NATIONAL QUALITY FORUM

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MEASURE APPLICATION PARTNERSHIP POST-ACUTE CARE/LONG-TERM CARE WORKGROUP

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FRIDAY
DECEMBER 12, 2014

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The Workgroup met at the National Quality Forum, 9th Floor Conference Room, 1030 15th Street, N.W., Washington, D.C., at 9:00 a.m., Carol Raphael, Chair, presiding.

PRESENT:

CAROL RAPHAEL, MPA, Chair
JOSEPH AGOSTINI, MD, Aetna
LOUIS DIAMOND, MBChB, FCP(SA), FACP, FHIMSS*
ROBYN GRANT, MSW, National Consumer Voice for Quality Long-Term Care
ROGER HERR, PT, MPA, COS-C, American Physical Therapy Association
BRUCE LEFF, MD, Johns Hopkins University School of Medicine
MARC LEIB, MD, JD
ALAN LEVITT, MD, Centers for Medicare & Medicaid Services (CMS)
SEAN MULDOON, MD, Kindred Healthcare
ALLEN NISSENSON, MD, FACP, FASN, FNKF, Kidney Care Partners
ELIZABETH PALENA HALL, MIS, MBA, RN, Office of the National Coordinator for Health Information Technology (ONC)
DIANNA REELY, Providence Health & Services
PAMELA ROBERTS, PhD, OTR/L, SCFES, CPHQ, FAOTA, American Occupational Therapy Association

CLARKE ROSS, DPA, Consortium for Citizens with Disabilities
DEBRA SALIBA, MD, MPH
SUZANNE SNYDER KAUSERUD, PT, American Medical Rehabilitation Providers Association
CAROL SPENCE, PhD, National Hospice and Palliative Care Organization*
THOMAS VON STERNBERG, MD
ARTHUR STONE, MD, National Pressure Ulcer Advisory Panel
MARGARET TERRY, PhD, RN, Visiting Nurses Association of America
JENNIFER THOMAS, PharmD, American Society of Consultant Pharmacists
LISA WINSTEL, Caregiver Action Network*

NQF STAFF:
CHRISTINE CASSEL, President & CEO
HELEN BURSTIN

TAYLOR DAVIS

MITRA GHAZINOUR

LAURA IBRAGIMOVA

ERIN O'ROURKE

WENDY PRINS

ROB SAUNDERS

*** present by teleconference**

T-A-B-L-E O-F C-O-N-T-E-N-T-S

P-R-O-C-E-E-D-I-N-G-S

8:58 a.m.

CHAIR RAPHAEL: I just want the operator, Cathy, to know that we are beginning.

OPERATOR: Okay. I'll go ahead and transfer you now.

CHAIR RAPHAEL: All right. And let me just check on the three Workgroup members who were supposed to be on the phone. Lisa Winstel?

OPERATOR: Yes, she has joined.

CHAIR RAPHAEL: Okay. Carol Spence?

OPERATOR: She has joined also.

CHAIR RAPHAEL: Okay. And Lou Diamond?

OPERATOR: He joined, but he has disconnected.

CHAIR RAPHAEL: Okay. I'm going to hope that he gets reconnected. So let me start by introducing Chris Cassel, who's the president and CEO of the National Quality Forum and who would like to make a few opening remarks. Welcome, Chris.

DR. CASSEL: Thank you, Carol. And Carol knows, because she and I worked together many years when I was in New York, that this topic of today's MAP meeting is one that's near and dear to my heart as a geriatrician, and someone who's spent my career devoted to many of the issues that are before you today.

So I want to, in my role as president of NQF, welcome you here and thank you for the contribution that you're making to this important work. This concept of the multi-stakeholder consensus process is really essential to setting the standards that are going to be applied across the health care world, in so many different parts of health care, that ultimately really have to be effective in driving better quality and more affordability for the citizens of this country and the people who we serve in the health care system.

So these discussions are rarely, if ever, simple and straightforward. There are many, many complexities involved in them, and

that's the reason why we need all the stakeholders and perspectives around the table. And we really value your time, and particularly at this time of year when people are beginning to think about the holidays and other things. It's particularly valuable that you've joined us today.

The second thing I want to say is that we've worked very hard over the year to streamline the process and improve the materials that you have and to make your job go more smoothly and work better. And we had the hospital group with us earlier this week and got some quite positive feedback about the changes and we want to not prejudge what you think, but hope that you find that both the organization of the meetings and the kinds of materials that you received really are helpful and useful. But we also welcome your thoughts on what we could do better, what works, what maybe might be done to continue to improve this process. So let us know what you think.

And the last thing I would say; and I'm sure this group knows this, is that this is a particularly interesting and, I was going to say, impactful time for post-acute and long-term care, because of course the IMPACT Act that passed just recently has many, many dimensions.

But one of the important dimensions is that it does a lot to drive standardization of measurement across all post-acute settings. And hopefully to both enhance the information that goes to providers and provider organizations about their performance, but also to make more meaningful information available to consumers, to patients and their families.

So let me just stop there and offer again my thanks. And I'm happy, Carol, to take any questions people might have.

CHAIR RAPHAEL: Thank you, Chris. Are there any questions or comments that you would like to share with Chris?

(No audible response.)

DR. CASSEL: People are raring to go.

(Laughter.)

CHAIR RAPHAEL: They are.

DR. CASSEL: Right. Okay. Thanks very much.

CHAIR RAPHAEL: All right. Thank you so much. All right. I now am going to turn it over to Helen who is going to go through some of the important steps that we need to make sure we cover.

DR. BURSTIN: Good morning, everybody. Just to add my welcome to Chris'. I'm the chief scientific officer here at NQF and will be in and out with you most of the day. I have the responsibility this morning for helping you do disclosures of interest as part of our welcome. We know many of these familiar faces have been around our tables in the past. We do need to go through this process, because it's related to the specific work.

We'll combine disclosures with introductions just to keep it most efficient. And we'll also have to divide the disclosures

into those of you who sit as organizational members, versus those of you who sit as independent subject matter experts, because the disclosures are actually different. So for example, if you're an organizational representative, we fully expect you're here today representing your organization. You're wearing that hat in a way that's very different from the subject matter experts at the table.

So we'll only ask you one limited question in light of that for those of you who are in fact organizational representatives. So as part of your introductions please disclose if you have an interest of more than $10,000 related to any entity potentially involved in the work of this Committee. We'll go around the table first for the organizational members and then we'll come back and do those of you who are subject matter experts. So with that, perhaps we'll -- actually, Carol, are you organizational?

CHAIR RAPHAEL: I'm individual.

DR. BURSTIN: Individual. Okay. So

we'll come back to you. So we'll start with Joseph.

MEMBER AGOSTINI: Hi, I'm Joe Agostini. I'm a geriatrician and National Medical Director for Aetna Medicare. I'm an employee, full time, of Aetna. No disclosures.

MEMBER ROSS: Hi, I'm Clarke Ross. I'm employed by the American Association on Health and Disability. I'm here today representing the Consortium for Citizens With Disabilities, a 41-year-old national coalition with 113 national disability organizations. And I'm the liaison for the next 12 months between the Workgroup on Persons Dually Eligible for Medicare and Medicaid, and this Workgroup. Thank you.

DR. BURSTIN: Any disclosures?

MEMBER ROSS: And none. Thank you.

MEMBER NISSENSON: Hi. Good morning. I'm Allen Nissenson. I'm a nephrologist. I'm representing Kidney Care Partners, and I am a full-time employ of DaVita HealthCare Partners

where I'm Chief Medical Officer.

DR. BURSTIN: And if you could also just indicate if you have any disclosures, just as part of your interest.

MEMBER NISSENSON: Okay.

MEMBER REELY: Okay. Diana Reely. I'm the Vice President of Quality for Providence Senior and Community Services, which is part of Providence Health and Services, providing health care in Washington, Oregon, Alaska, California and Montana. And we have post-acute services including home health, hospice, long-term care, adult day health, many other programs. And I am an organizational representative, and no disclosures.

MEMBER HERR: Good morning. My name is Roger Herr. I'm a physical therapist, and I'm a board member of the American Physical Therapy Association, and I have no disclosures.

MEMBER THOMAS: Good morning. Jennifer Thomas. I'm an employee of Delmarva Foundation. I'm representing the American

Society of Consultant Pharmacists, and I am a pharmacist with no disclosures.

MEMBER LEVITT: Alan Levitt. I'm the medical officer in the Division of Chronic and Post-Acute Care at CMS, and other than being a taxpayer I have no disclosures.

(Laughter.)

MEMBER ROBERTS: I'm Pam Roberts. I'm the Program Director for Rehabilitation at Cedars-Sinai Medical Center and I'm here representing the American Occupational Therapy Association, and I have no disclosures.

MEMBER SNYDER KAUSERUD: My name is Suzanne Snyder Kauserud. I'm a physical therapist and I am the administrator at Carolinas Rehabilitations in Charlotte, North Carolina, which is part of Carolinas HealthCare System. And I'm also on the board of directors for the American Medical Rehab Providers Association and I'm here on behalf of the American Medical Rehab Providers Association as an organizational member. I have no disclosures.

MEMBER LEFF: I'm Bruce Leff. I'm a geriatrician at Johns Hopkins, here as an organizational member for Johns Hopkins. I'm on the board of the American College of Physicians and the American Academy of Home Care Medicine. I do some personal consulting for Abt Associates, which has contracts with CMS on Medicare home health payment issues.

MEMBER MULDOON: Good morning. I'm Sean Muldoon. I'm the senior vice president at Kindred Healthcare, a provider of post-acute care services from which I receive salary and benefits.

MEMBER STONE: Good morning. I'm Art Stone. I represent National Pressure Ulcer Advisory Panel. It's my first meeting and I look forward to the day. And I'm one of the board members for National Pressure Ulcer Advisory Panel.

MEMBER LEIB: I'm Marc Leib for --

DR. BURSTIN: We'll come back to you, Marc, because you're a subject matter expert.

MEMBER LEIB: Oh.

DR. BURSTIN: Thank you.

MEMBER TERRY: Good morning. I'm Peg Terry, a nurse, and I represent the Visiting Nurse Associations of America, which represents non-profit home health and hospices around the country. And I have no disclosures.

MEMBER GRANT: Good morning. I'm Robyn Grant. I'm the Director of Public Policy and Advocacy with the National Consumer Voice for Quality Long-Term Care, and we're a non-profit organization that advocates for quality long-term care across settings. This is also my first meeting, and I have no disclosures. I'm here representing the Consumer Voice.

DR. BURSTIN: We'll skip Tom. Liz?

MEMBER PALENA HALL: Hi, good morning. My name is Liz Palena Hall. I am the Long-Term Post-Acute Care Coordinator in the Office of the National Coordinator within Department of Health and Human Services. Again, this is my first meeting. I'm also a nurse. I have no

disclosures.

DR. BURSTIN: Wonderful. Thanks. And I know we have a couple organizational members on the phone, so Lisa Winstel, please?

MEMBER WINSTEL: Good morning. This is Lisa Winstel. I'm the chief operating officer for Caregiver Action Network. I'm an organizational member, and this is also my first meeting. Caregiver Action Network represents family caregivers across the life span, so whether they're caring for somebody for aging-related issues, chronic disabilities or diseases, we help the family caregiver.

DR. BURSTIN: Wonderful. Thank you. And Carol Spence, please?

MEMBER SPENCE: Yes, hi. This is Carol Spence. I'm Vice President for Research and Quality at the National Hospice and Palliative Care Organization. I am representing that organization and I have no disclosures.

DR. BURSTIN: Excellent. I think I've gotten all the organizational members. Did I

miss anyone?

Okay. So next for those of you are subject matter experts, this is a little different because you're sitting here as individuals. You bring your expertise to the table. So we would ask you to give a bit more of a detailed review of your background. You don't need to recite your résumé. We have too much work to do today, and we know how skilled you all are since we picked you.

So please if you could just give us a disclosure of any interests that you may have that relate directly to the work before this Committee today. Again, you sit as an individual. You may have organizational hats, but your role today is to sit here as an individual subject matter expert. And it's really not an issue of how much you're paid for those disclosures. We really want to understand any biases or conflicts that might appear. So with that, we'll skip to those of you -- let's begin with Marc.

MEMBER LEIB: My name is Marc Leib. I am here as an individual, and I have no financial disclosures that bring any conflict here.

DR. BURSTIN: Or any conflicts, or any additional work you're working on that might be coming before the Committee?

MEMBER LEIB: Nothing that would come before NQF.

DR. BURSTIN: Great. Thank you. Tom?

MEMBER VON STERNBERG: Dr. Tom von Sternberg from HealthPartners. I'm here as a subject matter expert to contribute regarding technology and electronic medical record perspectives. I am involved in Web-based electronic medical record work and medical care through Virtuwell, which is a subsidiary of HealthPartners, where I work.

I'm also on the advisory board for an organization called Healthsense which makes monitoring components for assisted living in homes for frail elders. And then I'm a medical

director at HealthPartners for nursing home, transitional care, home care, hospice and Government programs.

DR. BURSTIN: Great. Thanks, Tom. And, Lou, I believe you're on the phone. If you could give your disclosures?

MEMBER DIAMOND: Yes, thank you, Helen. So I've got three disclosures relating to volunteer work. I am related to the RPA, I am a delegate for RPA at the AMA House of Delegates. I'm in a leadership position with the End-Stage Renal Disease Networks. I'm on the board of directors of Network 5. And I serve in a leadership capacity currently and previously with HIMSS, the Health Information Management Systems Society.

On the consulting side, I have three that I would wish to disclose. I've received consulting engagements with Genentech, AstraZeneca, Merck, and Pfizer within the last two to three years. Secondly, I have a consulting arrangement with the Alliance for

Continuing Education in the Health Professions on a project to embed education into quality improvement. And thirdly, I have a consulting and strategic business relationship with See City that has an IT platform that facilitates quality improvement. Thanks, Helen.

DR. BURSTIN: Okay. Thank you. And, Deb, you walked in at just the moment to introduce yourself as a subject matter expert.

MEMBER SALIBA: I'm Deb Saliba. I'm a geriatrician and heath services researcher in Los Angeles. I direct the UCLA Borun Center. I also work in the Veterans Administration in the geriatrics group at the VA and at the RAND Corporation.

It sounds like we're doing conflicts as well. I have several research projects funded by various government agencies and not-for-profit philanthropies, none from corporate or for-profit interests.

DR. BURSTIN: Great. Thank you. I think that completes everybody's -- oh, I haven't

done -- I'm sorry. I'm forgot about the Chair.

CHAIR RAPHAEL: It's all right. I don't have any financial interests or conflicts to disclose, but just in terms of my other affiliations, I have been on the board of the New York eHealth Collaborate, and the chair for six years. I'm the chair of AARP. I'm the chair of the Long-Term Quality Alliance. And I'm a senior advisor to Manatt Health Solutions.

DR. BURSTIN: She's very busy.

(Laughter.)

DR. BURSTIN: So just lastly, thank you to all of you for making that go so well. One of the really important things we want to emphasize is at any point during this meeting if you any discomfort that somebody is expressing bias or conflict, please come to Carol or myself or one of the senior staff.

We just learned over time it's much easier to kind of deal with those issues in real time, and then we can see if there's an opportunity for us to kind of resolves any

conflict or bias. So please speak up and let us know if you have any concerns. And in that spirit, does anybody have any questions or concerns about any of the disclosures that have been raised so far?

(No audible response)

DR. BURSTIN: Excellent. All right. Let's get to work. Back to you, Carol.

CHAIR RAPHAEL: Okay. Thank you. So let me just kind of briefly review what we're going to try to accomplish today. This is our annual meeting to review and provide our multi-stakeholder input on the measures that are under consideration for federal programs that are applicable to our post-acute long-term care settings.

We continue to identify and hopefully reduce the high-priority measure gap areas that exist. And we also will finalize our input and recommendations to the MAP Coordinating Committee which will be meeting in January. So that is what we hope to accomplish today.

I don't know, Mitra, is it possible to go to our kind of schematic and the key areas that we have constantly been emphasizing before we --

MS. GHAZINOUR: The core concepts?

CHAIR RAPHAEL: The core concepts. Just to make sure that -- we have a number of new members, they are aware of that.

MS. GHAZINOUR: Sure.

CHAIR RAPHAEL: Okay. Great.

MEMBER DIAMOND: So, Carol, this is Louie here. Do we have a WebEx today, because I did get Mitra's email from yesterday, which has a document attached to the email. Is there in addition a WebEx that I should be looking into?

CHAIR RAPHAEL: All right. Mitra, what should Lou be looking at? I have the slide deck.

MS. GHAZINOUR: Yes, that document that was attached to my email, that was the voting instructions and also --

MEMBER DIAMOND: Right.

MS. GHAZINOUR: -- there was a link for the updated Discussion Guide.

MEMBER DIAMOND: Right.

MS. GHAZINOUR: So we'll be looking at the Discussion Guide. We'll be screen sharing the Discussion Guide.

MEMBER DIAMOND: Okay.

MS. GHAZINOUR: Okay?

MEMBER DIAMOND: That's fine. Thank you.

MS. GHAZINOUR: Sure.

CHAIR RAPHAEL: So this is slide 20. Okay. So just to make sure that everyone is aware of the work that we have done, we have really tried very hard to zoom in on what we think are the most high-leverage and important areas in performance measurement in post-acute and long-term care.

And we came up with six key areas. And the key ones that we have constantly been emphasizing are function, and we include cognitive status function in that; goal

attainment and making sure that we include the patient and family and caregiver goals; patient engagement, and that includes the experience of care and shared decision making.

Care coordination, and we particularly are concerned about transition planning since many of the people in post-acute and long-term care have a number of transitions; safety, and we challenged ourselves to reduce safety to three core concepts, which were falls, which for us had traditionally been falls with injury, pressure ulcers, and adverse drug events.

And then I can't emphasize this enough, because in post-acute and long-term care you do have cost and access issues that differ from other parts of the system. So we have emphasized that and that includes avoidable admissions, infection rates and inappropriate medicine use.

