particular framework to 19 develop a good quality value set that is 20 relatively harmonized with a particular clinical concept so that we do not have these areas of 21 22 unnecessary overlap.

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And I realize that does involve 1 2 terminology to some extent, but I would ask that, I think, while we have those issues in our head, 3 to sort of move forward from that and think we 4 can't solve the terminology issue, although, 5 Chris, I wish we could, trust me. I'm in total 6 7 agreement with you, and I'm not saying that just because I like you. I really do agree with that. 8 9 But I think we need to sort of try to develop 10 some framework around how we can try to harmonize 11 so that we have a pilot process that we can start testing sometime in the next month. 12 13 Before I get to Dr. Rallins and Dr. Lieberman, we do have somebody else that's 14 15 entered the room. So I do have to introduce him, 16 and I would want to anyway. So, Kevin, I hate to put you on the spot, but why don't you introduce 17 18 yourself? 19 DR. LARSEN: Sure. Kevin Larsen from 20 ONC. I think I know most of you, and thank you for doing this. As part of our work in measure 21 22 alignment across HHS, one of the latest things

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we're working on is what's called micro-1 2 alignment. So we've realized, through analysis from things like value and analyses like this, 3 that, even though we've committed to aligning 4 measures, if we all say NQF is 0018, that doesn't 5 necessarily mean that that's the specifications 6 7 we're asking everyone to do in every program and every place. 8

9 So this is kind of our round two of 10 our alignment activities. This is the very start 11 of it, which is to think about where do we align 12 on all the details of measures that are key and 13 important, and how do we figure out what that is?

We're really happy to have NQF doing 14 15 this. This is not trying to solve all the value 16 set problems in the world. It's trying to solve value set problems as they pertain to measures. 17 18 We know that value sets are used for lots of 19 things, but NQF is, very specifically, an expert 20 at measurement. And so we are really hoping to start this pathway, this journey here. And thank 21 22 you all for participating.

MR. GOLDWATER: Thanks. So as I turn 1 2 it now to Dr. Lieberman and then Dr. Rallins, let's try to focus, for the next 30 minutes, 3 until we take our break, you know, on what are 4 your thoughts about what constitute a good value 5 set, how do we assess whether it's a good value 6 7 set? CO-CHAIR LIEBERMAN: Thanks. I just, 8 9 I have, I guess, one last comment on the last 10 part before we move to that. But, I mean, so it 11 seems that for a value set, what we're really starting with is a clinical concept. And it 12 13 should be, I mean, well described with language to start with. And I was just reviewing some 14 15 value sets, and maybe I'm not looking in the 16 right place, but, you know, a concise description of really what you're getting after with trying 17 18 to put together these sets of values would be 19 useful. 20 And then I think we need to kind of move down the line from there to a representation 21 22 of that concept in some codified manner. And

we've discussed, you know, SNOMED would seem to be the best method to do that for a diagnosis. But as the process goes on, you then take that initial description, that initial coded description, and it loses precision as you move down the line. So then we use other types of code sets, like ICD, for that.

But then when you think about the 8 9 clinician and how that information is getting 10 into the system, they're not, they may be 11 choosing an ICD code, they may be choosing some other sort of description that's available in 12 13 their record that allows them to do that. They may be using that as a diagnosis they need to 14 15 attach to a lab test they order, and it might not 16 really be what the patient has that you're So you lose kind of precision all the 17 seeing. 18 way down the line as that information gets into 19 the system.

I mean, I think that's something that can be addressed elsewhere in the process as well, where do you get this information? And I

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know early on in this process, we've talked about -- not this process, but in kind of the eCQM process -- is where do you get diagnosis Should it be just from the problem information? 4 Should it be from encountered diagnoses list? and so on?

7 And I think the idea initially was, well, really it should be the problem list as 8 9 kind of the source of truth for what diagnoses to 10 associate with a patient. But we all know that 11 that doesn't always work well either and that problem lists are problematic for their own 12 13 reasons.

But we have to do the best we can in 14 15 each of those steps. So I think there is some 16 room for improvement at the outset in terms of describing what the concept is that we're trying 17 18 to get after. And we want to keep as much 19 precision throughout the process as possible, and 20 I think there are a couple of, you know, we've touched on the code issue and I think that that's 21 22 something that we potentially could make a

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recommendation around, although maybe perhaps that's better left for another day. But it's kind of a manageable issue, whether we talk about whether it's a similar measure, as opposed to the exact one that we're talking about.

6 But the other issue then is, you know, 7 how do we manage the similar concepts to make 8 sure that we actually want to use, that there is 9 the need for a similar but distinct concept when 10 perhaps the original one would have been good 11 enough. And that's, I think, where we could take 12 this discussion at this point.

MEMBER RALLINS: Jason, I really appreciate your summary. And I do believe that we need to really focus on developing highquality value sets that we can harmonization.

I do think we will have to contemplate
the vocabularies and make this comment in that,
Dr. Lieberman, you mentioned sort of, you know,
looking at the concepts to make sure you
understand the meaning. But as we move towards
the vocabularies, like SNOMED, LOINC, and RXNorm,

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there are other things, other complexities within 1 2 those vocabularies that are creating the challenges that we're having now because you 3 don't get the true detail by just reading this 4 string of a SNOMED code or a LOINC code. 5 And I think that's where the challenge is. 6 7 So while we don't want to get into it, it's kind of in the weeds. I think, at some 8 9 point, this conversation or another, we're going 10 to have to revisit that. 11 MR. GOLDWATER: Ms. Martins? MEMBER MARTINS: So I did want to 12 13 support Rob in his comments about, you know, what is a good-quality value set, how do we create a 14 15 good value set, because that's really fixing the 16 machine. We're preventing further misharmonizations. But we also have to address the 17 18 backlog, right? So I think there's really two 19 discussions that need to happen in order to fix 20 the problem at hand for implementers but, at the same time fix the process. 21

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And in terms of fixing the process, I
really think that, and, actually, even with a 1 2 non-harmonization of value sets that exists right now, the interesting thing about how different 3 measures were developed by different people and 4 the same concept was represented in different 5 ways in the same terminology is really 6 7 illustrative of a lack of a framework, right? Because if we can put some rules around that, 8 9 what a good value set looks like, there's, I quess, a first draft in that in the VSAC with the 10 11 authoring best practices. It's a three-page document and 12 13 probably should be 30 pages, you know. We should build on what's there and really define, and I 14 15 think we need to go into the weeds, as Marjorie 16 said, in the terminology. What are the term types that we should be using for RxNorm? 17 18 Do we include anything that could meet 19 the intent of our concept in the value set, or 20 are we parsimonious in choosing concepts that are, you know, are we just creating noise with a 21 22 huge value set that puts, you drop everything

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that could potentially be used in a system, when you know that perhaps this information is not structured in systems yet, and so you have an opportunity to actually standardize at the point of entry. So that's the sort of guidelines I see around what a good-quality value set would look like.

And then, lastly, everyone is trying 8 9 to reverse-engineer value sets. So implementers 10 have to reverse-engineer value sets to make sense of whatever it is that the value set creator 11 I can tell you that all my value sets 12 meant. 13 have purpose statements in the VSAC that is not accessible by anyone at the implementer level. 14 15 They're there. No one sees them. So there's a 16 problem with accessibility right there. That would be a huge implementer help, I would say. 17

And then as we look at other measure developers' value sets, we also don't have the ability to see how the value set was created, that history. And you mentioned the mappings, the documentation of how that value set came to

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be is important for harmonization because that's where the trust can come from. So we need to stop reverse-engineering value sets and just have all the information necessary to interpret them, both on the developer side and on the implementer side.

MR. GOLDWATER: Dr. Chute?

MEMBER CHUTE: In a rare demonstration 8 9 of being willing to move on, I actually want to 10 second and perhaps reinforce those points that 11 you made on what constitutes a good value set. 12 You're quite correct. Hiding meta data in a 13 place that is not visible to developers and users or worse, even the provenance, and forcing that 14 15 to be reverse-engineered is not acceptable.

16 That begs a question that maybe a 17 micro-education session during this meeting might 18 be apt. And I'm wondering if, Rob, you might 19 lead that. Specifically, what is the information 20 model around a value set this week in VSAC? 21 Specifically, does it, for example, require a 22 fully-specified name? Does it require a human

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language description, preferably English? I'm not sure I want to get into bilingual issues. Does it require a set of relationships to other related value sets as a required field or component of a value set?

I mean, what model does exist? 6 Ι 7 assume it's a derivative of many of the vocabulary value set models. As you know, CTS-2 8 9 is my hobby horse, and favorite pony. But that being said, what does VSAC currently have? 10 And from a context of NQF and designation of future 11 value sets, it might be prudent to have an audit, 12 13 and maybe this is already done, of how complete that information model, how completely populated 14 that information model is for value sets that are 15 16 actually used. And whether that should be a requirement that, you know, value sets will be 17 18 deprecated unless they have fully-populated and 19 validated components of this information model, 20 that's a question to you, Rob. MR. GOLDWATER: Dr. McClure? 21 22 I'm certainly willing MEMBER McCLURE:

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to show the VSAC, and what its parts are, and 1 2 what we have. I can answer with regards to how well populated the value sets are. I mean, many 3 of us are going to raise points that we wish were 4 better in reality, so here's an example of that. 5 I think probably, like all of us, you 6 7 can guess, I'm a great advocate for clarifying what our meaning of the value sets. That's why I 8 9 made the point, and I think it's really critical. 10 I think Howard and every implementer struggles with this. 11 But the VSAC, originally when it was 12 13 created, there's a field and it is, unfortunately, not visible to anyone who isn't an 14 15 author, which is a problem and that needs to be 16 The NLM knows it's a problem and is in solved. the process of solving it. It's called "the 17 18 purpose." I'll take full blame for that name, 19 and I now dislike that name. A better word is 20 "scope," so it describes the scope of this clinical idea that the value set is intending to 21 22 represent.

The value set is a collection of 1 2 concepts that all of which are intended to be considered, and I'm going to put air quotes 3 around this word, equivalent to that idea, right? 4 The idea that -- and if you've got this recorded 5 in your patient's data, then that patient meets 6 7 the criteria, they fall within the scope. So, obviously, the question of what is that scope is 8 9 central to the meaning of the value set and the content of the value set. 10

11 We originally, in the VSAC, made that set of -- there's actually four segments to that 12 13 in order to, as a tool really to help people think through all of the elements that they 14 15 should in creating that. That was originally 16 created as a required field, and because, as a tradition, value sets, the idea of a value set 17 18 had not been, you know, this kind of information wasn't included in value sets. And so as we are 19 20 kind of front-end loading all the material that was necessary to get the eCQMs up, essentially 21 22 none of them have this data and we ran into

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timing issues.

2	And so, right now, a small percentage
3	and small is probably wrong because, to be
4	honest, I actually don't know and, in fact, maybe
5	we do know that now. I think we did do an
6	analysis of this, so Julia
7	DR. SKAPIK: So we've currently been
8	in the process over the last couple of weeks of
9	scouring through to find missing purpose
10	statements of meta data and have it filled in by
11	owners. We're over 50-percent complete, at least
12	through the 2014 content. Of course, you can't
13	see that, as Rob pointed out. And, hopefully,
14	we'll be able to make downloadables available for
15	2015 measure update that includes that meta data.
16	MEMBER McCLURE: So we have 50
17	percent. That's not great, but it's a heck of a
18	lot better than it was six months ago. And so I
19	think, you know, again, and I keep thinking of
20	these virtual white boards where we're going to
21	be capturing this stuff, because even I can't
22	remember all of the things that are going to come

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up in this process, because it's central to what I do.

But I think that this idea of being 3 clear is something that is fundamental to value-4 set creation and is fundamental to value-set 5 harmonization because, otherwise, we have to make 6 7 guesses as to whether, you know, flu vaccine value set A and flu vaccine value set B are, in 8 9 fact, should be harmonized or whether they're 10 different.

And I'll make one last comment, and 11 then I'll turn off my thing, and that is that, 12 13 again, many of us, I think, understand this, but I can't tell you how important it is when you 14 15 really get to the pragmatics of this, and that is 16 looking at value sets outside of their known use, and this is actually at odds with the idea of 17 18 value set harmonization and value set re-use, 19 which is also a great tenet of, I think, a goal, 20 and that is that we want value sets to be re-And I've really --- my thinking on this 21 used. 22 has matured over time, and there are clearly

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value sets that I think are the sort that should be promoted as reusable. There are general value sets.

But there are many value sets, and I 4 don't know what the percentage is, but if I was 5 forced to give a number I would say that the 6 7 reusable value sets is a smaller percentage than the non-reusable value sets. And that so this 8 9 other non, not necessarily forcefully re-used 10 value sets, non-reusable value sets, the point to highlight is that, in order to really understand 11 the scope of that value set, you need to 12 13 understand how it's being used.

And so we try and bring that in in 14 15 terms of expecting authors of value sets to, in 16 some way, describe that in the context of its That doesn't mean that another use can't 17 scope. 18 be identified and that value set could be re-19 But it gets to this point of being very used. 20 clear about, yes, these are all -- again, using this made-up example -- flu vaccines except this 21 22 one because, in fact, a good example is that

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perhaps you want all of the administrable 1 2 vaccines, vaccines that use CVX codes that are actually truly, you can order them and go and 3 give them to a person, versus those vaccine codes 4 that are meant to represent historical records of 5 vaccine use that you can't go and say I'm going 6 7 to order one of these because it's not specific because it's intended to capture a person's 8 9 recollection, which isn't going to be specific. Now, those both look like, you know, 10 value sets that have flu vaccine, but they have 11 very different requirements and you can't 12 13 harmonize them. And so getting to that knowledge is central to doing harmonization work. 14 15 MR. GOLDWATER: So let me sort of 16 summarize, I think, kind of where we are on that third bullet on resolving issues. 17 There seems to 18 be a discussion that there are really two 19 separate pathways here. There's one for 20 implementers of value sets, and then there are ones for developers of value sets, and the --21

Now, without getting into how we're

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going to do this, the issues for resolving, 1 2 thoughts of resolving issues around implementers are accessibility of the value sets, 3 understanding the meta data behind the value 4 sets, the provenance for the value set creation. 5 In terms of development, going back to 6 7 what Dr. McClure was saying, understanding the clear meaning or the clear scope of what the 8 9 value set is being created for and how then to 10 develop the value set to be in alignment of what 11 that scope is. Is that a fairly accurate representation of what we have discussed? 12 Dr. 13 I'm sorry. Ms. Martins? Chute? 14 MEMBER MARTINS: So I -- sorry, I need 15 to bring up my points because I forget. So I 16 think one point that you were making, Rob, that I think is really important is that information 17 18 around a value set is not sufficient. The 19 relationship of value sets needs to be described, 20 as well. And I think that's something that hasn't been done, the tools don't support. 21 22 But as a new value set is developed

and it's clearly not equivalent to a value set that already exists, that needs to be documented, as well, so that, again, people don't have to reverse-engineer these separate value sets and try to figure out what the differences are. Those differences should be illustrated, and this is bigger than any definition around a single value set.

9 And then my second point would be 10 around, for those of you who remember the God-11 forsaken HITSP specifications for the eCQMs, they actually were really good about defining value 12 13 And I wish we hadn't blown that to pieces sets. and started all over again because they had all 14 15 sorts of information around the value sets. They 16 had intentional definitions for the value sets, which goes back to the reverse-engineering. 17 If 18 you have an intentional definition, that's the 19 engineering of the value sets, so you should have 20 a clear picture of what's in and what's out. So I think we should recover some of those concepts 21 22 and some of that thinking that went into the

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HITSP specifications as far as value sets are
 concerned.

MR. GOLDWATER: Dr. Chute? 3 MEMBER CHUTE: Yes, there were many 4 babies that went out with the HITSP bath water, 5 I have a very short question and a very 6 sadly. 7 I heard, to my surprise, that specific one. purpose or scope is a hidden variable. Now, I 8 9 admit naivety about what's actually going on, but 10 is there some intellectual property reason or 11 other reason why we just can't turn that, in fact why we can't turn everything about a value set on 12 13 in terms of having users be able to see it? I'm incredulous. 14 15 DR. SKAPIK: So, Dr. Chute, I will say 16 that, you know, initially, as content was being brought into the VSAC, there were some 17 18 intellectual property sort of general issues 19 surrounding the value sets. I think, over time, 20 a lot of those concerns have been assuaged. And as Rob mentioned, you know, it was an initial 21

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requirement of the VSAC that no value set could

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be published without that meta data, but that had 1 2 to actually be backed out of the system because of limitations on timing and the ability to get 3 the work done in accordance with the publication 4 of the measures. 5 So we're working to re-institute that, 6 7 and I'll let Rob comment on that --I'll let Dr. McClure MR. GOLDWATER: 8 9 interject, and then I'll go to the chairs and 10 then --11 MEMBER McCLURE: So just to Yes. 12 answer that question, so the fact -- again, so 13 authors, those people who are creating value sets and do have access to being able to view the 14 purposes that in the --- for existing value sets 15 16 -- but general users don't. And the simple answer is that, I'll just characterize that as an 17 18 oops. I mean, it just clearly, as your 19 incredulity is noted, as is many others, the 20 development process to get that out and available is high on the development priority list, and it 21 22 just hasn't happened yet.

1MR. GOLDWATER: Dr. Lieberman?2CO-CHAIR LIEBERMAN: Yes, I wanted to3go back to Robert's example about flu vaccines4that are administrable flu vaccines. So,5actually, you know, part of this is my love of6SNOMED, as well, but you could start with your7set of all flu vaccines and then have a subset of8those which are administrable. And it would seer9that if you're actually trying to maintain a set10of codes to manage measurement of flu vaccine and11other things, you would want to go about it that12way.13So you would start with your value set14for all flu vaccinations, and then you could have15a subset or describe a subset for these special16purposes that you have. And that gets into this17question of, you know, what is the best way to18represent a concept within a value set and should	
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18 represent a concept within a value set and should	
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19 it be, you know, SNOMED-based description logic	
20 or something of that nature so that you're as	
21 specific as possible.	
22 And part of that is I don't know quit	
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what the scope of this is, as well. So when we 1 2 talk about what exactly is the purpose, the very specific purpose of a value set, it really is 3 kind of this, I think it's this collection of, we 4 use it as a collection of codes to express a 5 concept, and we start with the concept. 6 And it 7 probably should be limited to that and it's not more than that in terms of thinking about 8 9 measures and measure-authoring tool and 10 developing phrases because we have other tools within the measuring authoring tool and ways of 11 describing concepts using the measure in any 12 13 measurement so that we don't need to kind of overload a value set. But we should be clear in 14 exactly what we expect from a value set. 15 16 MR. GOLDWATER: Zahid? CO-CHAIR BUTT: Yes, so I think the way 17 18 sort of that it appears that the issues for 19 developers are really the same issues that the 20 implementers need to know. It's just that the developers are doing a different thing, whereas 21 22 the implementers are doing a different thing, but

they both have, like, scope and what constitutes the concept, if there's a variation. The implementers are as interested in all of that as the developers are. So it's just that the work they're doing is different, but I think there's really commonality in all of those issues between the two sides.

Dr. Schneider? MR. GOLDWATER: 8 9 MEMBER SCHNEIDER: Yes, for those of 10 you who know me, I've got a manufacturing background and this is a manufacturing process 11 that I see unfolding here. And in manufacturing, 12 13 I once faced a situation where we had made a room full this size with defective pacemakers, and the 14 15 answer that we were pursuing was just make more 16 pacemakers in order to get our production out because we have to do that. And, of course, it 17 18 kept on filling up the room.

So I would suggest that if we know what -- and I think I'm hearing that much good work has gone into what does it take to make a good value set, what are the requirements of

I would say we don't necessarily have to that. 1 2 collect that today, but it ought to be collected quickly, put into a recommendation of this group. 3 And then my other recommendation would be stop 4 the madness, and that is, basically, you must, in 5 order to do a new value set as of today or 6 7 tomorrow, you must follow these regulations. And if you do not, it is not a value set that gets to 8 9 It's draconian, but it's the only way to VSAC. 10 cure a patient of their ills. 11 MR. GOLDWATER: Dr. Bregman? 12 MEMBER BREGMAN: Well, one value we 13 are endorsing or it sounds like we're moving towards endorsing is transparency, which I fully 14 15 agree with. And the second value that I would 16 like to recommend is, essentially, compromise. And I would just play on Dr. 17 18 Schneider's manufacturing analogy, if you talk 19 about two car manufacturers, if Jaguar decides to 20 make a gas cap and Maserati is making a gas cap, it's very natural for them to say, you know what? 21 22 We can design the best gas cap, so we're going to

do it ourselves, and who cares if it fits
 Jaguar's, right?

And I think it's the same basic issue. 3 If you're an expert committee, and I've not 4 served on one, to develop a quality measure, it's 5 very easy to say, well, you know what? 6 This 7 other value set that was created for this other purpose, that's not quite good enough, so we'll 8 9 create ours, which will be 98 percent the same 10 but it will still be ours and it will be 11 perfectly suited for our measure. That's the kind of lack of compromise that I think we need 12 13 to move away from, which is that if you need to introduce some lack of specificity or even, 14 15 potentially, error, although probably I didn't 16 want to go into that word, but, in order to use a value set that already exists because the 17 18 benefit, because the reduced cost is worth the benefit, that should be a value that the measure 19 20 developers should value. MR. GOLDWATER: Dr. Chute and Dr. 21

21 MR. GOLDWATER: Dr. Chute and Dr. 22 Rallins.

I think we all agree MEMBER CHUTE: 1 2 that re-use of preexisting work is important, but I very much like the point that was made about 3 nesting those value sets. And at the risk of 4 becoming ontological, it really is true that most 5 value sets are derivatives or subsets of other 6 7 more global, more generalizable value sets. It's an interesting question of 8 9 whether this committee wants to recommend the 10 relatively academic exercise of requiring that 11 all value sets be specified as either subsets or, you know, what the Venn diagram relationship 12 would be with other value sets. 13 It would have a huge advantage to implementers because then 14 15 there'd be clarity of what the relationships are. 16 It would, however, impose a fairly rigorous and, I might say, challenging but, nevertheless, 17 18 useful step in the development of value sets. 19 So it really is are we after a very 20 robust, reliable, clearly-defined relationships between and among value sets, or is it okay when 21

we think about harmonization to say, well, as

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long as they're grossly overlapping and, you 1 2 know, they sort of adhere to some generalized kind of principle. How rigorous can or should we 3 And I might add my prejudice here is the be? 4 more rigor that we require in value set 5 definition and development, the easier it will be 6 7 for implementers to make sense of all that. MEMBER RALLINS: So I wanted to point 8 9 out that value sets are not developed in 10 isolation, right? So they're developed for a 11 purpose. And usually, right now, the value sets that are in the VSAC were developed to describe 12 13 the data elements that are part of quality 14 measures. 15 And so, you know, we have some overlap 16 because those quality measures themselves, more than likely, were developed in isolation of each 17 18 other. So I think that, you know, that's where 19 we get to the issue of compromise, and I think 20 we'll have to get to an element of tolerance, if that means the same thing, because if you look at 21

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the root cause of why, one of the root causes of

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why they look like they do, that might be
 something to consider.

MR. GOLDWATER: Okay, so, Helen go 3 ahead --- okay, Dr. McClure? 4 MEMBER McCLURE: Okay. So a couple of 5 One, to Chris's point, and this aligns 6 points. 7 with what Marjorie was saying, the value sets, if you look at it in a pointed-headed way, if you 8 9 look at it academically, if you look at it and just say what codes are inside of value sets and 10 11 how do they align with other codes of value sets, there's, without question, lots of overlap. 12 But 13 in considering this, we also need to consider the fact that, even though value sets are at times 14 made in isolation, at times not, measures are 15 16 made in isolation frequently, although with some, I think, eyes looking to other things. 17

And then in doing that, there's an issue of provenance so that, even though there are two value sets that have significant overlap or even complete alignment, there is a political issue -- I'll use that phrase -- of who owns that

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value set, and this is particularly important in the context of value sets that build upon other value sets that we have to consider.

So if I have a value set that has got 4 50 concepts in it, and another value set that is 5 more general, looks at that and says, well, yes, 6 7 those were 50 that were in mine, and I've got these other 25, in order for that second 8 9 organization to say what I'm going to do -- and 10 I'm not going to go through the technical process 11 but basically build upon that first one, take that one, say I'm just adding, I've got another 12 13 set that I'm adding to that first set, they have to trust the steward of the first value set. 14

15 And in considering this issue, we were 16 unsure as to how to create an environment where that trust could be easily identified and agreed 17 18 upon. And so the expectation was that, in fact, 19 while that would be encouraged and we were still 20 working to create an environment to support that, and I think many of the things that this 21 22 committee will arrive at will, I would hope, I

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think, inform how something in the VSAC called VSAC collaboration, the VSAC collaboration tool, will function.

Until we have an environment that 4 makes that process easier, we're going to have to 5 live with the fact that there will, at times, be 6 7 -- I'll air quotes -- justifiable lack of harmonization because of this concern around 8 9 provenance and trustability. So I think we need to live in that world and figure out how our 10 recommendations live in the current world and 11 then suggest solutions that could reduce that 12 13 problem in the future.