So I just want to be sure that we all have this frame as we look at the measures that we're considering today, because this is really

overall where we are headed. And I think we in particular have contributed to the National Quality Forum by trying to emphasize two things, which is understanding the importance of chronic conditions and functioning in our population, and making sure that the patient experience is really central, that we just don't look at a disease, we look at the whole person.

So with that, we're now going to kind of circle back and Erin's going to describe the approach that we're going to be using as we consider the measures today. Erin?

MS. O'ROURKE: Thank you, Carol. So as Chris noted, NQF has been working to improve the MAP meetings based on input from a variety of stakeholders and we've made some changes to our meeting process. We've implemented a new voting procedure to allow the Workgroup to move quickly through its decision making process for straightforward and non-controversial measures, reserving your valuable time for discussion to build consensus on sensitive issues.

We realized that we have used the term consent calendar a bit loosely, so please bear with me as I explain this. We did get some feedback after the Hospital Workgroup that perhaps consent calendar means something different than we're assigning it, so we just ask for your patience.

So, for the first step Mitra and I will review the consent calendars. These are based on the results of the preliminary analysis that staff put together using the MAP measure selection criteria, the PAC/LTC core concepts and high-leverage opportunities that you see right in front of you, and the programmatic objectives derived from the PAC/LTC Workgroups fall Web meeting.

These preliminary analyses are non-binding. They're just a starting place for conversation. They represent our attempt to take all of your previous input and apply it to the current measures under consideration, just to give you a summary of how these measures right

relate to what you said in the past. We're just trying to digest all of the information out there and make it a little bit easier for you. But again, feel free to challenge any of these.

So the next step, Carol will ask the Workgroup if you'd like to pull any of the measures off the consent calendar presently under review for discussion and propose a different disposition for the measure under consideration. So if we gave it a preliminary analysis of conditional support but you feel it should be fully supported, you can go ahead and say that it should be fully supported and note your reasons why. And we will then open it up for conversation among the Workgroup about where you think the appropriate categorization for that measure would be.

So after we go through each of the consent calendars, pull all the measures, re-categorize them as the group sees fit, we'll pause and Carol will ask for public comment from the audience members in the room and on the

phone. The Workgroup is not obligated to respond to these public comments, but we hope you'll consider them carefully in your deliberation and final vote.

Carol will then call for a vote on the consent calendar once we're all finished with conversation on it. The vote will be binary. You'll be asked to approve or not approve the consent calendar as it's presented to you. We'll need a 60 percent majority to confirm the preliminary recommendations. This will establish them as an official Workgroup recommendation that we'll pass along to the MAP Coordinating Committee for finalization.

If we reach 60 percent on the vote, discussion on those measures is concluded. If we have not reached the 60 percent consensus, the Chair will ask participants to identify the measures that are perhaps holding you back from supporting that consent calendar and we'll reopen discussion on those measures. We'll keep going through this process until we find the measures

that are holding us back and the group is able to come to a majority opinion on them.

We're going to try to push this group to reach a decision on every measure under consideration. We're really trying to avoid the split decisions that we've had in the past. That would mean we just kick it up to the Coordinating Committee without the benefit of this group's input. So as much as we can Carol's going to push you all to try to come to consensus on a preliminary recommendation for each measure under consideration so that the Coordinating Committee can have the benefit of your input on that measure.

So I think with that I can pause and take any questions, because I know that's a lot and it's very different from what we've done in the past.

CHAIR RAPHAEL: Okay. One other thing that as I went through this that I thought it was important to clarify. We have two categories of measures, those that are fully developed and

those that are under development. And I think we should just go over first of all what does that mean?

MS. O'ROURKE: Absolutely. I apologize. I meant to do that and then skipped it in my notes. So as Carol noted, this year we'll have two pathways, one for measures that are fully developed. We are considering that measures that have completed testing. They might not be NQF-endorsed, but they're on their way to that process. These will receive our traditional MAP recommendations of support, conditional support, do not support.

The change this year is we've developed a new pathway for measures that are still in development. We received some feedback that perhaps the MAP was being a little too hard on measures that are up an coming, if you will. They're not quite fully ready, that the group might have reservations about giving them a support or a conditional support, but we don't want to say do not support and stop the

development of a really innovative measure that could move the field forward.

So for these measures under development, we're just going to recommend that development continue and we'd encourage this direction, or we do not consider, or we would not consider -- we would not encourage further consideration of this measure. Basically the Workgroup feels this is not the direction we want to be going in. Don't continue to spend resources to develop this measure.

CHAIR RAPHAEL: Okay. So let me now turn to all of you and see if we have questions about the process that we're going to be using for the first time in the Workgroup. Okay. The other thing that I thought it might be valuable for Workgroup members to briefly understand is what is the endorsement process?

MS. O'ROURKE: Absolutely. Helen, would you want to take that? You're probably better equipped than me.

DR. BURSTIN: So when we describe the

endorsement process, what we're referring to is whether the measure has previously been submitted to NQF or it's been reviewed against our key four criteria of importance to measure import, which also includes evidence and opportunity for gap, opportunity for improvement. It includes whether the measure has in fact been tested and is reliable and valid, whether it's useable and feasible. So measures that pass that test are ones that will clearly be indicated as having been endorsed.

As you'll see for many of the measures under development many of them have not yet been submitted to NQF. Some of them are in that process, as you'll see. Some of them are sometimes very early concepts to give you an opportunity. And so the idea of splitting them, also, was to allow you the opportunity to speak favorably of a measure even though it's still very early in its development, if you want to encourage that continued development on the part of the developers.

CHAIR RAPHAEL: Okay. Thank you, Helen. All right. So if there are no questions, then we're going to begin. And we're starting with the Inpatient Rehab Facility Quality Reporting Program. And, Mitra, you're going to give us a brief overview of the quality reporting program and also the staff's preliminary analysis and recommendations.

MS. GHAZINOUR: Sure. Thanks, Carol. So we're reviewing the Inpatient Rehabilitation Facility Quality Reporting Program as the first program to consider. Just a brief description of the program. This is a pay-for-reporting program and the inpatient rehabilitation facility providers, they must submit data on quality measures to CMS to receive annual payment updates.

And failure to report quality data will result in a two percent reduction in the annual increase factor for discharges occurring during the same fiscal year. So also there's a plan for public reporting of quality measures,

and the providers will have an opportunity to review the data prior to its release. And no date has been specified to begin public reporting of quality data yet. The program goal is to address the rehabilitation needs of individuals, including their improved functional status and successful return to the community post-discharge.

So the statutory requirement for this program notes that measures should align with the National Quality Strategy priority relevant to IRFs and including patient safety, reducing adverse events, better coordination of care and person and family-centered care.

And also the new IMPACT Act requires post-acute care providers to report the standardized patient assessment data and also to create new quality measures that address domains such as functional status, medication reconciliation, incidence of major falls and resource use measures.

MAP had previously recommended that

the program measure set is too limited. And this recommendation is from previous years, and since then measures have been added to the program measure set. And so, MAP had felt that the measure set should include concepts such as care coordination, functional status, medication reconciliation and the safety issues that have high incidence in IRFs.

So, going back to the agenda. So for these programs we have five measures under consideration, and based on the staff preliminary analysis all the measures received conditional support.

The first measure to start with is venous thromboembolism prophylaxis, which is an NQF-endorsed measure, Measure 0371. This measure evaluates the number of patients who received VTE prophylaxis or have documentation as to why they have not received it. So this measure is part of a set of six nationally-implemented prevention and treatment measures that address VTE. And also its use in the Joint Commission's

accreditation process.

We have received six public comments on this measure. And as I mentioned, this measure received conditional support. So the preliminary analysis concluded that this measure addresses the NQF's priority of safer care, which is relevant to the priorities of IRFs. This measure would create alignment across programs. This measure is currently finalized for use in hospital IQR, Inpatient Quality Reporting Program, and also in meaningful use for hospitals and critical access hospitals.

And this measure is also under consideration for Long-Term Care Hospital Quality Reporting Program. However, this measure is not specified for inpatient rehabilitation facilities, so we have given conditional support to this measure.

In terms of public comments, they were mostly supportive of this measure and they noted that this is a audited standard of practice and it's inpatient rehabs -- they already provide

data on this measure. And the only concern that they had that this measure excludes stroke patients, and also patients who have length of a stay over 120 days.

So moving on to the next measures. We have four functional outcome measures: change in self-care score, change in mobility score, discharge self-care score and discharge mobility score for medical rehabilitation patients. And the preliminary analysis that was given to these measures were conditional support.

As mentioned before, functional status is the primary goal of rehabilitation and also this is a PAC/LTC core concept not currently addressed in the program. And it is a required measurement domain under the IMPACT Act and also functional status is a priority area for measurement for the duals population.

These four measures, they're all fully specified and tested for use in IRFs and also they have been submitted for NQF endorsement under the Person and Family-Centered Care Project

Phase II Project.

So we have received average of six to eight comments for each of these measures, and generally the comments were not supportive of these measures. Public commenters, they noted that the inpatient rehabilitation facilities, they collect data and report data through the FIM instrument part of the IRF pie for post-active payment system purposes. And introducing these measures, which will use the Care Tool, may create undue burden on the providers. And also they had expressed some concern about the risk adjustment methodology, testing and the sample size. So I think CMS would like to provide some comments on these measures before we open it up for discussion.

CHAIR RAPHAEL: Okay. Alan?

MEMBER LEVITT: Okay. Thanks, Mitra and Carol.

MS. GHAZINOUR: Sure.

MEMBER LEVITT: First of all, can I invite the leads up so they can also participate?

CHAIR RAPHAEL: Sure.

MEMBER LEVITT: Charles Padgett is the lead in the Inpatient Rehab Facility Quality Reporting Program and Tara McMullen, Dr. Tara McMullen is also the lead in our function work at CMS. So thank you for coming.

I want to first make a clarification, and it was noted in the public comments that there was some confusion about the change in the self-care and mobility measures as to what the numerator and the denominator are. As you might know from our readmission measures we use the terminology sometimes it's not a simple numerator and denominator, and that applies here as well.

The denominator that was listed here is really from the denominator statement which asks for the target population, and that's the target population that we're talking about in terms of the rehab patients. When you're really looking at the numerator and the denominator of the measure, it essentially is you -- take self-care, for example. You sum up the admission

self-care items and you sum up the discharge self-care items for an individual patient and you get a change in self-care for that patient over whatever episode we're looking at.

And you then also get -- based on a risk adjustment factors of the patient, you also get an expected change that you would have on that individual patient. And so now you have an observed individual change and an observed expected change. You take the average for a facility of all the observed changes. You get an average of that or a mean observed and then you get an average of all the expected changes, mean expected. And so then the measure is actually a ratio of the mean of the observed over the mean of expected. And then we multiply it by the national average so that when it's reported it makes sense to everyone.

Does anyone have any questions on that? I hope that cleared up the confusion on that.

CHAIR RAPHAEL: Do you want to add

anything, Charles or --

MEMBER LEVITT: Yes, Charles, is there anything else, or Tara, on that particular --

CHAIR RAPHAEL: Okay.

MEMBER LEVITT: Okay. I don't know if you want any particular individual --

CHAIR RAPHAEL: Why don't we --

MEMBER LEVITT: Okay.

CHAIR RAPHAEL: -- sort of see if there are questions, just general questions before we come to the issue of whether or not we want to pull any of these for more discussion?

I had one question, which was one of our criteria is parsimony, because we repeatedly hear from providers that they have so many measures that they have to report on. And I was just wondering as so why --- and this is terrific in terms of our core concepts in emphasizing self-care and mobility, but I was wondering why we needed it both for change in self-care, change in mobility and then discharge self-care score and discharge mobility score.

MEMBER LEVITT: Well, and once again, we were trying to look at patients and trying to give information that we can report out and people can understand. It's really two different concepts. One is looking at really -- people can look at the change that patients have within a facility. The second type of measures are really to look at the percentage of patients that meet their expected score, so that it gives an understanding of what percentage of patients get where they should get. And so, it's two really different concepts.

Once again, when we look at function and as we get into the IMPACT Act, we're trying to have people also understand differences in function itself in terms of what the deficits might be for a particular patient. It may be people who are looking at, well, most of the deficits are self-care, so I want to know how a facility does in that regard. Same thing for mobility. So again, it's really trying to help patients, consumers really understand the

different performance that facilities have.

CHAIR RAPHAEL: Okay.

MEMBER LEVITT: Tara, did you want to add anything? Charles?

MEMBER DIAMOND: So, Carol, when you have a chance, this is Lou here.

CHAIR RAPHAEL: Okay.

MEMBER DIAMOND: I wanted to ask a question, if I could.

CHAIR RAPHAEL: Thank you, Lou.

And don't be afraid to speak up if you're on the phone so that I'm sure to recognize you.

But, Tara, did you want to add anything?

DR. McMULLEN: Yes. Just to add on to what Dr. Levitt said --

CHAIR RAPHAEL: Is your mic on?

DR. McMULLEN: Oh, okay. Cool. I can hear myself, yes. Just to add on to what Dr. Levitt said, we also have four measures: the self-care, the mobility, one at admission, one at

discharge, to be able to link together a full episode of care. The point of the PAC-PRD, the development of the care tool and into the IMPACT Act is to be able to demonstrate looking at patient complexities and really uniformity of data, but across all episodes of care, multiple episodes of care, looking at those assessments. So we have those four measures to help delineate that and to really link and piece together.

MEMBER MULDOON: I find the change in mobility scores perfectly acceptable, particularly as it relates to the ratios of the observed and expected. I put that risk adjustment in the as good as it gets category, but when I get to the discharge score and see the statement meet or exceed an expected discharge self-care or mobility score, to what degree is that -- well, who sets that and to what degree is it standardized?

MEMBER LEVITT: It uses essentially the same type of risk adjusters to establish an expected score for the patient within whatever

that -- whether it's mobility or self-care. And then essentially it looks at the discharge score versus the expected score. And so the percentage is the patients who meet or exceed those expected scores.

MEMBER MULDOON: So that is satisfactory, but I'm stuck with the redundancy. You're not going to capture everything that's important to someone, but is there a way to separate the high performers from the low performers? My guess is there's a fairly strong correlation between those two that we don't really need to tweak out at the general global level.

MEMBER SNYDER KAUSERUD: I have a question kind of tagging onto what Sean said about the expected numbers. Is the expected number coming from the PAC-PRD study that was done or the analysis on the care tool? Is the database of where you're pulling expected from significant enough that it's capturing the entire -- it's descriptive of what the population would

do?

MEMBER LEVITT: Again, Tara, do you want to answer first? Okay. Rather than me answer, maybe we can -- is the phone open for Anne?

MS. DEUTSCH: This is Anne. Can you hear me?

CHAIR RAPHAEL: Yes, we can hear you.

MS. DEUTSCH: Okay. So, Anne Deutsch. I'm with RTI International and the Rehab Institute of Chicago, and I was part of the team work on the development of these measures.

So, Suzanne, to answer your question, the expected score is based on the risk adjustment, just like Alan said, so basically the patient characteristics and the coefficients from the regression models, which were based on the post-acute care payment reform demonstration data were used to calculate the expected values.

And just to I guess add on what Alan and Tara mentioned, consumers have, in previous research, found it difficult to understand what a

change in function is, and so consumers are more used to looking at information like the percent of patients who achieve certain things or have certain processes done. And so that was in part why the two different sets of measures are being put forward.

CHAIR RAPHAEL: Okay. Lou?

MEMBER DIAMOND: Yes, so, Carol, thank you. Just two quick questions, if I could. So this measure is for all-cause, all diagnostic categories and all patient populations, I presume. I'm not sure what the risk adjustment is. Is it risk adjusted by age and by primary disease and comorbid condition?

MEMBER LEVITT: Yes. I mean, there -- Anne, you can answer, but again there are multiple risk factors that are involved including those that you mention.

MEMBER DIAMOND: So I guess --

MS. DEUTSCH: Yes, so we --

MEMBER DIAMOND: Sorry.

MS. DEUTSCH: Yes, so we do adjust for

age groups, comorbidities, primary diagnosis, prior functions.

MEMBER DIAMOND: So just an observation from someone who is not really immersed in this particular subject; and excuse me for then making the comment, but it does seem to me that this is potentially a very valuable measure for quality improvement purposes with feedback on a regular basis and actions that can then put in place improved patient outcomes.

But my question then is what do we know about the ability of the institutions that are being held accountable to impact on the outcome? Because this is a measure that's being proposed for public reporting, is that correct?

MEMBER LEVITT: Yes, it is.

MEMBER DIAMOND: So it's an unfair question to ask you but what do we know about the impact, whether these observed this as expected outcomes can be impacted by the institution that is being held accountable?

MEMBER LEVITT: Yes, that's correct.

MS. DEUTSCH: Alan, do you want me to get started on that?

MEMBER LEVITT: Sure. Sure.

MS. DEUTSCH: So currently the inpatient rehab facilities are paid under a prospective payment system. And over time length of stay has gone down. And some research has shown that as length of stay has gone down, functional improvement has decreased with some of the existing function data available. The results have been some research demonstrating differences in functional outcomes by different groups. For example, race, ethnicity groups, different groups based on payer status. So we do believe that there is an opportunity for improvement in these areas.

MEMBER DIAMOND: Okay. Thank you.

DR. McMULLEN: And this is Tara from CMS. It also should be noted, Lou, that we are building -- I mean, really with the advent of the IMPACT Act we're building and most of our post-acute care settings are monitoring evaluation

efforts. So in implementing a lot of these measures, it may possibly -- public reporting these measures in the future we will be tracking facility differences and changes in progress and patient status and things, discharge transitions, care coordination, things of that nature.

MEMBER DIAMOND: Thank you.

MEMBER ROBERTS: Just on the discharge scores, following up on what Sean said, is just I hope that we can pay attention to providing access for people that may make change, but not have high discharge scores and still are able to go home to the community, that people are coming in access because public reporting and having to have higher expected versus observed discharge scores.