And then the second thing I want to 14 15 say again, this ties to this issue about 16 understanding how value sets are used. And that is a part of this, right? So the idea of saying, 17 18 okay, these value sets have, they are close but 19 actually, for documented reasons, differ. And 20 as, you know, as Howard was saying, but in the real application of this, so we deal with this a 21 lot, I think, throughout how the process of 22

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building value sets, low-loan harmonizing value 1 2 sets, how important is it in the context of a quality measure -- what are quality measures used 3 to do, right? And in terms of identifying 4 evidence of quality. In the real process of 5 actually doing clinical care and then documenting 6 7 clinical care and then doing data analysis on documented clinical quality care, is the nuanced 8 9 difference between these codes important? And you can't do good -- this is 10 really not so -- it is important in the context 11 of creating value sets, but I believe it's much 12 13 more important in the context of harmonizing value sets. How does this committee provide 14 15 guidance so that measure developers can really 16 assess that in a protected way so that they can communicate to their stakeholders that this is 17 18 good enough? 19 MR. GOLDWATER: Helen? 20 DR. BURSTIN: Yes, thanks. This is a great discussion. 21 In some ways, it's very 22 reminiscent of the conversations we have about

harmonizing measures. Really, this is not any 1 2 different. Replace measure with the word value And I think --- perhaps I've just been 3 set. doing this for too long, but I think part of my 4 concern is we should not be repeating the issues 5 we have with the other data sources with 6 7 eMeasures since they are our data source of the future. And if there are opportunities for us to 8 9 kind of push ahead and be bolder, even if it's on 10 a time line, I think we do need to get to the 11 exact vision, exactly what you said, Chris: robust, reliable, clearly-defined relationship 12 13 among value sets.

If we can't do that, we cannot 14 15 harmonize measures anymore. It doesn't make 16 sense to have different definitions in these value sets for the different eMeasures because 17 18 they are not, in fact, harmonized. And if we 19 look at the secretary's announcement of just a 20 couple of months ago or a month ago, the idea of moving towards value, looking across episodes, 21 22 moving away from measurement that is, in fact,

setting level of analysis, and clinician-based is really changing.

3 So you're going to have measures that, 4 in fact, have to work for the clinician, the 5 hospital, the nursing home across a patient-6 focused episode. CHF has to be CHF. It doesn't 7 make sense anymore to have a different lens.

And I totally understand how this grew 8 9 up, Marjorie. It makes perfect sense for how it emerged through MU if this is the measure we're 10 developing for this clinician set. But going 11 forward, this is supposed to be about us going 12 13 So I would hope you really do embrace forward. the ideas of being bold, even if there's a time 14 15 line attached to it. We cannot harmonize 16 measures unless we can, in fact, get these building blocks harmonized. 17

MR. GOLDWATER: Ms. Smith?

MEMBER SMITH: I just wanted to add to
what Rob said. It's not just trust between
measure developers. It's also very real timing.
If I base my value set on his and mine needs to

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be updated for meaningful use and his does not, 1 2 then I need to know that his is going to be updated when I need it to be updated so that I 3 can use it. 4 5

MR. GOLDWATER: Dr. Che?

So we, as human beings, MEMBER CHE: 6 7 have this tendency to figure out other part of thought process. So that's, you know, between 8 9 the measure developer and the user. As a user, 10 you're trying to figure out how the author 11 developed -- I mean, what's the thought process in there? 12

13 So I think, you know, the meta data, you know, the purpose and scope, inclusion and 14 15 exclusion, will help to define what you're trying 16 to represent in that concept. But also a lot of times, people will think, you know, for the same 17 18 diagnosis, we will have maybe this code, but it's 19 not included in your original value set, so I'd like to have that code, or this code you define 20 in your value set, I never used in my clinical 21 22 setting, so this is useless.

So maybe, sometimes, I'm not sure it's 1 2 a good idea to capture, you know, that frequency at a code level when you define a value set. 3 You know, then people can evaluate, you know, why you 4 use this code for a diagnosis or why you include 5 the doses of the medication in your value set 6 7 because you know this is only applicable to just the, you know, the children, you know, or vice 8 9 So maybe, you know, at a code level, the versa. 10 capture is necessary. 11 MR. GOLDWATER: Matt? 12 MEMBER HUMPHREY: I just wanted to 13 play devil's advocate a little bit because there have been some comments about getting close 14 15 I guess the goal, especially in the enough. 16 realm of the clinical quality measures, is to have a machine-readable electronic consumable 17 18 measure. And in that sense, I don't care how the 19 implementers feel or are able to consume these 20 value sets if a machine is doing it for them. A value set in the clinical quality 21 22 measure realm serves one purpose in my mind, and

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1	that is a logical ore, so the only reason we use
2	it is because we don't want to build a measure
3	that says this code or this code or this code.
4	It's just a grouper.
5	And so if we value getting the measure
6	logic exactly correct, we should probably value
7	getting the value set content exactly correct, as
8	well. So just to urge caution in getting close
9	enough.
10	MR. GOLDWATER: Ms. Martins?
11	CO-CHAIR LIEBERMAN: So first, along
12	that, for that comment, I mean, you say you don't
13	care how the implementer brings it in.
14	Unfortunately, even a machine-readable measure
15	will likely require some manual mapping when it
16	comes into play. I mean, just with my experience
17	with them, there's always that last step of
18	mapping whatever the terminology is used for the
19	measure to the codes that are used in your
20	system. And so there is, there is some issues at
21	that point with trying to maintain the precision
22	of the measure, as well.

But the other comment I wanted to make 1 2 is when we talk about trying to get measure developers to harmonize measures, you know, we 3 have to think about what are their incentives to 4 We know that there's a lot of incentives 5 do so? We've heard about what those are, about, 6 not to. 7 you know, wanting the timeliness of the measure, having it being exactly like you like it; and we 8 9 can think about incentives, one of them being, 10 well, we won't accept your measure unless it's harmonized, but we should think about what else 11 12 can we do to make it more palatable for people to 13 harmonize them.

And along those lines, you know, is 14 15 there another entity that can take over some of 16 the work of maintaining that value set? I don't know if that's within VSAC's realm or not. 17 But 18 for a certain set of these value sets, the ones 19 that are commonly used, CHF, diabetes, and so on, 20 again, it doesn't really make sense for lots of different people trying to maintain those over 21 22 time when we are really, most of us are all after

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the same concept.

2 So is that enough of an incentive if you say, if you use this value set, you know, you 3 aren't on the hook to maintain it and that will 4 be maintained by some organization, which I think 5 is part of what we're here tasked to decide what 6 7 that organization might look like. And along those lines, you come up with, for value sets, 8 9 can there be different levels of value sets? So, 10 you know, these are the preferred set, these are level one value sets that will be maintained by 11 12 this third party. And then are there level two 13 value sets which we understand that, you know, this is still a good value set that has its need 14 15 to be somewhat different from the level one and 16 then level three value sets and so on? And when 17 it comes time to measure acceptance, we then look and say, well, you know, if you've used value 18 19 levels one and level two, that's acceptable. If 20 there's level three, you need to, you know, provide some reason for that and so on. 21 So you 22 can kind of begin to see a system where it's not

cut and dry where there are good or bad value 1 2 sets but varying levels of value sets that can be used and benefits to using the ones that are the 3 more accepted level. 4 MR. GOLDWATER: Okay. Ms. Martins and 5 then Julia. 6 7 MEMBER MARTINS: So along the lines of Howard's comment in terms of compromise and 8 9 Marjorie and Matt's comments in terms of the 10 compromise that is needed for harmonizing value 11 sets, I agree we need to weigh in the costbenefit of creating a new value set that isn't 12 13 quite right but maybe it's good enough. But I think that it can't be -- we need to assess the 14 15 value of the value set that exists. So just 16 because a value set exists it shouldn't be default, there shouldn't be a default assumption 17 18 that it is the best value set that should be 19 used. And I think there's a really clear 20 criterion to decide that. Is it evidence-based? Is it helpful in quality improvement? 21 Is it 22 meaningful for the users who are capturing the

And I think these are other criteria, data? 1 2 other values that should be assessed when determining whether something should be 3 harmonized, whether an existing value set should 4 be replaced with another one. And some of these 5 value sets really do require a very broad input 6 7 into what they should look like. If we're talking about level one value 8 9 sets that are perhaps reusable across various 10 settings with a large number of users, a large 11 number of re-use potential, those are the value sets that are probably, getting them right makes 12 13 So that was my first comment. sense. Then I also wanted to ask the group 14 15 because we're talking about value set 16 harmonization within the context of eCQMs, but that's not everything that implementers need to 17 18 deal with. They have to deal with CDA reports 19 that use value sets that are not only different 20 but sometimes conflicting with eCOM value sets. So how do we figure that out? So I just wanted 21 22 to throw that out there.

And then to Anne's point and also 1 2 Mike's point in terms of the incentive for harmonization, I'm going back to tools. 3 Right now, it's just there's no tracking whatsoever 4 who's using what value set, who's dependent on 5 whom to update a value set and when. 6 So we need 7 to be able, I need to be able to see who's using my value set so that I can reach out to these 8 9 people and say, well, here's what I intend to do 10 with it, is it going to break your measure, 11 something along those lines. So, again, tooling, I think, is going 12 13 to be critical for this whole process to work. DR. SKAPIK: 14 Those are some great 15 points. One thing I want to point out to both 16 Helen's point and to Rute's point is that there's a legacy issue involved with value set 17 18 harmonization here. In my mind, the reason we 19 have to do this project is not because, 20 hopefully, we'll need to do major harmonization efforts over and over moving forward but, rather, 21 22 that, because originally users in the measure

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authoring tool couldn't see other value sets at all, they naturally have to create their own value sets, and so there are many different similar value sets created by necessity in order to specify the measures.

And, here, I like the idea that has 6 7 been brought up by Rute and Helen which is that we come up with these sort of not necessarily 8 9 formally-endorsable but these high-value, high-10 quality, reusable concepts. There have been a number of different groups, including a group of 11 implementers, who suggested there should be a 12 13 menu of these high-quality items and that measure developers should be required or encouraged to 14 15 select only from that set unless they can justify 16 why they need to create new content that's separate from that and that there be a process 17 18 for the community to endorse and provide feedback on the creation of new content so that 19 20 implementers in the field would have sort of a complete set of content they could expect and 21 22 would express almost any concept needed in the

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current programs.

So I would be very interested to hear feedback from this group on that approach and how one might execute it.

MR. GOLDWATER: Dr. Heras?

Yes, I just wanted to MEMBER HERAS: 6 7 comment on the process of developing value sets. So a lot of the --- currently the VSAC right now 8 9 is so much better than a couple of years ago but 10 right now only captured the appropriate So a lot of the development work is 11 statement. still outside of the VSAC. Just here on this 12 13 2014 eMeasure annual update, just so much work is outside, you know, it's captured in spreadsheet, 14 15 a lot of repetitive work. So, for example, if I 16 go there to review a value set, I don't know, you 17 know, what will stand. And people, when they 18 took the spreadsheet, want to go back to review 19 again, oh, they have to re-do it again.

20 So just all these details, you know, 21 you would see comments captured on spreadsheet 22 what this code is not, you know, it should be

removed. But all those details are just not captured anywhere.

So I think, in the future, if we could 3 somehow, you know, if we have the tooling to 4 support that, that would be wonderful. But if we 5 can't get there that quickly, maybe somehow we 6 7 can capture that and just have a formal process to possess that, you know, commenting. And when 8 9 I first put the value set together, you know, how 10 these codes are selected, why. And sometimes they see people, you know, like if it's a 11 finding, but they put a codifier as no code. 12 So 13 for that level of detail, you know, we have structured, you know, guidance how to do that and 14 15 capture the flow so we don't repeat the QA 16 process and also more people can comment on in the future. 17

So that's one part. And also the other side is I'm actually really interested to see -- if we could do this, that would be great -- is now we have measures actually being submitted to CMS, so if we could take a couple of

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measures to see exactly what data has been, you 1 2 know, sent and exactly what codes people have been sent for that particular measures, we can 3 actually see how the data, you know, just from 4 the, you know, first hand to see how the quality 5 of the data and whether the value sets are 6 7 different and also, especially, if people pick SNOMED code versus ICD-9 code versus ICD-10, do 8 9 they make any difference in the performance rate? 10 So I'm just always curious to see 11 exactly the impact when we define value sets, sometimes we just pick a code but exactly what 12 13 the impact is, you know, to the real measure. MR. GOLDWATER: Matt and then Zahid. 14 15 Zahid? 16 CO-CHAIR BUTT: Yes, just in terms of, I know we talked about how does or what is the 17 18 best way to represent a clinical concept through 19 a value set. Perhaps a framework might be that 20 concept needs to be defined either at an the individual value set level, which means that it's 21 22 a single terminology involved, or at the grouping

level where multiple terminologies might be in 1 2 place. So perhaps a framework to define whether you are attempting to define the concept either 3 at the group level or at the individual value set 4 level may be something to consider. 5 So Ms. Martins and MR. GOLDWATER: 6 7 then I'll summarize and we can take a short break. 8 9 MEMBER MARTINS: I just wanted to say 10 that I completely second Yan's idea of seeing the We've been working on this for three or 11 data. 12 four years now. We don't have any data. This is 13 ridiculous to some extent, but I'd like to see that information fed back into the VSAC à la 14 15 LOINC where you know how the codes are being used 16 and ranked according to their frequency of use. And I'd like to see that for my value sets and 17 18 see, oh, maybe I can just get rid of some of 19 these values here. That would feed into the 20 maintenance process. And, actually, that's a comment I 21 22 wanted to make on the slides where there's the

value set life cycle. It really doesn't end when 1 2 it's published. It never ends, and the maintenance piece cannot be underestimated 3 because it is very significant. 4 DR. SKAPIK: And I'll just say NLM is 5 very interested in having that information. 6 7 They're not clear what the best way of capturing it is, so suggestions from the group would be 8 9 also helpful. 10 MR. GOLDWATER: All right. So Dr. 11 Chute, Dr. McClure, quickly. MEMBER CHUTE: A brief zinger before 12 13 the break. I hope we all realize that value sets as a way of characterizing a clinical concept 14 15 are, in fact, a very poor surrogate. If we want 16 to get really pointy-headed about this, the fashionable phrase is high throughput clinical 17 18 phenotyping, and it typically involves a series 19 of algorithms that, oh, by the way, invoke value 20 But there's a whole lot of logic. sets. If you want to find your pool of diabetics, you look at 21 22 drug utilization, you look at laboratory results,

you look at diagnostic codes, you look at 1 2 procedures, and you look at permutations, multiple permutations of all of those puppies. 3 So I hope we realize that when we're 4 talking about value sets, we're still talking 5 about a very poor cousin to the actual goal of 6 7 what we're trying to achieve. Now, for quality metrics, it may be satisfactory. But I think we 8 9 have to understand that, as soon as we dip our 10 toes in the grand unified world of clinical 11 application versus quality application, that what we use for quality may not pass in a clinical 12 13 decision support environment. MR. GOLDWATER: Dr. McClure? 14 15 MEMBER McCLURE: Actually, I'm going 16 to comment on that, and then I'll say what I was 17 going to say, and that is I agree with you, 18 Chris, but I would actually characterize that as 19 just, you know, complex logic in the context of 20 still using value sets. Certainly, there are value sets that become smaller and smaller in 21 22 terms of their targeted set of expectations

within the data. But you are very much on track 1 2 to this issue of, I think everybody understands the question is how is the Committee going to 3 accomplish this with regards to understanding 4 that value sets, evaluated in isolation, is 5 I mean, we have to think in the context 6 useless. 7 of how you create a good value set, particularly how you harmonize. When you look at it and you 8 9 say, well, these could be harmonized, but, in 10 fact, one group was ignoring the fact that there's these various issues going on and another 11 group understood it, and so they were more 12 13 discrete in their logic, whereas these aren't. And so we can't harmonize these 14 because really what needs to be harmonized is the 15 16 model of the quality measure. And then the value set will fall out. 17 18 So we would really be remiss if we 19 don't tackle this larger problem without somehow 20 getting stuck in the mud of trying to actually do measure harmonization and not just -- so that's 21

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But the second thing, I just wanted to 1 2 highlight something because it's something I've thought a lot about and we've mentioned it and 3 it's really important, and that is there are many 4 ways to characterize value sets, but, in the 5 context of our use, there really are two. 6 One of 7 them I think predominates, and we pretend it's the other. And those two things are there are 8 9 value sets that the measure developer is saying I 10 think that -- I'm guessing people don't really capture this, I'll use the word in code. 11 We don't really capture this, and so I'm giving 12 13 guidance about the fact that I want this captured, this is an important piece of 14 15 information. Maybe you capture it sometimes but 16 not all the times, and so I'm communicating to you through the series of concepts and, quite 17 18 honestly, through the measure that this is the 19 kind of information that you're expected to do. 20 Now, I don't know if we were asked what percentage the measure developers really 21 22 honestly would say that that's going on. But

given the kind of implementation issues that we 1 2 hear occur all the time, the fact is that's a gigantic percentage of what's happening. 3 The other is I'm confident these 4 things are captured, and I need to make sure that 5 I've got the entire scope of concepts that are 6 7 captured, are in my value set. In essence, I'm telling the implementer, hey, don't worry, I've 8 9 got it in here, so if you're capturing it you 10 don't have to worry about taking something that's detailed in the context of clinical care and kind 11

12 of walking up the hierarchy or mapping it to 13 something else that I actually have because I 14 know you're capturing it and, i.e., the ICD 15 situations.

16 That first piece, though, if we create 17 value sets with the same mind set for both of 18 those situations, we create havoc. And in 19 particular, when you're communicating to folks 20 here's the set of concepts that -- or here's the 21 thing that I want you to capture, particularly in 22 the context of what's really going on, i.e. if

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they are already capturing it and it's in their local environment, then they're going to have to do mapping.

And so I'll take this to the logical 4 and somewhat improper end point. You could put 5 one concept in that value set and say map 6 7 everything to this. Now, that's obviously not a great solution because then you're not 8 9 communicating probably sufficient to do good Because, again, part of the 10 mapping, right? whole issue around value sets that we have to 11 embrace and that we've been pretending doesn't 12 13 happen is mapping. And the fidelity of mapping, it's kind of important. 14

15 Anyway, what I'm trying to communicate 16 is that I think it is actually important to separate out the constructs about particular 17 18 value sets in harmonization and also in creating 19 when what you're doing is communicating to say, 20 hey, in the past you might have captured this, you might not, there might be a few things, 21 22 here's what we want you to encode. And in those

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cases, do we want to give a value set of 5,000 1 2 concepts versus those places where we're confident there's capture and reliable high-3 fidelity mappings already in place with regards 4 to the code system that we're going to use in our 5 value set and, particularly when you've got big 6 7 things, say, okay, these are the 5,000 that I know are out there and all of them are equivalent 8 9 Those are very different in my context. 10 situations, and if we pretend they're the same we 11 create havoc downstream I think. 12 MR. GOLDWATER: Okay. Zahid, the last 13 word, and then I'll summarize. CO-CHAIR BUTT: Yes. So I think it 14 15 sort of is along the lines that Rob just said. 16 In terms of what values get used in terms of implementation or what data gets captured, again, 17 18 depends upon the use case. So for example, you 19 could have a very long value set of RxNorm codes 20 in the implementation process. That really doesn't change whether that's a short list or 21 22 long list because the pharmacy system would have

the entire thing of RxNorm in there. The issue there is does the value set contain a medication that's not in the system or if there's a new medication.

5 But when it comes to any kind of value 6 set that's used for a pick list of some sort that 7 a clinician has to, that needs to be, again, very 8 --- sort of parsimonious, and often people will 9 take a long list and they'll shorten it and just 10 implement 5 of the 50 that are in there, and so 11 that's what they'll capture.

12 And so it kind of depends upon the use 13 case in terms of what gets captured and how it 14 gets implemented.

15 MR. GOLDWATER: Okav. So with that, 16 I think we're going to take a 15-minute break. When we come back, I'll run you all through some 17 18 of the pre-work analysis that we did because I 19 think it is highlighting a number of these issues 20 that we've talked about. And then what we would like to get into then is sort of categorizing 21 22 these issues and start developing potential

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mechanisms of resolving them. And then after 1 2 lunch, we'll start developing a more formalized process that we can then start testing. 3 So thank you. This has been a great 4 discussion. It's everything we thought it was 5 going to be and more. So thank you all very 6 7 much. (Whereupon, the above-entitled matter 8 9 went off the record at 10:49 a.m. resumed at 10 11:10 a.m.) 11 MR. GOLDWATER: Okay. So, let's 12 reconvene. Thank you for those that have. 13 Dr. Schneider, are you a basketball fan? 14 15 MEMBER SCHNEIDER: College. 16 MR. GOLDWATER: College, oh. I was going to say, well you know, the Mavericks and 17 18 Rockets are playing tonight, let's --19 MEMBER SCHNEIDER: Oh, well, secondary 20 matters. MR. GOLDWATER: We should interface. 21 22 Like I say, I'm from Dallas originally, which is

the only reason why I have an interest. 1 2 All right. So what we're going to do at least for the first 15 parts -- minutes of 3 this -- second half of this discussion is, I want 4 to go over some of the pre-work analysis that we 5 did for ONC prior to this meeting. 6 7 And I want to make this disclaimer. Ann, Katie and I all worked on this together. 8 We 9 are not physicians. We do not claim to be 10 physicians. We do not play physicians on TV. And we did not make any sort of 11 deductions based on our lack of clinical 12 13 expertise. We simply looked at concepts that look similar that were represented in two 14 15 different ways, and pointed those out. 16 So, --17 CO-CHAIRMAN BUTT: And many of us are becoming like you guys. 18 19 (Off mic comments) 20 MR. GOLDWATER: I'll take it as a compliment. So, what we want to do is go through 21 22 what the analysis that we did. Because I think

some of it does align with some of the 1 2 discussion. Get your feedback on that pre-work 3 And then again, start delving into how analysis. 4 we sort of tune, finely tune some of these areas 5 of harmonization that have been discussed. 6 7 So, we took on some pre-work analysis 40NC and the basis for this was a paper developed 8 9 by Wittenberg and Bodenreider. Which we used 10 sort of as the core methodology rather than 11 devising one ourselves, we used one that had already been published. 12 13 Which looked for assessment for completeness and correctness in value sets. 14 And 15 looked for opportunities for harmonization by 16 eliminating redundancies in groups of like-minded value sets. 17

The measures that we used -- we used the meaningful use two measures. We first started by asking Kevin and Julia, who were very gracious and used their staff to provide data back to us on the most frequently reported

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meaningful use measures, thinking that would be a 2 good starting point.

That we would look at those that had 3 been reported the most, and see if there was any 4 sort of variance or deviations or overlaps. 5 And we didn't find anything initially in the most 6 7 frequently reported.

So, we just kept working our way down 8 9 -- until eventually we got to five measures divided between eligible provider and eligible 10 11 hospital measures that we used as the basis for 12 analysis.

13 And we took the overall value set and the OID that was associated with that. And then 14 15 from that parent value set, when we delve into 16 the subvalue sets to see what level of overlap there may have been. 17

18 We compared the codes and content in 19 the same topic measures. We did this manually, 20 which I would not recommend doing with some -with value sets that extended into the -- yes, 21 22 like beyond the capabilities of Excel, then you

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certainly know how many you have. 1 2 And the method for comparing the similarity and diversity, we used a Jaccard 3 Index. Which again goes back to the Wittenberg 4 and Bodenreider analysis as that's what they 5 used. Next slide. 6 7 So, our eligible professional measures using the Jaccard Index, one of the measures we 8 9 used was depression. Depression screening after 10 nine months. And we looked at two value sets. 11 The Jaccard threshold was .49 and above. Anything 12 that fell below .49 we did not include. 13 And also, at the request of ONC, CMS 14 15 and NLM, we only looked at terminologies that 16 were SNOMED, LOINC, RxNorm and CPT. We did not look at ICDs at all. 17 18 We did however note whether there was 19 some overlap between the SNOMED codes and the 20 ICDs that we looked at. But we did not delve into that analysis. 21 You can see some of the value sets 22

that we found with one measure as opposed to another. And the types of measures that we were looking at.

And again, without being a clinician, we found a value set for depression diagnosis and then another value set for major depression including remission. We found depression screening denominator and counter codes new and then a BMI and encounter code set where there was a correlation.

And then even towards the bottom of 11 this, we found a value set for bipolar disorder. 12 13 And then another one for bipolar diagnosis. The high Jaccard indicates that there was high 14 15 overlap in the subvalue sets that were associated 16 with each of these parent value sets. Next slide. 17

Some of the other ones that we found, which I personally found interesting not knowing what the differences were with these. We found some subvalue sets that looked at like recurrent depression which is characterized as a disorder.

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And then recurrent major depression as 1 2 a disorder. And I'm not sure what the difference is between those two. Or chronic depression or 3 chronic recurrent major depressive order. 4 Or major depression and partial remission or 5 recurrent major depression and partial remission. 6 7 Again, these had Jaccard Indexes that were high enough indicating that there was 8 9 overlap between these two. And again, it gets back to the issue of is this acceptable degrees 10 11 of overlap, or is this redundancy that needs to be harmonized. Next slide. 12 13 We looked at a manual comparison of eligible hospital measures. Ann Phillips took 14 15 the yeoman's task of doing the stroke and BTE 16 measures, which have thousands upon thousands upon thousands of value sets. 17 18 So, we both thought there has to be an 19 automated way of doing this, which we will be 20 investigating at some point in time. And these are the measures that she 21 22 found where there was significant degrees of

overlap, at least .49 and above. Because there's 1 2 so many value sets, we did not break this down. Otherwise, we would be here for a couple of hours 3 and not having a discussion. 4 But you can see in some of the stroke 5 measures, particularly those that dealt with 6 7 therapy and medications, there was significant degrees of overlap. Next slide. 8 9 So we examined all the value sets 10 associated with these measures. Again, dealing with AMI and stroke. 11 And these two particular value sets, 12 13 both of which the Joint Commission is the steward, were entirely identical. 14 There were no 15 unique codes amongst them. They were exactly 16 alike. And used throughout the measures that are listed. Next slide. 17 18 With these five OIDs, so these five 19 parent value sets, again, most of these were done 20 by the Joint Commission, except one was developed by Lantana. And again, in measures that were AMI 21 22 and stroke based, we found some interesting

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observations.

2	Is anticoagulant therapy complete?
3	Can it be harmonized with perinatal
4	anticoagulant? We found antithrombolytic therapy
5	was missing in may aspirin products that were
6	found in the aspirin value set.
7	And we found another injectable factor
8	prophylaxis was missing. The same type drugs
9	found in the perinatal anticoagulant. So
10	parental, sorry.
11	See, I'm not a physician, Kevin. I
12	don't even know how to pronounce the words.
13	So, in some cases we would find a
14	complete value set of drugs. And in another
15	value set we would find none of them at all.
16	Even though they were dealing with the same
17	condition.
18	Which again sort of goes back to,
19	what's the scope? What's the intent? And then,
20	there was no way of tracing them other than we
21	know the Joint Commission was the steward.
22	There was no way of sort of tracing it

back to how was this created? What data was 1 2 used? And so forth. Next slide. And then you can actually see in one 3 value set for antithrombolytic therapy, there was 4 a list of medications. And in another one for 5 aspirin, there was a list of medications. 6 7 And in one of those value sets, some of them are completely missing. They're not 8 9 there. Go ahead. 10 11 I will say that you are MS. PHILLIPS: looking at probably an eighth. Maybe less then 12 13 an eighth of the entire spreadsheet for this, that I put together between three or four 14 15 different drugs. That it had some overlap and a 16 lot missing. 17 MR. GOLDWATER: So, and again, no way 18 to go back and trace this. And no way to understand how this was developed initially and 19 20 what refinements had or have not been made. Next slide. 21 22 Again, identifying five other value

sets and the measures that they are associated 1 2 with. Again, with AMI, stroke and BTE being the ones that were examined. 3 Statin specific, value set list of 4 medication names, but didn't have any dosages. 5 Antithrombytic specific, was duplicative with 6 7 antithrombytic therapy. But dosage information was not in the specific measure. 8 9 Antithrombytic specific and 10 anticoagulant specific were almost entirely duplicative. Warfarin did not include any dosage 11 information. 12 13 And the other one, which I'm not going to pronounce, was missing the same ingredient 14 15 drugs. Although other measures similar to that, 16 had that formulation. Next slide. 17 Okay. We're --18 (Laughter) 19 MR. GOLDWATER: I am unbelievably 20 efficient. I know, yes. Right. So, I think in summary, I think you 21 can see, I hope, that we got some of this right. 22

Some of the very issues that were being brought 1 2 about, which were, again, what is the scope of the measure? 3 And then what are the scope of the 4 value sets that have to constitute that measure? 5 Are the value sets sort of adequately, as best as 6 7 possible, representing the clinical intent of those particular measures? 8 9 How do we get to the provenance of how these value sets were created? And understand 10 sort of their different variations and versions? 11 12 Because clearly, these are measures 13 that have been around for a while. We did not get with measures that are just started. 14 15 Those of you that have been NQM 16 understand VTE, stroke, AMI have been around since I was starting to work in this area 20 17 18 years ago. So, these are not new. 19 So, there are certainly, what changes 20 or variations have been made in the value sets as they have evolved. And then sort of getting back 21 22 to understanding what these value sets are, how

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then do we sort of come up with a clear 1 2 consistent value set that has all the correct information? 3 How do we evaluate that? And then 4 what direction do we give to indicate this is how 5 it should be constructed in a way so that we 6 7 don't find these things again as we're moving forward. 8 9 And so I think where I want to start with the discussion is, I think it gets back to 10 11 Dr. McClure's point, how then do we sort of understand mapping the scope of a measure to its 12 13 value set? And how do we measure the scope of a 14 value set? Kevin? 15 16 DR. LARSEN: Yes, just a little bit of framing. And I'm sorry I wasn't here at the 17 18 beginning. So this isn't a way to point any 19 fingers at anybody. 20 You know, we are uncovering things that were created. And there are lots of reasons 21 22 why things are the way they are. So, it's also,

this is an -- the intention here is to be a pilot
by example.

3 So, we also think or probably think 4 that we're not going to be able to go through, 5 you know, 15,000 value sets to this level of 6 detail. And there just is, you know, no way a 7 committee like this can do that.

But we're hoping by sort of raising 8 9 some examples up and having a discussion that we can continue to evolve and inform how this 10 11 process could look. And how it lines up to an overall measurement strategy and an overall kind 12 13 of NQF set of processes of evaluating which kinds of measures are of high value and which kinds of 14 measures need more work. 15

MR. GOLDWATER: Zahid?

17 CO-CHAIRMAN BUTT: So I think in terms 18 of sort of the process that we need to go 19 through, you've got two specific, I think, use 20 cases. One is that you have all these existing 21 value sets out there that we know are 22 duplicative.

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In some cases they have errors in 1 2 them. And so there's a specific goal to try to find a way in how do you take care of the legacy 3 issue. 4 And the other is that, you know, if 5 there are new measures and new value sets, what's 6 7 the entry point for that? Now there's an overlap. Obviously the same -- hopefully the 8 9 same process will inform both situations. 10 But the entry point is somewhat 11 different. And so, that's sort of the scope in 12 the sense of it. 13 MR. GOLDWATER: Dr. Chute? MEMBER CHUTE: Rute had mentioned in 14 15 the earlier session the HITSP work on intentional 16 value sets. And Marjorie actually was in -- and I and Rute were chatting about it during the 17 18 break. 19 But these examples are really 20 characterizations of what I would call drug classes. And efforts, arguably imperfect efforts 21 22 to enumerate what elements, what RxNorm drugs or

whatever, actually belong to a member of that particular drug class.

In the context of measure development, 3 it seems perhaps desirable to entertain that 4 measure authors might perhaps specify the drug 5 class, rather than try to make up their own darn 6 7 value set. And at a very authoritative forum, which was Don Lindberg's retirement party last 8 9 week, I was chatting with Olivier Bodenreider on 10 this very point.

And I said to Olivier, you know, gosh, are you guys going to deliver drug classes that we can rely upon? Because one of the big problems with drug classes is that they were in NDF-RT and other environments.

Well, I could prattle on. Suffice it to say that RxNorm now has, according to Olivier, specified a more robust characterization of drug classes. And where it fails to be sufficiently robust, obviously NLM is welcome to input. The point being, why are we going through this whole value set exercise ourselves?

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When lots of other organizations and presumably 1 2 highly authoritative and designated organizations like NLM, in the case of drug class 3 specification, are investing considerable 4 5 resources and expertise to engage in that process for us. 6 7 So, first Chris, you MR. GOLDWATER: must be a blast at parties if that's what you're 8 9 talking about. 10 (Laughter) 11 MR. GOLDWATER: And so Dr. Che? So I just want to comment 12 MEMBER CHE: 13 on these efforts. So, we have done something similar about two years ago on the medicine 14 15 harmonization. 16 So I want to say, it doesn't have to be the manual effort. That we have developed a 17 18 tool where you can scan at a code level between 19 any sets of the value sets. 20 So, that's, you know, has been done. So, in terms of the result, we brought this kind 21 22 of similar kind of comparison to the value set

steward of developers. And we want to ask them, 1 2 what's your reasoning? First of all, are you aware of these, 3 you know, duplications? And what was your 4 reasoning if you want to stay with the way, you 5 know, your value set is now. I mean, you have to 6 7 provide some justification. So a lot of times they can provide the 8 9 justification. So, I think you know, that could 10 be some of the process, you know, we can go 11 through. You know, you have to look at each individual set of values that you determine why 12 13 you want to, you know, treat that way. And you can also capture that original 14 15 thought. And you know, provide it to the user. 16 And the user likes to know that as well. MR. GOLDWATER: Ms. Martins? 17 18 MEMBER MARTINS: So my babies are on 19 display. And they're horrible. I mean, no, no, 20 I just --(Laughter) 21 22 So, this is very MEMBER MARTINS:

interesting because the analysis was done with no 1 2 prior knowledge of what had gone into this. So the results are actually quite interesting. 3 It goes back to the lack of 4 documentation around how value sets are made. 5 For instance, the value sets that was name end 6 7 with specific are actually value sets that were only include ingredients for RxNorm. And they 8 9 were created to solve an implementation problem. 10 So, you know, --11 MEMBER MARTIN: Well they are -- now they're mine. 12 13 (Simultaneous speaking) 14 MEMBER MARTIN: Oh, no. 15 DR. BURSTIN: We get a transcript of 16 this meeting --17 (Laughter) 18 MEMBER MARTIN: Warfarin is actually 19 my bigger baby. But, so it does go back to the 20 lack of documentation I think around some of 21 these. 22 And an interesting point about this is

that I am fully aware that some of these value sets have a ton of overlap. And we've never really addressed it. Because initially, when they were developed, they were developed in 4 different fronts. Different people, all of that legacy issue.

7 But, I have a table. And I've had this table probably since late 2012 that shows 8 9 what the overlap is. We never addressed it because this would mean actually creating better 10 11 value sets, but to the cost of the implementation 12 community.

13 So, that's an interesting factor to consider here is that, we would need to create 14 15 smaller units, smaller value sets that we could 16 then use to build up these antithrombytic versus anticoagulant for stroke versus VTE patients. 17

18 And we never really did it because of 19 the cost it would bring to the implementation 20 community. Having said that, it's something that we're happy to do if that's something that the 21 22 implementation community feels is valuable.

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1	And it would also actually lower the
2	cost of maintenance to it when we think about it.
3	Because you don't have to do it multiple times
4	and multiple value sets.
5	So, just to throw some context around
6	some of these findings.
7	MR. GOLDWATER: So, yes, we had no
8	idea what the past history was. I mean, we just
9	knew who the steward was. And it was just
10	basically a line by line analysis of all of this.
11	And I wish we knew that there was a
12	tool. And so, we'll talk to you about that later
13	when this
14	MEMBER McCLURE: It took a long time
15	for me to get to that point where I was just
16	going to interrupt.
17	So, the did you look at the
18	purposes? Because for example, the ones that end
19	in specific all do actually have purpose.
20	So in the context of your analysis did
21	you look at the the description? Now, the
22	comparison

1	MR. GOLDWATER: So so
2	MEMBER McCLURE: Oh, you're not
3	authors.
4	(Laughter)
5	MR. GOLDWATER: Right.
6	MEMBER McCLURE: Never mind.
7	MR. GOLDWATER: And so Dr. McClure,
8	the other reason why, again, I did not want to
9	extend the boundaries of what we are not
10	qualified to do. So, I admit, we're pretty
11	adept.
12	But, I we wanted to sort of get
13	away from any sort of conclusion about the
14	differences between recurrent major depression
15	and major depression. I don't know what those
16	differences are.
17	So, you know, they just look alike to
18	me. And the Jaccard was indicating an overlap.
19	So we highlighted it. You know, that, to me,
20	indicated what there was a purpose for.
21	Before I get to Dr. Bregman, I do want
22	to sort of get back to, you know, the focus that

Zahid wants to sort of lay out here. Which is we 1 2 got legacy value sets, a lot of them. And then we have, you know, the idea 3 of making new value sets which happens fairly 4 frequently. So, in terms of legacy value sets, 5 which a lot of what is what we're focusing on 6 7 here, again, how do we sort of constitute what is a good value set as opposed to one that needs 8 9 some degree of refinement? And how then do we determine what some 10 11 -- when something needs to be harmonized and when something does not? What's acceptable overlap? 12 13 Dr. Bregman? MEMBER BREGMAN: Well, I'm very 14 15 interested in the history of these value sets. 16 However, that interest is limited because it doesn't really matter. 17 18 It doesn't matter what the history of 19 these value sets are. The question is, what are 20 we going to do from here? Now Dr. Chute has proposed a rather 21 22 radical solution, which may be an effective

That's something I think we should solution. 1 2 discuss. But really, look, some of these value 3 sets are synonymous and should not be distinct. 4 Some of them clearly ought to be distinct for 5 whatever reason that we may not know now, but 6 7 they should be. Where we going to go with this? Would 8 9 we have to reconvene all of the committees that 10 created them in order to do anything with them? I'm afraid that the answer might be 11 And that would just -- then we would just 12 yes. 13 throw up our hands and say, well forget it. That can't be done. 14 15 Or is there another way to do it? I'm 16 not saying I know the answer. But, for example if, could the NLM own value sets based on 17 18 pharmaceutical class? --- and maintain them and 19 then the measure stewards would basically say 20 yes, that's what we meant. We just meant stating in whatever form 21 22 they are. And therefore, we are going to abandon
our current value set and we're going to go to 1 2 the NLM maintained value set. Which may just be based on the statin pharmaceutical class and 3 nothing more granular then that. 4 But that's the kind of solution we 5 have to come up with. Hopefully by the end of 6 7 Something like that. the day. And I'm glad that we are focusing on 8 9 Because I suggested -- I was talking to drugs. 10 Nancy and I said, if all we did today was only 11 come up with a solution for pharmaceuticals only, and didn't even tackle laboratory results or 12 13 other SNOMED concept or diagnoses, which who wants to touch that, I think that would be a big 14 15 achievement just to tackle drugs. 16 And I think a lot of clinicians would like that a lot. Because that's what they often 17 18 struggle with. 19 MR. GOLDWATER: Sharon? 20 I'd like to just DR. HIBAY: Yes. play devil's advocate about whether or not going 21 22 back to the measure developer themselves is a

prudent option?

2 That will depend upon their level of Their skill, their knowledge. involvement. 3 Their ability to capture history. All of those 4 5 pieces. So, it would seem that we would look 6 7 for a solution that would be a consistent measuring stick across all measure developers. 8 9 So, especially at this time. So one of the premises of this 10 11 proposal when we first went after it, was you know, the efficiencies that would be utilized by 12 13 harmonizing. So you can be new or somewhat novice to the measure development space. 14 15 And you can come in and say, you know

16 what, I don't have to go and figure out what is 17 diabetes. So it's a bit umbrella for diabetes 18 and what are all the subdiagnosis umbrellas, you 19 know, value sets for those.

20 Someone's already done that work for 21 me. So if I would go to Sharon Hibay, measure 22 developer, and say, well, let me decide what is

diabetes, I just don't think that quite goes to a 1 2 -- I don't know how else to say this, but to a higher enough authority. And one that would be a 3 consistent and reliable measuring stick. 4 So I just would kind of put that out 5 6 to the group. 7 MR. GOLDWATER: Dr. Lieberman? I think to CO-CHAIRMAN LIEBERMAN: 8 9 build on what Howard and Chris said, I think the, 10 you know, the medication classes would be great. 11 I haven't looked at RxNorm recently to know whether or not their medication class system 12 13 would meet the needs of this project at this time. 14 15 But that would be a -- I mean, that's 16 exact what we do --- is when we look at a measure and they're looking for beta blockers, yes, 17 18 that's how I look at my list that eventually 19 comes out in the EMR and says okay, those are the 20 beta blockers, but it's not finding something So was there another way to look for it? 21 else. 22 So, that would be very, very useful.

And you wouldn't necessarily need, you have to 1 2 decide, you know, where do -- where do we use a value set versus where do we use this 3 terminology? 4 And it may be that, you know, you 5 might need to reproduce and have a value set for 6 7 each of the drug classes to start with. And then you know, combinations after that. 8 9 But what you do need is, what I think 10 would be useful is, then to have in the definition of the value set, you also have a 11 logic statement using one of these terminologies 12 13 such as, you know, all beta blockers except for ophthalmic ones. Or whatever that is. 14 15 But you can express that in a logic 16 statement so it's very clear what you plan to And that I think, you know, eventually 17 use. 18 would help the implementers as well in 19 determining how to implement that in their 20 system. And it maybe is, you know, we all have 21 22 this ideal of the electronically consumable

electronic measure. But -- and that may happen 1 2 someday. But before then, you can take -- you 3 can be more accurate in your implementation if 4 you have that type of logic to work from. 5 And especially if there's a, you know, good 6 7 supporting terminology around that. And you could do a similar thing for 8 9 diagnosis as well. 10 MR. GOLDWATER: Zahid? CO-CHAIRMAN BUTT: 11 So, yes, I think medications do sort of cover the broadest 12 13 spectrum of the issues in this area. And the reason why some of the levels of granularity are 14 15 required or were felt to be needed in medication, 16 comes down to the use case or the workflow at what point. Especially at negation occurred. 17 18 And so, that's where sometimes if it's 19 a physician ordering negation, it was felt that 20 the values that needed to be at the ingredient Potentially in some cases it could be 21 level. 22 even at the class level.

And if it is negated at the point of administration, it's got to be at the fully specified RxNorm level. Because in the workflow, that's kind of where all of these things are occurring.

And so, that's sort of to me the piece 6 7 that forces this level of you know, multiple layers of value sets presumably within the same 8 9 family of measures. And so, I think if we can 10 come up with a process of how do you determine that in the context of the workflow, because 11 eventually that's what's important in the 12 13 implementation.

And I agree with Chris 100 percent that for the things that are already specified as a standard through either NLM or somebody that for that type of usage, it should be basically used -- we should use the ones that are already standardized and available.

But, if the need is for something different, then that needs to be called out and say, you know, why is it different? And what's

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the metadata, what's the concept supporting the difference?

MEMBER SMITH: So, I just want -- I just want to caution people. Because all of these value sets, just as a reminder, go to specific measures that were developed many times in concert with a set of clinicians or experts who agreed that certain types of people needed certain treatments.

10 And the measure is really trying to 11 narrow it down to these are the people. And this 12 is the event that should happen.

And so when we talk about, you know, maybe this value set is good enough and we can reuse it. But it's not really targeted at the set of people that were meant to receive that type of treatment.

18 Then we talk about physicians who 19 maybe can't achieve 100 percent. And people will 20 say, well why can't you get higher than an 80 21 percent? Well, because I have all these people 22 in my measure that I have to report on that

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really shouldn't have received this treatment. 1 2 So, I think we need to balance. Ι mean, not that no value sets can be reusable. 3 But I think we have to balance with the end 4 result as well. 5 And say, if we're going to create 6 7 value sets that are good enough. Or that you have to reuse, then we also have to look at the 8 9 downstream effect and say that maybe a physician 10 isn't going to be able to get 100 percent either. 11 MR. GOLDWATER: Joe Schneider? 12 MEMBER SCHNEIDER: Just, I wanted to 13 pick up on Howard and Sharon's comment about the -- you know, what do we do about all the things 14 15 that are there? 16 I heard we've got 1,500 value sets. Some of which are good. And some of which are 17 18 possibly significantly defective. 19 And the concept that we would go back 20 to the steward as if the steward was the owner, is, I don't think, a good one. 21 I want to 22 distinguish between, there are stewards and

there's owners and they're different. 1 2 And when you create a value set, I would like to -- maybe it's already been done or 3 proposed or whatever. But when you create a 4 value set and you submit it into the VSAC ---5 that you are giving up ownership rights of that. 6 7 You may be the steward in terms of keeping it current and so on. But you no longer 8 9 own it. And whether you get to change it is 10 something that the VSAC or a body within the VSAC 11 gets to say whether you can do that or not. 12 MR. GOLDWATER: Zahid? 13 CO-CHAIRMAN BUTT: So I think just to follow up on what Ann was saying. 14 I think 15 conceptually what we're trying to do is to say 16 that the variation is acceptable as long as it is done through exception and it is well documented 17 18 in a transparent way, why the exception was 19 necessary. 20 Sort of the framework that we should try to reuse them as the default. But if there 21 22 is a need to not to use the default, then there

needs to be full disclosure as to what concept 1 2 constitutes. And that should be visible to 3 everybody including the implementers. 4 MR. GOLDWATER: Dr. Rallins? 5 MEMBER RALLINS: And just to build on 6 7 that further, on Ann and Zahid's points, so whoever is actually receiving, you know, say the 8 9 new value sets that are based on logic statements. Also, have to be able to interpret 10 11 them in that way. I mean, so we can be very clear on how 12 13 we see them. But when you really get to implementation on the value sets, so receiving 14 15 them and interpreting the data, well, you know, 16 that's a whole another world then this one, so. MR. GOLDWATER: Dr. Schneider, did you 17 18 have something else? Okay. Yes, Kevin? DR. LARSEN: 19 Yes, could you go back to 20 the depression one for a sec? MR. GOLDWATER: 21 Sure. I think another tension 22 DR. LARSEN:

that would be interesting to hear this group talk about is the kind of specialist versus generalist tension that we sometimes face in these measures.

And when I look at the depression 4 issues here, I try to wear two hats supporting 5 the psychiatry community that has very nuanced 6 7 differentiation between diagnostic terms and the generalist community which has a less nuanced 8 9 differentiation. And sort of would be interested 10 in how this group thinks about those kinds of 11 issues as we approach this in a kind of national suite of tools and measures. 12

13 MR. GOLDWATER: So, I think --- I 14 guess, trying to move forward a little bit. Let 15 me start off with, I guess, there's two issues 16 that have sort of come up, that have surfaced.

So the first is, this is a large
undertaking by any stretch of the imagination.
Certainly there is an awful lot to do in now five
hours, six hours.

21 So, do we as a Committee, do you want 22 to focus on perhaps developing a pilot process

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that specifically just focuses on medications? 1 2 And that would be what we do for the rest of 3 today. And not do lab tests, diagnoses, et 4 And Kevin, is that acceptable? 5 cetera. DR. LARSEN: I mean, we're -- we Yes. 6 7 want you guys to pilot something that you think makes sense. 8 9 MR. GOLDWATER: Right. Does that seem 10 agreeable to -- Dr. McClure? 11 MEMBER McCLURE: I saved you from the 12 very last part of that sentence. Let's see, how 13 am I going to approach this? The -- well, first off, let me say 14 15 that I'm in support of focusing on a particular 16 And medications, I think, are a reasonable area. thing to do. 17 18 But, I do want to say a couple of 19 other things. You've heard me say now a few 20 things that I think we need to capture. And I know you're transcribing and doing that. 21 22 I really want to see us identifying

certain things. There's good ideas that are coming out that we can't address in the context of -- or certainly today, and perhaps even in the phase of the work that we're proposing to try to accomplish.

But the fact that they've been said, 6 7 it needs to be recorded because they're the sort of things that get said in the context of this 8 9 work in general across a lot of different 10 meetings. And then they just kind of get lost. 11 And you know, when you hear them 15 times, you realize they're important. But nobody 12 13 ever really puts them on a priority list to actually deal with. 14 15 And so, I really would like this 16 Committee to identify those things. And endorse

17 that they get addressed at some point.

And so, I just want to -- I can't say too strongly how strongly I feel that we need to do that as part of our work. Maybe not today. But as part of our work.

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And in the context of that, so making

a decision for example, to say okay, we're going to focus on medications. There's some elements to this that I'm still a little -- struggling a little bit in order to understand what's our charge?

6 Because we've talked about various 7 ways of kind of cutting this. And I think we do 8 need to be very clear about that. Because I 9 think it's possible to accomplish things. And 10 then again, these other things go on a priority 11 list.

So, for example, the difference 12 13 between addressing existing ECQM value sets and harmonizing those. Versus saying how 14 15 harmonization should be approached in the future. 16 The difference between addressing and identifying opportunities -- so there I talked 17 18 about how you harmonized. Addressing and 19 identifying those value sets that should be 20 harmonized versus how one should look and utilize

existing value sets in the process of creating

22 new value sets in the future.

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The issue with regards to the -- how 1 2 one -- what kind of information should be available to -- should be documented by authors 3 for existing value sets. And I don't know that 4 there's going to be a lot of difference between 5 what you would then do it in the future. 6 7 But, what kind of information do we think is necessary in order to do harmonization 8 9 versus and in complement to, create knowledge 10 about value sets going forward, i.e. this issue about drawing in elements of how is this value 11 12 set used? Right. 13 And then finally, as I look at this, this really highlights for me too, the issue of 14 15 understanding code systems. And then, you know, 16 this is what -- Chris brought this up. And we've talked around this. And we're going to --17 18 there's dragons in this. 19 So, the idea of -- the knowledge 20 inherent in any terminology and how you use that. And how that plays into again, our two kind of 21 22 areas, one the expectations around harmonization.

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3 So for example, and I'll just point 4 this out as an example of that, but just very 5 much aligned with this idea of drug classes, 6 7 which has its own unique brand of dragons. Ι can't help but see Game of Thrones when I say 8 9 that. 10 But, sorry. So, I'm going to even 11 actually misstate, but tympanometry. How do you 12 actually pronounce it? Tympanometry. 13 Tympanometry testing. And then next with high frequent tympanometry. My guess is, 14 15 without, thank God, knowing this as a fact, is 16 that the tympanometry testing is a collector concept from SNOMED. 17 18 And therefore, is -- and a very useful 19 concept in the context of all tympanometry. And 20 the other one is a specific one. And so, part of the details that I 21 22 wish we wouldn't have to deal with. We have to

Very much overlapping but different from the expectations in terms of creating new value set content.

say something about though, is expectations with
 regards to those concepts being in value sets.
 And their use.

I mean again, this really covers both what we want to tell people in terms of creating great value sets. Because honestly, people don't know how to make good value sets.

8 And I would be thrilled, I mean, 9 thrilled if I -- if this Committee can do work in 10 that context. That we could bring back to VSAC 11 to support better value set creation.

I mean, that would -- because quite honestly, I can't imagine another situation arising where I can participate and then bring that knowledge back. You know, so let's do it.

But it then speaks to this issue of expectations that we could give. And then guidance to tool developers. Which by the way, that's what NLM is.