MEMBER VON STERNBERG: Along that line I think there's been a trend at least in our community in Minneapolis that the acute rehab stay is also considered the initial aggressive therapy and that patient is then transitioned appropriately to SNF level for rehab, or, to the

previous comment, home for rehab. So how we then distinguish facilities that have supportive systems and continuums of care that will have end-point discharge function levels that may not be as high, shorter length of stay, possibly lower cost, higher satisfaction, or conversely monitoring our people forced along a continuum not in their wishes. So I think it's just an important element around the score, but as well connecting it to what were the consequences post-discharge?

CHAIR RAPHAEL: I have Debra next.

MEMBER SALIBA: So in speaking to the question of actionability of the measure, in nursing homes, at least, it's been shown now in randomized trials that a nurse/aide-based intervention actually does lead to functional improvements, even in long-stay nursing home residents. So aside from the issue that shorter lengths of stay mean less functional recovery, which still doesn't really disprove that this could have just been the natural history of the

progression of the event, this is really convincing evidence. And it's now been also done in post-acute care populations as well. So I was a skeptic that we could significantly alter this measure, but these studies are very convincing.

MEMBER ROSS: Hi, I'd like to talk to the general context of these proposed measures from the perspective of the Workgroup on People Dually Eligible, which is the only National Quality Workgroup focused on people, as opposed to settings. And so, I'd like to reinforce the purpose and intent of the proposal. I don't know if each measure actually measures what's intended, but a number of us on the Duals Workgroup, the moment anyone uses parsimony, it's one of a whole bunch of criteria. It's not the criterion.

So the reason I like this is because it promotes consumer understanding and clarity. That means engagement. That's helpful, if it promotes alignment across settings. One of the great frustrations of consumers is that the

nursing home tells me one completely different perspective and the rehab facility tells me completely different. That's all confusion to both the family and the individual with the condition.

So any alignment activity across settings is helpful to the individual. As we move with ONC to an integrated electronic health record, we want more alignment. We want less difference. I know it's going to cost both effort and money to make adjustments. Helen has emphasized over and over that we should be also focused on giving up measures. So most of the provider arguments I've heard here in two-and-a-half years are you're adding. And it's true, but what's not focused on is what can we give up that's not as meaningful in order to promote the additional new alignment consumer understanding issues?

So those are some contextual points I wanted to make. Thank you.

CHAIR RAPHAEL: To make sure everyone

knows that -- I believe, Clarke, you are the liaison between the Dual Eligibles Workgroup and the Post-Acute Long-Term Care Workgroup.

MEMBER ROSS: Yes, I'm here today, for the next twelve months as the liaison between the two workgroups. Thank you.

CHAIR RAPHAEL: Thank you. Alan?

MEMBER NISSENSON: I just want some clarification. It's actually on 0371. And so the recommendation from the staff is for conditional support, but right above there it says the measure is not ready for implementation, needs further development and testing in this setting. So how are those two things reconciled as opposed to being in a different category, which is needs further development?

DR. BURSTIN: So needs further development is only for measures that aren't already fully developed and tested. So in this instance it's a modification to the measure we think can be done and can be brought back to NQF for further approval. So we would put that in

the conditional category. Measures that are fully developed we don't put in the encourage continued development bucket. Is that right?

MEMBER NISSENSON: I understand what Helen said, but then this says it's not fully developed. So I'm just trying to reconcile, and maybe I'm just misunderstanding it.

MS. O'ROURKE: I think that might be a typo in the Discussion Guide. We moved that down late last night. So we apologize for that. This measure, we had reclassified it based on what Helen said, but this is a modification, not a measure still in development. It was tested and endorsed for hospitals, so now that it's being tested for IRFs, we just wanted to give the Workgroup that context and that perhaps you'd want to conditionally support it based on it coming back for NQF review for this expanded setting.

CHAIR RAPHAEL: Thank you. Liz?

MEMBER PALENA HALL: so thank you for your comments, Clarke. I appreciate that.

One thing I just want to point out for awareness of the group is there are now available health IT standards for cognitive function, and also for functional assessment. And so I just want to make you aware of that and encourage alignment as these measures are being developed so that you look at what is available for the health IT standards and provide any comments on any gaps. So as we're going forward if you could go with the impact legislation and future development. I just want to make sure there is an awareness and an alignment. Thanks.

CHAIR RAPHAEL: Suzanne?

MEMBER SNYDER KAUSERUD: I have a question, a clarifying question and then maybe a comment or two.

I'm confused about our process here. Are we talking about all of these five measures that are being presented, or were we just --

CHAIR RAPHAEL: What I had hoped to do was to just take questions. And then what I was going to ask was whether or not we're comfortable

with moving ahead on all five of them, or we wanted to pull any of them from the bundle of five and really have a discussion about them. But it's sort of like bled into the other here. So let's just keep going.

MEMBER SNYDER KAUSERUD: Okay. Well, one quick comment on the VTE prophylaxis one. They mentioned already that stroke was excluded in the hospital measure and that perhaps in the IRF measure it should be included. And I would support that.

The other thing that kind of threw us off was the 120-day exclusion for patients who are in the facility longer than 120 days. And unfortunately in some states, mine included, we do have some difficulty discharging certain types of patients. And so, even though the patient might not need 120 days of inpatient rehab care, we find at 120 days the are still in our facility. And so, I would think at 121 days, getting a DVT is just as bad as getting it on day 10. So I'm not really sure what that exclusion

was there unless it's applicable in acute care.

DR. BURSTIN: Just a quick comment on that. It's actually included only in the hospital measure, just to keep this in mind. So this could be potentially one of the issues you would like the developer to explore as this measure gets adapted for IRFs.

MEMBER SNYDER KAUSERUD: Right. And then for the functional measure I think the public comments really stated the case for the industry quite well. I think the most alarming thing that we have is the concern about there being two measure scales, two very similar measure scales. One a six-point scale and one a seven-point scale measuring very similar things between our required documentation for payment, which is the claim tool, and then the required documentation for quality, which would be in this case the care tool.

And so if you're coding transfers, you have the same clinician coding transfers for payment and then one for quality, the opportunity

for confusion is very high. And then the opportunity for the quality of both data sets to be lessened is there. And so I think just more concern than anything.

And I know that there's a lot of moving parts on this, but just if there was a way for the changes to be -- if we are going to go to the care tool, which again that's a whole other issue in the field -- but if we did move that way, that they in some way be coordinated to lessen the burden of having to teach two scales at the same time and maintain competency and data integrity on two scales at the same time.

CHAIR RAPHAEL: Okay. Liz, did you want to say anything else? All right. Then let me ask at this point whether Workgroup members would like to pull any of the measures; and there are five here, out of the consent calendar and really have discussion on that measure. Pam?

MEMBER ROBERTS: I'd like to pull the falls off for the consent for discussion.

CHAIR RAPHAEL: Okay. Which number is

that?

MS. GHAZINOUR: The fall rate. That measure is no longer under consideration for this program.

CHAIR RAPHAEL: All right. So let me just kind of go around and see if any Workgroup member wants to pull any of the five measures for further discussion and review.

All right. Bruce? Sean?

MEMBER MULDOON: I would be in favor of grouping the four rehab ones together and kind of being an all or none, because they're highly related. The VTE one in and of itself has five categories, or five sub-measures, which adds complexity to that.

CHAIR RAPHAEL: Mm-hmm

MEMBER MULDOON: So if I was a splitter, I would say let's take the VTE out.

CHAIR RAPHAEL: Okay. All right. Art, anything?

MEMBER STONE: No.

CHAIR RAPHAEL: Okay. Marc, can you

just --

MEMBER LEIB: I agree with ---

CHAIR RAPHAEL: And then the VTE separately? Okay.

Peg, anything here? Robyn? All right. Let me just go to this side. Joseph?

MEMBER AGOSTINI: I wouldn't anything right now.

CHAIR RAPHAEL: Okay. Clarke, I think we got your views.

Deb?

MEMBER SALIBA: I agree with this one.

CHAIR RAPHAEL: Okay. Dianna?

MEMBER REELY: Same.

CHAIR RAPHAEL: Anyone else who disagrees?

All right. So then let me now put forth the Nos. 2, 3, 4, and 5, and see if we have a motion to approve those four measures for conditional support.

Okay. Suzanne?

MEMBER STONE: I would so move.

CHAIR RAPHAEL: You would move? Do I have a second?

All right. Suzanne?

MEMBER SNYDER KAUSERUD: And again, the clarifying question that -- conditionally support is we support the direction, but we're not saying that it's ready to roll at this point? It's not ready to be implemented as is?

CHAIR RAPHAEL: Okay. So let's just clarify. What do we mean by conditional support?

MS. O'ROURKE: So, yes, conditional support means that we support moving forward with this measure but we will note all of these conditions that would need to be met before we would really recommend this measure going into the program. So as we noted, NQF endorsement resolving these data concerns between the current tools and the care tool and all these caveats, if you will, to the measure.

CHAIR RAPHAEL: Do you think you have the key kind of conditions that we have come to agree upon? You have? Okay, fine.

All right. Then let me take a vote. All those in favor of -- oh. Oh, we use our devices? Oh, wow. Oh, my goodness. All right. So run us through this, Laura, so we do this properly.

MS. IBRAGIMOVA: Okay. So my name is Laura Ibragimova and I'm the project analyst here on the PAC/LTC Workgroup, and I'm just going to give you some voting tips.

If you're a voting member, then you all received a clicker. And for the purposes of today you will only be pressing either button 1 or button 2.

So you can only vote when the screen is in full screen. And bear with me because we're going to -- depending on the way the discussion is going to go, I'm actually going to be live editing, like I just was. For the purposes of the record I'm going to be reading the slide that we'll be voting on and then reading the question and then telling you to vote either one or two. One yes, two no. We'll cast

the vote and then I will read the results.

If you happen to change your vote, you can do so and only the last button that you press will be captured. So if you press a button by accident, then you can change it really quick if you need to.

So shall we go into vote?

CHAIR RAPHAEL: Yes. So we're going to No. 2.

MS. IBRAGIMOVA: So voting on a specific measure?

CHAIR RAPHAEL: On No. 2, because we pulled No. 1.

MS. GHAZINOUR: One is yes, two is no.

CHAIR RAPHAEL: Are you reading something to us or --

MS. IBRAGIMOVA: Yes, I'm going to be reading the consent calendar --

CHAIR RAPHAEL: Okay.

MS. IBRAGIMOVA: -- and then you're going to be voting on the consent calendar.

CHAIR RAPHAEL: Okay. Do not vote

yet.

MS. IBRAGIMOVA: So consent calendar 1, Inpatient Rehabilitation Facility Quality Reporting Program, conditional support: IRF functional outcome measure, change in self-care score for medical rehabilitation patients; IRF functional outcome measure, change in mobility score for medical rehabilitation measure; IRF functional outcome measure, discharge self-care for medical rehabilitation patients; and IRF functional outcome measure, discharge mobility score for medical rehabilitation patients.

CHAIR RAPHAEL: Okay. Should we vote now?

MS. IBRAGIMOVA: So this is the voting slide.

CHAIR RAPHAEL: Okay.

MS. IBRAGIMOVA: So do you agree with consent calendar 1, Inpatient Rehabilitation Facility Quality Reporting Program conditional support calendar? One yes, two no.

(Voting)

MS. DAVIS: And when voting can you point your clickers toward Laura and not the screens is where it will capture. A number should pop up on your clicker. Toward Laura.

MS. O'ROURKE: And for members on the phone, staff can cast your vote as a proxy. So if you could send us a chat through the Webinar platform, we can cast those for you. If you're not on the Webinar platform, if you're comfortable just saying your vote, we'll log them.

CHAIR RAPHAEL: All right. Let me just check in with Lou, Carol and Lisa.

MEMBER WINSTEL: Hi, this is Lisa and I was just now sending my vote to Mitra through chat.

CHAIR RAPHAEL: Okay.

MEMBER WINSTEL: So they can confirm if that works or not.

MS. GHAZINOUR: Yes, I got your vote. Thank you.

CHAIR RAPHAEL: Okay. Lou?

MEMBER WINSTEL: Oh, okay. Thanks.

MEMBER SPENCE: This is Carol. I did the same.

CHAIR RAPHAEL: All right. And, Lou, are you still there?

MEMBER DIAMOND: Yes, I'm still here and I'll vote in the affirmative, yes.

CHAIR RAPHAEL: Okay. And Lou voted yes.

MS. IBRAGIMOVA: So the slide didn't capture your votes, so if you can recast your votes.

CHAIR RAPHAEL: So we should all recast our votes?

MS. IBRAGIMOVA: Yes.

CHAIR RAPHAEL: All right. We should aim them at you again?

MS. IBRAGIMOVA: Yes.

CHAIR RAPHAEL: All right.

MS. IBRAGIMOVA: So the results are 89 percent yes and 11 percent no.

CHAIR RAPHAEL: And our bar is 60

percent, so this carries. Okay.

All right. So now we're going to go back to No. 1, the venous thromboembolism prophylaxis measure. Are there any comments that anyone wants to make on this one?

All right. Pam?

MEMBER ROBERTS: Just a clarification question. So for some of the comments that were brought up for additions to the measure, how does that work?

MS. O'ROURKE: So we'll capture those as the conditions for your support when we put together the table of all of the Workgroup's decisions. So we'll capture Suzanne's concerns around the 120-day exclusion criteria and the previously noted that this should be retooled for use in IRFs and resubmitted for NQF review.

MEMBER LEVITT: Yes, I just want to note that CMS read the public comments and we will be going through the measure and specifying it with our experts to make it an IRF-appropriate measure.

CHAIR RAPHAEL: Sean?

MEMBER MULDOON: Alan, just a we got that covered would be okay, but when these come to mind, I'm thinking that 10 years from now will we still agree over what "overlap" means and will we still agree on what frequency of platelet count monitoring is necessary and will we still agree with what discharge instructions entail, or will they -- is built that into that the flexibility to over time through regulation change what those individual parameters are?

MEMBER LEVITT: Well as you know, Sean, every measure that's NQF-endorsed goes through maintenance and through maintenance that would be reviewed. And again, depending on the review, NQF would look at those measures, and if they are a measure that has a substantive change, we would put that through rulemaking.

MEMBER MULDOON: So the goal here is for every single patient, because the denominator is every patient, to be asked the question, and if the answer is just then to go through the

subsequent ones of monitoring, overlap and instructions.

DR. BURSTIN: Well, just a clarification. This is only one element of those various Joint Commission measures. This is only the one on VTE prophylaxis is my understanding. VTE 1 only, right. We do regularly update those measures as the evidence has changed and new drugs have come on line, et cetera.

MEMBER ROBERTS: I just want to make sure that -- so the comments with the stroke and being included would be looked at?

CHAIR RAPHAEL: Yes. Okay. I'm going to call the question. Do I have a motion to approve the VTE measure?

MEMBER SALIBA: So moved.

CHAIR RAPHAEL: Second?

Okay. So now, Laura, we turn to you. Are you ready? You're going to read this?

MS. IBRAGIMOVA: Yes. Consent Calendar 2, Inpatient Rehabilitation Facility Quality Reporting Program for conditional

support, venous thromboembolism prophylaxis.

So don't vote yet.

So do you agree with Consent Calendar 2, Inpatient Rehabilitation Facility Quality Reporting Program conditional support calendar? One yes; two no.

(Voting)

CHAIR RAPHAEL: Okay. We have Lisa, Lou and Carol.

MS. GHAZINOUR: Okay. I just got --

CHAIR RAPHAEL: You got that? And, Lou, do you want to say how you vote on this?

MEMBER DIAMOND: I will vote yes.

CHAIR RAPHAEL: Okay. Thank you. So Lou is yes.

MS. GHAZINOUR: Do you want to all just vote one more time just to make sure --

CHAIR RAPHAEL: Bruce is out of the room.

MS. IBRAGIMOVA: Oh, okay.

So the results are 100 percent yes,

and 0 percent no.

CHAIR RAPHAEL: Okay. Cathy, we're now going to turn to any public comment on Inpatient Rehab Programs and Facilities.

OPERATOR: Okay. At this time if you'd like to make a public comment, please star then the number one.

(No audible response)

OPERATOR: There are no public comments at this time.

CHAIR RAPHAEL: Thank you very much.

So we're going to go on to pre-rulemaking input on the measures under consideration for ESRD Quality Incentive Program. And we have three reactors with us: Andrew Narva from the National Institutes of Health; Peter Crooks from Kaiser Permanente Southern California; and Tom Manley from the National Kidney Foundation. I believe they're all on the phone. But are they on the phone, because we're early?

DR. BURSTIN: Operator, could you

please check if those individuals are on the line?

OPERATOR: Okay. One moment. I'm not showing them on line.

CHAIR RAPHAEL: Too early. So what do you recommend that we do?

MS. GHAZINOUR: So we may want to do the skilled nursing facility.

CHAIR RAPHAEL: So do you want us to flip and do skilled nursing at this point? But is Rabia Khan on the phone from CMS?

MS. GHAZINOUR: No, Rabia will be for the Medicare Share Savings Program, not for this one.

CHAIR RAPHAEL: Oh, okay. Not for this? Okay.

So then if you can bear with us, we're going to go to what was in the afternoon session, which is measures under consideration for Skilled Nursing Facilities Value-Based Purchasing Program, and come back to ESRD.

All right. And, Mitra, you're going

to provide an overview of this program and the staff analysis and recommendations.

MS. GHAZINOUR: Sure. So this is the new program, the skilled nursing facility value-based purchasing, newly established program on the Protecting Access to Medicare Act of 2014, or PAMA Act. And it directs the secretary to establish a SNF Value-Based Purchasing Program under which value-based payment incentives are made in fiscal year to facilities beginning in fiscal year 2019.

And also this act requires that, no later than October 1st, 2015, the secretary shall specify a skilled nursing facility all-cause, all-condition hospital readmission measure for this program, and also not later than October 1st, 2016, the secretary shall specify a measure to reflect an all-condition risk-adjusted potentially preventable hospital readmission rate for SNFs.

So going back to the agenda, looking at the measure -- now it is included in the

Discussion Guide. So the measure under consideration is a skilled nursing facility all-cause 30-day post-discharge readmission measure. And it's submitted for endorsement. The number is 2510. This measure estimates the risk standardized rate of all-cause unplanned hospital readmissions for patients who have been admitted to a SNF within 30 days of discharge from their prior proximal hospitalization.

And so based on the staff preliminary analysis, this measure addresses an important PAC/LTC core concept, which is avoidable -- unavoidable readmissions and is a required measure for this program under the PAMA Act. MAP had reviewed and supported the direction of the measure concept. This measure was a concept in 2013 when MAP reviewed this measure and MAP supported the direction of this measure.

This measure is currently under review for endorsement and it's in the final stages of receiving endorsement. And also this measure was recently finalized for use in a Medicare Shared

Savings Program in the physician fee scheduled final 2015 rule. The preliminary analysis result is to support this measure for this newly established program.

We received one public comment for this measure which was very supportive of the measure.

So now I would like to turn it back to the Workgroup.

CHAIR RAPHAEL: Okay. Let me see if there are questions on this measure.

(No audible response)

CHAIR RAPHAEL: Well, I had a question. How does this measure compare to the readmission measures that we have for other post-acute and long-term care settings?

MEMBER LEVITT: Okay. Well, first of all, I don't know if Joel Andress -- if we want to invite him up. He's our readmission lead.

But to answer the question, the readmission measures that you're talking about, the other measures, are measures that really are

looking at care coordination, and those are readmission measures that are post-discharge. So in other words, 30-day post-discharge measures.

This is a different measure. This is 30-day during a SNF measure. It's primarily an in-stay measure. It may also include post-discharge if the patient gets discharged during that 30 days. But the goal of the measure was really to harmonize with the hospital-wide readmission measure, which is a 30-day measure as well.

CHAIR RAPHAEL: Okay. Question --

MEMBER LEVITT: Does that answer? Okay.

CHAIR RAPHAEL: Okay. Let me take any questions from the Workgroup on this. Sean?

MEMBER MULDOON: So this is Sean from Kindred. We're pretty happy with this because it seems to have rung a couple good bells. One is that the clock starts when you get to the SNF, not after discharge. So that harmonization is correct. Just want to make sure you've thought

through the gap that you're allowed to have between the short-term discharge and the SNF admission. We think of that as the next day, but not always.

And it is important that the fee for services or the managed Medicare is taken out of this so that they can more creatively use post-acute care not just from those groups that are coming directly from short-term hospitals. So we're good with this one as written.

CHAIR RAPHAEL: Thank you.

MEMBER AGOSTINI: I had two questions if anyone can answer. One was for the exclusions for the planned readmissions, is that a similar list that's already been developed for other admission/readmission measures to the hospital? That was one question.

MEMBER LEVITT: Yes, that's correct. I mean, we use the I guess Yale planned readmission algorithm so to speak that is our basis, but then we've also added planned readmissions that may be more appropriate for the

SNF setting.

MEMBER AGOSTINI: Thank you. And then the second question was around cancer diagnoses. I see any medical diagnosis for cancer was in the exclusion from the denominator. I'm just trying to understand the thinking around that because there still could be unnecessary readmissions for people with cancer. What's the rationale there?

MEMBER LEVITT: Joel's walking up. Joel, do you want to answer this one, or you want -- this is Joel Andress, our lead here. It's about the cancer exclusion.

MR. ANDRESS: All right. Okay. So we started off in developing this measure, as Alan said, with the intent to align it with the hospital-wide readmission measure as much as we possibly could, primarily in terms of what we considered to be appropriate exclusions and what we considered to be the guiding principles of what the measure was trying to accomplish.

So we started with the exclusion criteria that the hospital-wide readmission

measure included. One of those is, as you mentioned, for certain cancer patients. We should note that cancer patients are not themselves excluded from the measure, but what you're actually looking at are discharges for particular cancer-related admissions and discharges.

The way that this was put together is that we started off with a clinical team looking at the kinds of issues that we believed would be appropriate for exclusion. We ran analyses starting off originally with the hospital team running analyses trying to identify what kinds of admissions should be excluded or what kinds of patients should be excluded, and then we put it through our standard system.

So I would say that as we do that there's typically a balance with these codes because there's a recognition that some of these codes will include patients who are appropriate to capture as a readmission as being a failure in care. And there are other patients within the

codes who are less clearly so. And there's inevitably a bit of noise. So we try to balance that noise out with clinical expertise in terms of whether or not you're capturing a greater weight of readmissions, which is important, without also potentially incentivizing poor behavior on the part of providers who may attempt to game the system of the readmissions.

So that's how we approach it in general. Did you have a specific exclusion in mind that you were particular concerned with?

CHAIR RAPHAEL: The question was raised about a specific one.

MR. ANDRESS: Why but within --

CHAIR RAPHAEL: Why that cancer was specifically excluded.

MR. ANDRESS: Oh. So cancer specifically was excluded because in the original development of the hospital-wide readmission measure the population was stratified among five groups and -- or, I'm sorry, originally seven groups, one of those being cancer. And what they

found was that cancer patients are typically very different from other patients in terms of readmissions patterns, and it was deemed by the development team and later by CMS that in including them in the measure, you were essentially capturing a different course of events from the other populations within the readmission measure.

And so, a cancer readmission was seen to be as noise in a particular kind of population that actually muddied the waters in trying to assess the performance of the facilities in providing treatment to those patients. And so we decided to exclude them from the hospital-wide readmission measure.

In reviewing for the SNF measure, we concluded that the same issues were also present in the SNF population, and so we decided to retain the same exclusion.

CHAIR RAPHAEL: Joseph, you want to respond?

MEMBER AGOSTINI: Well, I mean, I'd

like to hear from others. I hear the point. My point is just around the concern for there are avoidable readmissions potentially within the oncology -- the medical diagnoses for cancer. So I know there may be noise. I just want to be concerned for that population of patients, that we still are concerned about unnecessary and avoidable readmissions.

CHAIR RAPHAEL: Okay. Robyn?

MEMBER GRANT: So my question is whether in developing the measure and testing it anyone looked at the potential unintended consequence of this impeding the ability of residents who really, really need it to get hospitalization when they're critically ill.

We hear all the time from family members who've been in the situation where their loved one has been the nursing home. They can tell something is seriously wrong and they are asking for the resident to be sent to the hospital and that for a variety of reasons, the facility will not accommodate that request and

refuses to send them there with the subsequent result that the resident suffers harm or in fact dies.

And so, I think our concern very much is that that's what we're hearing is happening now without something that incentivizes nursing homes not sending residents to the hospital. So we're very concerned that this could impede residents getting the care they need. So I just wondered if that had been looked at and considered.

MR. ANDRESS: So this is something that was also raised when the hospital readmission measures were originally developed. I think the particular concern was that readmissions would drop down because hospitals would refuse to readmit patients and they would simply die as a consequence of that. So one of the things that CMS did at the time was to develop partnered condition-specific mortality and readmission measures.

And so, since we started developing

those measures we've watched in hospitals, which for this measure essentially -- this measure is essentially a slice of the population that hospitals are discharging. We've looked for that. And what we found is that there is not a strong -- you would expect to find a strong negative correlation between the two measures if hospitals were dropping their readmission rates at the expense of greater mortality of patients, and we don't see that. In fact, there tends to be a fairly positive correlation in hospital performance for this.

Now we don't have a partnered measure for the SNF setting. I think that's certainly something that we've talked about as something that we'd like to push forward. Current statutory limitations would prevent us from implementing it in the SNF Value-Based Purchasing Program, but that doesn't mean that there aren't other avenues where it could potentially be reported on. Of course, a mortality measure for the SNF population carries its own difficulties

in specifying.

MEMBER GRANT: Thank you.

CHAIR RAPHAEL: Okay. Dianna?

MEMBER REELY: Can you speak a little bit to the timeliness of reporting this measure, because the risk stratification will be part of establishing the measure? Oftentimes organizations wait a long period of time to see what the results will be. And we can calculate the results internally, but not always knowing all of the elements of the risk stratification. It is challenging for organizations. So just length of the measure, you know, will it be 12 months post-the actual hospitalization occurrence, or will the measure be something that's reported more timely than that?

MR. ANDRESS: So I would say the risk stratification is actually not the primary reason that there's a lot of time that goes into producing -- a lag in producing the measure. That tends to be more a lag in developing the measure. It takes time to put together the

model, but once you have the model, it's simply a matter of obtaining the data. But really, lag is a consequence of the use of claims data.

Now typically, that is because we recognize that at the end of a particular year, you still have up to a year to correct claims that are submitted to CMS. And so we allow for a runout of -- well, I mean it can vary, but I know there are groups that use three months. We use six months to allow the claims data to mature, to ensure that we've got as correct of data as we possibly can, recognizing that we can't wait -- waiting a full year gives us as complete a data as we're going to get, but of course, it causes lag.

I think the current lag in reporting is roughly -- we're looking at what I'll call a year following the end of a particular data period. So we're using one year --

MEMBER LEVITT: At six months, I think.

MR. ANDRESS: Well, the runout, the

runout is.

MEMBER LEVITT: Yes.

MR. ANDRESS: But in terms of actually calculating and producing the measure and being able to put it up for reporting, the lag is about a year from the end of a particular data period. So if we're looking at calendar year 2013, you're probably looking at the end of December in 2014 before we would be able to produce the measure. And then, of course, it's a matter of the time lines for whatever vehicle you're reporting the measure on.

MEMBER LEVITT: And in terms of -- if you actually read the section 215 of PAMA, it really specifies this measure is supposed to be by October 1, 2015, provide feedback reports by October 2016, public reporting of that by 2017, and then the actual VTE program is October of 2018. And so, you know, there is a time line for it.

CHAIR RAPHAEL: Okay. Tom?

MEMBER VON STERNBERG: I think in

follow up to Joe's question of December 30, your answer about cancer exclusion just didn't work for me at all. But having said that, my reason to comment that is a patient with cancer who gets transferred to SNF, who gets PE because they did not have adequate anticoagulation, pretty seminal event, pretty important. I can't see why we would exclude it. Cancer is different in many ways, but it's still highly in need of coordination and attention.

I think the -- I resonate somewhat with the challenge of a facility that doesn't understand it needs to readmit somebody. I still think though that doesn't mean we shouldn't measure there. But one of the questions I have is as we get harmonization with a hospital's 30-day readmission rate to the SNF, I think that's very helpful. The challenge at the SNF level, however, is I'm receiving admissions from hospital A, hospital B, and hospital C. And the connectivity, the safety of the transition, the communication, information, can vary.

So is the SNF at a higher degree of risk of score based on where they're receiving folks from? Now granted that would incent them to perhaps ask for better communication and partnership. The hospital doesn't have that same additional burden of things in the same manner.

Can we reconcile the fact that a SNF measure will include many hospitals whereas a hospital will be just one hospital?

MR. ANDRESS: So I would point out that -- this is actually something else that came out in the development of the hospital measures. We have looked at -- we looked at that hospitals -- I should say that one of the complaints that we got early on was that when we were looking at hospital readmissions, we weren't risk adjusting for where the patients were going to, right? And the rationale for that was one, the hospital is part of making the decision about where a patient is being discharged to. And that was partially the hospital's responsibility.

I think for SNFs, you have a -- you

have a balancing act to make in terms of risk adjustment. Risk adjustment, frankly, is frequently that. You're making a judgment about what kinds of things should be risk adjusted for in a particular measure.

In this case, I think it's inappropriate to risk adjust for the hospitals who are coming in precisely because we want SNFs to be reaching out to those particular hospitals. And because that coordination is a shared responsibility between the two facilities. And I think we're hesitant except under particular circumstances -- under specific circumstances to include that in the risk adjustment model because we're typically hesitant to risk adjust for things that we consider to be under provider control or under the decision-making processes of providers.

I think what you point out, too, is one of the glaring inherent complexities of dealing with care coordination is that our measures are typically designed to assess a

single provider type and a single provider at a time. But of course, care coordination is very much dealing with the interaction of multiple providers and this is one of the issues, I think, that we face and will continue to.

MEMBER VON STERNBERG: The follow up would be 72 hours, is also an important, perhaps, distinction of readmission rate around that short window about truly chaotic transitions. Any interest or any conversations about a submeasure of within 72 hours of bounce backs?

MR. ANDRESS: So we've actually received the opposite that maybe we should exclude the first 72 hours because anything that happens should be the responsibility of the hospitals. We don't ascribe to --

MEMBER VON STERNBERG: I would agree there's this conversation.

MR. ANDRESS: Oh, there is conversation. I think our fear is that that's -- when the patient is most at risk for readmission is the point at which you have to

include -- or you want to avoid excluding them from the readmission measure.

In terms of a submeasure, we have looked at different time periods, 30 days, 15 days, 7 days. I don't know if we looked at 72 hours specifically. But we could go back and take a look. I think what we found is that typically for the rating of SNFs, it doesn't make a lot of difference which of those time periods we use. The ratings tend to be fairly consistent regardless of the time period.

CHAIR RAPHAEL: Marc?

MEMBER LEIB: I'm still a little concerned that there might be what I'll call checks and balances of this. It echoes a little bit of what Robin said. Prior to this measure coming up, if a hospital discharged a patient on the early side and the patient went home or somewhere else and required rehospitalization, the only institution that suffered a ding, shall we say, was the hospital because they discharged them early.

Now you've got both places where the patient might be at risk for a negative mark, neither one of which wants to suffer that. And so the hospital is not going to want to take the patient and the nursing facility is not going to want to send the patient and this patient is going to languish somewhere in between until they're so sick that there's no doubt about where they have to go or they go out horizontally. And I'm really concerned that when a patient goes home, the family will take the patient back to the ED, but the SNF is going to be incentivized not to bring them back to the hospital with this negative measure here, so there's no check and balance in the program when you have both sides being negatively affected on a readmission.

MR. ANDRESS: Well, so I'll just note that in the case of hospitals, they are also held responsible for 30-day mortality for a number of commissions. And of course, if the patient dies within 30 days because they weren't readmitted to the hospital, and those measures are part of the

hospital value-based purchasing program as well.

For SNFs, I agree that I would want to see something like that in programs and again for the value-based purchasing program you have statutory limitations you're running up against for the -- in terms of measure development, I think mortality is a measure that needs to be addressed. We simply haven't had the opportunity to develop a measure for it yet.

That said, I think that care coordination, in and of itself remains something that we need to pursue, particularly among post-acute care facilities. I think this is -- the transitions of care are critical ones for these patients. And while I agree that more needs to be done in the process of assessing quality and developing the programs that these measures are incorporated into, I think the question then becomes do you wait -- do you then not assess care coordination at all until you feel like everything that could be in place is in place or do you move forward with the program? I think

from that perspective we feel very strongly that we need to start addressing care coordination in SNFs and other settings.

CHAIR RAPHAEL: Okay, Bruce?

MEMBER LEFF: Yes, just a clarification, can you describe what the statutory limitations are in terms of including mortality? That's mystical to me.

MR. ANDRESS: Sure. So the SNF value-based purchasing program allows for two measures. The first one we believe should be this measure, which is why we submitted it.

CHAIR RAPHAEL: Could you speak a little louder?

MR. ANDRESS: Sorry. So the SNF value-based purchasing program from the pending legislation allows for two measures. The first is this measure which we -- well, I should say we believe it should be this measure which is why we presented it here. But it also requires the development of a potentially preventable readmissions measure, which is essentially this

measure -- well, I think it will probably end up being this measure with additional exclusions for readmissions that are not considered to potentially preventable. That's not something that we've managed to define yet, so we don't have that measure to present here.

But the intention of the legislation is that ultimately that measure will replace this measure once it's been developed and it's ready for implementation, but there's no -- we have no authority to implement measures beyond those two in the program.

MEMBER LEFF: There's no way to somehow account for SNF-based mortality in the formula for the measures you have statutory authorization to pursue? Is that a correction based on mortality or something else?

MR. ANDRESS: So I won't say that there's no way; I'll say that it's not something that we've considered as an element of our readmission measures as a goal. This measure was developed before we had the SNF VTE language to

go by. That might have been something that we would have looked to address had we been aware of the limitation at the time the measure was being developed.

For now, there's not currently an adjustment for morality in the measure. That said, the fact that we are resisting the measure fairly robustly is one of those protections that goes in. That's the entire point of risk adjustment is that facilities are on the level playing field so that if they do have patients who are sicker than you might find at other facilities, they are assessed fairly. That's the entire point of a risk adjustment in the first place. So I'll say it's not entirely ignored, but we didn't specifically go out and add a correction for mortality rates at the facility level.

CHAIR RAPHAEL: Alan?

MEMBER LEVITT: Yes, just to add on to what Joel just said that again, there are the statutory requirements and you know, you read the

law and again, by no later than October 1st, 2015 the Secretary shall specify a skilled nursing facility all cause, all condition, hospital readmission measure. And so it's specific in the language. And then we will be back. You can look at the IMPACT Act and you can look at this legislation and you can predict what we're going to be talking about at this table in the future because it says not later than October 1, 2016, we will be specifying the measure to reflect an all condition, risk adjusted, potentially preventable hospital readmission rate for skilled nursing facilities. So again, very specific and those are the two measures. The second will replace the first.

MEMBER NISSENSON: This is a question for Joel. It's a variation on Tom's comment and question.

How confident are you about the ability to attribute the rehospitalization to this setting? What work has been done to look at the specific causes of the readmission and then

to see whether they're actually attributable to something that has gone on in the skilled nursing facility?

MR. ANDRESS: So I think that the first thing to point out is that this is an issue that has come up in NQF a couple of times, particularly in looking at post-acute care settings because frankly most of the readmissions work that has been done has been done for hospitals. So for most of the post-acute care settings, the number of studies that have looked specifically at intervention for readmissions at post-acute care settings is fairly limited. SNFs are actually one of the strongest of those. There have been a couple SNFs, which I will not attempt to recite from memory, but which we have available in the measure documentation that we can provide for you if you're interested in looking at it.