20 And NLM has many hats. But the one 21 that is -- the hat that's closest to us in the 22 VSAC, the VSAC is a tool. And so what we need to

,	
1	bring back to the NLM is expectations with
2	regards to tool functionality.
3	It's a very different thing to also
4	talk about desire with regards to terminology
5	content. Because there are a few of those too.
6	So NLM has a different hat in a
7	different part of the world where it makes
8	RxNorm. And we could say, gosh, there's
9	something missing from RxNorm, that if we had,
10	you made available as a part of your tools,
11	authors could be encouraged to use. Right?
12	All right. I'll stop there.
13	MR. GOLDWATER: Chris?
14	MEMBER CHUTE: Never at a shortage for
15	radical or arrogant recommendations, I'm
16	wondering if in the context of drugs, and I
17	incidentally agree with the goal of perhaps
18	focusing on drugs as a handy use case. Because
19	whatever lessons and exemplar might emerge from
20	that, could be, hopefully, generalizable to
21	others.
22	That has implications. And one of

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2 value set definitions be done in terms of drug classes. 3 For example, let's talk about 4 Let's talk about penicillin 5 allergies. allergies. Well, anybody who's ever read a 6 7 pharmacopeia knows that the proliferation of penicillin is daunting. 8 9 And to have anybody try to make yet 10 another list of which penicillins are bad for you 11 or good for you, is probably not a useful It exists in RxNorm. 12 exercise. I mean, that was 13 the Bodenreider classes that I referred to. And furthermore, it may turn out that 14 15 if you actually look at a quality metric, you 16 don't care about penicillins as much as you actually care about beta-lactam drugs. Which, 17 18 for those you that don't know, is a more 19 generalized category and tends to share antigenic 20 properties. Oh, okay. Well, you really meant 21 22 beta-lactam drugs. And it would be cool if the

them might be that in future, all drug related

value set specification were done at the level of drug classes as they exist in a resource like RxNorm.

That has the implication that all these quaint historical value sets that we're agonizing about are irrelevant. Because they would be recast in the context of drug class categories.

9 That's not to say that a value set 10 could not have explicit exclusions. And I very 11 much like the example that was brought up about 12 ophthalmologic beta blockers because they tend 13 not to have systemic absorption, therefore their, 14 you know, therapeutic indications and use are 15 somewhat different.

And you know, that would be a grand -then the value set would be a larger statement that is, you know, NLM beta blockers exclude or minus the ophthalmologic ones. And those also would be enumerated.

If one pursues that path, I can
predict one would quickly discover that Olivier's

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collection of handy drug classes as they exist in the NLM RxNorm are not satisfactory for many of the use cases that we would encounter. We then have two solutions.

5 We can go back to the nasty old 6 business of making up our own enumerated list in 7 our backyard. Or, we can work with NLM to say, 8 you know, Olivier, it would be really handy if we 9 had a list of ophthalmologic beta blockers which 10 may or may not already exist, but let's assume 11 for the moment that they don't.

12 And you know, rather than NQF going 13 through the exercises specifying what those are, 14 we request that NLM -- we make a use case 15 requirement that it would -- that these are --16 this is a drug class that should exist within 17 RxNorm.

And that it's -- because of these use cases and requirements, and I can imagine that it would happen. In other words, we outsource the whole task of drug enumeration to a community and an organization that is already doing it.

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That is doing it transparently. That 1 2 is doing it with good principals. That is doing it in the public interest. And that is doing it 3 with more than a modicum of authority. 4 In which case, we can have lunch. 5 MR. GOLDWATER: So, so not to run 6 7 counter to your radical argument and set of ideas, I think that's, you know, if the 8 9 inevitable conclusion of the project is -- and I don't think that's a bad one, which is that NLM 10 11 takes the responsibility for this task. And I think invariably, that's 12 13 probably what that's going to lead to. Our charge as NQF, let me clarify, is not to solve 14 the problem and then be the steward for lack of a 15 16 better word, to continually solve the problem 17 indefinitely. 18 That's not anything I think that we 19 are looking to do. I think it is to work on 20 coming up with a methodology to potentially solve the issue. And then determine who will take that 21 22 on from that point forward.

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That's what our charge, that's what 1 2 the contract is. So, I think Chris, the ideas that you're presenting are perfectly acceptable. 3 My issue, not issue, but, I think my 4 question is, for measures that are going to be 5 created, I think leveraging a different way of 6 7 looking at medications by focusing on the class within RxNorm, is probably certainly something to 8 9 consider. 10 But, it goes back to what Dr. McClure 11 was just saying. Which is, we have ECQMs that already exist. That are already being used. 12 13 That are being used in programs nationally. That are the basis for compensation or incentive 14 15 payments to physicians or to hospitals. 16 So, with that and those existing value sets, what do we do with those? I think that, 17 18 you know, it goes again to Zahid, we have legacy 19 value sets. And then we have value sets to be 20 created. The two be created, if we think of a 21 22 different methodology that leverages drug classes

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rather than sort of the very specific elements 1 2 that at times are overlapping, that's something we can discuss as a recommendation. But for 3 legacy value sets that are currently in use, you 4 5 know, how do we propose to begin the process of harmonizing those? 6 7 And I think that's sort of what our analysis is showing. And what I think the focus 8 9 probably needs to be. 10 Ms. Martins? 11 MEMBER CHUTE: Can I just -- just to 12 follow up. Because I -- in my commentary, I did 13 go so far as to say, they should be deprecated 14 and recast. 15 MEMBER MARTINS: So, I think that the 16 generalization of drug classes for RxNorm is really -- we need intentional definitions for 17 18 value sets. 19 And that answers the question for new 20 That answers the question for value value sets. sets that are in existence in terms of a starting 21 22 point to see should these value sets even be

harmonized.

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2	There's an incredible amount of work
3	that needs to go into existing value sets.
4	Because they are enumerated lists. And we may
5	not have that documentation of the history.
6	So it will require building these
7	value sets again as intentional value sets. And
8	then correlating the intentional definitions and
9	the resulting lists and see is this something
10	that should be harmonized.
11	So that's the first question, right?
12	And then going back to how they should be
13	harmonized.
14	I have to say that explicitly leaving
15	out the people who determined that there should
16	be a value set. And who know what the purpose of
17	the creation of that value set is, is probably a
18	misstep in my opinion.
19	But, I think what would be
20	interesting, would be to run a pilot where you
21	have the stewards involved who know what the
22	value set is all about. And another group that

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has to reverse engineer the value set and 1 2 harmonize and see what we come up with. I think it's an interesting question 3 in terms of whether or not the stewards should be 4 involved. But so, I think that if we focused a 5 discussion and going back to should we do RxNorm, 6 7 if we just focused a discussion on RxNorm, as the ideas started coming up, we're talking about 8 9 specifically drug classes. 10 And we may run the risk of providing -- having recommendations for RxNorm only that 11 are not necessarily generalizable. So I would 12 13 caution against that. MR. GOLDWATER: Dr. Lieberman? 14 15 CO-CHAIRMAN LIEBERMAN: Well, yes. 16 No, I think first of all, I think Chris' point is 17 a good one. 18 That we don't -- that we can -- we can 19 continue to use current measures and we can say 20 that they are -- and we can deprecate them over And we can build in this requirement to 21 time. 22 express the concepts using a hierarchical

terminologies as part of the review process. 1 2 And you can even, you know, you can set it up in such a way that prioritizes some 3 measures over others if they do this. So that 4 over time you will -- again, it will be more 5 advantageous to a measure developer to do this 6 7 work as opposed to not do it. And when you run into areas where the 8 9 terminology doesn't meet the needs, you can still deal with that through other tools that we have 10 around the measure definition and the measure 11 authoring tool and what not. So even if you 12 13 can't find ophthalmologic beta blockers, if you have a route or some other information that you 14 can use to build out that concept in the overall 15 16 measure, you can do that.

So, but we definitely do need a
process in place to have the most useful concepts
built into the terminology over time. But I
don't think that it has to be a limiting factor.
MR. GOLDWATER: Zahid and then Dr.
Schneider.

1	CO-CHAIRMAN BUTT: So I think one way
2	to sort of look at this legacy issue is that we
3	know that disease exists, right? And so now we
4	need to find out what led to the disease and what
5	is the treatment.
6	And once we do that, hopefully we can
7	then prevent the disease from occurring again.
8	Which is forming new value sets.
9	So, I think we need to figure out, you
10	know, let's just say there are a bunch of value
11	sets in the medication area. The question will
12	be, and that's where the stewards are going to
13	have to be central, especially if there are more
14	than one steward involved.
15	And you know, who is the authoritative
16	source? What is that consensus building process?
17	Who determines?
18	Because once you determine that in the
19	context of an existing problem, you can use that
20	same process to then prevent the problem from
21	occurring in the future. Obviously you would
22	have to take into account some governance issues

and so forth.

2	But I think that what may appear
3	sometimes to be duplicative may have good reason.
4	And so like the one that Rob was point out
5	through this tympanometry testing, so let's just
6	assume that there are ten of these, some high
7	frequency, some medium frequency.
8	So there is the granularity issue
9	involved here. Potentially the ones that get the
10	test would get it at the high frequency or at
11	that granularity. So if it's some test that was
12	done and performed and documented, it would be at
13	that level.
14	But the physician who is supposed to
15	order that doesn't want to negate it if they
16	don't want to order it at that granularity. They
17	want to negate it at tympanometry test not done
18	because it was not indicated.
19	So, there is a use case issue that
20	gets involved. And we have to be very careful
21	that we don't make some sort of sweeping
22	recommendation that doesn't take that into

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account.

And that's where all the stewards have to be at the table. I believe implementers, 3 software vendors have to be, because they now 4 have some experience.

So these things are very closely tied 6 7 to each other. And so, somehow we've got to figure out a process and a way in which there is 8 9 some consensus building around what should be 10 done.

11 MEMBER SCHNEIDER: Yes, thank you. Just -- I wanted to pick up on Mr. McClure and 12 13 Chris' and the other concepts of, you know, how do we get -- how do we stop the madness of making 14 15 new things that don't -- that aren't right? And 16 clean up that which is.

I think Mr. McClure was sort of right 17 18 on when he said, there's some really good 19 concepts here. And we rapidly have to get those 20 put in place.

We have to designate a governing body 21 22 that says, that is the place where you look for

these things. And that's how you create value 1 2 sets from here on out. And then may I make a suggestion? 3 Because this is how we did it with the pacemaker 4 So at a certain point, we have rejects. 5 thing. You have, Dear Stewards, you have X 6 7 period of time to comply to get your value set into this format. And if you don't, then at the 8 9 end of that time, you are cast out by the 10 authority. You are no longer a recognized value 11 set. 12 Now that again, draconian type 13 efforts, but I think the fact that we've got 1,500 things that they are -- and probably more 14 15 coming our way almost every single day, I would 16 say demand some pretty rapid action. And the best way is, control what's 17 18 coming in. And then give a time period for clean 19 up by the stewards. And if not, out you go. 20 MR. GOLDWATER: Dr. Lieberman? CO-CHAIRMAN LIEBERMAN: Just a brief 21 22 comment here. I did look up tympanometry and

there's only one child concept, which is high frequency tympanometry.

3 So, but that's a good example where 4 you didn't really need, I mean, the measure 5 developer shouldn't have to worry about that. 6 They should just say tympanometry and if there 7 had been 15 sub-concepts that should have been 8 included as well.

9 So again, I mean, we really want to 10 take advantage of these other -- this information 11 that's built into these other terminology systems 12 that we have. And not put the onus on somebody 13 to choose every -- choose and maintain every 14 applicable code.

15 MR. GOLDWATER: Ms. Cullen? 16 MEMBER CULLEN: I recognize the interest in wanting to kick things out. 17 But 18 these measures have -- the values sets are 19 associated with measures that are used in 20 programs. Which means you are kicking measures 21

21 which means you are kicking measures 22 out of programs outside of a regulatory cycle.

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And that's a problem.

2 MR. GOLDWATER: Right. I mean, that 3 does bring up a good point. Which certainly I 4 don't think we're going to have an extensive 5 discussion about. Which is, sort of the cycle of 6 how measures are created and how measures are 7 maintained.

8 There is a regulatory process for this 9 once a call for measures is out. Once they are 10 submitted. The three year cycle of measures 11 being maintained. So, you know, punting out 12 value sets may fundamentally alter a measure 13 before it's in cycle.

So, I think we've -- there may be a way of looking at sort of a happy median here to do that. I don't want to thoroughly reject the idea. But we do have to keep in mind sort of the regulatory constraints.

19 MEMBER MARTINS: I think more than 20 regulatory, and this is something that we've come 21 across multiple times as we develop ECQMs. We 22 hit the limitations of the framework every day

because it's being developed.

2	Because these tools are new. I mean,
3	the value set authority center was developed
4	after the first value sets were published. So
5	that's how much tooling is lagging behind.
6	And when we talk about drug classes in
7	RxNorm, and I don't claim to be an RxNorm expert,
8	but I think they got in also after. They were
9	created after the first RxNorm value sets were
10	created.
11	I don't know how complete the drug
12	classes are. And so I think we need to find that
13	happy medium. But knowing where our technical
14	limitations are so that we don't shoot ourselves
15	in the foot and all of a sudden have to move to
16	these from imperfect value sets to another set of
17	imperfect value sets with the time limitations.
18	So I think all of these need to be
19	carefully considered as we think about blowing up
20	some value sets and moving to others.
21	MR. GOLDWATER: Sharon?
22	DR. HIBAY: I think I'm chiming the

sentiments of a number of people who have spoken 1 2 on this. I think that we've said, or the group has collectively said, there's a different 3 process for those measures, as Cindy would say, 4 5 that are currently in use. And those measures that going forward 6 7 we would like it to be ABC and D. So perhaps I might throw out a proposal to say, we would look 8 9 at developing a process that would be those going 10 forward. 11 And then also then say, with the recognition of the limitations or the additional 12 13 considerations we need to look at related to those measures that are currently in use, you 14 15 know, how might we do this differently? 16 I -- and again, I just want to also state a little bit slightly different what I said 17 18 earlier. About measure developers being involved 19 in the process and the ultimate decision making 20 authority. I don't know, I feel like I'm dancing 21 22 around words that aren't yet, sort of concepts

that aren't yet quite formalized. But, who would 1 2 be the ultimate owner of the value set. We certainly would want the input of 3 the measure developer. It's vital to 4 understanding the concept, the purpose statement, 5 The scope of the value set. 6 whatever. 7 When I initially wrote language for this proposal, I stated that, you know, there's 8 9 different ways value sets are created. You know, 10 I was a developer of the BMI measure follow up. 11 So, if you love it, you can smile. But if you don't, please don't throw things at 12 13 The value sets in that were created for me. 14 very, very, very, explicit purposes. 15 One of the value sets in there would 16 be follow up for a high BMI. Okay. That is not a value set that you would say is, and I used 17 18 this language previously, harmonizable. It's 19 It's a very fit for purpose. Very measure not. 20 specific value set. A value set where you might want to 21 22 look at diabetes, you know, you could look at
that whole giant umbrella of what is diabetes. 1 2 And then develop it into subset diagnosis. And say okay, so for a measure I would 3 want to look at diabetes, but do I need to look 4 at gestational diabetes? And do I need to look 5 at steward induced diabetes? 6 7 So you would have that giant umbrella. And then you would have some smaller subsets 8 9 underneath that umbrella. And then, you know, 10 what's -- who is the authority? Who are the 11 How do we vet? How do we test? How do people? we endorse? 12 13 How do we approve value set concepts from here going forward? And I would like to 14 15 harken the group back to Helen's chart, which is don't be afraid to be bold and innovative. 16 This is a great opportunity for us. 17 18 So we have -- we can look now and then 19 going forward into our new space. But then also 20 we recognize there's going to be varying different considerations for those measures and 21 22 those value sets that are already in place.

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And we should know also that those 1 2 value sets were built in measure development After the measures were developed, then 3 silos. we tried to come together and hold hands and sing 4 5 Kumbaya. But we didn't do it. And we were very 6 7 secretive in the beginning. And I know that because I was one of the measure developers. 8 9 And so now we're trying to harmonize 10 based upon these walls that were erected. And now we're trying to disassemble the walls. 11 So, it will require a different either subset of 12 13 rules or some nuance to the rules. Or something like that. 14 15 So I just want to encourage the group 16 to think about it from those two perspectives. MEMBER McCLURE: Just informative. 17 18 So, actually the first one's not so informative. 19 Two different really issues. 20 So one is this issue of the use of the word steward and author. It would probably be 21 22 good, to be consistent in terms of our use of

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that word in this context.

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2 So let me tell you what it means in the context of VSAC. And so in the context of 3 VSAC, the steward is the person who is ultimately 4 responsible for the content of the value set in 5 this place. 6 7 So that word owner and So, they own. steward are synonymous. 8 9 The idea of there being both a steward 10 and an author comes from the reality of the 11 process of creating value sets. Particularly in 12 the context of ECQMs and the CMS contracting 13 around that. But it's true in general. And that 14 15 is, there's somebody who's responsible for the

15 Is, there's somebody who's responsible for the
value set. And the intent there is, is that you
17 could always go to that entity and that's where
18 the buck stops.

19 And then there's other entities that 20 are responsible for actually doing the work. And 21 sometimes there's almost more than arm's length 22 between them. And you know, acknowledging that

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is important.

2	But also you'd have a tool. And tools
3	require user logins and things like that. And
4	they have different roles and responsibilities.
5	And I think it works actually. And
6	so, that's what those mean. So, if I may, and
7	particularly given the fact that we're talking
8	about creating guidance that will result in
9	recommendations back to tool developing
10	development in the context of the VSAC, that we
11	get that kind of in cement.
12	So, stewards are people who own, or
13	entities that own and have responsibilities for
14	ongoing maintenance and content. If there's an
15	issue with content you talk to the steward, you
16	don't talk to the author.
17	Authors are just people who actually
18	do the work of making sure that the content is in
19	there. They're a tool user in essence.
20	And so, I think that's pretty straight
21	forward and it makes sense. And I think this
22	issue of what and let me also say that there

is no problem with changing stewardship of value sets.

3	And so if someone as a steward of a
4	value set in the context of one particular
5	process in creating. And then, you know, we give
6	guidance about the fact that we believe that
7	certain value sets by criteria should have
8	ownership, i.e. stewardship transferred to some
9	other entity, certain we could give that guidance
10	and the tool could support that.
11	So, the other thing I wanted to talk
12	about, and this one, boy. You know when I said
13	there were dragons, here's where the dragons are.
14	So in the context of medications, drug
15	classing is a dragon. It is Drago. And it is
16	not set. There's this has been a side issue
17	for me for a long time.
18	And there's more you know, none of
19	the players are literally in this room. So, and
20	NLM is the smallest of the potential players.
21	FDA has a big say in this and is basically
22	well, I'm not going to say.

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So, it's very interesting in some 1 2 approach. And so the -- so what we see, so when you spoke with Olivier, Olivier was reflecting 3 his work on creating a tool that utilizes the 4 data that's been brought into the RxNorm from 5 NDF-RT. 6 7 RxNorm has no drug class information inherent in it. NDF-RT does. And that work is -8 9 - what's a nice word for this? I was very much 10 responsible for this. So this -- it's schizophrenic in that 11 there is some content that has class related 12 13 information that's a derivative of one part of work. And there's other class information that 14 15 is very much current and is a derivative of 16 another set of work. And those two things don't perfectly 17 18 align. And so including -- while I absolutely 19 agree that we want some of the work that we might 20 now be focusing on in terms of this focus on medications, could -- our recommendations could 21 22 easily be to utilize as, you know, Chris

elegantly said, utilize the experience and 1 2 knowledge of authoritative sources as a preamble if not a basis for any work that would be done. 3 Both potentially backward looking, 4 i.e. dealing with legacy issues in terms of 5 identifying how to better harmonize. As well as 6 7 future looking things. And I'm very much in support of that. 8 9 So I want that to be very clear. 10 But I just want to say that there's 11 not -- unfortunately that's not a really piece of solid ground that we can point to, to say here's 12 13 where there's clarity. So part of what we might need to do is say this is so important that there 14 15 needs to be encouraged work on making that ground 16 solid. Because one of the things that I've 17 18 been a pain about, quite honestly in this area, is that of all the things that we are working to 19 20 do, identification of drugs that are to be associated with a particular drug class, has to 21 22 be solid. Because patients will die if there's

inconsistency and lack of transparency about what a drug class means.

And particularly, you know, I mean, there's practical tightness around this that I don't want to get into. But we tended to think about drug classes for two things.

7 One of them is, drug classes are 8 really valuable and NDF-RT actually created them 9 to support drug ordering. In order to be able to 10 provide drop down lists so that I didn't get 11 thrown ten thousand things in one big flat list.

So I wanted -- if I'm interested in a certain series of drugs, I wanted to see only those drugs that fell into that class. And I needed a way of being able to create a drop down list.

17 That's a very useful use of drug 18 classes. If you go and look at drug classes and 19 say oh, okay. I'm not going to worry about that. 20 I'm also going to use them as a way of 21 identifying let's say allergenic substances. 22 That's a very different use case.

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And if you pick a drug class that was 1 2 designed to support a drug ordering environment, and use that same concept to represent something 3 that a patient is allergic to, I hope you're kind 4 of sensing that those are two very different and 5 very dangerous things that intersect in a place. 6 7 But one takes you to the yellow brick road and the other one takes you into the dark forest. 8 9 And if you don't realize that, then 10 you've got a problem. And so one of the things that we've worked to do, but it's turned out to 11 be much harder, is to have an open and 12 13 transparent place where there is one drug classification that everybody agrees to. 14 15 And then it's the same. So when I'm 16 looking for drugs that I want to order, I can pick the same concept to say, I know this patient 17 18 is actually, if you were about to order any drugs 19 that are a descendent out of that list, you 20 should avoid them. And I'm confident of that. So if I pick this concept and it shows 21 22 up down in Florida and it also shows up in

Oregon, that patient, no matter what, is not 1 2 going to be exposed to the same orderable drugs. And so -- and to finish, that's 3 actually something the NLM -- the NLM is very 4 concerned about being handed tasks that have two 5 bad elements. 6 7 One, they don't have any money for. And two, that there is some knowledge that the 8 9 NLM must have in order to be able to successfully 10 do it. And the NLM will tell you, they are 11 not knowledge creators. 12 They are knowledge 13 manipulators and cataloguers. And manipulators, i.e. RxNorm is not creating knowledge. RxNorm 14 15 reflects knowledge that it gets and produces a 16 tool that makes it much more accessible. But they aren't -- you know, they work 17 18 very hard to try and not create. For example, 19 that's why drug classes are not in there. 20 Someone gave them an authoritative source for drug classes, i.e. the VA in the context of NDF-21 22 RT, they'll use it.

So, again, I want to highlight that I 1 2 am in -- I think I'm in significant support of focusing on medications as a starting point. 3 But if our solution requires rock 4 solid drug classification for example, then we 5 have to realize that doesn't exist right now. 6 7 And so we would be telling someone that they need to actually do the work of creating that. 8 9 MR. GOLDWATER: Chris? 10 MEMBER CHUTE: Dr. McClure, sir, 11 they're not dragons. They're alligators. Because there are a heck of a lot more of them. 12 13 And otherwise I agree with everything I would say that with some caveats 14 you said. 15 though. I -- this conversation is based on 16 hearsay, so it's clear that more due diligence needs to be done. 17 18 But actually, Olivier, again at the 19 authoritative retirement party, was 20 characterizing work that is actually synthetic of multiple drug classes. I agree, that the NDF-RT 21 22 drug classes are severely problematic and

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incomplete.

And let me give you a pragmatic
example. And I was going to do this earlier, I
didn't think it was relevant, but maybe it is.
Topical corticosteroids for example.
In NDF-RT, half of the products are the drug
class is topical agent. Well, that's a true
statement.
The other half of the same darn kind
of drugs, are classified as corticosteroids. One
of the major problems with NDF-RT is that it had
a mono-hierarchy.
You could be you could belong to
one and only one kind of drug class. And they
made highly arbitrary and inconsistent decisions
about which specific agents were in which class.
That is intolerable for the kind of
use case that we're talking about. I have not
verified this, so again, this is hearsay, it
needs to be validated.
But what Olivier told me at the party,
was that in fact, RxNorm now has a new

independent drug class component that did not 1 2 previously exist. That is synthetic from FDA. That is synthetic from SNOMED. That is synthetic 3 from NDF-RT and other sources. 4 That is a poly-hierarchy. 5 It's quality needs evaluation. And I cannot sit here 6 7 and say, darn it, it's the one we should use. Because due diligence needs to be done. 8 9 But I do think we need to go And I do think that we cannot and 10 somewhere. 11 should not advocate that NOF or for that matter any other single organization, make up its own 12 13 ersatz drug classifications, which frankly, the value sets you showed me are exactly that. 14 15 They are, I don't mean to be 16 disparaging, but they are, well, I won't be They are independent efforts, let's 17 disparaging. put it that way, at creating drug classes that 18 19 may or may not reflect state of the art. 20 And I'm simply asserting that one's approach to moving forward is to identify an 21 22 organization that would curate best knowledge and

best evidence. That's what NLM does. To generate drug information.

And that in fact, quality control, quality checks because it's true NLM doesn't have infinite resources. They are probably one of the tighter ships I know in government.

7 That the quality assurance on that 8 could be the NQF community that might find, you 9 know, dorky things like topical corticosteroids 10 are either a topical agent or a corticosteroid 11 and not both, as a -- and I think that's been 12 fixed incidentally, in the RxNorm drug 13 classification convene.