That indicates that SNFs do have a capacity to reduce readmission rates among their patients. From that, there's -- apart from that,

there's a simple matter of face validity that you have patients who are going to a SNF who are being treated following an acute care stay who have obviously been sick in the very recent term and have been judged appropriate for the setting, which means that there's some degree of continuing care that is necessary for the patient before they go home or to another setting.

And from our perspective, we see the fact that you have this transition of care from acute care to a post-acute care setting is indicative of the fact that you have a patient who still needs care and that care may either be good or bad. And that there may be consequences for that patient's outcomes depending on the quality of the care that is provided. And for that reason, as well, we think that our readmission measure for this particular transition for SNFs is certainly appropriate and called for.

DR. BURSTIN: Just a brief comment. This has been an issue, obviously, in many years

at NQF through both the endorsement and the selection functions at MAP. And I'll say that prior work of the hospital MAP group and other groups and the querying over the years have made the case that the best approach here is to, in fact, have readmission measures across the widest range of settings. So it's less about attributions of what happens to a single institution, but instead if we have measures across multiple different settings of care, do we get a more complete picture recognizing that it's, in fact, very difficult to tease out what happens where and that it is really about shared accountability and shared attribution.

And you know, certainly having had the scars of looking at readmission measures over the years at NQF, this is an issue I think the more we have -- the hospitals have certainly taken the first hit on much of this. I think there is now a sense that the hospital plus the other groups together would provide a better picture of what's happening now.

MEMBER DIAMOND: Carol, this is Lou again.

CHAIR RAPHAEL: Lou --

MEMBER DIAMOND: Can I ask a question?

CHAIR RAPHAEL: Hang on. I have Pam and then we'll come back.

MEMBER DIAMOND: Okay, thank you.

CHAIR RAPHAEL: Go ahead.

MEMBER ROBERTS: One, I have a clarification question, and one, if you look at the original documents from the readmission group on SNF, there are some studies that have been done that have been published regarding SNF and the opportunity for readmission. So they are clearly laid out in there.

The question I have was the recent consensus standard approval approved this readmission measure with conditions. So would this quality metric include those conditions?

DR. BURSTIN: Yes, it has not gone through our board yet for final approval, but yes.

MEMBER ROBERTS: Right, but if it was approved, then that's the way it would be?

DR. BURSTIN: Absolutely. And if you want, I'll just state those two conditions one of which is that all the measures that went through the admission/readmission project would go back to that standing committee to consider whether some of those measures might be appropriate for SES adjustment, how that NQF has put forth that report indicating we have a willingness now to consider measures with that level of adjustment.

And secondly, a requirement for a one-year lookback for any concerns about unintended consequences. And since that's already been raised at this table, I want to put that -- ensure that as well.

CHAIR RAPHAEL: And I was just a member of that committee, so I just want to reiterate that we did spend a lot of time on the SES adjuster, as well as wanting to keep these measures constantly under the microscope that we just don't end all work and move on, but that we

are constantly getting feedback and reassessing.

All right. Lou?

MEMBER DIAMOND: Yes, thank you. Thank you, Carol. In your earlier comments about dual accountability is obviously right on the mark. I guess my question is how can we get to the dual accountability reporting piece? Am I correct that we're not actually reporting based on the dual accountability concept. Is that correct?

DR. BURSTIN: Not reporting it, but each entity is held accountable, so there is a sense of each -- if a hospital has a measure and a SNF has a measure and they're both being held accountable, that would be the logic, but they don't necessarily share that accountability in each individual measure. I'll defer to CMS on anything further.

MR. ANDRESS: So I'd also note that most of the information that we use for this is obtained through claims data. There's nothing that we use from the NDS for the SNF readmission

measure. The risk adjustment data are obtained through claims data, Part A claims data, I should specify. And so there's no additional reporting burden one way or the other.

Now we've talked -- we actually talked about it again during the NQF project about the possibility of creating a hybrid model that used both NDS and readmissions data. We had some concerns with regard to that because there was a -- there are other -- there is a possibility to do that, but in order to do that, you end up with some limitations in terms of what you're able to do, do with the measures.

One of our greater concerns, obviously, is matching up the NDS data with the claims data, which when you have two separate data sources that can always be adventurous. So it's not something we've incorporated. Of course, when we started out from this, we were basing it again on the hospital-wide readmission measure, which is a self-claims based.

I think one of the advantages to the

measure is that it doesn't require an additional report burden from the facilities. And when we think about shared accountability, we don't generally think about accountability, or at least I don't, in terms of having to report data.

My concern of shared accountability is that if there's an event where a patient is inappropriately transitioned from one area of care to another, the providers who are responsible for that transition of care are aware of it and they can improve upon a few tractions to ensure that that doesn't happen again or as usually the case as frequently as it has in the past.

CHAIR RAPHAEL: Okay, Sean?

MEMBER DIAMOND: Real quick, can I just follow up?

CHAIR RAPHAEL: Go ahead.

MEMBER DIAMOND: Is it a fact that we had reporting across multiple settings on these readmission rates and that the patient populations that are being reported on and the

time frames are all similar so that we, in fact, are getting a proxy for shared accountability or variable difference? Do you understand what my question is?

MR. ANDRESS: I understand what your question is. So there are some differences. I would say that's more in effect a consequence of the development for a lot of these settings, measure development in a lot of these settings being in its infancy.

For instance, and I'll give you an example here, the LTCH and IRF settings have readmission measures that cover transition after the discharge of a patient from the LTCH or to the IRF, which is different from this measure. We're actually undertaking development efforts to develop within the same measure that is roughly analogous to the SNF measure that we have currently. So our goal is to address that. It's simply a matter of getting the resources in place to develop it.

So there are some differences in the

current measure suite, but we're working to address that.

MEMBER DIAMOND: But Carol, it does seem that the committee may want to consider this as a recommendation to CMS. And since we all know this is a very important issue, but it's also a very contentious issue in terms of who is accountable for what. And the notion of the dual accountability, but based on what Helen said, it's a virtual dual accountability that we are promulgating at this stage of maturation. And some kind of effort to align the time frames of the patient populations across these multiple measures would be very helpful it seems to me.

CHAIR RAPHAEL: Helen, did you want to chime in?

DR. BURSTIN: Just to point again in addition to the details reported, they are the same time frames, they are all 30 days. And they are based on the basic model of the work that's been done to date on the hospital model. Is that correct, essentially?

MR. ANDRESS: That is correct. Right. So to clarify when I say within the same measure for, for instance, the IRF or LTCH, it's the same transition. You've been discharged from a hospital. You're going to an IRF or an LTCH, and then the question is are you readmitted to the hospital within -- well, I'll say we're actually talking amongst ourselves whether it's within 30 days or limited to the stay. Because if you do 30 days, then there's a potential that that and the measure that already exists will actually double count an individual patient. And so we're talking about the potential consequences for that as we develop the measures.

CHAIR RAPHAEL: Sean.

MEMBER MULDOON: My comment is related to the risk of the perverse incentive of not transferring a needy patient. We have been measuring a very similar measurement for about two years and had the same concerns going in. But what we have learned over the last couple of years is that in the absence of this metric, all

the incentives are to transfer. When someone starts to look bad, if you -- when you transfer them you avoid getting the doctor involved when he or she doesn't want to. You avoid having to go to a lab that's not on site. You avoid calling in a radiologist and you avoid turning an inexpensive patient into an expensive one.

So with all those incentives saying send them, this one says not dig in your heels, but just whoa. Stop and think. Is there another way to do this for this particular patient? And then when you step back, are there systems we can put in place that can catch these things when they're small rather than big?

So although I am sure that there are some patients or places who have dug in their heels on the issue, that has not really borne itself out in our two-year experience.

CHAIR RAPHAEL: Okay, thank you. Dianna.

MEMBER REELY: Very similar to Sean's comment. On behalf of Providence, for at least

the last couple of years, in alignment with our hospitals in the system on our skilled nursing facility site, we too, have been putting processes in place to reduce readmissions and primarily because it's the right thing -- we believe it's the right thing to do and also because other non-Medicare payers have asked us to do that and are basing their decisions on who to contract with based on one indicator being readmission rates including even large employers now as we work on developing accountable care organizations.

So my comment is that this is not necessarily something new for skilled nursing facilities, particularly in all of our regions, but it would allow for more consistency in the definition of how readmissions are calculated and reported.

CHAIR RAPHAEL: Thank you. Clarke?

MEMBER ROSS: Just an observation from the consumer beneficiary perspective. This discussion reinforces for me the need to

accelerate measure development in continuity of care, care coordination, and transition planning which is really what this is all about, but because of legislators and people want to save money, we're focused on readmission rates, which we have to do. But to me, we should just accelerate these more important, larger concepts and do what you have to do with this, but get on with the bigger picture.

CHAIR RAPHAEL: Robin?

MEMBER GRANT: I realize that there is the review for unintended consequences, I think. When you said SES, since I'm new, is that socio-economic status?

CHAIR RAPHAEL: Yes.

MEMBER GRANT: So I guess my question was just up front was there any examination of the impact that this might have on low income and minority residents, who may often be found in facilities that are predominantly minority? And we know from research that predominantly minority facilities often have far poorer quality of care

than dominantly white, so I'm just wondering if anything had been done to look at that?

CHAIR RAPHAEL: Alan, do you want to say anything or Joel?

MEMBER LEVITT: Well, I'll let Joel answer that and then I have a comment to make.

CHAIR RAPHAEL: Okay. Joel?

MR. ANDRESS: Sure. So to clarify, we've not included SES as part of the risk adjustment in our measures. But we do -- you've come to anticipate that we're going to be asked about it, obviously, so we do look at it.

Our findings actually across settings seem to be fairly consistent on this point. There tends to be a relatively small gradient in that facilities that have large numbers of patients with low SES, tend to have a slightly higher rate on these measures and it's a fairly modest gradient. But what we've also found and we've also found that a similar gradient, I believe, for instance, where you see facilities with larger numbers of African American patients,

the main point that we've made though is that in addition to looking at the gradient or the correlation between the two -- the SES and race and the facility rates is that we've looked at the variation within those groups.

And what we find is that the variation within those groups is fairly wide and that they almost entirely overlap each other. And what that means is that you have facilities that treat large numbers of African American patients who do very poorly on the measures. And you have facilities that treat large numbers of African American patients who do very well on the measures. And then you have facilities who have relatively few African American patients who are also on both ends of the spectrum.

And so what we've argued, and I think what we've concluded from this, is that yes, there is some potential for impact, but it's also clear that the fact that a facility treats large numbers of what are traditionally considered disadvantaged populations, that does not

necessarily prevent those facilities from being able to provide a high quality of care as it's indicated through readmissions.

CHAIR RAPHAEL: Alan, you have the last word.

MEMBER LEVITT: Okay, and just to add to what Joel said, in the measure submission there are, if you want to look in the appendix we have tables. We really did look at this, and as Joel said there were effects that were seen, but again, there was such a wide gradient that it showed that clearly, there were facilities that did quite well and facilities that did not actually in both categories.

Just to make the final comment, again, this is an outcome measure and outcome measures are very difficult. Everybody has their own opinion as to what should be in and what should be out. CMS does not have the expectation that there should be no readmissions to the hospitals, that this -- there is obviously things that are out of anybody's control that will cause

readmissions, but that there is a piece of those readmissions that we can influence.

Thank you, Dianna, I mean I hope everyone is doing what you are doing, really looking at their programs and trying to decrease the readmission rate.

CHAIR RAPHAEL: I was just told that Lisa, who is on the phone, may have a question. So let me just do a check in. Apparently not.

We now move to a vote on this skilled nursing facility value based purchasing all cause readmission measure. And do I have a motion to approve the recommendation which is support?

CHAIR RAPHAEL: Motion seconded?

Any further discussion? Okay, Laura.

MS. IBRAGIMOVA: So consent calendar skilled nursing facilities value based purchasing programs support calendar; skilled nursing facility all cause 30 day post-discharge readmission measure. Do you agree with the skilled nursing facility value-based purchasing programs support calendar? One, yes. Two, no.

CHAIR RAPHAEL: Lou? Lou, Carol, Lisa, are you still on the phone?

MEMBER DIAMOND: Yes, Carol. This is Lou here. I'm going to vote yes.

CHAIR RAPHAEL: Okay. Lisa, are you still on the phone?

MS. IBRAGIMOVA: I got Lisa.

CHAIR RAPHAEL: Clarke?

MEMBER DIAMOND: I apologize. I'm going to vote no.

CHAIR RAPHAEL: You're voting no. Lou is voting no, to record that.

MS. O'ROURKE: I think we'll need to take a revote so that we can properly account for Lou's change of heart. So if we could do a revote when Laura gives you the --

MS. IBRAGIMOVA: You can vote.

MS. O'ROURKE: Looks like we're missing one vote. Could everyone make sure you hit your clicker and point it towards Laura?

CHAIR RAPHAEL: Should we do it one more time?

MS. O'ROURKE: One more time.

MS. IBRAGIMOVA: The results are 68 percent yes and 32 percent no.

CHAIR RAPHAEL: Okay, and our threshold is 60 percent for approval, so this is approved.

Thank you, everyone, for a really, I think very productive discussion.

We are now going to take a short five-minute break.

(Whereupon, the above-entitled matter went off the record at 11:08 a.m. and resumed at 11:17 a.m.)

CHAIR RAPHAEL: All right, we are moving on to the ESRD area. Let me just make sure that we have our three reactors on the phone. Andrew Narva?

MR. NARVA: I'm here.

CHAIR RAPHAEL: Thank you.

MR. NARVA: Can you hear me?

CHAIR RAPHAEL: Yes, we can hear you. Peter Crooks?

MR. CROOKS: Good morning, I'm here.

CHAIR RAPHAEL: Thank you. Tom Manley?

MR. MANLEY: Yes, good morning. Hi, everyone.

CHAIR RAPHAEL: Okay. So we're going to begin with Mitra giving us a brief overview of the ESRD quality improvement program, and the preliminary analysis and recommendations from the staff.

MS. GHAZINOUR: Thank you, Carol. So the end stage renal disease quality incentive program is a pay-for-performance program as well as a public reporting program. Under this program, payments to dialysis facilities already used, if facilities do not meet or exceed the required total performance score which is the sum of the scores for established individual measures during a defined performance period.

Payment reductions are on a sliding scale which could amount to a maximum of two percent a year. A facility performance in the

end stage renal disease quality incentive program is publicly recorded to three mechanisms: performance score certificate, the dialysis facility compare website and ESRD QIP dialysis facility performance information.

The program goal is to improve the quality of dialysis care and produce better outcomes for beneficiaries. The critical program objectives include the statutory requirement for this program which notes that the program measure set should include measures of anemia management and also dialysis adequacy patient satisfaction and other concepts important for dialysis facilities.

MAP had previously recommended that the measure set should expand beyond dialysis procedures to include non-clinical aspects of care such as care coordination, medication, reconciliation, functional status, patient engagement, pain, falls, and measures covering comorbid conditions such as depression. And also MAP has recommended to explore whether the

clinically-focused measures could be combined in a composite measure for assessing optimal dialysis care.

And so going back to the measures under consideration, we had seven measures under consideration for this program and we have grouped the first set of measures in one consent calendar and as you might notice, this group we have two different decision category. One of the measures has received support and the three others, they have received conditional support. However we grouped them together because we felt that they were kind of related.

So starting with the first measure, cultural competency implementation measure, this measure is NQF endorsed and this is an organizational survey designed to assist healthcare organizations in identifying the degree to which they are providing culturally competent care and addressing the needs of diverse populations as well as their adherence to 12 of the 45 NQF endorsed cultural competency

practices prioritized for the survey.

And so -- the staff's preliminary analysis concluded that this measure addresses a critical program objective which is to expand the measure set to include other aspects of care such as patient engagement, culturally competent care in groups, patient engagement issue is also a priority of national quality strategy.

This measure is not publicly reported. However, it could be used as a means of evaluating whether standards for providing culturally competent care are being met. And specifically, the degree to which healthcare organizations are adhering to the NQF endorsed preferred practices for providing culturally competent care.

So we gave this measure support based on our preliminary analysis and I believe that we have received one comment on this particular measure and this comment, it's not supportive of the measure for the reason that the commenter indicates that this measure is not adequately

validated in dialysis facilities which, in general, are smaller than the institutions in which the majority of testing has occurred.

Follow up to that, there is a similar measure in the set, measure number two, cultural competency reporting measure. This measure is designed to collect data needed to score the first measure, NQF 1919. And the comment was similar for this measure and based on our preliminary analysis, we have given this measure conditional support. We think the concept is important. However, we recommend that this measure would serve as an important first step in implementing the cultural competency survey. So MAP would encourage the rapid implementation of NQF 1919 which is the first measure, the cultural competency implementation measure.

Moving onto the third measure, documentation of current medications in the medical record. This measure is also NQF endorsed and this measure is percentage of specified visits for patients age 18 years and

older who reach the eligible professional attest to documenting a list of current medications to the best of his or her knowledge and ability.

So the staff supported this measure conditionally. The condition is the measure currently is tested for at a clinician level. So this measure needs to be tested at the levels appropriate for ESRD facilities. And it also addresses a critical program objective that the measure should include other aspects of care such as medication reconciliation. And this measure is also included -- is in the MAP 2 standards so it's a priority measurement for the duals population as well.

It promotes alignment. This measure is used in clinician programs such as PQRS and meaningful use and was recently finalized for use in medication savings program.

We received one public comment for this measure. So the commenter supports this measure under certain conditions and the commenter recommends that the testing for this

measure of the timing and strategy when the reconciliation or documentation happens should be identified, should be clarified when the testing happens.

The fourth measure is a version, is a reporting version of the NQF endorsed medication documentation measure and this reporting measure is also designed to collect data needed to score the above measure in the ESRD QIP. And the public comment is the same for this measure and the preliminary analysis concluded that this measure is important. The concept is important. However, if this reporting measure needs to be quickly converted to the actual NQF endorsed measure in the ESRD QIP, if that NQF endorsed measure is tested and is specified for ESRD facilities.

So that concludes the first measure set, the first consent calendar.

CHAIR RAPHAEL: Okay, so let me just turn to CMS and see if you have any comments that the work group should be aware of.

MEMBER LEVITT: Well, first of all, Carol, it should be noted that the first measure, if the MAP doesn't think it has an influence on CMS, the first measure was brought to our attention at last year's MAP and so you do make a difference in terms of note, the discussion.

CHAIR RAPHAEL: How heartening that is. I will convey that message to the entire MAP.

MEMBER LEVITT: I think it's very important. We did -- we were hoping that the reporting measure for that cultural competency measure would also be fully supported.

Joel wears many hats at CMS and he's also the ESRD lead. Joel, did you want to say something about why we would hope that that would be approved?

MR. ANDRESS: Right, so first of all, I think this is the last topic that you're going to have to listen to me about, so in terms of the reporting measure, so we essentially submitted the same measure twice. One as a measure that

has -- in both cases, a measure that's been endorsed by NQF, and second as a reporting measure. Now this is a reflection of the structure of the QIP which includes both clinical performance and reporting measures and its implementation. We received a suggestion from our own legal office that we should consider submitting these as both reporting measures and clinical performance measures for review.

I think our expectation with the reporting measure is essentially that you would be collecting -- as with all of our reporting measures, if we propose this as a reporting measure, it would be collected not to assess facility performance, at least as a reporting measure, but to collect the data and get data from facilities so that one, it's emphasizing that facilities should be paying attention to this, and two, allows us to get a sense of where we are in terms of cultural competency without also then financially penalizing facilities for the measure.

So I think in terms of its role in a program, the reporting measure from our perspective has a number of advantages. In terms of how it assesses a support or conditional support, we found that when we go through the rulemaking process that on occasion, the distinction between the two can have some impact on the extent to which we can implement this in a program, not just here, but in others as well.

So I think the question that I actually put before you is if you believe that the performance measure is supportable, do you not -- is there a particular reason that the reporting measure which simply collects the same data, but does not penalize facilities for it in a value based purchasing program would also be supportable under the same circumstances. And that was our primary concern that we wanted to raise with regard to this measure.

CHAIR RAPHAEL: Before we turn to our reactors, is there anything more you want to say as to why it's different between support and

conditional support for the two cultural competency measures?

MS. O'ROURKE: Just to explain the staff's perspective of why we did the conditional support for the reporting measures and to caveat the work group is welcome to make a motion to change these out to full support.

We thought that based on previous MAP input, MAP would want to get to the outcome measure, if you will, and get that up and running and fully publicly reported. We recognize the reporting measures are a very important first step to getting that information, but wanting to send a signal to our colleagues at CMS that MAP strongly encourages outcome measures and getting that information out to the public.

CHAIR RAPHAEL: Let me turn now to our reactor panel members and to ask them to provide input on these four measures that have to do with cultural competency and current medications and documentation of that.

Andrew Narva.

MR. NARVA: Sure. Can you hear me?

CHAIR RAPHAEL: Yes, we can hear you very well. Whatever you're doing we want to expand because we haven't heard anyone as well as we're hearing you today.

MR. NARVA: Well, I'm delighted to be a reactor although I'm sometimes known as a hot reactor, but so I think both of the -- these four measures address two very, very important issues. I think my concerns are that implementing a tool that is not ready for prime time might be worse than having a better tool implemented a little bit later.

My concerns about the cultural competency tool and having spent most of my career taking care of dialysis patients in the Indian reservations, this is clearly a big issue. I have concerns about -- I don't know a lot about the RAND survey and it's not a lot I could find in the literature or even on Google, but there are several sections in that survey which are concerning and some that may not really be

helpful in dialysis.

The RAND survey suggests the CEO of the core organization sign off on the assessment. I'm not sure how that would work in current dialysis organizational structure. And it may be that this needs to be more adapted. The piloting of this measure says that they approached seven dialysis units in Texas and the response rate was ten percent. So it appears then that we're moving forward with an implementation assessment based on experience of its administration in one dialysis unit in Texas. I may have misunderstood what I read.

I think it's important that whatever measure is used can maybe show some difference after there's an assessment. And I wonder if the idea of reporting could be -- might be endorsed as a way of sort of getting people to pay attention to this issue and defer the tool until it's refined a little bit better and maybe better validated in the dialysis setting. I can also tell you that there's sort of a cadre of young

investigators who are really starting to look at a lot of these issues in a very rigorous and creative way. And I think that there may be some insights and new science developing in the next couple, three years, that may help produce tools which can really address this barrier to better care in a way that may actually improve outcomes.

I can also comment on the pharmacy issue, if you want me to go ahead and do that now.

CHAIR RAPHAEL: Why don't you do that?

MR. NARVA: Okay, again, this is incredibly important. I also have had a lot of experience trying to develop systems in Indian Health Service especially to assure that there's a single medication list available both to the dialysis unit and the hospitals and clinics that care for those patients. And again, I'm a little worried about doing something that's not optimal now versus -- that might be worse than sort of delaying and doing something better.

This appears to be kind of a high

workload, sort of check-boxable metric. And I'm not sure that it's going to improve medication reconciliation.

Looking at the specifics of this measure, the metric that percentage of specified visits, you know, that may not be the right metric. Frequency may not be the right metric. And I'm not sure that's going to achieve medication reconciliation which is a fairly involved process.

I'm afraid that what might happen is it might be handled just as posing a single question to the patient at each visit, "have any of your medications changed?" which is often what happens.

And you know, then the person who does this would need to have some specialized training. Medicine reconciliation is tricky and again, I'd be worried that just a yes/no question might fail at meeting the measure. It's also important to include over-the-counters, herbals, all the non-prescription medicines and that

involves patients bringing all of their meds and to do that -- so this is a lot more involved than you might think.

Also, comparing the list of external medications obtained for a patient or hospital or another provider with what the dialysis unit has is rather involved. And the question is who would be an eligible professional, and who is going to do that. In other performance measures related to dialysis, it implies an advanced practitioner. And I just -- it's not clear who is going to do this. Is this going to be the nurse or the dietician or who? And again, in addition to having the technical skills, the ability to communicate on these specific issues is really important.

So you know, my response is that there's a lot more -- this is an incredibly important thing to address effectively. It's very complicated to address effectively and I just worry that putting a measure in place that really isn't going to get to the problem may not

be that helpful and may make it harder to implement something that may have a bigger impact later on. Thank you.

CHAIR RAPHAEL: Thank you, Andrew. Peter?

MR. CROOKS: Can you hear me now?

CHAIR RAPHAEL: Yes, we can hear you.

MR. CROOKS: Okay, am I as clear as Andy?

CHAIR RAPHAEL: Yes, pretty clear. We're doing great.

MR. CROOKS: All right. Very good. Could I ask a question first before I react to the competency? Actually, this applies to both. Why does this get into a reporting measure and an outcome measure? I'm not clear what the -- how they work together and what the need is for both of them. Can someone briefly explain that to me?

CHAIR RAPHAEL: Okay. That's a good question. And CMS to answer. Joel.

MR. ANDRESS: So in the past, we've presented measures as performance measures that

we then later propose through rulemaking as reporting measures. And basically, our lawyers told us that we needed to present them as reporting measures to the MAP. So we presented it in both forms because we weren't entirely sure we agreed with that, but we were absolutely sure we didn't want to argue with our lawyers about it next year.

So we presented them here in both forms. I think we're not looking at them in competition with one another. We see them as -- and just to respond to Andy's concerns, I think Andy raises some very good points about both measures, about why we would consider them for reporting measures as opposed to as performance measures, at least initially.

I think that there's -- I think I disagree to some extent that I think there is some value in pursuing reporting measures for these kinds of issues when we don't have the perfect or even just a really good performance measure that we would like to have. In the case

of something like cultural competency, we really don't have a good sense of where ESRD is on this except that we kind of assume it's probably not where we'd like to be. And this gives us the opportunity to grasp with that. The thing about it being tested in a handful of Texas facilities -- well, I hope after looking at the SNF, you get an idea of what kind of testing I like to see in the measures that I take anywhere with me. That's not what I would consider ideal, but I think the fact is that this measure addresses something that is as Andy raises a very critical topic.

I think we are fortunate enough in the QIP to have a mechanism by which we can address it without then fiscally penalizing facilities for something that we don't have a good performance grasp on.

With regard to medication reconciliation, the logic is essentially the same as was mentioned. This is actually a PQRS measure that we're looking at to address a

similar issue that's relevant for dialysis patients.

Clarke, as you raised before, a lot of care coordination deals with readmissions. This is, I think, an opportunity to address something -- a key component of that that's relevant, that's important to this population which tends to have a lot of medications and a lot of providers that they're trying to juggle at the same time.

So that's really the rationale for why we decided to present reporting versions of these measures. I think -- I don't want the one to be ignored because of the potential for the other to be used. And we're kind of looking for them to be assessed individually, to potentially be implemented in a quality program in the future.

CHAIR RAPHAEL: Okay, Peter, back to you.

MR. CROOKS: So to see if I understand that. The measures are similar. The one -- reporting measure, does that refer to the measure

is if you report or not, or is it reporting as in public reporting?

MR. ANDRESS: It's reporting as in -- well, I mean the particular structure depends on the language in the rule, but it generally means that you get credit for having reported the data --

MR. CROOKS: Okay.

MR. ANDRESS: -- to CMS.

MR. CROOKS: Okay. And whereas the original measure 1919, does that take the data and actually does an evaluation of what's submitted, or is that also basically just scoring on whether they report or not?

MR. ANDRESS: So the measure is a facility-level survey. So once a year each facility fills out a set of survey items and then submits them. And there's a --part of the survey that RAND developed is a scoring algorithm for those items that --

MR. CROOKS: Okay.

MR. ANDRESS: -- is part of the

endorsed measure.

CHAIR RAPHAEL: Okay.

MR. CROOKS: Okay. Thank you. Okay. So regarding the cultural competency, I agree that it's a very important issue to look at. I think it's fine at this point to just reward for reporting, because I don't think we know how the data can be interpreted or used in ESRD facilities. I think it's great and important to take a look at that. And so I think rewarding for reporting is sufficient at this point, if that's the difference between the two measures.

I don't have a lot more to say on the competency metric other than saying that this is an area that is important and it's time to start looking at it.

But medication reconciliation, I agree with Andrew it's very, very important and I'd like to share some experience I've had both with using this metric as it currently is used for the electronic health records, and also the experience that I've had with Medicare or CMS

ESRD demo projects some 15 years ago, and how we approached that, and with what I think was a very effective approach that might be looked at in future programs.

So, in terms of the effectiveness we were in Kaiser Permanente and our electronic health record had recently been told that we have to do medication reconciliation with every visit with every patient. And after a month of so of running this up and down the organization and the lawyers we concluded that as long as you check the check box, you can close the encounter.

It was programmed in such a way that you cannot close the encounter without checking the check box. We were also informed that we only needed to worry about medications that we were managing. So for instance as an nephrologist, I'm seeing a patient, I'm managing their anti-hypertension medications, maybe their cholesterol medications, and whatever medications I've dealt with. I didn't have to try to eliminate all the old medications or deal with

medications that were not my responsibility to manage.

So on the ground that's what's happening. And I presume that whoever is looking at these metrics understands that, yes, it's a far from perfect metric, but it is a check box metric. Providers are forced to check it off to close the encounter. And so I think it is important to be focused on medications, but I have some doubts about how effective that's going to be at really helping patients out.

So I'd like to just take a minute or two to talk about our experience with the ESRD demonstration project back in 1999. 1998-'99 we started enrolling a thousand Medicare patients into Kaiser as part of a Medicare demonstration project. And then our model -- those on the panel may be aware that in ESRD there's sort of a multi-disciplinary team approach.

Medicare expects that dialysis facilities will have social workers seeing patients, as well as dieticians. We added to

that team pharmacists, we call them the renal pharmacists, in our programs. And so at each of our 12 medical centers in Southern California we knew that team had a social worker, a dietician and a pharmacist.

And every three months the dialysis patient would come in for a visit with the multi-disciplinary team. This is a visit in addition to their regular hemodialysis treatment, which are usually don't at contracted units. And so each team member would see the patient. And the patient was instructed to bring in all of their medications in a big brown bag, and they would spend time with the renal pharmacist, up to 20-30 minutes, going through that bag of medications. And I always made sure the pharmacist saw the patient before I did, because that was really the toughest part of the visit.

And you may know that dialysis patients tend to be on a lot of medications. Typically 20 or more medications are on their list. And as our pharmacist would go through

these bags of medications, it was amazing. Patients were taking duplicate medications.

And these were patients who were now getting into the Kaiser system where we have some ability to coordinate care, but patients were still getting prescriptions from all sorts of different doctors. And so we'd find duplicate medications. We'd find incorrect doses for patients with ESRD. And by the time the patient would leave, their brown bag would be half as full as when they came in.

Now, in the demonstration project the patients at Kaiser Permanente had a decrease in mortality of 40 percent, which was not that great at the other main state in Southern Florida. And the evaluators headed by CMS could never really figure out what was the difference in the mortality rate. And without other data, but just in this experience, I've always suspected that this medication reconciliation that went on every quarter with every patient with a pharmacist was really contributing to this mortality advantage.

So I would just like to put it out there for those from CMS and other measure developers in the room that in a patient complex with a dialysis patient who is often in an uncoordinated care position, it really does take somebody like a renal pharmacist, or somebody who can sit down and really go through the medications one at a time and knows interactions and knows dosing can really make a difference.

I'd like also like to point out that we talk about what lists are we reconciling, and this measure would be I guess end up reconciling the medication list at the dialysis unit, but most patients also have a medication list, some electronic health record somewhere, the physician's office, the hospital. The patient has their own list. And then the pharmacy where they get their medications has their own list.

So there's at least four different lists of medications out there that are probably never reconciled, in most cases, completely. So

this is quite a challenge. I think it's incredibly important and I think I'll limit my comments there. Thank you.

CHAIR RAPHAEL: Okay. Thank you. Thanks a lot, Peter. Now we're going to go on to Tom, Tom Manley.

MR. MANLEY: Yes, I think the National Kidney Foundation's positions on these measures are very similar to what Andy and Peter just expressed. We applaud. We think there's tremendous value in the cultural competency measure. Obviously there's a very diverse population in the dialysis place, so the idea of developing culturally-appropriate health care is wonderful.

And we also appreciate the need for continuity of measures across health care organizations, but we're wondering about the specificity of this measure to dialysis units, and in particular we're concerned about the burden of implementation in some of the smaller dialysis units. I think that the large dialysis

organizations could take this on quite easily, but there's still a large number of small dialysis units which would have difficulty with some of the implementation in this measure.

So the idea of a sequential implementation of the measure is where we first start with reporting and then going to an implementation measure may be appropriate way to evaluate this. And again, as Andy expressed, it doesn't appear that this has been well tested or validated in dialysis units and we would like to see that in advance, I guess, as well.

And I don't think I have anything to add in terms of the medication reconciliation. We would definitely be supportive of that. It's a very valuable measure and I think it would be nice to have a frequency defined and maybe have that validated in a dialysis unit, the frequency of the reconciliation. I'm not sure that with every dialysis session that this is appropriate, but maybe if you did it on a monthly basis with a renal pharmacist that might be a way of looking

at this and be better at affecting care. So I think that's all I have to add.

CHAIR RAPHAEL: Thank you to our three reactors. We really appreciate that. I would just say, looking back to our last meeting, one of the areas that we as a workgroup did spend a good deal of time on was how to insert more non-clinical metrics into kidney dialysis centers, because we really felt they were a complex population with multiple chronic conditions, in some ways overlapping with some of the dual eligible population, that they have many issues and really go to those centers with frequency.

And we really were grappling with what more could be accomplished when they are spending a lot of time at these dialysis centers and is there more that could be done in the primary care, non-clinical care realm. So that was kind of a tension we heard from dialysis center providers, that they really don't have the resources nor the bandwidth to do a lot of these other things that may be desirable. So I think

in a way this reflects an effort of this Workgroup to begin to move in that direction. And we've heard some of the issues that accompany that effort.

The other thing that we've always had as a principle is if you find a problem, react to the problem. Because we've always said don't just screen for depression. There has to be some intervention after the depression. So we've really tried to avoid any identification that doesn't have some follow-up action.

So with that, I'm now going to turn to the Workgroup comments. I see there are a few people. Jennifer, I'm going to start with you. Lou, I assume you're going to want to join in.

MEMBER DIAMOND: Yes, just put me in line, too. Thank you.

CHAIR RAPHAEL: I'll put you on the list. Okay. Jennifer?

MEMBER THOMAS: I want to comment on the documentation of the medications in the record, and I want to completely agree with what

Andrew said on every single point, and Peter as well, from the standpoint of this issue seems to be quite a check-off measure. And there are pieces within the description that -- I think one thing that's critical, that's missing here is why is the medication being used? What's its indication?

And when we talk about across transitions, this is key. We don't have any standard way of documenting medication use or records at all. Everybody does it differently. From the standpoint of CMS, really the only standard documentation platform that I'm aware of is the MTM, the medication therapy management, that's now required as part of Part D for the beneficiaries. That's a benefit that's provided to beneficiaries.

It's very labor-intensive to complete it, so my suggestion is that this would be a great area that we standardize what we do, whether it has to look the same, but the elements should definitely be consistent across all the

care settings. So the elements that I think, again, what's missing is we don't have a -- what's the indication for use? I'd like this to be more than a check-off-the-box because I'm a little worried that that has really a lot of relevance.

And then I guess one thing, if you all could clarify for me, is what makes this a non-clinical? What does that term mean as non-clinical within the definition for this particular measure?

MS. GHAZINOUR: We meant more cross-cutting measurement areas rather than only measures that evaluate dialysis adequacy.

CHAIR RAPHAEL: Right. So it's what the result of the dialysis process. But this sort of says what other medications are you on that may not be derived from dialysis, but may be because you have diabetes or you may have heart disease. You might have arthritis. So you are on 20 medications, many of which are due to the fact that you have other conditions which

intersect.