14 So, there's lots of work that needs to 15 be done. And again, they're not dragons, they're 16 alligators because there are so many of them.

MR. GOLDWATER: Dr. McClure then Ms.
Martins.

19MEMBER McCLURE: So just a response to20my dear friend, Chris. You're right.21And so, but just to be clear, in

essence what Chris is saying is why I said what I

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Which is the work that he references for said. 1 2 the retirement party of our dear friend who is the longest serving government employee I think 3 in existence, is research work. 4 And so, it's not -- it is actually 5 available on a website. It's partial and it's 6 7 incomplete. And so part of -- as I say, so if part 8 9 of what we do is we say we're not picking 10 medications just simply because they're easy, we're picking medications for a variety of 11 reasons that mean they're the best first place to 12 13 go. And in order to be able to succeed 14 15 here, one of the things that we need in order to 16 actually show how this kind of thing is valuable in other domains also, is to have drug classes. 17 18 And in order to get drug classes right, we need 19 to make sure that we have solid ground. 20 And that work might in fact best be something that, you know, NLM's ability to curate 21 22 knowledge from a variety of sources could be an

important part of that. 1 2 MS. MARTINS: So I think I have a question and not a comment. And specifically to 3 drugs and drug classes. 4 You know, once we have a drug class, 5 is that going to solve all of the problems for 6 7 all of the measures that we're looking at? Not in terms of, you know, the specific process of 8 9 harmonization, but are they appropriate to be used within each and every measures? 10 So, is it possible that certain 11 anticoagulants are used for one condition? 12 And 13 others are used for another condition? So, I would propose that these drug 14 15 classes and whatever we do with other 16 terminologies, that the idea of having these high quality, very broad, value sets is great. 17 And 18 that value sets for specific measures should be derived off of those larger sets. 19 20 For example, I'm thinking about the Kaiser problem list set that is published, I 21 22 think along with SNOMED, is it? That is -- and I

don't know if that's a high quality core --1 2 exactly, there you go. It's not Kaiser anymore. All right. 3 (Laughter) 4 MS. MARTINS: So that's sort of a 5 starter set that would preclude a lot of the 6 7 harmonization issues from happening. But at the same time, as I think about these overlapping 8 9 value sets that were just shown here for stroke for instance, if you create a value set for 10 antithrombotics and a value set for 11 12 anticoagulants, then you also have to see how 13 these fit together and which are the building blocks of others. 14 15 So it's guite the task. Even just for 16 medications, to have that clear picture of the drug classes and how they fit together and relate 17 18 to each other. 19 And then building from that, value 20 sets that are measure specific. MR. GOLDWATER: Zahid and then Dr. 21 McClure. 22

CO-CHAIRMAN BUTT: So, I think 1 2 conceptually really we're at -- I think we're sort of moving towards is that perhaps a process 3 would be that you first try to specify in a class 4 that's existing. 5 If you can't do it, go to the next 6 7 level. Which might be a specific indication that you have to create a value set for. And within 8 9 that, then you need to make sure that it's not 10 already in existence and reconcile that. And so it's sort of some sort of a 11 12 gated process needs to be defined, which to some 13 extent even the existing measures may have to go through if here is duplication. Because -- and 14 15 in terms of terminology, I suppose I'm looking at 16 the criteria that we were supposed to develop. One of the things might be that is 17 18 there a concept of a standard value set or 19 standardized value set? What should it be 20 called? And -- because everything sort of follows that concept. 21 22 Because, you can say something is

duplicated in reference to something that's the standard perhaps going forward. Right now everything is created de novo and there's duplication, but if the concept is that this is the standard, then everything is compared to that.

And so, what do we call that and how
does that work? I think that's a very
fundamental type question in terms of what we're
trying to do in harmonization.

11 MR. GOLDWATER: So, I think that the 12 second part of this was actually, absolutely what 13 we needed to do, which is we sort of started off 14 with the larger concepts of value sets, the 15 issues with value sets. Delving somewhat into 16 the terminology, but also I think the more 17 practical.

18 The issues of value sets from both an 19 implementation and a development perspective. 20 And then we sort of got to the beginning of the 21 process of how we're going to at least try to 22 rectify this issue. And narrowed it down to

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medications. 1 2 So I think we'll take a lunch break. I know it's Chris' favorite time of the day. 3 And we will -- after lunch is over 4 with, then we need to start establishing the 5 criteria and building out the process for what we 6 7 would like to pilot test. And the measures presumably where we would like to test this out 8 9 on. And again, starting with the criteria 10 11 and the process, and some way that is operational both for measures going forward and if possible, 12 13 measures that already exist. So with that, let's take a break. 14 And 15 we'll see everybody in half an hour. Or 45 16 minutes. (Whereupon, the above-entitled matter 17 18 went off the record at 12:33 p.m. and resumed at 19 1:27 p.m.) 20 MR. GOLDWATER: All right, so let's I know we're almost at 1:30 p.m., we have 21 begin. 22 until 4:00 p.m., and I think, given the

discussions that have taken place this morning, we should be able to get something down before we adjourn at 4:00 p.m.

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So after, I think, consolidating 4 information that we received earlier this 5 morning, I think what we want to do now, and what 6 7 we need to do before we do depart, is to come up with a process and methodology that we can pilot 8 9 test against a set of measures that hopefully 10 you'll direct us to which ones those should be. 11 And what we want to do is to come up 12 with a process that will deal with the 13 harmonization of only medications, for now, and

14 try to start with crosscutting processes that go 15 with measures that are new and measures that are 16 existing.

And in the course of our discussion, if there are times where we need to discriminate between one or the two, then we'll deviate in that way, as appropriate, but for now, I think we want to start with a discussion about what elements of this process would be applicable to

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both de novo and to existing value sets, with 2 respect only to medications. So, Zahid, you want to start off? 3

CO-CHAIR BUTT: So yes, I think, in 4 that same sort of framework, if you look at the 5 development of measures, you sort of start with 6 7 the intent of the measure and then from there, you have a measure construct, which it kind of 8 9 follows the same process for most measures.

10 And so within that you have, sort of, 11 definition of the inpatient population, the denominator population, and the exclusions, then 12 13 you, sort of, get into the numerator inclusion criteria, exceptions, exclusion criteria, and 14 15 that's where, sort of, the value sets, sort of, 16 get plugged in and that's where issues of 17 workflow get plugged in.

18 So the they are, the two are very 19 closely related, because in the case of, for 20 example, medication, you could see where they are used to define a denominator population, or where 21 22 they're used to find an exclusion, or they're

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used to find a numerator inclusion, and an 1 2 exclusion, or exception. And so those sort of components are all common to all measure 3 constructs. 4 And so that's where, I think, the 5 value sets get applied and that's where it's 6 7 going to be, sort of, what is the framework that can be used as a use case for medications to, you 8 9 know, what part of that construct do we associate with a specific workflow, realizing there are 10 different workflows in different settings. 11 12 But is there a, sort of, a common 13 workflow, for example, physician ordering, or medication administration, some of those types of 14 15 things? 16 I think that's where we are going to try to narrow this down, so that we can say okay, 17 18 for this harmonization, perhaps, it should be, 19 for this use case, this workflow, this component 20 of the measure, perhaps, it should be at a higher level of granularity, as opposed to a lower, 21 22 because that's, kind of, where we'll have to

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land.

What granularity makes sense? And then, of course, you have to then decide which one is the court standard value set and who gets to, sort of, decide the variation and that sort of thing.

7 MR. GOLDWATER: So if I'm hearing you right, Zahid, do we want to start off with, and 8 9 somewhat being consistent with measure 10 development, measure evaluation, do we want to start off with the intent and scope of the 11 measure first, what is the intent of the scope, 12 13 which gets back to an issue that the Ms. Martins brought up earlier, and that Dr. McClure has also 14 15 brought up, do we want to start with that as, 16 like, step one? CO-CHAIR BUTT: So I think each 17

18 component will have a reflection of what the 19 intent is to accomplish within that component. 20 MR. GOLDWATER: Yes. 21 CO-CHAIR BUTT: So there's an overall 22 measure intent, but our goal is more focused on

1 2 MR. GOLDWATER: Right. -- how, within let's 3 CO-CHAIR BUTT: say you select stroke measures and pick, okay, 4 within this stroke measure the intent of the 5 measure is to define these and we will pick the 6 7 ones that has medications in it --Okay. MR. GOLDWATER: 8 9 CO-CHAIR BUTT: -- what are the 10 components that the measure is trying to reflect 11 the intent of the measure for that piece of it where the drug is used and what is the associated 12 13 workflow, if there is one, attached to it, and what is the right granularity of that value set? 14 15 And then, of course, the content of 16 the value set itself, obviously, is also up for discussion, as to how does it get captured, does 17 18 it get captured through some sort of a standard 19 process, like, if you're referencing a class, do 20 you need to define the components of the class in a value set that too develops, or could you just 21 22 reference the MLM class and say, or just pull it

from there? So I think these are, sort of, the
 basic concepts that will be repeated, I think, in
 most situations.

MR. GOLDWATER: So we do have to 4 present a process to our Technical Expert Panel, 5 which actually will represent a group of people 6 7 that implement this on a fairly regular basis, and so the reason we chose them is because of 8 9 their familiarity and experience with the 10 limitation, and that what we want to is to give a 11 process and a test measure and have them 12 implement the process against the measure for 13 medications, get results back from them, and then report those results back to you, so we 14 15 understand whether what we are proposing is 16 working or where refinements need to be made. So not that I want to overly simplify 17

18 this, but I do want to get a process in place 19 that when we talk to the TEP we have something to 20 say here's what you do. So with that in mind 21 then, step number one, again, not trying to 22 simply, but what would the first step be for them

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to do?

Given that we are focusing on medications, given that we are looking at trying to come up with a pilot process for harmonization of those medications, and given that we are, at the moment, looking for, I guess, guidelines, or approaches, that cut across both new and existing measures. Ms. Martins.

9 MEMBER MARTINS: So I'm assuming that 10 the pilot is going to be focused on value sets 11 that exists, so the second part that we had 12 discussed, I will underline the importance of 13 having a process for the first, as well, so the 14 new, the moving forward path.

I would suggest that the first step is, really, you need to understand what the value sets are about, and that meaning that you have informational gaps.

19 The people who are going to be doing 20 this don't know everything about the value set, 21 and so they may not have access to the purpose 22 statements, they may not know how the value set

is used in the context of how many measures, all of that.

3 So I'd say that the first step is, 4 really, determining the gap in knowledge of the 5 two value sets that are being compared, as a 6 starting point to the determining whether they 7 are, and this, I would suggest, is probably the 8 second step, determining whether harmonization is 9 warranted.

MR. GOLDWATER: Dr. Chute.

11 MEMBER CHUTE: Perhaps I'm being a bit 12 provocative. I have that tendency. But I, the 13 fact is, when you harmonize historical existing value sets, legacy value sets, the very act of 14 15 harmonizing them creates new value sets. I mean, 16 that's the inevitable consequence, the derivative will be different, if it's harmonized, or, or, 17 18 and that really begs the question, why are you 19 bothering to do that?

20 Because the alternative, in my mind, 21 is to invoke what we talk about the way going 22 forward, you know, the new way, a more principled

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way, ideally. Whether we invoke drug classes, or not, remains to be seen.

But going forward, you're going to create new value sets, so the obvious question in my little mind is, heavens, if we're going to create new value sets, in any event, why not just create new value sets that are fit for purpose in the context of those use cases and deprecate the historical value sets?

Because, it's obvious, persons will spend huge numbers of hours going through the tedium of comparing legacy value sets, if only to create a new value set in the end, anyhow, and the alternative of saying okay, what are they really trying to do in this measure and that measure, are they the same?

17 If they are the same, then how do we
18 specify an intentional value set using drug class
19 level information that satisfies that use case
20 and move on?
21 MR. GOLDWATER: Mike.
22 CO-CHAIR LIEBERMAN: I was just going

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to ask if, I mean, really, the first, so have we 1 2 already decided on the value sets that we're going to use, or do we need to have that be part 3 of the process, as well? 4 MR. GOLDWATER: So no, we haven't 5 decided on the value sets, what we've decided on 6 7 is we're going to tackle medications, as a subject area. The value sets we'll look at will 8 9 be largely determined by the, I think we have to 10 choose three measures we're going to pilot, so 11 those three measures, those will be the value sets that we'll be looking at, again, only 12 13 focused on medication, though. Right, and how do 14 CO-CHAIR LIEBERMAN: 15 we choose the measure, sir, have we done that 16 already? MR. GOLDWATER: No we have not done 17 18 that, so what we want to do is come up with a 19 process by which we can propose on how to 20 harmonize medication value sets. And then, when we have all agreed, or 21 22 at least tried to come to some consensus on what

that process is, then to take recommendations, 1 2 especially from those of you that have developed measures for a significant period of time, what 3 pre-measures you think we need to be focused on, 4 as part of the pilot. 5 DR. LARSEN: I'm going to have to run 6 7 to go speak at another meeting, but just a little bit of sense of, kind of, what the ideal outcome, 8 9 at least to my mind, of this, kind of, process 10 is. You know, again, this is trying to 11 pilot with something specific, so we can actually 12 13 know what we're doing, but use that in a 14 generalized way. 15 And as NQF is the privier of what 16 constitutes a good measure and convenes the people that say yes this is a measure ready for 17 18 national scale, or not. 19 The goal here is to be able to provide 20 that kind of guidance around value sets, so when NQF does an analysis, or litmus test, and brings 21 22 to a committee and says, here is new measure X,

or, here is old measure Y that's coming back to get re-endorsed.

There's a value set domain in that 3 analysis, and that the output in the work of this 4 group can actually inform those kinds of 5 decisions, so that committee that's looking at 6 7 all the blood pressure measures could say, gee, these five blood pressure measures really get 8 9 great scores, because they fulfill all the value set criteria that has been set forward, but these 10 11 four, boy, we're just unhappy with what they did with their value sets. 12 The committee is not 13 impressed.

So that's the kind of frame that we 14 15 have for this. We don't know if it's a separate 16 process for measure endorsement, or if it's part of measure endorsement that that's not yet worked 17 18 out, and you don't have to work that part out, 19 but that's the kind of frame this, eventually, 20 needs to rise to, that kind of high level of non-value set technical people to be able to 21 point to Measure A, or Measure B, and say this 22

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one got value sets right, this one didn't. 1 2 MR. GOLDWATER: Zahid. CO-CHAIR BUTT: So I think that there 3 are pros and cons to picking the existing versus 4 If we go down the new path, then we 5 new ones. first have to select a new measure that has no 6 7 existing value set created. So no? MEMBER CHUTE: If I may? When we talk 8 9 about the new path, it's a way of thinking about 10 and offering value sets. There's no reason why 11 existing measures that have legacy value sets 12 cannot be recast --13 CO-CHAIR BUTT: Oh, okay. 14 MEMBER CHUTE: -- in the new way. 15 CO-CHAIR BUTT: Okay. So okay. 16 I thought I misunderstood what you said Thanks. earlier. Because, I think that the existing 17 18 measures would be the ones that would, obviously, 19 be available now, and they would have more, 20 potentially, more than one value sets in existence. 21 22 And so the process that needs to be

defined is that you take a measure and you start to look at wherever the medications value sets are used.

And, I suppose, a process needs to be 4 defined, whether you first look at the existing 5 ones and say what is missing, or you set yourself 6 7 up by saying, we're not going to look at the old value sets and we'll create a new one and then, 8 9 we'll go back and see how that differs from the 10 That that's, sort of, what I think Chris ones. 11 is suggesting.

12 So that's certainly an approach. It 13 would include some of the concepts that we have 14 discussed that you first look at, potentially, a 15 class, if that can accomplish the goal, it would 16 still have to be applied to the different 17 components of where it was used and all the 18 workflows that are associated with it.

So I think that that's, I guess, one sort of consensus, if we can agree, that that's the approach that the work groups, the technical experts.

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And they may have to include some of 1 2 the measure developers. And I don't know whether that's a good idea, or not, but, but it looks 3 like the task for that expert group would be 4 that, here are two measures that have medications 5 in them, and the task for them is to, first, come 6 7 up with the different value sets that are applied to different components of the measure and the 8 9 intent of the measure that's applied to the 10 measure construct and then at some point they'll 11 have to see what they have created. It might simply be a reference to a 12 13 class, and see if that, how does it differ from what is there now and are there any 14 reconciliation issues involved and does it meet 15 16 the measure intent, in terms of what component of the measure needs to be satisfied? 17 18 MR. GOLDWATER: Dr. McClure. 19 MEMBER McCLURE: Just a quick comment 20 on the, it's probably a more technical issue, but it's important, I think, in our context of 21 22 deciding what we can and can't do.

1	So, Chris, you know, was noting that
2	we could just change the value sets and, in the
3	context of existing measures, and I want to
4	clarify that.
5	We can, technically. And the way that
6	we do it is similar to what you said, but not
7	exactly in that, because part of what folks would
8	be concerned about is, is that the measures,
9	themselves, in the context of the math, have
10	voids, you know, that identify the value sets.
11	And so changing, if we were to create
12	a completely new value set, and that means give
13	it a new void, a new identifier, it has
14	downstream ramifications.
15	And we don't have to do that, because
16	we can create a new definition for an existing
17	value set, and that new definition, you know, can
18	be whatever we want, as long as the intent of the
19	value set aligns with the intent of the original
20	value set, i.e., just like concepts, you can't
21	change the meaning of a value set willy nilly.
22	And so, as long as we are adherent to

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the original intent, preferably as described by a 1 2 purpose, then we can make substantial changes in who we define the content of the value set 3 without ruining anything. 4 MR. GOLDWATER: So let me have a 5 follow-up question to Dr. McClure, and then, Ms. 6 7 Martins. So with that in mind, if I were to say give me the first two steps that somebody that's 8 9 going to implement this new process would have to 10 follow, what would you tell me? 11 MEMBER McCLURE: You're pre-supposing 12 I know what the new process is that we have to 13 define. 14 MR. GOLDWATER: A process for 15 harmonizing medications --16 MEMBER McCLURE: Yes that was a very 17 18 MR. GOLDWATER: -- value sets --19 MEMBER McCLURE: -- not very tricky 20 way of asking me, so it didn't work. (Laughter) 21 22 MEMBER McCLURE: But, so sorry, are

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you saying, because we can --1 2 MR. GOLDWATER: So we're going to come 3 up with a --MEMBER McCLURE: A new way of building 4 5 new value sets, or --MR. GOLDWATER: Or a process --6 7 MEMBER McCLURE: -- harmonizing? MR. GOLDWATER: -- for building, 8 9 harmonizing medications value sets in either new, 10 or existing, measures. MEMBER McCLURE: Well, I mean, you 11 12 know, so I'll put on my, I was a value set 13 developer at one point in my life, and so like everyone here is kind of eluding to, the way that 14 15 you think about creating, really, any value set, 16 but it's very evident in a medications value set, is to think about the class of concepts in the 17 18 class of medications. They're important. 19 There are occasionally value sets 20 where that's already clear and you're really just going out to figure out what concepts represent 21 22 the idea that you already very much have in mind.

But often times, you're talking about capabilities of medications that you need to represent, and then you need to go and find all of them and do a good job. And that's why it's so important that we do have ways of being able to do that.

7 And I'll just reiterate again, I feel 8 moderately confident in telling you that there is 9 no existing non-proprietary drug classification 10 system that we can just simply point to and use, 11 that is because of the complexities of multiple 12 code systems in play, and the fact that it has to 13 be high fidelity and updated on a regular basis.

This is, if we think that it is critically important for the well-being of our constituency, it's probably something that we're going to actually have to ask people to do. But it doesn't mean that all of the value sets are that way, you know.

For example, some of the ones that were shown in your examples where they're very specific and they have very few concepts in them,

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probably, because it was like the Warfarin-specific, right? And that was Warfarin-specific is exists so that you can say I'm allergic to Warfarin, and you do that at an ingredient level, and there's probably just one concept in that value set.

7 And so those are pretty straightforward. So there are some that are like 8 9 that, but I suspect we're going to have to take, 10 you know, kind of, say this is a need and then 11 move on, in order to be able to get to the 12 subsequent steps, which gets to this issue of 13 and, in fact, it's what Olivier did that was one of the reasons that we're, you know, he went 14 15 through and did this analysis of value sets, as a 16 research project, he used your card stores, as you know, and found all this overlap. 17

And so, you know, that's what we need to do is that we probably need to have some way of assessing the intent of the value set, and then, and you have to describe that, and then having then described that intent, then you can

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begin to go and identify code system
 characteristics that align with the
 characteristics of your intent, and that's the
 process of both, in my opinion, good value set
 creation and good, you know, mining for
 harmonization operations.

MR. GOLDWATER: Ms. Martins.

So I do want to make MEMBER MARTINS: 8 9 a comment about legacy value sets, because I 10 don't think we can really escape them, as much as 11 that saddens me, just because, if we think about the path forward, if we think about new value 12 13 sets and how we're going to be developing them, we're always going to be developing them against 14 15 those that are already out there, and seeing the 16 harmonization is always going to have to happen with what already exists. 17

So if, well, if we have a new concept and it's very similar to something that has already been created, you're going to have to deal with that legacy value sets and make a decision on whether you're just going to create a

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new one and replace that one, whether you're going to use the one that already exists, so you can't, really, escape the value sets that already exists.

5 If we were starting from scratch, I 6 agree, we could, we didn't need to consider the 7 existing value sets. But because we are, there 8 are value sets that we have to live with, we're 9 going to have to make a decision.

10 It could be that we don't use the 11 existing value set and we just start anew, but 12 the fact that the value sets are already out 13 there, means that we have to deal with them.

So as far as steps are concerned, in terms of this new process, I think that whether we're talking about harmonizing existing value sets, or creating new value sets, as Rob indicated, we need to define what is it that we're talking about?

20 And, to me, that goes back to the 21 intentional definitions, right? And it doesn't 22 have to be at a very terminological-specific

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2	Jim Shalaby, who taught me 80 percent
3	of what I know about terminology, he always
4	describes the definition in plain English, what
5	the nurse, to doctor, whatever, who is defining
6	this concept, what does it mean, and you put some
7	boxes around it. What is it that you want to do
8	with it? Or, what is it that you want to
9	encompass? And that, and to include in what, and
10	that means inclusions and exclusions, and then
11	you refine those, as you move along down to more
12	computable ways of defining that first plain
13	English.
14	So that would be the purpose
15	statements, I guess, that you would start with.
16	And once you have that then you can path one, new
17	value set, you can go to the existing value sets
18	and, really, search by name, codes that you think
19	could be included in that value sets to try to

identify what your legacy is, and see if they're appropriate, or not, or if you do need to create a new value set.

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1	MR. GOLDWATER: Dr. Schneider, and
2	then
3	MEMBER SCHNEIDER: Can I propose,
4	perhaps a five-point program? The
5	MEMBER MARTINS: Yes.
6	MEMBER SCHNEIDER: I would pick up,
7	very much, on what we were talking about this
8	morning, which is, you really need to identify
9	what is a good value set, that's sort of, you
10	have to establish the gold standard so that as
11	whatever work out of the future fits that.
12	And I think that a group that is in
13	charge of that needs to be established and firmly
14	established and they need to be recognized as
15	such. It doesn't have to be the federal
16	government, in fact, if it wasn't it would be
17	even better. Once you've got that, I think they,
18	and sorry if I'm too naive in this, I think there
19	are what I would call disharmony candidates.
20	You, kind of, showed us some of these
21	here where it's like, yes, something's wrong
22	here, or maybe something's wrong here, and that

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might be internal to single measure, for example, it might be internally consistent, or it might be we have two measures and the value sets from them that are seemingly inconsistent with each other, so identify several of those.

Then, the third piece would be, get 6 7 the intent from those stewards, steward owners, because we established that they're the same 9 thing, get the intent of those clearly defined.

10 And then, the next step after that is, 11 get the steward owners together and say, you 12 either have to justify to our new organization 13 that we created that's, sort of, our governance organization, why these should remain as 14 15 separate, the sets, or bring them together as a 16 single harmonized set.

And then, step five would be to, same 17 18 base idea, take that new, whatever that new thing 19 is that comes out of it, or the justification 20 that you have to have two, and gets some real live implementers to try and actually implement 21 22 this thing to figure out whether it is usable.

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And I just, that could be a, it, I mean, I offer that as a framework to kind of run things through that would help to deal with, it deals with the old legacy stuff, because you're kind of working it item by item, but it also creates the framework of which new things must be 7 done.

CO-CHAIR LIEBERMAN: Yes, I think I 8 9 was coming up with many of the same ideas. And I 10 think the, there are a couple parts here. First 11 of all, if we think about the new measure process, as opposed to an old, retooling old 12 13 measures, you would see that a developer that has a concept that's thinking about something, they 14 15 need to be able to go out and find out if there 16 is an existing value set that meets their needs. So you need a repository of these high 17 18 value sets and in that you need an arbiter to

19 decide what is a high value set and who's going 20 to collate that and organize that? So that's, part of this would be who, 21

you know, who's going to do that work and it, you

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know, it may be one group, it may be different groups, based on the domain and that sort of thing.

Then the developer can then either decide to use one of these, or they may decide that it doesn't meet their needs. Then there's good reason why it doesn't meet their needs, and so they can choose not to.

9 And then you also then, if they go 10 that route, probably, part of the measure 11 endorsement process has to be some sort of 12 determination whether that was the correct 13 choice.

So, you know, is there, again, you 14 15 need an organization that looks at that and says 16 yes that's reasonable, that is truly a different concept, or no, you know, it's close enough, and 17 18 that may be, again, part of the, it would be nice to be able to move that into the endorsement 19 20 process, but that might be a separate process, as well. 21

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And that's, I think, is going to be,

you know, one of the real sticky points here is who is going to do that work of both, of making those value judgments on those value sets, and then, if you, so that's, kind of, from a new measure perspective, and you can see the same, similar thing what happened in this harmonization process.

So it'll still be that you would, 8 9 basically, go through the same process, but you'd 10 have to figure out who's going to make those 11 decisions, as to whether there should be one, or 12 two, concepts in each of those cases, and if so, 13 what is the best definition for that one concept? MR. GOLDWATER: 14 Chris. 15 MEMBER CHUTE: I want to address the 16 question of legacy. And let's be clear about what I mean by legacy versus non-legacy. For me, 17 18 legacy, or the old way, is essentially an enumerated extensional value set. 19 20 And the new way would be a more intentional, whether it's drug class, or 21

whatever, but some kind of intentional design.

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But that's, so we're clear about what we need by old and new.

When electric cars came on the market, we didn't require immediately that all gas cars 4 get off the road. Both kinds of cars can share the road.

7 And correspondingly, if we introduce a new paradigm that is to say, an intentional 8 9 design principle for value set use in quality metrics, or other use cases, it doesn't 10 11 necessarily mean that all legacy value sets have 12 to get off the road. They can continue to exist. 13 They will live in the VSAC, they can continue to be used, it's just that we probably don't want to 14 15 mine them for creating a new paradigm of value 16 Excuse me. sets.

So the whole question of whether we 17 18 try to harmonize existing value sets, at least in 19 my simplistic world, goes out the window. 20 Because, what we would do is persist legacy value sets and then going forward, focus on the quality 21 22 metrics and the use case it's trying to address

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and create an intentional value set, that is to 1 2 say, a class level specification of what's needed, and effectively ignore the enumerated 3 tedium of the existing extensional value sets. 4 MR. GOLDWATER: Rute. 5 MEMBER MARTINS: So I think we've 6 7 established a criteria, in terms of which value set wins, and that is the intentional value set. 8 9 So as long as there are only extensional value 10 sets, as we move forward and create value sets 11 for new concepts, or existing concepts, if 12 someone goes through the work of creating an 13 intentional value set that actually produces a lot of overlap with the extensional, then whoever 14 15 has the extensional is probably going to have to 16 work to use the new intentional value set. Intentional beats extensional. 17 18 MR. GOLDWATER: So I think this is an 19 interesting process. It does bring up an

interesting point, which is, we do have to pilot
test something, so should the pilot test then be,
we choose three measures, we look at the existing

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medications value sets, we map --1 2 (Simultaneous speaking) 3 MR. GOLDWATER: You're saying no? CO-CHAIR LIEBERMAN: No, go ahead. 4 MR. GOLDWATER: Again, I am not a 5 physician. I don't play one. I am just trying 6 7 to reconcile these various thoughts into a 8 process. 9 We take the existing value sets, 10 medications value sets, are we then looking to 11 try to map them to the classes that are, are they 12 in RxNorm now, or are they still in NDF-RT, or? 13 CO-CHAIR LIEBERMAN: So I think that's the part that we're not quite sure, but I think 14 15 the idea behind it is, is that you take three measures, you look at the medication groupers in 16 them, and you see if you can come up at the very 17 18 high level purpose statement, are they really the 19 same thing, are they trying, are they going after 20 the same concepts? In the cases where they are, you then 21 22 create your intentional definition of that using

med classes and, hopefully, NDF-RT, or RxNorm has 1 2 the capability to that, you then write the description using that, and then, again, using 3 the relationships within the terminologies. 4 You can then explode out a list of 5 RxNorm concepts that you could compare against 6 7 the previous sets, just for, kind of, an informational perspective, so the people would 8 9 know what they're using. 10 And that, it may always be the more the definition that's used, but that could change 11 12 over time as the relationships, or as the 13 terminologies change, but I think that would be the general idea behind it would be to start with 14 15 that, that definitional, the intentional, 16 definition of it, and then explode that out to determine what actually that encompasses. 17 18 MR. GOLDWATER: Dr. Heras, and then, 19 Chris. 20 Yes, when we say about, MEMBER HERAS: to define intentional medicine, I just want to, 21 22 you know, make sure that we're actually, you

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know, define a clear process, because I think, 1 2 previously, you know, for now, all the eCQMs are actually, is tied to a more static value set. 3 So if we're doing intentional value 4 set, then we have this different year of 5 reporting. I'm not quite sure, you know, how 6 7 we're going to do that, because we're always, like, a one year behind, you know? 8 9 Like, this year we come out with the 10 2015 measure, which will be used for the 2016 11 reporting year, so if you're building, if you're 12 sending a report, creating reports during 2016, 13 and saying we are using intentional value set, at that time, what exactly, you know, are you going 14 15 to always using the most up-to-date value set? 16 So I think that's kind the issue, not just simply say intentional value set, but 17 18 actually we make this very clear and the 19 implications to eCQM development. 20 MR. GOLDWATER: Chris, and then 21 Marjorie. 22 I want to reiterate Dr. MEMBER CHUTE:

Lieberman's point, because I agree with
 everything he said, but I want to make some
 points of emphasis.

The process is, as I see it, is we 4 would take three measures and we would look at 5 their purpose and scope, but I also think we have 6 7 to go back to the developers of those measures and clarify with them, because the three, or 8 9 four, sentences that they wrote in purpose and 10 scope may not be as complete as necessary, 11 shockingly.

12 And therefore, I think we really have 13 to have a dialog with the developer of the 14 measures, what exactly was your intention here, 15 and have exquisite clarity, maybe, rewrite the 16 scope in more detail. Once we have done that, 17 then we can create an intentional value set.

18 The interesting question is whether 19 that intentional value set should be informed in 20 any way by the legacy extensional value set and 21 being, you know, a China-bashing-radical, trying 22 to, as in China sets, not the country, then I

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would assert that it really serves no purpose to examine the historical legacy value set, because it was just an approximation of what, inevitably, of what the measure developers had intended in the first place.

6 And we would get much more value and 7 substance and reliability by going to the measure 8 developers and saying what did you mean, and 9 starting over again in an intentional context, 10 then we would by trying to peer into the tedious 11 detail of historical enumerated content.

MEMBER RALLINS: Chris took the words 12 13 out of my mouth. And I'd like to go a little bit further and put a finer point on it and say that, 14 15 I think we need to involve the measure developer, 16 along with the committee that helped to do that, but also, to recognize that this represents a 17 18 significant culture shift that we need to think 19 about.

I think I said that earlier in the day, but it really does represent a culture shift, because these measures, I don't know which

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ones we select, but more than likely, these are 1 2 measures that are used to report on, right, in So that, I mean, there's another whole 3 programs. community, or industry, that takes the next step. 4 DR. HIBAY: Yes I, not to sound 5 redundant, but perhaps some of this may be. 6 So I 7 agree with Chris, there's a lot of great work done with the work, you know, that we've already 8 9 done with these value sets that are existing in 10 the MU2 measures. 11 And my premise was always that you 12 cannot look at the content, the concepts, the 13 absolute details of these codes, without the people who authored them and understanding what 14 15 their purpose was, and so they must be involved 16 with the process. I just don't see how we could 17 do that any other way. 18 And I agree with, also, just that 19 these concept, we can't throw the baby out with 20 the bath water, there's a lot of good intention

21 that went behind there.

And then, also, Dr. Heras, if I could

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just comment to your, I think you were stating some governance issues. So what do we do around value sets and how do we keep these in and keep these out and what's the process and how do we inform and those kinds of things?

So I think the charge of this 6 7 committee is to imagine how we want the future to be, and I think Jason very clearly articulated 8 9 this morning that we have some parking lot issues 10 that we need to be concerned with, and some of 11 those are: yes, we recognize there's going to be 12 governance issues that come out of this; yes, we 13 recognize that our process that we are going to develop is going to ask us to look back at the 14 15 MU2 measures; and, yes, our process is also going 16 to ask us to look forward, not just at new measures now, but, you know, additional measures, 17 18 too, because we also are working with other 19 groups, some of you may be involved with Rob 20 McClure's group, which is looking at when we have to make substantive changes to a value set, you 21 22 know, midstream, or mid-implementation year. So,

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you know, we can see the parallels that will go 1 2 with those three iterations, but, you know, we want to think about those things that are 3 governance, but really are charges to be 4 innovative, bold, all those good things, and 5 create a process that works, if that's okay. 6 7 MR. GOLDWATER: Ms. Martins. So it seems to me MEMBER MARTINS: 8 9 that we're really all saying, and going back to the issue of legacy and comparing directly and 10 all of that, none of that can be done without 11 knowing what the intent is. 12 13 It's just a matter of how you're asking the question. Are you asking, does this 14 15 belong, does this not belong, does this meet your 16 intent, does this not meet your intent, which is really trial and error versus having the people 17 18 who established the value set articulate the 19 purpose, and that's hard and iterative, but it's 20 what should be done. So really there is, it's a non-issue, 21

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whether we're doing the extensional list

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comparison versus the intent. The intent is 1 2 needed to do that extensional comparison, it's just keeping it at that level to make it a 3 process, better process, moving forward. 4 And then, my second item, which I, of 5 course, forgot, is, oh, the issue of intentional 6 7 definitions versus the expansions. I agree with you, Marjorie, it is a huge shift, but do we have 8 9 to, are we biting more off, more than what we can 10 chew, at this point? 11 So I would propose that there's a There's a happy medium of value 12 happy medium. 13 sets that have intentional definitions, and that produce expansions that are frozen and used in a 14 15 program for a specific year. We don't lose the 16 intentional definition that will be key to maintaining value sets harmonized, but we're also 17 18 not saying oh my God, everyone is going to have 19 to deal with dynamic value sets right now. 20 MR. GOLDWATER: Dr. Che. 21 MEMBER CHE: So I want you to look at, 22 a little bit, of end state of this work. After

we develop a set of, you know, wonderful 1 2 principles developing the value set, or harmonizing the value sets, how we can, you know, 3 distinguish this set of value sets. Say, this 4 has been reviewed and applied it with this set of 5 rigorous principles, so other people, or a future 6 7 user, can see it and will trust that this set of value sets. 8

9 I mean, literally, today in VSAC,
10 anyone can create a value set, whether it's, you
11 know, has a good intention, or a bad mistake, the
12 duplication will be created.

13 So for future user, if this set of value set has been applied with the principle, 14 15 and so they will trust, they will trust that, you 16 know, all the maintenance, or all the good stuff has been in place, then we will know this value 17 18 set is something we'd like to use. You know, 19 that certainly have higher score than the rest of 20 the value sets on there. So, I mean, this is probably just some end state that we want to 21 22 apply, please.

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1	MR. GOLDWATER: Dr. McClure.
2	MEMBER McCLURE: Thanks. So a couple
3	of things. The I'm going to mention it and
4	then I'll come back to it this issue of the
5	use of class, drug class, we need to be careful
6	about basing all of our, kind of, core work on
7	the assumed existence of a class system that we
8	can utilize, because I don't think it exists,
9	yet.
10	And so I think there's a lot of other
11	things we can do that isn't dependent on
12	literally getting an intentional definition,
13	based on a class, and doing analysis of the
14	actual expansions that are generated, based on
15	that, comparing against that sort of stuff. I
16	mean, that's part of it, but I think there's
17	other things that we can do that will be really
18	useful, also.
19	And so what are those other things?
20	So I think, we talked about this, and I think
21	there's a lot of value and we don't even have to
22	stay just on drugs, if we wanted to do this, and

that is getting clear scope, or purpose statements.

So again, we talked about the need to 3 go back and work with the stewards of these value 4 sets, usually, steward of the measure that was 5 utilizing them, and work with them to understand 6 7 what is an extremely clear, concise, thorough, purpose that is what we need in order to be able 8 9 to actually do harmonization. So establishing 10 the criteria by which that can be done and doing 11 it, as a part of the work that we need to do, it doesn't have to be restricted to drugs and is no 12 13 small feat, having been struggling to get people to do it. 14

15 So I think that that's one kind of 16 thing that's an important element of our work 17 that applies both in the harmonization process 18 going forward, process can be done right now, it 19 doesn't require anything more than what we 20 already have available to us.

21 Similarly, other things like that, 22 that are a part of what I would call value sets

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metadata, you know, we could tackle, like, and 1 2 you had mentioned, and I actually liked this idea, in that typing, I'll use this general 3 phrase, typing value sets, and by that, I mean 4 classifying, giving them a type, and thinking 5 that through, in the context of the sort of 6 7 things that I had talked about. And others have talked about, like this idea that certain value 8 9 sets are in the context of use describing a 10 request that data be encoded, and that has 11 certain qualities, with regards to the concepts that you want to put in there that are different 12 13 from, actually, drugs fall into this second category more often, an exhaustive list of all 14 15 possibles that aren't traditionally captured, and 16 therefore, you need to be good about making sure your definition really does get all of them. 17 18 You know, these other ones, that may

19 not be true. And so coming up with ways of 20 thinking about the types of value sets there are 21 that give clear guidance about differences in 22 approach is also something I think we can do and

that doesn't require, I mean, we have all the 1 2 tools available to us, I think, to do that. Another element to this is, well, that's -- let 3 me just stop there, with regards to those things, 4 I just want to answer some other questions. 5 There is, once we really get going on 6 7 actual content, we step into some important technical issues that everybody has to understand 8 9 in order to really, you know, I think, 10 participate in a valid way. 11 So we talked about some of them, like the idea we can make suggestions with regards to 12 13 the definition of a value set. The whole idea of value set definitions, and I'm so glad to hear 14 15 some of my colleagues using the words value sets 16 expansion, that there's a difference between a value set definition and a value set expansion, 17 18 and I hope everybody understands that here, and 19 if you don't, it would be worthwhile to take a 20 little bit of time to clarify that, because value set, the use of value sets uses value set 21 22 The creation of value sets at a expansions.

value set definition, and while many times they are in many ways the two sides of the same coin, they aren't always the same coin.

And the fact is, we can make changes, as you were mentioning, once we get to the part where we're really suggesting for a particular value set a particular change, we can make those suggestions without impacting regulatory activities right now. That is an absolute fact.

Now, how we do that requires us
specifying things that, traditionally, people
haven't thought about. This idea that a value
set definition is one thing, and what regulations
use is another thing, it's a value set expansion.

And so I'm saying that as one example of a number of things, where I wonder if the committee, there are some places that we can begin to do work that I think would be extremely valuable work that doesn't get us into an area that I have grave concerns about, with regard to the medications example, specifically.

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And that if we propose that our

deliverables are an exact analysis of specific value sets, clearly part of what the charge was that you were given to do work on harmonizing 3 value sets, but when we get to that point, if we 4 focus on medications, likely, we will want to use drug classes as a way to support that, and I'm 7 telling you, that thing is not ready.

And so I don't want us to immediately 8 9 get to that door and give up. I want us, I think 10 there's other things that we can do before we get 11 to the point where we, then say okay, here's exactly the qualities of a drug class system that 12 13 are needed, and where do we get that so that we can actually make defensible, valid changes to 14 15 value sets based on that.

17 CO-CHAIR BUTT: So yes, I think I 18 agree with Rob that we'll find many use cases in which the existing classification will not 19 20 support the need for a specific use case in a specific measure, so I guess, in terms of, since 21 22 we are sort of forward thinking and so forth, one

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could enunciate some sort of ask that perhaps the situation should be then handled by, obviously, creating a value set that fits, fills a need now, but then, whoever is, sort of, responsible for that domain is then asked to fill the gap and define what time frame it would be needed to fill that gap.

Because, you know, we're going to have 8 9 to, sort of, you know, sort of, dance and chew 10 gum at the same time in many of these instances, 11 so there needs to be some guidance, in terms of, you know, what are the couple of different things 12 13 that we would recommend, as a committee, that need to be incorporated. And while there's, sort 14 15 of, a dual track that you just don't sit while 16 somebody is going to add a new class, or whatever, but there's got to be some intermediate 17 18 way to handle the need, the immediate need. 19 MEMBER McCLURE: Just one quick 20 And, you know, I keep harping on this response.

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drug class thing, but there are other things that

we can say about medications. You know, RxNorm

doesn't, people may disagree with this, but 1 2 RxNorm doesn't have drug classes in it. It's extremely useful and it uses it 3 by the fact that it's not a hierarchy, it's a 4 series of attributes, and there's a lot of what's 5 done in creating the current drug value sets that 6 7 use those attributes in order to be able to create the content. So there are some things, 8 9 again, getting to definitive suggested, what appear to be disharmonies that could be resolved 10 11 by describing an intentional statement, with regards to use of code systems that we can do. 12 13 CO-CHAIR BUTT: Right. 14 MEMBER McCLURE: We just can't do this 15 one, one other thing. 16 CO-CHAIR BUTT: Right, and -- the other thing is this extensional versus 17 18 intentional. They're again, sort of, pros and 19 cons in terms of actual implementation, because 20 no matter how you look at it, an extensional is obviously clear, because it's there. 21 Intentional needs translation and that 22

translation needs to happen either at the 1 2 implementation level within an EHR, or within the data extraction process where there's a 3 transformation involved, or at the level of the 4 eCQM engine, somewhere along the line there has 5 to be a translation that needs to happen for it 6 7 to be reflected properly. So there is that level of, in a sense, shifting of the overhead that 8 9 would be required. And especially if, on the 10

11 implementation side, they have to incorporate things that are captured within an EHR, and drugs 12 13 is probably not the best example of that. It's much more when they have to capture things like 14 15 device applied, or those types of things that are 16 documented either by a nurse, or a physician, then they would have to internally reference the 17 18 ontologies and maintain some level of that. 19 And knowing some of the hospital that 20 we run into, it's going to be a challenge for

them to manage that whole process. I'm just

putting on the table the reality of what's out

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there in a lot of these hospitals where they are 2 just, basically, barely able to understand what VSAC is. 3

DR. SKAPIK: So I think that, you 4 know, Rob's point is a good one and there are a 5 number of points that I think we've heard today 6 7 that are perceived this early on in the process as potential, real limitations, or barriers to 8 9 this overall work.

I would suggest, and I think it would 10 11 be helpful to us to hear right now from you, not right now, aloud, but perhaps for you to compile 12 13 this list of potential limitations and barriers that you see today ahead of you. Because there 14 15 are potential streams of work, and there are 16 actually some ongoing streams of work to address some of these problems. 17

18 And hearing from the Committee that 19 this is going to limit your ability to get the 20 job done on this specific project, I think you're one of many groups of people who have faced these 21 22 limitations and been harmed by them, and so it

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might help to encourage us to really push some of this work forward, even as you continue to work on this project.

MEMBER RALLINS: Just, we've just 4 covered a lot of ground. And I was wondering, 5 Jason, if we could summarize? Because in the 6 7 context of harmonization, what it sounds like to me, and I could be wrong, is that we're not 8 9 necessarily harmonizing across, you know, disparate value sets. What it sounds like is 10 11 we're taking various measures in looking at the value sets that exists within each measure and 12 13 looking at it a different way.

So taking the extension and the intentional, the extensional that already exists and looking at how we can build an intentional value set. That in and of itself gets you to some type of harmonization. Is that where, is that where we are?

20 MR. GOLDWATER: That's correct. Before 21 you speak, Julia, do you want me to, sort of, 22 summarize and talk about where we are?

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(Off mic comments) 1 2 MR. GOLDWATER: Okay. So, and I'm summarizing and compiling the many thoughts that 3 have circulated in the last hour, but it seems 4 that there was two trains of thought. 5 The first was to set up a pilot process by choosing three 6 7 By then, engaging and, presumably, measures. that would be NQF that would take the lead on 8 9 those. 10 Engaging with the developer of the 11 value sets to specifically get at the purpose and scope that is probably as, I think, there was 12 13 consensus maybe inadequately defined in the documentation. 14 15 And that we need to then have a 16 conversation to get a much more expansive view of 17 what that scope is. Once we get a better 18 understanding of what scope is and we have 19 clarity over what that is, is then subsetting to 20 medications, which was the initial proposal, was then to, sort of, create an intentional value set 21 22 based upon what that scope was defined as, and we
are informing from that intentional value set what those medications would be, within each of those three measures, Marjorie, that we are discussing. And that would get us to some degree of harmonization.

I do want to add that it's a pilot 6 7 test, so this is not something that we're going to do and it's going to go live and then 8 9 everybody's using this, because, I think that would be highly problematic, and given, sort of, 10 the issues surrounding medication intentional 11 12 value sets. That could be very problematic, to 13 some extent, so we don't want to be doing that.

But it was just a pilot process to see 14 15 if we are able to get to the actual purpose and 16 scope of the value sets, look at intentional value sets and create them, are we able to get to 17 18 some degree of harmonization that would then be a 19 new path forward, and as Marjorie, I think, very 20 eloquently put, is a massive and significant culture shift in the way we are doing things now. 21 22 The other train of thought is what Dr.

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McClure was saying, which is in a nutshell, those 1 2 types of values, intentional value sets with drug classes are not ready. They're not ready for 3 Perhaps, we should not be focusing prime time. 4 on medications exclusively, perhaps we should 5 either look at something else, or be more 6 7 expansive in what we are doing. But in reality, before we get into any sort of pilot testing of 8 9 anything, that we should be examining more 10 specifically, you know, the issues that are surrounding why harmonization is an issue in the 11 first place. 12

13 Getting, again, to the intent and purpose of the value set, understanding why the 14 15 value set was created, potentially looking at a 16 way of typing quote, unquote value sets and having, I guess, a classification scheme with a 17 18 different types of value sets that there are, and 19 that that's sort of may be the activity we 20 pursue, rather than pilot testing, which was the So, Marjorie, that's sort of the 21 initial goal. 22 two things that we were discussing. Go ahead.

DR. SKAPIK: Yes, so to the scope of 1 2 the project, I think, you know, sort of, there were a lot of ideas back and forth as to whether 3 or not the scope should be related to specific 4 measures, or it should be related to domains that 5 exist across measures. I think that, you know, 6 7 as the client we would be very pleased if you took on three domain concepts that exists across 8 9 measures, as much as if you looked at the entire 10 content of measure value sets, specific measure 11 value sets. And I think that in terms of pilot 12 13 testing, I certainly agree, we don't expect widespread implementation during the pilot phase. 14 15 You know, it may be that you decide that you're 16 going to get better information by doing widespread community engagement and review of 17 18 content, as much as a single site implementing it 19 might give you less information. So I think 20 we're open to, you know, discussion about what the most effective way of determining whether or 21

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not a proposed solution is successful, and that

1 2 MR. GOLDWATER: Right. DR. SKAPIK: -- the domain is still, 3 in my mind, on the table. 4 MR. GOLDWATER: Right. So before I 5 get to my goals, I mean, we may pilot the 6 7 process, it may fail miserably, we may, I mean -usually failure's a harsh word, but it may not 8 9 be, it may not work. We may think, Dr. McClure's totally right, we should have listened to him all 10 along. Why were we considering anything other 11 12 than his? So, I'm sorry, blah, blah, blah, blah. 13 But, I mean, that's the purpose of piloting something is to see if it is going to be 14 15 successful. Dr. McClure. 16 DR. SKAPIK: And one more comment on 17 that. 18 MR. GOLDWATER: Sorry. 19 DR. SKAPIK: In the terms of 20 medications, I could see you doing the work in a way that would set you up to put in the drug 21 22 class information that's appropriate and

reliable, in the future when that would be available. If, you know, assuming that you, sort of, the way that you go about the process leaves you a space to plug that information later, if need be.

CO-CHAIR LIEBERMAN: And I think it's 6 7 all related in that what we started with is that we had these collections of values that seem to 8 9 mean the same thing but are different. And what 10 we've come up with is that we need to really 11 define well through the statement of purpose, or whatever, what that concept is that we're 12 13 addressing, so that we can decide if in fact they really are the same. And I think that's 14 15 absolutely the first thing to do.

But then, I think the second part is, when you're trying to determine whether or not they're the same, or whether or not this concept meets what you want to do, that what would be really useful is to have that, what we're calling that intentional definition, or that logical definition, using existing medical terminologies

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that will allow us to do that.

2	So that it could be using drug
3	classes, if they're there and they work for that
4	concept, my guess is beta blocker, or ACE
5	inhibitor, or, you know, ARB, it's probably in
6	NDF-RT now, and probably would work well, and
7	there are lots of occasions where it wouldn't,
8	but I think there are occasions where it would.
9	And there might be other examples, maybe, SNOMED
10	and drug classes in SNOMED and concepts in SNOMED
11	would work well, as well, to define that concept
12	that you're going for.
1 2	But if you could put it in terms of a

But if you could put it in terms of a 13 standard terminology that we have, then that 14 gives you the ability, in theory, over time, to 15 be able to actually compute what that list looks 16 17 like, in terms of other, you know, other types of information that might be collected. And it 18 makes it, it gives you the potential to have that 19 20 electronically presumable measure that we're looking for that is easier to maintain over time, 21 22 as well.