MEMBER THOMAS: Yes, and I think that actually when I looked at that term as being non-clinical, and I think Peter's description of what was happening at Kaiser was definitely clinical. This whole process and medication reconciliation, that goes beyond just beyond the record of medication listing.

CHAIR RAPHAEL: Right.

MEMBER THOMAS: But the reconciliation piece is much more in-depth and some, again, categories or elements that could be included is what are the problems that have been identified? Do the lists match? And what discrepancies did we find? And I don't think there's any of that being captured here. Or will it be captured here?

CHAIR RAPHAEL: So I think your point is well-taken. So we probably ought to substitute for non-clinical, sort of maybe more cross-cutting and more person-centered approaches. Allen?

MEMBER NISSENSON: So a few comments. First, I appreciate Andy and Peter and Tom's comments, and I'm not going to reiterate everything that Peter and Andy said, but I agree with the vast majority of their comments. But first, Carol, I just wanted to address something you said a minute ago, which is the deliberation about the ability of the current program to absorb more of this stuff.

And I think there's general agreement these are critically important areas to work in with these very complex chronically ill patients. And in fact, when you look at what the whole industry is doing in the setting of care coordination, in capitated payment systems, in commercial ACOs -- we're going to be moving into ESCOs, the Medicare ACOs for kidney disease, these things are an integral part of those programs, and very important in maintaining patient health, keeping them out of the hospital and improving survival, as well as their experience of care.

But in the fee-for-service world where the payment is constrained and in fact, as MedPAC has pointed out repeatedly in the past several years, not even equivalent to the cost. So this is a whole program supported by cost shifting from commercial payers. That's the entire support of the ESRD program at the moment. With that reality it's very hard to just do more and more and more stuff.

So I just wanted to give that context and a couple of specific things about these four metrics. And they have a similar theme, and I think Andy mentioned these. It would be very important to actually test this cultural competency implementation measure in the setting that's being proposed. So whether it was one unit or seven units in Texas, whatever it actually was, that's just not adequate to see whether this is a valid and feasible metric to use in this population.

And I'd add, in contrast to what Tom said, as you all know two big companies dominate

the dialysis industry. In many ways it's harder for the larger companies to implement programs like this because there are thousands of facilities that we have to oversee. So it might seem like we have more infrastructure and it would be easier. In fact, it's not necessarily easier. In fact, it provides all kinds of extra complexity.

So one would be -- so, I'd switch Joel's request a little bit and I think that having one and two, these two measures, 1919 and 3716, have the same recommendation I think makes sense, but I would suggest changing 1919 to conditional until appropriate testing was done. And that would be true also of the 3716.

On the medication reconciliation one, there are just two point I'll make: One is first of all the measure hasn't been tested at all as far as I can tell, not even in seven dialysis units. The testing that's been done has been on a clinician-physician level, and that's totally different from what goes on in dialysis units.

So I think that evaluation needs to be changed and that these medication metrics need to undergo appropriate testing in dialysis facilities.

And then the second comment relates to something Peter said, which is patients are on an average of 8 to 10 different medicines. They are prescribed by four to six different doctors, none of whom generally write prescriptions in the dialysis facility. Some do. Some nephrologists when they visit will write a few prescriptions. Most of the prescriptions are actually initiated outside the dialysis facility.

And until we get into ePrescribe and some more -- which hopefully is going to happen in the next few years -- get into more systems that will allow capture of data, whether it's through HIEs, ePrescribe or whatever the system is, that will aggregate information from multiple providers, holding the dialysis facility accountable will only occur through the method that Peter outlined.

We don't use the brown paper bag. We

use the shoe box as the way we tell patients to bring in their meds, because there are so many. And having someone sort through that every month and try to figure this out is just not feasible. And it's also not necessarily accurate because that means the patient has actually brought in all the medicines.

And no one's bragging about the state of medication management in ESRD facilities. It's not what it needs to be. But I think again these are metrics that are not ready for prime time yet.

CHAIR RAPHAEL: Thank you, Allen. Joseph?

MEMBER AGOSTINI: A comment and a question around the cultural competency measures. So I'm very supportive of cultural competency, and obviously the importance. What I don't fully understand, and maybe I missed this because it's my first meeting, was what exactly is the tool or survey? I mean, how comprehensive? How long? What domains does it cover? I don't feel fully

informed about voting on it when the survey seems unclear to me. Can someone describe that in more detail?

MR. ANDRESS: So the survey itself was developed by the RAND Corporation and submitted to NQF. And the full documentation is available on NQF's Web site. Actually, that's where we first identified the measure.

MEMBER AGOSTINI: I missed it. Sorry.

MR. ANDRESS: All right.

MEMBER AGOSTINI: I was looking, but I couldn't find it.

MR. ANDRESS: Sorry. So, yes, but it's available on the NQF Web site. The survey itself is fairly lengthy and addresses a number of domains around communication, sensitivity and so on.

I think there was a question about burden implementation. I would just say that it's only done once per year per site. So we actually presented this internally, and people

were jumping on us that we were requiring patients to fill out extraneous surveys that were actually burdensome. And the fact of the matter is that because it's only done once a year, the burden on the survey itself is relatively low.

The survey is designed to be implemented across multiple setting types. So the mention was made of the seven Texas facilities. There were hospitals. And I may have mis-remembered here, but I believe SNFs, LTCHs and rehabilitation facilities were also included within the testing approach, or the testing of the survey itself when it was first designed. Does that --

MEMBER AGOSTINI: Yes.

DR. BURSTIN: I can provide a bit more detail. So this measure resulted from some work NQF had done funded by the Robert Wood Johnson Foundation to come up with a set of preferred practices of what should always be done to enhance cultural competency. There were 45 preferred practices endorsed by NQF.

We then had additional support from RWJ to have a group of experts prioritize those 45 practices to pick the ones they thought were most important. So the survey actually assesses implementation of the 12 highest prioritized practices. And we would be happy to share the tool with you.

I believe most of the original testing, Joel, was actually done at community health center facility level up front. But again, happy to clarify that as well. And then RAND actually did the work to create the tool and validate it using basically the work of the cultural competency practices.

MR. AGOSTINI: That's helpful.

MEMBER LEVITT: Mitra, I just emailed you the PDF for the measure. And the survey is at the end of the measure, if anyone wants it.

CHAIR RAPHAEL: All right. Lou?

MEMBER DIAMOND: Yes, Carol, thank you very much. So I concur with many of the comments that made by Andy, Peter and Tom earlier and by

Allen Nissenson.

Let me just summarize very briefly. There is a burden that relates to this issue for both sets of measures. The testing it seems to me is incredibly important, especially for -- well, for both of them, but from the cultural competency set of measures an important issue. And the testing has to deal with both data collection applicability to the dialysis facility and that patient population, but also on the back side, if you will, on the reporting piece.

How are these metrics going to be reported out that would be valuable to the facility so that they can improve their care, and how is it best to be reported out so patients can understand the measure and the metric and participate in the engaged set of activities? So the burden is important. The testing is important.

But then I did want to raise another important issue that I think is just absolutely critical. I think it does not do a service to

this patient population and to the providers if we focus the attention on the QRP program, the ESRD QRP Program, without taking into account all the other programs that those facilities and the nephrologists are being, if you will, be subjected to at the moment.

So for the facilities, and Allen mentioned this, we have a public reporting program under Dialysis Compare. We've had a good explanation of what the QRP program is all about, and these measures are meant to be focused on that particular program, but we have two other programs that are part of this entire ESRD Program. One is about to be rolled out, a Star Rating Program, with a whole set of other measures, with a whole set of other reporting that will be, I think, confusing to consumers and others.

And in addition there is the evolving -- what is called the ESCO Program, ESRD Seamless Care Program, which is an ASO program under the Medicare Program, and we're landing on measures

as we speak, some of which are discussed here, which are the medication, quote-unquote, recording and reconciliation measures.

It does seem to me that it's critically important before we rush into identify new measures for these various programs that we make a more firm commitment to aligning these measures across these multiple programs within the same program, in this case the ESRD Program subjected on folks on the facilities, not to mention the nephrologists who also are under programs for reporting programs, PQRS, meaningful use and maintenance of certification, all of which are kind of under the umbrella of the program and all covering these same issues, especially the medication reconciliation issue.

So I'm actually, to be frank with you, in a good mood, but I would want us not even to conditionally support these measures because my concern is I think we will end up rushing in to deploying them quite rapidly. I think we need to take a step back, freeze further measure

deployment in these programs until we've got a better understanding of the context of how these measures are being applied across the various mandates that are currently in place, not being planned, but actually in place. Carol and colleagues, those are my comments. Thank you.

CHAIR RAPHAEL: Thank you. Liz?

MEMBER PALENA HALL: Thank you. I just want to bring an awareness again to this Workgroup about some recent recommendations in November from the IOM around capturing social and behavioral domains in electronic health records. A number of those domains are very similar to the domains discussed here today, including race, ethnicity and a number of others. So would encourage the Workgroup to look at those recommendations and its alignment to the survey that's being discussed.

CHAIR RAPHAEL: Thank you. Peg, did you want to say anything?

MEMBER TERRY: No, I was just going to comment on the medication one, and I think it's

well taken that in fact it's very hard when you have multiple physicians, and you do not have the ability to really change some of these meds for the patients. This is a problem throughout the post-acute world, specifically in hospice. So I just want to say I think it's an issue that needs to be looked at as we move forward. And I understand what you're saying, so --

CHAIR RAPHAEL: Okay. So I think I'm going to see -- oops, if either Alan or Joel want to have any concluding comments here before we go for a vote.

MR. ANDRESS: Okay. So on the issue of program alignment, I think to clarify, I think there was some concerned raised that the programs are clashing with one another. So to clarify, first of all, the Star Rating Program is essentially an augmentation of DFC, so they're essentially the same program. We're just reporting information in a star rating format for it. So there's that.

The CMMI -- the Innovation Center's

ESCO project is a payment demonstration. It's not a competing program. It's one that involves voluntary participation that certainly uses measures that are specified differently because they're applicable to the ESCO as opposed to a specific dialysis facility. So you would expect that there are going to be some distinctions in terms of how measures are specified in that case with regard to the relationship that the QIP has with these, right?

So the QIP is unusual, is different from DFC in a number of reasons. For one, the QIP can require the collection of data of its own authority, or as far as I'm aware, DFC is not able to do that on its own. Now what we can do is, for instance, take data that are being reported under other authorities and put it up as a purpose for public reporting, but the purpose of DFC is to report data to patients so that patients have access to quality information about facilities.

The QIP, on the other hand, is

primarily a value-based purchasing program and its role is to adjust payment in a fee-for-service environment in such a way that quality is also taken into account when facilities are reimbursed by CMS. So I think I would be concerned that a measure be eliminated from consideration simply because there are other programs related to it.

I would also point out that while the Innovation Center is, as far as I'm aware, still considering the medication reconciliation measure, or a version of it, for implementation, the other programs do not implement measures in these areas of any type. And so I think when we're talking about clashing, it's not as if we have another cultural competency measure that we can implement, but we're simply choosing to implement this one.

This is a measure that we are seeking to implement specifically because it addresses this issue, and we think it's the best measure available at this time. And I would say that the

medication reconciliation measure is also in that circumstance. And I just want to make clear that we're not setting these up in competition with other measures and other programs. These are the measures that we think are best for these particular areas.

CHAIR RAPHAEL: So we are going to move to a vote. And let me see if I can get a motion to move toward approval of the first cultural competency implementation measure which we right now have as support. And let me ask, Laura, is there a way to do support, conditional support and no support? We've been doing yes and no, but I wanted to see if I could do three categories this time.

MS. O'ROURKE: Yes, but I actually have to create that slide.

CHAIR RAPHAEL: All right. Well, let me just see if I can get a motion to bring this up for a vote now. Anyone want to move approval of the recommendation as it is?

MEMBER SALIBA: So moved.

MEMBER LEVITT: I just had one clarification. How does the 60 percent rule apply?

CHAIR RAPHAEL: Oh, you're right. That's a good point. All right. So let me do the following: I don't know if this is going to work. Do we have a precedent here? All right. Go ahead.

MS. IBRAGIMOVA: In hospital we invented a precedent. We did an informal poll to see where the group was feeling between the support, conditional support, do not support. And then we put it on that consent calendar for the final vote that would need the 60 percent. So we have precedent of taking just an informal non-binding vote to see where the pulse of the group is right now.

CHAIR RAPHAEL: Okay. Great. All right. That's a good suggestion. So how many people would vote for support? Just this is informal. And please raise your hand so we can get a sense.

All right. None. Conditional support?

(A show of hands.)

One, two, three, four, five, six, seven, eight.

All right. Do not support?

(A show of hands.)

CHAIR RAPHAEL: One, two, three, four, five. And let me get the people on the phone. Lou?

MEMBER DIAMOND: Yes, I'm not supporting.

CHAIR RAPHAEL: Okay. I'm up to six. Lisa?

(No audible response.)

CHAIR RAPHAEL: Carol?

(No audible response.)

CHAIR RAPHAEL: Oh, conditional? So we have nine condition, six do not support. All right. So is that now binary? Do we now take the formal vote on conditional and do not support?

MEMBER LEVITT: I just had a question.

CHAIR RAPHAEL: Sure.

MEMBER LEVITT: For conditional support are you going to define the conditions that the support --

CHAIR RAPHAEL: -- would relate to?

MS. O'ROURKE: Let me say I would say it's probably just -- the Workgroup can correct me if I'm wrong, but pending additional testing to ensure this measure works in ESRD facilities.

MS. IBRAGIMOVA: So to confirm, it's just Measure No. E1919 without the reporting measure?

CHAIR RAPHAEL: Yes, we're just going to do this one and then I'll do the reporting one. Okay? All right. Any other questions?

(No audible response)

CHAIR RAPHAEL: So now -- yes, Allen?

MEMBER NISSENSON: Just to follow up on Alan's question, I'm concerned by, one, the lack of public comment. If you know this sector, the idea that you'd get one comment is

inconceivable and to me represents the fact that there's a window of just a few days to respond and send comments.

And secondly, if the conditions are based on just this conversation we've been having the last half hour, to me that's not sufficient to say we're going to give conditional support and here are the three things that this group of people came up with in this conversation. That doesn't seem like it's really a very rigorous way of setting the conditions.

So is there some other method, or is there a time frame for people to provide input that articulate the conditions so that's clear sort of what the sense of the group is?

MS. O'ROURKE: Absolutely. So one of our improvements for this year is that we've expanded the public commenting. So we had the week before this meeting for us to gather comments for this Workgroup to consider.

After this meeting we're going to summarize your findings and put all of that out

for public comment, starting, I believe, December 23rd. That will run until January 13th. So we'll have about a three-week public comment period where we'd encourage everyone to submit their thoughts. If there are inadequate conditions around the measure, we can certainly incorporate those into the report.

The public comments will be taken to the MAP Coordinating Committee so that they will have the benefit of the Workgroup's input and the public's input when they make their final review and recommendation of the measures under consideration for this program.

CHAIR RAPHAEL: All right. Debra?

MEMBER SALIBA: My understanding, also, conditional approval meant that they were giving them guidance, that they would come back with additional information and it would be re-discussed and re-reviewed. So it's not saying that it just gets checked off and then it's approved. Am I correct with that?

CHAIR RAPHAEL: Is that a correct

interpretation, Erin?

MS. O'ROURKE: I will defer to my CMS colleagues, but our current interpretation is no, that they would not be required to bring this back to us, just to consider our conditions when they're implementing the measures.

MEMBER LEVITT: And again, well, just to clarify, if a measure is conditionally supported, if that measure ended up in a rule, and the rule we would be reviewing MAP recommendations, we would be also including the conditions. And then, as Joel would say, our lawyers -- but, no, again, we would be responding to those conditions in the rule.

MR. ANDRESS: And just to clarify on that, all facetiousness aside, when we seek to implement a measure that the MAP has looked at that has concluded anything other than full support, we take it on as part of our responsibility to provide a rationale for why we are implementing that measure in the face of something other than full support.

Now in the past that's been because since the MAP has looked at it we've completed development of the measure, or we've addressed the issue, or we've done additional analyses that we think answer remaining questions that the MAP had. So there are a number of different ways in which that can be addressed.

But the point of it is that once it becomes a part of the report that ends up going out from the MAP, it's something that we don't have -- well, that sounds awful the way I was about to say that, but we do not and cannot ignore it simply to implement the measure during rule writing.

CHAIR RAPHAEL: Okay.

MEMBER LEVITT: That's why I was asking the question of what conditions, because I wanted to know.

CHAIR RAPHAEL: Right. I mean, in terms of conditions, and I'm trying to summarize this, we had two key issues that were raised. One was the burden, and the second was the

testing. The burden was answered by Joel that it's a one-time-a-year survey. The testing was -- I think, Helen, you talked a bit about the experience at NQF with the Robert Wood Johnson Foundation grant, and the work that resulted in these 12 high-priority measures that we think may have been tested in community health centers, but still in a limited number of dialysis centers. So those were the conditions, Alan, that I heard. Sean, did you want to say anything?

(No audible response.)

CHAIR RAPHAEL: Okay. Then let's move to --

MEMBER DIAMOND: Lou here.

CHAIR RAPHAEL: Yes, Lou?

MEMBER DIAMOND: Just put me in line, please. I can go? So, Carol, with respect, the burden it seems to me doesn't get answered by saying it's a one-time-a-year survey. It's a much more complex question than that. I mean, every survey is incrementally more -- every additional amendment is incrementally more of a

load on facilities' physicians, and, importantly, on the patients. And the patients are now being asked to complete multiple surveys in the dialysis unit and multiple inputs, etcetera. And we need to be cautious about that. So that's my first comment.

My second comment, it would be helpful, Carol, at some other time after this meeting -- so, I know that the staff puts this kind of data together, about this history of measures that were conditionally approved in the past by the MAP and how they were handled going forward.

Were they in fact subsequently implemented, and under what conditions were they subsequently implemented? It would be helpful to see that in the future. Thank you.