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1	MR. GOLDWATER: Dr. McClure.
2	MEMBER McCLURE: All right, just a
3	couple of things. One, I forgot, in terms of the
4	things that you were listing that I would
5	encourage us to consider for this additional
6	metadata of value sets, so one is this typing.
7	The other is, I think something that you
8	mentioned, and it's certainly an NQF thing,
9	quality, right? And so if there's a way that I
10	would encourage us to think about describing
11	quality of value sets and having some way of
12	being able to describe that.
13	And the other thing was, I forget. It
14	was some technical thing. But anyway, I forget.
15	Oh, I know what it now is. We've talked about
16	the importance of scope. There's another part of
17	this: the name of the value set. And so I think
18	we ought to tackle good naming practices, and we
19	suck at that.
20	(Laughter)
21	And so any, you know, good, I think,
22	if we can give really clear expectations with
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regards to naming that would really be 1 2 beneficial, in terms of harmonization and describing things. I would add to that, we need 3 to consider in the context of the way the VSAC 4 works and its use of grouping value sets and what 5 are called the numerating value sets, but grouped 6 7 value sets that those are qualities that are different. 8

9 Those are different kinds of value 10 sets and we need to come up with guidance that clarifies expectations with regards to the use of 11 12 grouping, right? I have some biases about that. 13 And then, how that applies to these things that we just talked about, what do we expect to see in 14 15 the context of a good scope for a grouping value 16 set, versus the grouped value set, and similarly, the naming conventions. 17

I think that would do a lot for our core deliverables, which is make it clear when things are the same, or not, when you just look at lists.

MEMBER CHUTE: Very briefly. Many

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artifacts, in terminology and elsewhere, have two names, because if you make what's called a fully-specified name, which is usually some long run on sentence that nobody wants to use, it doesn't get used, shockingly. But you need those to disambiguate what the heck you're talking about.

So I think we have to think about 8 9 this, in terms of having a fully-specified name 10 that is really almost a kind of documentation, 11 and then, maybe, a friendly name, or a common name that references the same artifact. And you 12 13 have to separate those puppies, otherwise, you're going to say oh that name's too long, we can't 14 15 use it. And it's okay for a fully-specified name 16 to be too long, because nobody's going to use it. So I just wanted to 17 MEMBER MARTINS: 18 go back to your summary, Jason. And, you know, the notion of intentional definitions and how 19 20 that would provide harmonization in and of itself, and how, and I think, Mike, you spoke a 21 22 little bit to more, how harmonization is going to

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occur once we have determined what the intention 1 2 is, right, what the intentional definition is. If the intentional definition matches, 3 then we have a problem with duplicate value sets, 4 really. We haven't gone into the weeds seeing 5 which particular codes are not aligning. 6 Cool. 7 And so what I wanted to say, really, is that that's an extremely iterative process, both 8 9 within, we each defining each value set and then 10 trying to identify where the mismatches are. You don't know what you don't know 11 until you're faced with someone else's 12 13 intentional definition of something that may be related, but not quite what you're trying to get 14 15 So just a cautionary comment there that to. 16 there are going to be some hurdles, I would say, that you can't just really sequentially address 17 18 this and now we have definitions, so now we're 19 going to compare, we're probably going to have to 20 go back and forth. And then, I really like the idea of 21 22 all of this quality criteria for quality of a

value sets, and I think we should build it in 1 2 into the intentional definitions. We should build intentional definition templates for 3 certain types of value sets that can then be 4 populated with the domain-specific information, 5 but to have the terminological part figured out. 6 7 So that's, I think, a way to marry those two approaches, or those two areas that were being 8 9 discussed. 10 (Off mic comments) 11 Okay. Dr. Zahid, and MR. GOLDWATER: 12 then, Marjorie. 13 CO-CHAIR BUTT: So I think Julia mentioned, like, domains going across measures, 14 15 so I guess one definition might be domain might 16 be medications going across measures, or what I was trying to define earlier was the concept of 17 18 each construct within a measure, like, you know, 19 the different populations and their use cases. 20 Because, I think, again, when we talk about the quality of a value set, there may be 21 22 some qualities that can be defined in treating

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the value set, simply as an isolated entity, 1 2 which has no relationship to anything else. You could define some qualities, or attributes, or 3 best practice in creating a code set. 4 But, I think, in many cases, the use 5 of that value set in the context of an eMeasures 6 7 implementation, has other aspects that get into play. For example, which component of the 8 9 measure construct is it going to be applied at? 10 Because your, you know, granularity, 11 or value, might vary, you know, where you apply And the same thing might be true of how does 12 it. 13 it impact the data capture work flow when it's implemented? 14 So I think those need to be an 15 16 essential component, in addition to defining whatever characteristics are defined off a good 17 18 value sets and isolation. And so I think, 19 somehow, we need to capture that sense that gets 20 communicated to whichever group that is going to do this work. 21 22 MEMBER RALLINS: Mine was just a

follow-up question to Rute's. When you mentioned 2 about figuring out the terminological part, what did you mean by that? 3

MEMBER MARTINS: So for instance, if 4 you're thinking about a RxNorm value set and it's 5 a value set that is supposed to capture 6 7 medications to be administered, defining which term types you would want to include in the value 8 9 And that's the standardized way of making set. 10 it part of the intentional definition.

11 I mean, SNOMED would, if we went into SNOMED it would get it, Rob's typing of values 12 13 sets, right, how are we going to develop? So I don't know if we can fully develop intentional 14 15 rules for that sort of information, but we can 16 certainly try.

DR. SKAPIK: Yes, to Zahid's point. 17 18 I would consider medications an awfully huge 19 scope for a pilot. I think it might be nice to 20 try, maybe, a class of medications as a pilot. I would hope that, you know, whatever 21 22 process the pilot works out is something that

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with a significantly less effort could be scaled 1 2 up, so that if you were to take a single group of medications and create a process that was 3 successful that it would be relatively less time 4 and labor intensive to repeat that process for 5 other classes of meds. 6 7 MR. GOLDWATER: Dr. Bregman. DR. BREGMAN: I was just looking at 8 9 the agenda and it looks like we have an hour 10 until we're supposed to have public comment, if we're still sticking to that? 11 And we have a lot of good ideas, I 12 13 just thought we should start writing them down. I'm sure you're already writing them down, but 14 15 write them down in a place where we can see them, and just to make sure that we agree and that 16 we're not getting too ambitious about what we're 17 18 proposing. 19 And I think Julia just suggested a way 20 to limit it so that we aren't going to get too ambitious, but also that would be steps that 21 22 themselves aren't too ambitious.

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1	MR. GOLDWATER: Here's what I think we
2	have so far, in terms of what we would do for the
3	pilot. And let's see if we can, do you want to
4	write them down?
5	(Off mic comments)
6	MR. GOLDWATER: Are we able to write
7	them down on a we you able to create a slide?
8	A white board? It's right there. So
9	we're going to go to rudimentary technology for
10	this one.
11	So I think there's going to be two
12	such of things we're going to do. Oh, one is
13	going to be the pilot test. Actually, I'm going
14	to say there's three things we're going to do.
15	So one is the going to be the pilot
16	test and we'll set that up. The second are going
17	to be some of these other issues that surround
18	value set harmonization that we will continue to
19	analyze throughout the course of the project that
20	may affect value set harmonization, but we don't
21	want it to interfere with our conducting of the
22	pilot test.

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And then, the third are, these 1 2 wonderful ideas that we don't want to lose, that we want a parking lot to go back to in the course 3 of these discussions we'll have with you and with 4 our technical expert panel. 5 So in terms of the pilot test, the 6 7 first thing we will do, and we'll have to do this after we write this down, are three measure 8 9 domains. Julia, is that what you want, domains 10 that cut across measures? Okay. So we want to 11 identify three measure domains. 12 We then need to have, secondly, 13 conversations with the value set stewards to identify the purpose and scope of the value sets 14 15 within these domains. And NOF will take the 16 responsibility of that, so that we are very descriptive with the purpose and the scope. 17 18 We will select a class of medications, 19 rather than taking on medications as an entire 20 So these are a couple of things we're topic. going to need to resolve in the next few minutes. 21

We will then go to our technical

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expert panel and ask them, on three separate 1 2 occasions, to take one of those measure domains, make sure we are explicit with the purpose and 3 scope of the value sets, what medication class we 4 are looking at, specifically, and ask them to 5 create an intentional value set, presumably, 6 7 using RxNorm, unless it's not, or -- Chris. You could use the MEMBER CHUTE: 8 9 standard medical, standard medical terminology. 10 MR. GOLDWATER: Use the standard 11 medical terminology? What terminology should we 12 use? 13 MEMBER CHUTE: Yes, I don't have to micro-specify that, but I'm getting tripped up on 14 15 this class bit. I didn't understand your point. 16 Because, quite frankly, the whole premise of intentional value set definitions, particularly 17 18 in medications, is that you would use drug class 19 to specify what you mean. 20 So you wouldn't be focusing on a class, you'd say, you know, I want an 21 22 antithrombotic, you know, that's a drug class.

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That's the value set. You're done. Then you leave it for one of these nomenclatures to do the 3 expansion.

And by the way, Rob just came over to 4 me with a news flash that yes indeed RxNorm does 5 have drug classes. We don't know their quality, 6 7 but they are, at least, begun in a more comprehensive fashion. 8

9 MEMBER McCLURE: So he's right. Yes. 10 Made a couple, they added, this is new, but there's something called ATC Codes. 11 Now, ATC Codes have been around a long time, they've 12 13 actually, they're used internationally. We won't engage in a discussion about their quality. 14 15 There are very strong opinions about their 16 quality, but they are now in RxNorm.

And so I'll ask, there's actually two 17 18 now, they put in also links to match, which I 19 believe, probably, are coming through NDF-RT 20 there, and some of the other work that's being And so that one also may be spotty, in 21 done. 22 terms of it, but there are embedded now in RxNorm

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ways of using drug classes.

2 You know, for example, Penicillin G, using ATC, or is it MeSH, one of them doesn't 3 have beta-lactams as one of the classifications. 4 So there's that. 5

The other point, just, if I may, since 6 7 I've grabbed the mic that, you know, again, we're focusing on medications, I think, for some 8 9 reasons that we've discussed.

But this idea, you know, kind of 10 jumping on what Chris was saying, of using 11 classes, let's be a little cautious about using 12 13 the word class, because what we're talking about is hierarchies, right? And that applies 14 15 everywhere.

16 So it's a little wrong to say class when you're talking about some of our other 17 18 terminologies, but it's always right to say 19 hierarchy, and that's what we're talking about. 20 And the point that Chris is making,

which I think is worthy of some discussion, maybe 22 not right now, but at some point, is this issue

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of having then specified, you know, and you have
 to do some analysis.

You have to say okay, I'm going to go look. Oh that terminology has that classification system, there's a concept that I want. I'm going to say that concept, you can't just walk away.

8 Now, you know, what Chris is saying is 9 it may be in some domains given the kind of trust 10 relationship that makes sense, in terms of the 11 process that you're describing.

12 You put any antithrombotics I'm done. 13 I don't care what's underneath there, because the 14 group that decided what's underneath there is 15 more reliable than I am and I'm ceding 16 responsibility, in a sense, to that process to do 17 that.

But that's going to be the kind of thing, again, I want us to not skip over that. That's exactly where we need to provide guidance so that authors know when they can do that and what that means to them versus when they

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shouldn't.

2	So they, you know, and shouldn't
3	means, in this case, go and get it and look at it
4	make a change to it. Record that change as a
5	part of your definition, right?
6	Now you can't just say this thing and
7	all of its decedents, you can say this thing and
8	all its decedents, but now remove this, remove
9	this, and what are the consequences of that?
10	Guess what, now you're in the game, every single
11	time the thing is updated, right?
12	So these are all, I think, elements of
13	our process that would be wonderful to see
14	specified by an authoritative group and that
15	would then make the process of harmonization much
16	more clear, because you could almost, we could
17	almost get to the point, and I think Chris would
18	be in real support of this, where harmonization
19	is a mechanistic thing, right? Because you're so
20	well-specified in what you're doing
21	MEMBER CHUTE: Right.
22	MEMBER McCLURE: that you'll let

the computers do it, and then you just kind of 1 2 review it. Julia, and then, 3 MR. GOLDWATER: Howard, and then we need to get back to our --4 DR. SKAPIK: Yes, and perhaps I should 5 have been a little more clear, in regards to my 6 7 use of the term class, because obviously there are multiple ways to create classes with 8 9 medications. Specifically, I was intending, and I 10 think antithrombotic is a good example, across 11 the measures there are a number of different, 12 13 sort of, groups of value sets that describe things that are used for the purpose of 14 15 preventing, or treating, potential thrombotic 16 events. However, across the entire set of 17 18 measures there's a very heterogeneous groups of 19 those things. And for some of those, there's 20 very intentional reasons. And for others of those there are, and I mean intentional, the T, 21 22 and for others of those there's less clear as to

1 2 why there's lack of symmetry.

2 And I think, you know, antihypertensives, antithrombotics, those are 3 good examples of where you quickly, sort of, find 4 yourself in this murky place and you need to 5 decide, you know, knowing how heterogeneous a 6 7 group of things like this are, that might all satisfy the same criteria for some measures, but 8 9 not others, how do you harmonize, how do you 10 identify, where do you need to make those manual 11 decisions and where does an automotive process meet the needs of the overall goal, just to make 12 13 the value sets reflect as perfectly as possible the clinical intent without having any 14 15 unnecessary, like, whatever the term used at the 16 beginning, unjustified descendants, something like that? 17 18 MR. GOLDWATER: So before I go to Dr. 19 So, Julia, just let me be clear, what Bregman. 20 is it exactly that you want us to be looking at, is it medications, as a whole, is there a 21

particular type of medication, is it, you don't

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have to do that, just speak your answer. It's
 fine.

3 DR. SKAPIK: Well, Rob knows that one 4 of the items on my wish list was actually 5 encounters, but I'm not here to speak to the 6 group as to, you know, what you wanted to go 7 after.

Encounters is extremely challenging, 8 9 because it's present in a huge proportion of the 10 measures. So it may be to your benefit to go after something like antithrombotics where can be 11 a little bit more, sort of, mechanized, as Rob 12 13 said, than something like encounters in which you might experience a cat fight between measure 14 15 stewards over the exact definitions of what meets 16 the criteria to get into a measure population.

MR. GOLDWATER: Dr. Bregman, and then
we'll get back to this.

MEMBER BREGMAN: I just want to ask a
hypothetical. So suppose a value set,
essentially, was a list of penicillins, oral, not
in combination with other drugs. That's the

1	value set. What would the steward come back and
2	say if you asked them, just that?
3	MEMBER CHUTE: If I could try to
4	answer? And so I'm confused about stewards and
5	articulators and authors at this point. But
6	let's say that the value set, sorry, the quality
7	metric developer really intended oral penicillins
8	and wanted to exclude other kinds of penicillins.
9	I think an approach to that would be
10	for them to specify the drug class of penicillins
11	and ideally reference a terminology such as
12	RxNorm, assuming that it's satisfactory, we don't
13	know that yet.
14	And then, in this case, specify the
15	route, which would be oral, so it would be the
16	union of those two things. You'd need some logic
17	statement in your implementation.
18	Now you, as an implementer, at least
19	at the vendor level, and I assume you're
20	implementing on behalf of your clients, would
21	then have the chore of looking up what
22	penicillins mean, and the RxNorm thinks that you

could do the expanded list, just to make it 1 2 practical in your backyard, and I don't know an epic, I should, because I'm at Hopkins now, but I 3 don't, I don't know if route is an explicitly 4 encoded variable, but let's assume that it is, 5 then the quality metric would be the union of 6 7 those two expanded lists. MEMBER BREGMAN: Okay, so then our 8 9 specification the response -- yes, I'm just 10 looking at 4(b). So what we're asking the 11 measure author to come back with is, essentially, a logical statement that defines the value set 12 13 using --And they have to draw 14 MEMBER CHUTE: 15 their logical statement predicates from an agreed 16 upon or -- this goes back to our first conversation today. The principle of what 17 18 terminologies would we designate as acceptable 19 for the framework. 20 I mean, you couldn't have quality metric developer A say well, I want NDF codes, 21 22 and then, you know, expand those. And then

another come back and say well, I want RxNorm codes. And then you get another one come back and say well I want First Databank codes. That won't work.

We have to say up front, okay, if you want to specify drugs, here's the menu. And let's assume for the moment that it's RxNorm drug classes, that they proved to be satisfactory eventually.

10 Then the metric developer would have 11 to choose classes from the menu that exists. And 12 they may need to do some logic, you know, 13 excludes, includes, like the wonderful example of 14 ophthalmologic beta blockers.

MR. GOLDWATER: Okay, so I'm going to go back, again, through the people that have raised their hands. And I would, again, just ask your comments to be brief, so that we can try to finish up here before quarter of 4:00 p.m. Zahid.

21 CO-CHAIR BUTT: SO I Would think, in 22 Howard's example, once they have selected

whatever class they were going to select, I would think that they would then be required to see the members of the class and see if they met the intent of the measure. And if it didn't, then they have to go the alternate path. I would think that would be part of this exercise.

MR. GOLDWATER: Dr. McClure.

MEMBER McCLURE: Yes, so actually to 8 9 answer that question, I mean, I still think we 10 follow this process. There's some technical 11 nuances here, but we do have the ability, for example, now in one place, to select things based 12 13 on classes and get the things that are orderables, or things that you get exposed to, so 14 15 that's good.

But to this point, I think that there will be many times where in fact given the way that these value sets were originally created, that the class ---- the available hierarchies in the selectable code systems that we would specify won't give you exact lists that you want. And so the assumption would be that you would, in fact,

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have to do some manipulations. We want to see if that's truly true.

And I think that gets to the point as 3 to how we -- how we phrase the process -- you 4 know, create the process and phrase the question 5 so that we do at some point -- one, ask them, 6 7 start with this, and then, two, say isn't it good enough, right? This whole issue of, yes, that 8 9 drug's not in there, and you would have to create 10 this one off thing, what should happen there? 11 Is it that they made a mistake and you know better, that class drug belongs in that 12 13 class? Or is it that you really need to do two things in your logic instead of one? You know, 14 15 that's a part of the process that we need to 16 clarify and engage them in, in order to be able to see how the harmonization process can occur 17 18 down the road. 19 MR. GOLDWATER: Julia, then Rute. 20 DR. SKAPIK: Yes, and again, we didn't set out to define what we thought you should 21

pilot. I do see that you have three domains

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listed as possibilities. I think that's a good 1 2 number. I would encourage you to select different data types for those three domains. 3 And it might be even helpful to pick 4 those three, sort of, domains today, so you can 5 decide which one makes the most sense to start 6 7 with, although, I think medications is a perfectly good one to start with. 8 9 Because I think we'll learn some 10 interesting things, as you try to harmonize 11 different data types and different concepts in 12 the measures, how a process that works for one 13 thing might be problematic, or need tweaking for a different kind of information. 14 15 MR. GOLDWATER: Rute, and then in the 16 back. So I just want to go 17 MEMBER MARTINS: 18 back to Zahid's point, in terms of the --19 certainly, the expansion is a big part of making 20 sure that your intentional definition meets the intent, really. 21 22 And that's what I mean when I say this

is an iterative process, because for sure your 1 2 first trial of expanding will -- surely, there's some suppository that you haven't considered in 3 your logical definition that will make it into 4 your value set. Then you need to go back and 5 revise your rules to make sure that you're 6 7 excluding those ---- or strength, yes. So that's the iterative nature of that. 8

I did want to point out that, from my 9 10 perspective, this whole movement to intentional -11 - they don't have to be competing, necessarily. And I would caution -- if we think about two 12 13 rafts, one is intentional, one is extensional, we're on the extensional raft, let's put a foot 14 15 in the intentional raft without taking the other 16 foot from the extensional raft, is what I'm 17 proposing.

Because we don't want to jump ahead and find that our intentional definitions really hit the walls of the incomplete class ---- drug classes in our RxNorm and that sort of thing. Can we really fully define these things

intentionally at this point? I don't know what
 the answer is to that.
 So I would keep the extensional lists,

4 both from a consumption perspective. For 5 implementers it may be helpful, and once we see 6 those maturing and everyone gaining in confidence 7 in the intentional, then pull the plug on the 8 extensional.

9 MR. GOLDWATER: Dr. Heras, Dr.
10 McClure.

11 MEMBER HERAS: Yes, Rute just said 12 what I was going to -- you know. Yes, I don't --13 -- I think we should keep the extension list just, you know, even if you have an intentional 14 15 definition, we need to have the enumerative list 16 for the implementation. And also, to -- because right now all the systems, they have been just 17 18 going through ---- taking the value set from the 19 VSAC directly. They don't have the engine to 20 actually process ---- to process the intentional definition to gather exhaustive lists. So that's 21 22 one thing.

And also, the other one, I actually 1 2 really wanted to see encounter to be on our catalog, as well. The reason is encounter has 3 been used in every single measure almost and 4 there are just inconsistencies there. And also, 5 the probably intentional definition might not use 6 7 very well for encounter. So I don't think the medication -- you 8 9 take medication out, I mean, that's great, but 10 the process we define, can we generalize to other 11 data types easily? So that's why I would hope that we have the encounter as another 12 13 alternative. Just in addition to medications, if 14 that's, you know --15 MR. GOLDWATER: Dr. McClure, then 16 Michael. 17 MEMBER McCLURE: So first I agree, I 18 think we need to do different domains. I think 19 that we're going to discover different things, 20 obviously, in different domains and that means that we probably need to have our focus, to some 21 22 extent, in terms of what we can actually deliver

will be somewhat different in the different 2 domains. And so I think that's very reasonable that that would be an outcome. 3

And I also would, third, the choice of 4 picking something like encounters. That ---- you 5 know, medications are going to be hard for one 6 7 set of things and this is going to be hard for another. In particular, there's a real strong, 8 9 what I would call reach back, into the logic of 10 the measures.

And the whole idea of behind what it 11 is it that you're trying to accomplish in your 12 13 measure by this attribute using this value set that becomes important in the context of creating 14 15 good value sets that is always there, but we can 16 ignore it in the medication pilot. We won't be able to ignore it in something like the encounter 17 18 pilot. So that's one part.

19 And the second is that the just a kind 20 of a technical issue to describe our ability to use ATC codes as class codes in association with 21 22 RxNorm.

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So one of the reasons people don't 1 2 like that class system is it's a single hierarchy And so I would encourage folks, as we 3 system. begin this process, that we'll clearly need to 4 understand the context of what it is we're doing 5 and understand that, as a pilot, the approach we 6 7 would take would be very influenced by -- in this case, ATC codes and the craziness that's in ATC 8 9 codes and the arbitrary, I would say, decisions 10 that are made at WHO.

I don't even know that ATC codes have 11 been touched recently, and how it separates out 12 13 various, you know, ingredients. Remember, because now you have the same ingredients going 14 15 to be in more than one code because there are 16 certain subcategories of that ingredient that fall into one subcategory, ATC, whereas another 17 18 strength of that ingredient are used someplace 19 else, and it makes ATC problematic. So it's 20 Then we'll have those issues to address. qood. MR. GOLDWATER: All right, so before 21 22 I turn it to the last comments, and I can let

conversation go until about 3:15 and then I'm

going to have to stop it, so that we can finish the task that we need to do, answer the questions we need to answer, and then make sure we have time for public comment.

There might be some leftover time to address some remaining issues, but after the next ten minutes, I do want to put a stop to the conversation, as much as I'm enjoying this.

10 CO-CHAIR LIEBERMAN: Yes, so I think 11 just, when we say three measure domains, I don't 12 think we really mean three measure domains. Ι 13 think we mean data types, is that what we're talking about? So kind of medications, 14 15 encounters, and perhaps one other? 16 CO-CHAIR BUTT: Diagnosis. 17 CO-CHAIR LIEBERMAN: Diagnosis. Ι 18 think diagnosis would be a good one as well, 19 because diagnosis has -- we have SNOMED for 20 diagnoses and that -- we should be able to develop an intentional statement using SNOMED to 21 22 describe a concept. That's kind of the whole

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idea behind it.

2	So I think that that's what I would
3	I would move to include those three things,
4	which are and we talked about doing three
5	measures. So we look at problems, meds, and
6	encounters, over three measures to see how far we
7	can get with this intentional definition and the
8	meaning of that.
9	The other part of that is, you know,
10	I think for encounters, I don't know of a good
11	system to give intentional definition to
12	encounter. So we may end up with just lists of
13	codes and what the intent was, in terms of the
14	English description of what that concept is
15	supposed to be.
16	MR. GOLDWATER: Dr. Chute.
17	MEMBER CHUTE: Two comments. One,
18	RxNorm is not just ATC, it's also MeSH, which is
19	poly-hierarchical. How that's implemented in
20	RxNorm we'd have to look at.
21	Two, this multiple data types.
22	Realize, everybody, we've done a 180 degree

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reverse from the morning and I want to speak 1 2 against that. Sorry, Julia. I really think we should stick with 3 drugs and only drugs. It's supposed to be a 4 If we start bringing in other domains, I 5 pilot. think we will no longer have a pilot, we'll have 6 7 intractable issues. Diagnoses are a minefield. I can say that with some authority. 8 9 And I would strongly urge that we not 10 expand to three data types, but stick to drugs, learn what we can from it, and illustrate the 11 principle of hierarchical renderings and 12 13 representation, which I think will be at least feasible in the drug space and then learn from 14 15 that. 16 I'm going to take the MR. GOLDWATER: Senior Director position off for a comment, which 17 18 I haven't done today, but I will. Which is that 19 is exactly what we said this morning, which is if 20 we take on diagnoses and encounters and labs that

is far too much to do in a course of one summer

where we're supposed to be piloting this and it

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is going to be almost impossible to try to get some results.

Which is why we initially said let's pick three measures and do medications under those three measures, learn what we are able to do, and think that that might translate into something that we may be able to pilot later.

And so we do seem to be backtracking against what we've just said and the moment that somebody said diagnosis my skin turned, which is like -- that is so much to do. I mean, we did this -- Ann and I, did this on five measures. It took a month to do, and we didn't do all of it.

And so we're asking three pilot tests in the course of a summer over three different domain areas. So I want to be conscience of, this is a time-consuming activity to do and we do need to gain lessons that we can translate into an ability to do in other areas.

At the same point, there are things we're going to be doing in parallel to this. So if we are going to reverse and say we're going to

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do three domains, I would ask that how do you 1 2 propose to do this in the time period that we 3 have, under the contract that we have, to do that successfully? 4 I mean, I would go back and say -- and 5 I can't believe I'm saying this, I agree with 6 7 Chris completely, which ---- I'm kidding, I'm kidding. Which is, I think we need to pick three 8 9 measures, because we have some very expert 10 measure developers here, we need to do 11 medications, and it's a lot easier to pilot with less to do and there are lessons to be gained 12 13 from that. Does anyone object, I mean, Julia, if 14 you object to that --15 DR. SKAPIK: I mean, if you're going to limit your pilot to medications, then I would 16 expect that you would look over the entire 17 18 measure set with the medication and not just 19 three measures. 20 MEMBER CHUTE: I think that's unreasonable. 21 22 MR. GOLDWATER: That's very

unreasonable. 1 2 MEMBER CHUTE: I think that's extremely unreasonable. 3 DR. SKAPIK: I don't mean all 4 medications for all measures, I mean --5 MEMBER CHUTE: That's what it comes 6 7 down to. DR. SKAPIK: -- take a class of 8 9 medications and do them across the entire set of 10 the measures. 11 MEMBER CHUTE: That's the wrong way to slice it, because we're trying -- intentional 12 13 definitions are premised on class. So if you're working within a class, it's meaningless. 14 15 MR. GOLDWATER: Dr. Schneider, and 16 then Dr. McClure. MEMBER SCHNEIDER: Yes, I'm also 17 18 agreeing with Chris here. Just a couple of quick 19 things. First of all medications, pretty clearly 20 defined NOF and the -- but even it has its fuzzy edges like we talked about in terms of classes 21 22 and so on.

You get into diagnoses or problems, a 1 2 swamp. You get into encounters it's even more of a swamp because as far as I know, there's no 3 authoritative group that says here's what 4 encounters are, and this group can't create that, 5 so I'm with you on that. 6 7 I would say we need to find a good old fashioned Texas compromise between the do 8 9 everything and the do -- you know, do three 10 because we can't do what you're asking to do, so 11 let's find a way to do that. One little minor technical thing, for 12 13 our scribe, a really good thought Chris put forward was the long and short name, if we could 14 15 ask that to be part of our little pilot that 16 would be a good idea. And then, substituting the word hierarchy for class, I think, is important 17 18 in there. 19 So again, just, you know, let's be 20 realistic. We'll swamp the boat if we go to the 21 three --22 I completely agree. MR. GOLDWATER:

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Dr. McClure, then Marjorie, then Dr. Che.

MEMBER McCLURE: So this is where I'm going to prove I don't have bias. I do think we 3 shouldn't just do medications. I think that medications is -- won't prove enough of what we need to deal with.

7 But I also think that this focus on understanding the requirements that you've been 8 9 given with regards to this particular project, 10 the focus on actually harmonizing specific value 11 sets needs to be weighed against the value of determining the right approach to clearly get 12 13 this -- what I call value set metadata specified and with the very, I think, correct assumption 14 15 that in doing so, even if it doesn't fall within 16 the final deliverable of this activity ---although I think it could, that will very much 17 18 inform ongoing work for, you know, someone else 19 to pick up, or just literally tell the developers 20 that they have to follow the approach.

And so because of that I think we 21 22 ought to actually tackle encounters and

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medications, but I'm also saying that I'm not convinced that means that we have to actually come up with proposed value sets for any of these particular things. I think that we should, but it doesn't mean we have to.

I think that we could, you know, by 6 7 making sure that we clarify and work through how the scope and purpose of a value set that's used 8 9 to describe encounters captures all of the 10 important nuances across the various places, you 11 know, a subset of the places that it's used, and determining the right code system that would be 12 13 used in case to reference that.

How one decides that. This issue of 14 15 -- in this case maybe not typing, but quality, 16 whether that applies there. All of those things can be done without then coming down with an 17 18 authoritative statement as to this is therefore 19 the value set. And ---- yes 20 Okay, before I get to MR. GOLDWATER:

21 the next commentary, can I propose a potential 22 compromise?

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CO-CHAIR BUTT: Can I say something 1 2 real quick? MR. GOLDWATER: Go ahead. 3 CO-CHAIR BUTT: Since I was the one 4 who blurted out diagnosis? 5 MR. GOLDWATER: 6 Yes. 7 CO-CHAIR BUTT: I --MR. GOLDWATER: I still like you, I 8 9 do. 10 CO-CHAIR BUTT: I wasn't proposing that it be done -- that all three be done 11 together, at least that's not what I was 12 13 thinking. Right. 14 MR. GOLDWATER: 15 CO-CHAIR BUTT: I was thinking more 16 that if there were three domains that we had to pick, those would be the three domains that would 17 18 be picked. 19 When they would be done was open, and 20 that had to do with a lot of your contract and what was the deliverable within this defined 21 22 I was thinking that, you know, this could scope.

be another job that we could --1 2 MR. GOLDWATER: So I really like the way you think, in terms of contracting, but --3 CO-CHAIR BUTT: -- in terms of going 4 forward, you know, that what we would do is --5 MR. GOLDWATER: Right. 6 7 CO-CHAIR BUTT: -- start with medication, learn from it, and potentially -- I 8 9 agree with Rob that we should start the pilot with something that is, hopefully, easier to 10 tackle than those other things, but that doesn't 11 mean the other things don't have to be tackled. 12 13 MR. GOLDWATER: So no, so I don't 14 agree. CO-CHAIR BUTT: Are we ---- do we seem 15 16 to be tackling hard things, is that kind of the 17 message? 18 MR. GOLDWATER: So here's, I guess, 19 the Texas compromise, also being from Texas, 20 which is, why don't we choose three measures? One measure, the first one, why don't 21 22 we examine medications? And why don't we do that

with the second measure, as well? And the third 1 2 measure that we choose, then why don't we look at encounters? 3 Rather than just choosing domains and 4 going across -- no, you don't like that idea? 5 CO-CHAIR LIEBERMAN: Can I? I mean, 6 7 T --MR. GOLDWATER: Okay. 8 9 CO-CHAIR LIEBERMAN: So the work of 10 this technical expert panel is going to be looking at specific value sets in trying to work 11 through the harmonization process. 12 13 And nobody said they have to do all the value sets and the measures that we're 14 15 looking at, I mean, I think the process is 16 understanding the -- is looking at the harmonization. 17 18 So the question is whether we'd be 19 better off having them do five medications, or 20 whether we'd be better off doing two medications and two problems, or two medications and two 21 encounter definitions. 22

And I do think that -- I feel like we 1 2 would get more value by looking at two different types of things, if there's enough time and 3 resources in the contract to do that. 4 You know, I have mixed emotions about 5 encounters. We can't do the type of intentional 6 7 definition that we are talking about here. So in some ways it's not as interesting, or perhaps, 8 9 you know, not as useful in that respect, but it 10 does kind of get down to the more mundane work of harmonization, which I think was part of the 11 intention of this as well. 12 13 Which is to look at a set of codes and come up with an agreement on what we're actually 14 15 trying to define and what codes would be used for 16 that. 17 MR. GOLDWATER: Marjorie. 18 MEMBER RALLINS: So I'm glad we got to 19 the compromise, because that was kind of where I 20 was going. I will say that I think it's important to know that when the committee made 21 22 recommendations as it relates to encounters, it

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wasn't from the administrative sense, and because 1 2 of that, I believe -- I don't have them in front of me, Ann might know, I'm told, as well, that we 3 use SNOMED for that. So there is a sort of a 4 hierarchal root. 5 I would also add that I do know that 6 7 the CPT folks are building some kind of data model and anthology around CPT, which is a 8 9 transition vocabulary, so we might have something to work with if we decide to go in that 10 11 direction. But I do believe we need to -- I do 12 13 like the idea of doing two at the same time, but not at the measure level, more at the concept 14 15 level, you know? So we do medications, or we do, 16 you know, diagnoses. Don't shoot me, but --So it's kind of similar 17 MEMBER CHE: 18 line, encounter we use SNOMED CT procedure code. 19 I mean, we started that same project, you know, 20 codes for the encounter and stuff. So I mean, it's not really a 21 22 harmonization issue. I mean, if you're looking

to the encounter, probably, you want to make it right, you know, look at it from what's the best code system to start with.

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DR. SKAPIK: Maybe I'm missing something here, but I don't understand how we would harmonize a single measure's content. The harmonization goal is to make a cross the suite of measures the content to match and align.

9 And Rob and I, with many of the people 10 on this committee, have been engaged in an 11 attempt to do that in a one-off fashion for 12 several years. And what we have found is, if you 13 are not inclusive of all of the related content, 14 then you just keep doing the harmonization 15 process over and over.

16 So that's my comment in regards to, 17 take a single concept domain and look across the 18 measures because otherwise you're going to be 19 doing this again.

20 MEMBER MARTINS: I was actually going 21 to suggest that we go back to the work that 22 you've done already in preparation of this

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meeting.

2	There's a small set of measures, there
3	are a lot of value sets, but maybe we can choose
4	some value sets across several domains even
5	potentially. We already know that there are
6	harmonizations there, issues there that we can
7	play around with. So the scope may be
8	self-defined already, so why are we trying I
9	think we're trying to boil the ocean here, at
10	some level.
11	I think it's unreasonable to think
12	that we can look at one domain across all of the
13	measures. It's probably as unmanageable as
14	looking well, anyway.
15	So I would suggest that we choose a
16	few measures. I agree with Julia that you can't
17	harmonize with one measure and look at
18	medications at one measure, because that, we run
19	and look at medications across, we want to get
20	different stewards at the table. We want to see
21	those cat fights. That's what this is all about,
22	right? So I

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MEMBER CHUTE: I want to propose a 1 2 Maryland compromise, now residing in Maryland. I actually agree with Julia. 3 Comparison across one measure is meaningless. 4 And I would even submit comparison across two 5 measures is trivial and not particularly 6 7 informative. And the compromise I'm suggesting is, 8 9 you know, pick a round number, half a dozen, ten. I don't know, but some finite number of measures 10 and look at medications and only medications, so 11 help me God, without overlaying it with other 12 13 domains at this time. Because, one, I agree with Rob, 14 15 there's a lot to learn about how to specify those 16 value sets in a rigorous, interpretable, transparent, machinable kind of way. We'd 17 18 exercise that. 19 Two, we'd have some scope in terms of 20 the kinds of hierarchical implications that we would discover exercising hierarchy candidates, 21 22 whether it's RxNorm, or something else.

And three, and perhaps most 1 2 importantly, we bring together a larger number of measure developers. In fact, if you want a 3 sampling strategy, I would say sample measures 4 that come from different measure developers 5 precisely so that you can look at these 6 7 cross-cultural notions of, okay, what do you mean by this kind of drug class, for lack of a better 8 9 And see if there's dissonance among the term. 10 measure developers when we talk about an 11 antithrombotic, or whatever. I think that would be a far more 12 13 trackable, much more informative process than two of these, two of those, and two of something 14 15 else. 16 MEMBER McCLURE: So I almost agree with Chris in that I would say we'd start with 17 medications. 18 I do think that we ought to tackle 19 something else also. 20 I think that -- again, I want to highlight that I don't think that that means we 21 22 have to come up with a final resolved solution

with regards to the content of the value sets, I can't say that too strongly.

But I do think that having -- and I 3 would say we start with medications because I 4 think there is a lot to learn, but I would like 5 for us to then move to something like encounters 6 7 because I think encounters -- I know encounters will bring other elements to this that by the 8 9 work we'll have learned we can apply there, and 10 then hopefully, address issues that, quite 11 honestly, just being able to solve the medication problem will not give us the tools that we need 12 13 to solve a lot of other problems. 14 MR. GOLDWATER: Chris, guickly, and 15 then I'll --

16 MEMBER CHUTE: If I may? You know, 17 whether we do encounters or not, that's a 18 separate discussion. But I would strongly 19 advocate that if we're going to do medications, 20 we do it soup to nuts. That we actually bring it to closure and we go all the way to specifying 21 22 the value sets --

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1	MEMBER McCLURE: Yes, you know what
2	MEMBER CHUTE: And here's why.
3	Because that last mile problem can usually get
4	you. And if we don't execute to the degree that
5	we go to that last mile, that is fully-specify
6	that enumerated value set from the intentional
7	definition, la-di-da-di-da. If we don't exercise
8	out the whole game, I don't think it's a pilot.
9	MR. GOLDWATER: Okay.
10	MEMBER McCLURE: Yes, let me I
11	absolutely agree with that. I think, in the
12	context of the medication ones, we need to go all
13	the way. Because that's really the meat of that
14	one, so I absolutely agree with that.
15	MR. GOLDWATER: Okay. Zahid, I'm
16	sorry, I'm going to have to stop here for a
17	second. So let me propose this, again. I feel
18	like I'm on the floor of the Senate.
19	So given what we have already done,
20	why don't we take now mind you, we are sub-
21	setting all the entire universe of measures
22	into those that are used in meaningful use

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because we know those are electronic -- those 1 2 eCQMs. So all the AMI measures, all of the 3 VTE measures that are in MU2, why don't we use 4 those for medications? What's that? 5 (Off mic comments) 6 7 CO-CHAIR BUTT: There is a total of 93 measures. 8 9 MR. GOLDWATER: Right. I understand 10 that, right. So I'm saying the subset of AMI 11 measures and VTE in Meaningful Use 2, we do those for medications. 12 13 (Off mic comments) MR. GOLDWATER: And Stroke. What's 14 15 that? I just added stroke. 16 MEMBER MARTINS: So can I --17 MR. GOLDWATER: And then --18 MEMBER MARTINS: So that's great, but 19 that's a lot, is what I would say. 20 MR. GOLDWATER: Okay, so --MEMBER MARTINS: And I think there are 21 22 ways that we can -- we know which measures are

kind of using, sort of, the same medications, or 1 2 medication that may overlap, so we can do a selection there. 3 MR. GOLDWATER: So Rute, I'm going to 4 Tell me which ones you think we should 5 stop you. do. 6 7 MEMBER MARTINS: Oh goodness. MR. GOLDWATER: Offline? Okay. So do 8 9 we, Julia, we want to do two of the three, one of 10 11 MEMBER McCLURE: So --12 MR. GOLDWATER: -- the three --13 MEMBER McCLURE: Hold on, just one thing about this, because I think in selecting 14 15 the advantages of some of these value sets are 16 used -- so to say a stroke measure, or a VTE measure that doesn't -- the value sets are used 17 18 in measures other than VTE, they were just 19 originally defined in VTE. 20 Right. MR. GOLDWATER: MEMBER McCLURE: So that's an element 21 22 that makes it a better choice in a sense that

you're getting, you know, more than one measure, 1 2 even though the measure steward originally created it for one. That's exactly what you 3 It's already being used, so there's an 4 want. element. And some of them were already chosen 5 and there's some compromises already that have 6 7 occurred.

8 So the criteria should be multiple 9 measures, multiple measure stewards, and multiple 10 stewards, and, honestly, you know, multiple kinds 11 of measures. So not just multiple VTEs, but I do 12 like the idea of VTE and stroke, or something, so 13 that you get this --

MR. GOLDWATER: Right.

MEMBER McCLURE: -- dynamic process.

16 MR. GOLDWATER: Okay. So we'll look 17 at Cindy's spreadsheet, thank you, ahead of time, 18 for giving us that, and we'll choose two out of 19 the three, and we'll focus on medications for 20 And then, depression ---- what's that? those. All -- soup to nuts, we're doing all 21 22 And then, depression we will do for of them.

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encounters, which is where we found the issues. 1 2 And depression measures, I know, have many different stewards. There's at least seven 3 different stewards that did the depression 4 measures in Meaningful Use. Who did the value 5 sets, I don't know, but we'll --6 7 CO-CHAIR BUTT: And they're ambulatory. 8 9 MR. GOLDWATER: They're ambulatory 10 that's correct. Is that acceptable to everyone? 11 I'm holding my breath. Great, the Chairs say 12 yes, fine. Good. Done. 13 All right, so other things we will work on, in addition to the pilot, and NQF will 14 15 take this on working with Zahid and Michael, and 16 probably having ---- we'll set up conversations with you all. 17 18 We may do some key informant 19 interviews, as well, but it would be looking at 20 Rob doing a sort of typology for value sets, 21 metadata typology. 22 Right, and then defining a criteria,

or establishing criteria for what constitutes a 1 2 good quality value set. Examining then mechanisms as well, for governance of value sets. 3 CO-CHAIR LIEBERMAN: Yes, I would just 4 say on that, along those lines, I mean, I think a 5 criteria for defining a good value set, and then 6 7 also, we need to come up with some ideas about who's going to assign those values and who's 8 9 going to maintain that. 10 MR. GOLDWATER: Right. 11 CO-CHAIR LIEBERMAN: Yes. Yes. 12 MR. GOLDWATER: So that's part of the 13 governance part. CO-CHAIR LIEBERMAN: 14 That's the 15 governance part, okay. MR. GOLDWATER: Yes that's a very 16 extensive discussion. 17 18 CO-CHAIR LIEBERMAN: Yes. 19 MR. GOLDWATER: I expect that to be 20 up, probably ---- Julia, a full chapter in our final report is here's what we learned about 21 22 governance and that's something when we convene

again in November, and I hope you all come back, 1 2 that we'll just -- that'll be part of our discussion. 3 I mean that, Cindy, I hope you all 4 So Cindy, did you want to say 5 come back. something? 6 7 MEMBER CULLEN: What version of the measures are you going to be working on? 8 9 MR. GOLDWATER: Meaning Use 2. 10 MEMBER CULLEN: Because the analysis 11 that was done is on --MR. GOLDWATER: 2 12 13 MEMBER CULLEN: -- measures that have -- no, what version of the measures? Because 14 15 you're using the 2014 version of the Meaningful 16 Use measures. 17 MR. GOLDWATER: Correct. 18 MEMBER CULLEN: The 2015 versions will 19 be coming out shortly. And some of this work --20 some of the issues that you had identified may have already been resolved --21 22 MR. GOLDWATER: Okay.

MEMBER CULLEN: -- through work that 1 2 the --3 MR. GOLDWATER: So --MEMBER CULLEN: -- measure developers 4 5 have done. So my recommendation would be, wait until the new ones come out --6 7 MR. GOLDWATER: Great. MEMBER CULLEN: -- and see what --8 9 MR. GOLDWATER: Done. 10 MEMBER CULLEN: -- you've got there. 11 MR. GOLDWATER: All right. 12 MEMBER CULLEN: That gives you a 13 couple of weeks to catch your breath. MR. GOLDWATER: See, this is no more 14 15 a democracy. It's finished. We're done, good. 16 Just don't say anything. Go ahead, Dr. McClure. 17 MEMBER McCLURE: Right, just a nuance 18 with regards to this quality thing, and most of 19 the things. I think we ought to have, as a goal, 20 that as much of the metadata that we would, you know, seek to associate with value sets -- I'll 21 22 use my word again, would be mechanistic, you

This idea of having an entity assign know? 1 2 quality statements with regards to value set, not a good solution. 3 Figuring out ways that we can say 4 something -- it may be that we don't call it 5 quality -- a quality measure at all, but they 6 7 provide one stop viewing of knowledge about governance, right? I mean, that's actually been 8 9 a topic of discussion elsewhere. Where the sort of things that are 10 11 important, particularly in a context of harmonization, am I willing to concede 12 13 responsibility for some aspect of my value set to somebody else, is going to be dependent on some 14 15 way of being able to assess governance and kind of trustability. Those are the sorts of things 16 that we want to be able to characterize in a way 17 18 that just happens automatically. 19 MR. GOLDWATER: Okay. Great. Great. 20 So I think those are the issues that -- so again, we'll do -- we'll work with 21 22 internally and we will discuss with Julia and

Kevin either AMI, VTE, or stroke, two of the 1 2 three, to focus on medications. Depression, we will focus on 3 encounters. We will look at metadata typology, 4 the criteria for quality, for lack of a better 5 word, and also examine governance, which will be 6 7 a significant issue, and that will carry on throughout the duration of the project. 8 9 And when we convene again in person --10 now we will have phone calls with you and we'll 11 get over to what those schedules are going to be. 12 When we meet again in November where we fully 13 expect there are some people that were not here today, in a way that's probably not a bad thing, 14 15 but they were -- when they arrive in November 16 what we will be doing is summarizing our results from the three pilot tests, discussing our 17 18 findings on these types of issues that have come 19 up that Dr. McClure and others have mentioned. 20 And I am also thinking we might invite somebody from the FDA to come give a small 21 22 presentation about policy in respect to

medications as well, I think that might be 1 2 helpful since we have NLM and we have ONC, and we have -- Dr. McClure's giving me this look, which 3 4 (Off mic comments) 5 MR. GOLDWATER: Okay, well, then you 6 7 can tell them that they're wrong. I'm kidding. Okay, I'm only ---- I'm only kidding. All right. 8 9 Okay. All right, so we are now at the 10 point for public comment, so we have to tell the 11 operator to open up. 12 MS. STREETER: Sure. Operator, could 13 you please open the line for public comment? Yes, ma'am. At this time, 14 **OPERATOR:** 15 if you would like to make a comment, please press 16 star then the number one. There are no comments at this time. 17 18 MR. GOLDWATER: All right, so our next 19 steps. We'll have a post-meeting call in the 20 middle of May, from 1:00 p.m. to 3:00 p.m., and then we'll start talking about the evaluation of 21 22 testing.

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1	Right now the tentative dates are May
2	27, June 24, July 28, and October 19th, and we
3	will be meeting again on November 10th, right
4	before Veteran's Day here once again, in this
5	building.
6	And there may be interim calls that we
7	do with some of you individually, or as a group,
8	and Zahid and Michael will be setting up the
9	schedule of check-in calls with you independent
10	of this. Are there any last questions? Go
11	ahead. Or comments? Yes, Rute?
12	MEMBER MARTINS: So yes, my only
13	and this is just informative, as you discussed
14	number one there, the Joint Commission is the
15	steward for VTE and Stroke.
16	MR. GOLDWATER: Yes, we know.
17	MEMBER MARTINS: Okay. So if you want
18	diversity in terms of stewards, that's something
19	to consider. And then, I see that the in-person
20	meeting doesn't have a time. I understand it's
21	in November, but my flight today leaves at 8:00
22	p.m., because the meeting was supposed to end at

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1	5:30 p.m., rather than a quarter to 4:00 p.m.
2	MR. GOLDWATER: I would suspect that
3	our in-person meeting will be the same time from
4	8:00 a.m. to 4:00 p.m.
5	MEMBER MARTINS: Okay.
6	MR. GOLDWATER: Unless we feel that we
7	need to change it, but right now I think that's
8	probably workable
9	MEMBER MARTINS: Okay.
10	MR. GOLDWATER: to give everyone
11	the opportunity to catch flights back to wherever
12	you're catching flights back to. Or, in our
13	case, drive you back to Howard County, which is
14	almost like taking a flight, to some of us
15	though.
16	Yes, Ann?
17	MS. PHILLIPS: So I have an
18	opportunity to set up a discussion board on our
19	SharePoint site to continue some of these
20	discussions, is this something you would all use?
21	So it would be like a regular bulletin
22	board, just for this group, and only accessible

for this group and we might be able to pose some 1 2 questions and engage in some discussion that wouldn't be an email, but it would be on our 3 SharePoint site, is this of interest? 4 MEMBER SCHNEIDER: Can I say that 5 those sorts of things can be of interest. 6 We 7 need stimulation to get us to go there and so on. So it really comes down -- if you set it up and 8 9 expect us to just do something, it won't happen, 10 but if you sort of nurture and cultivate us, 11 there's a chance we will grow. 12 MR. GOLDWATER: Yes, Dr. McClure? 13 MEMBER McCLURE: So let me understand. First off, full disclosure, I hate SharePoint. 14 15 So are you suggesting --16 MR. GOLDWATER: You're not the only 17 one. 18 MEMBER McCLURE: I'm sure I am not. 19 But so it's one thing to actually create a 20 mailing list, that I'm all in support of. Where I don't leave my mail environment, I just 21 22 communicate -- you know, I just send it and it

just goes out to the mailing list. 1 2 Is that what you're talking about? Or are you talking about going to SharePoint and --3 No, I would not encourage that. 4 yes. I -unless you don't want me to participate. 5 That could be actually a benefit, but I won't. 6 7 MR. GOLDWATER: Would a Google Hangout As much as -- I know, right? I'm learning work? 8 9 these things from my 12 year old. I have no idea what this stuff is, but we'll start an Instagram 10 11 page of some kind. 12 Unless there are any further comments, 13 I do want to thank all of you very, very much for your time and for the very spirited and a highly 14 15 informative discussion. I thank all of you for 16 working towards consensus to get us to an end process where we can be using a pilot process to 17 18 actually see if some of this work. There was some concern that the time allotted for this 19 20 meeting would not allow us to do that. My wife, who some of you know, 21 22 mentioned this -- yes last night when she heard

everybody that was going to be here, said man, 1 2 there are going to be some highly spirited 3 discussions with these people in this room. And I went, oh come on, they're all developers, 4 there's not -- they're all developers and doctors 5 it's going to be fine. 6 And so I can actually say, Cindy, I 7 was right and she was wrong and I rarely get to 8 9 So thank you all very much. say that. Ι 10 appreciate it. Thanks so much. (Whereupon, the above-entitled matter 11 went off the record at 3:37 p.m.) 12 13 14 15 16 17 18 19 20 21 22

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<u>CERTIFICATE</u>

This is to certify that the foregoing transcript

In the matter of: Value Set Harmonization Committee

Before: NOF

Date: 04-21-2015

Place: Washington, D.C.

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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