CHAIR RAPHAEL: Okay. Thank you. That's a good question that we will take a look at. So now we're going to vote. And, Laura, as I understand it, it's now for conditional support, it would be one. And if you do not

support, it would be two. All right? Should we now target this toward you?

MS. IBRAGIMOVA: Yes.

CHAIR RAPHAEL: Okay.

MS. IBRAGIMOVA: So consent calendar End-Stage Renal Disease Quality Incentive Program, conditional support of cultural competency implementation measure. Do you agree with the End-Stage Renal Disease Quality Incentive Program conditional support calendar? One yes, two no.

(Voting.)

MEMBER DIAMOND: And, Carol, my vote, this is Louie here, is no support.

CHAIR RAPHAEL: Okay. And, Carol Spence, if you could send your vote to Mitra.

MS. GHAZINOUR: Did Lisa sign out?

CHAIR RAPHAEL: Lisa signed off.

MS. GHAZINOUR: Lisa signed off. Okay.

CHAIR RAPHAEL: All right. How did it turn out?

MS. IBRAGIMOVA: So the results are 44 percent yes, and 56 percent no.

CHAIR RAPHAEL: So it's a no, is that correct?

MS. O'ROURKE: So I think this is one we'll ask the Coordinating Committee to weigh in on.

CHAIR RAPHAEL: Okay.

MS. O'ROURKE: Since we don't have 60 percent in either direction, we'll bring this to them for guidance.

CHAIR RAPHAEL: Okay. Very good. All right. I'm going to go onto the other one on cultural competency, sort of the partner to this one. And can you read that to us, Laura, so we can vote?

(Off microphone remarks.)

CHAIR RAPHAEL: Yes, that was recommended as conditional support. So now it's going to either be conditional support or do not support. Do you need to read anything to us?

MS. IBRAGIMOVA: Yes.

CHAIR RAPHAEL: Okay.

MS. IBRAGIMOVA: So consent calendar End-Stage Renal Disease Quality Incentive Program, conditional support for cultural competency reporting measure. Do you agree with the End-Stage Renal Disease Quality Incentive Program conditional support calendar? One yes, two no.

(Voting.)

MEMBER DIAMOND: Carol, Lou here. I'm not supporting.

CHAIR RAPHAEL: Okay. Thanks, Lou.

MS. IBRAGIMOVA: The results are 44 yes --

CHAIR RAPHAEL: They're the same.

MS. IBRAGIMOVA: -- and 56 percent no.

CHAIR RAPHAEL: Okay. At least we're consistent. All right. Now --

MEMBER NISSENSON: And, Carol, could I --

CHAIR RAPHAEL: Sure, Allen.

MEMBER NISSENSON: -- I just have gotten a little bit confused. So if our new system is you need 60 percent to approve something and you get 44 percent, then that means it's not approved. So I'm confused by why you would need 60 percent to say no? I mean, to me it's odd. I mean, is that the intent? Usually you vote and you have a threshold and it's either you exceed it or you don't.

CHAIR RAPHAEL: It was 44 and 56.

MEMBER NISSENSON: Yes, so if you need 60 percent to approve something --

CHAIR RAPHAEL: Forty-four was --

MS. GHAZINOUR: -- and you get 44 percent --

CHAIR RAPHAEL: -- conditional.

MS. GHAZINOUR: -- it's not approved.

CHAIR RAPHAEL: Fifty-six was no.

MS. O'ROURKE: So actually we set the voting up that we don't have a default position of no, so any of the recommendations would need to have hit 60 percent to have been finalized.

So since we didn't hit 60 on the no, the no didn't hit that threshold either. So it's just a split and it will go to the Coordinating Committee for a decision.

DR. BURSTIN: So this is something, Allen, that we now do across the entire organization to try to get a better handle on consensus. So even with our Endorsement Committees, for example, over 60 percent is the threshold for yes or no, whatever the case may be. Forty to sixty is what we consider gray zone where additional input or discussion is usually needed. And less than 40 is where we would have threshold for no. So in this instance it sort of at least fits into that middle category of just additional information to be sought from the Coordinating Committee.

CHAIR RAPHAEL: All right. We're going onto the medication, No. 3.

MEMBER ROSS: Carol?

CHAIR RAPHAEL: Oh, yes, Clarke?

MEMBER ROSS: I'm sorry. I hesitated

when we were discussing this. I want to speak in favor of documenting all current medications. I serve on a SAMHSA committee, an ONC committee and two National Quality Forum committees, and every specialty group says we're all for all of this, but we only prescribe and manage medication to treat melanoma, so that's all we should be accountable for.

And I realize this is incremental and it's burdensome, doesn't answer the big problem, but the only way we're going to get to this problem is require every specialty organization to make a good faith effort at documenting all medications that people use. And we're doing this hopefully through meaningful use and electronic health records.

But at some point sitting around talking about I can't do it, we're going to have the same problem, and this is a very severe problem. And this will facilitate and help consumers in the long run. In the short run we'll ask more questions and possibly cause

confusion.

But we're not going to get to the long-term objective by every specialty practice saying no, it's beyond our scope of practice. Documenting medications is not a scope of practice issue. It's a documentation issue. So I felt compelled to --

(Simultaneous speaking)

MEMBER DIAMOND: Carol, this is Lou here. Can I say something?

CHAIR RAPHAEL: Yes, Lou. Go ahead.

MEMBER DIAMOND: Yes, so for me the issue is not that this is not an important issue and for me it is not the issue that we shouldn't get started somewhere. For me the issue is simply stated the alignment question. Nephrologists have medication reconciliation as part of their measurement set and they are integrally part of the dialysis facility as they treat these patients, number one.

Number two, the ESCO Program is putting in place a medication reconciliation

measure. And it is true that it is done at the ESCO level, but the ESCOs are basically facilities, the aggregation of facilities. There's nothing else there. That's what they do. It's facilities and nephrologists.

So the fact that these measures are not reconciled across those various programs is a very important issue for me. And secondly, that's not been tested in this particular patient population. And doing it on a visit basis makes absolutely no sense given that these patients are being seen three times a week in the dialysis facility. So I just wanted to clarify that from my perspective. Thank you.

CHAIR RAPHAEL: Okay. Thank you.

So now we are going to vote on No. 3 on the documentation of current meds in the medication record.

MS. IBRAGIMOVA: Consent calendar End-Stage Renal Disease Quality Incentive Program, conditional support, documentation of current medications in the medication record. Do you

agree with the
End-Stage Renal Disease Quality Incentive Program conditional support calendar? One yes, two no.

(Voting.)

MEMBER DIAMOND: Carol, this is Louie here. I'm voting no.

CHAIR RAPHAEL: Okay. All right. We got Carol, I'm assuming. All right. Laura?

MS. IBRAGIMOVA: And the results are 44 percent yes, and 56 percent no.

CHAIR RAPHAEL: Consistent, consistent. All right. No. 4 on medication documentation reporting. Laura, please read it to us.

MS. IBRAGIMOVA: So cultural competency End-Stage Renal Disease Quality Incentive Program, conditional support, medications documentation reporting. Do you agree with the End-Stage Renal Disease Quality Incentive Program conditional support calendar? One yes, two no.

(Voting.)

MEMBER DIAMOND: Carol, this is Lou here. I'm voting no.

CHAIR RAPHAEL: Okay, Lou. We got it.

MEMBER DIAMOND: Thank you.

CHAIR RAPHAEL: All right.

MS. IBRAGIMOVA: And the results are 44 percent yes, and 56 percent no.

CHAIR RAPHAEL: All right. Thank you.

MEMBER LEVITT: Carol, can I just make one comment?

CHAIR RAPHAEL: Yes, Alan, you can.

MEMBER LEVITT: Essentially what just happened is the MAP has made CMS recommendations and even submitted measures to us that they felt were appropriate to our programs, and the MAP has just not supported what was previously given --

CHAIR RAPHAEL: You mean the Workgroup has not supported the MAP.

MEMBER LEVITT: The Workgroup. I'm sorry.

CHAIR RAPHAEL: Right.

MEMBER LEVITT: Okay.

CHAIR RAPHAEL: Right.

MEMBER LEVITT: Okay.

CHAIR RAPHAEL: Yes.

MEMBER LEVITT: I just want that noted.

CHAIR RAPHAEL: There's an internal fissure here, right? Okay. For the record. So what I would like to do now is break for lunch, if it's agreeable with everyone. We have three more ESRD measures that have to do with dosage levels, and we will take those up immediately after lunch. Can I just ask if our reactors can stay with us if we resume at 1:00?

MR. NARVA: This is Andy Narva. No, I'm not going to be able to do that.

CHAIR RAPHAEL: Okay.

MR. NARVA: But since those measures are -- I have other commitments, but I don't have significant comments. They're basically refinements of previous measures, and I basically support the intent.

CHAIR RAPHAEL: Okay. So you support

them. Peter?

MR. CROOKS: Yes, I can be back at 1:00 East Coast Time.

CHAIR RAPHAEL: Thank you. Tom?

MR. MANLEY: I'm not going to be able to be on at 1:00, but I guess I'd just say the NKF does support the dosing measure with maybe one concern caveat related to using raw numbers, versus calculated Kt over V. And I guess I'll also note that the KDOQI guidelines on hemodialysis adequacy are about to be published and they are consistent with these measures.

CHAIR RAPHAEL: Okay. Thank you, Tom. All right. So we are going to have a 20-minute lunch and resume at 1:00.

(Whereupon, the above-entitled matter went off the record at 12:38 p.m. to resume this same day at 1:00 p.m.)

CHAIR RAPHAEL: Okay. Let me introduce Rob Saunders to you. Why don't you introduce yourself better than I can probably?

MR. SAUNDERS: Thank you, Carol. So,

Carol asked me to provide updates on two issues specifically related to the last vote and to what's been going on overall. So, to explain the MAP process, in order for a recommendation to be made from a work group to the Coordinating Committee -- and the Coordinating Committee is the overarching body that finalizes all recommendations and makes the official recommendations to HHS. But in order for a recommendation to come from this work group there has to be a 60 percent affirmative vote.

So, the fact that there was not a 60 percent vote reached means that there was no recommendation from this group to the Coordinating Committee. There's no official recommendation from this group to the Coordinating Committee.

What the Coordinating Committee will receive, is they will receive this measure. They will understand what happened in this group and the discussions, but they will not get an official recommendation like that you've made for

other measures, where you've said the PCT/LTC Work Group recommends that you support this measure, or the PCT/LTC Work Group recommends that you do not support this measure.

Instead there will be an absence of a recommendation, because this group did not reach a consensus position. So that's the important part here. And I wanted to make sure that was very well specified for this group, that these measures weren't voted down in some way; rather, this group just didn't reach a consensus position, and, therefore, the lack of consensus position means that issue has to be resolved by our Coordinating Committee.

So, it's a subtle difference but I think it's kind of an important one in terms of process, in terms of what that means for these particular measures, and what the next stage for these particular measures are.

CHAIR RAPHAEL: Okay. Why don't you go on to the second point you were going to make, and then I will take questions.

MR. SAUNDERS: Yes, ma'am.

CHAIR RAPHAEL: Okay.

MR. SAUNDERS: So, the second point that Carol asked me to speak to is what is conditional support. Apparently, a number of folks had questions about that. So, support and do not support decision categories are relatively self-explanatory. We understand the conditional support decision category, though, does have some ambiguity.

In essence, what the conditional support category means is that this group is generally supportive of this measure, but they feel before this measure can go into a program it needs to meet certain conditions. And this group has the authority and, frankly, it has the responsibility to provide those conditions.

So, if this group conditionally supported a particular measure they could say it is conditional, we support this measure but our support is conditional on the fact that it needs to go through the NQF endorsement process.

That's a common condition. Or it needs to go for further testing because it's for a new setting. Perhaps it was for a hospital setting and it's been extended to a post-acute care setting and we would like to see additional testing for that setting.

But this group can attach whatever conditions that it feels are necessary in order to reach its support. And in practice what that means is the conditional support category is oftentimes a consensus category because that allows you to, if you're generally supportive of the direction of the measure but you feel certain conditions are not yet there and they need to be there in order for you to support this measure, this group can attach those conditions there.

Those conditions then go to CMS and the CMS interprets those conditions as guidance interpreting their rules. CMS, of course, has the final authority of what measures go in the programs or not, so these don't have the force of law, but they are the guidance that comes out of

the MAP and what the MAP says going forward. Does that help, Carol?

CHAIR RAPHAEL: Yeah, that is helpful. All right. Bruce?

MEMBER LEFF: That was a helpful clarification. Just to take it one step further. So, for instance, if on Measure X we vote conditional support, more data needed, who and how is it decided how that happens?

MR. SAUNDERS: So, the ultimate legislative authority still resides with CMS. CMS will decide, as they're putting together their rules on what measures go in programs, how to interpret and to use that guidance. So, it is only guidance to CMS. In fact, all of MAP's recommendations are only guidance to CMS. And the ultimate legislative authority still resides with CMS, and they have the authority to do with the measures as they see fit.

I do understand from our CMS colleagues that they take MAP recommendations very seriously, and that their team of lawyers

likes to make sure to see that the program staff have taken into account MAP's recommendations. I can't speak for our CMS colleagues, and I'm sure Alan could do a better job, but the ultimate authority still resides there.

CHAIR RAPHAEL: Okay. Alan, did you want to say something on this?

MEMBER LEVITT: No, the only thing I would add, I thought it was a great presentation. Can we just get maybe to the work group, including myself, just exactly what was presented so that way we kind of have an overall understanding of what that meant, particularly in terms of the voting that went on?

MR. SAUNDERS: I'm sorry, sir, can you repeat your --- can you clarify your ---

MEMBER LEVITT: The comments that you made, is there any way we could just get that also just in a written fashion or refer us to where that is in documentation?

MR. SAUNDERS: Sure. We'd be happy to follow up with you with written format. We have

some written documents of this already. And the final results of the vote will go out -- are being compiled by Mitra and the rest of that team, and that's what will go out for public comment.

But we're certainly happy to provide you a written document in terms of what consensus means, and also in terms of conditional support. Are those the two areas?

MEMBER LEVITT: Right. Right, exactly.

MR. SAUNDERS: Okay.

MEMBER LEVITT: Thank you.

CHAIR RAPHAEL: Okay. Sean.

MEMBER MULDOON: Looking for more clarity on the responsibility of this group on specifying what the conditions are. If a conditionally approved metric does not come back to us, then do we have to get very specific when we say things like needs further testing? Like, needs further testing in, you know, to be extreme, one hospital in Texas versus a sample across the country, and those results have to

show that there's impact? Or can we simply leave it with, "take it back for further testing, we like the direction"?

MR. SAUNDERS: And that's up to the discretion of this group. To the extent to which you feel that this measure needs very specific conditions because you're concerned that those conditions may not be carried out, then this group has the authority and the ability to provide very specific feedback. If you're comfortable with and trust that these conditions are going to be done, then you can give much broader guidance. And staff are sort of copying, as well, the discussions that are happening here and putting those in a rationale that's also attached to each of these decisions, as well.

CHAIR RAPHAEL: Tom?

MEMBER VON STERNBERG: I think that I'll just simply focus on the one measure that I voted in favor of, conditionally, related to ESRD was this sense of medication reconciliation? Critical, boy, have to keep it on the radar for

directionally a critique here of the flaws in that measure, I think are important. So, conditional support is let's make sure it doesn't get lost.

It seems to me, though, as we've talked about in other forums, med rec is a challenge based on the complexity of it. Nobody really has a great med rec measure. We continue to have it featured in all conversations about the critical nature of safe transitions.

I don't think this group has the bandwidth or the time to come up with the solution to med rec. And so the concern would be conditional support being directional as opposed to conditional support resulting in CMS saying, well, we're going to land on something. And I would struggle with that.

Having said that, we still need to come up with a solution about med rec for these high-risk transitions, not just ESRD but long-term care and IRF. It is critical. I don't have the answer.

MR. SAUNDERS: And, frankly, just from what other MAP work groups have done, that's why conditional support is a common recommendation in the sense that people support perhaps the direction that this measure is going in, but they have concerns about that specific measure and would like to see various changes made, but don't want to vote down the measure and put a do not support recommendation, which then carries a strong signal that this measure is wrong and should be out of the running.

So that's often why the conditional support is a popular option because it allows the group to signal their support for the direction, but then explain what conditions need to be met, that these are the concerns with this measure, this measure needs to evolve in certain ways, or this measure needs to be tested in certain ways, this measure needs to be reviewed by the NQF endorsement process, which allows for a much more in-depth analysis of the numerator, denominator, and all the measurement science pieces.

CHAIR RAPHAEL: Okay. Any other questions? Yes, Jennifer?

MEMBER THOMAS: I guess I have a couple of comments about, again, that medication documentation and we are using that terminology as a surrogate, apparently, for medication reconciliation, which I don't think that's what that measure specifies. If we want to say it's medication reconciliation we need to be very specific about what medication reconciliation is, and a list of meds is not medication reconciliation.

Two, the other point is that non-clinical, the wording in there, to me -- again, you can obtain a list of medications with non-clinical personnel. A patient can provide that, a pharmacy technician can provide that, a medical assistant in a nursing home or otherwise. So multiple folks can capture that information. How valuable it is, how accurate it is, if it's been reconciled, and so there's been some clinical connection with that, so I think that's my

concerns with the measures as they're stated.

CHAIR RAPHAEL: Okay, thank you.

MEMBER DIAMOND: Carol?

CHAIR RAPHAEL: Yes?

MEMBER DIAMOND: This is Lou.

CHAIR RAPHAEL: Yes. Go ahead, Lou.

MEMBER DIAMOND: Yeah, thank you. I'm sorry to come back again, and I appreciate the clarification. But just, again, to explain my previous vote. I have a deep concern, and have for an extended period of time, about the alignment question. And it does seem to me that if we continue to roll out measures and even conditionally approve them without some firm commitments on the alignment issue, that creates a big concern for me.

The second issue, which I didn't mention in my earlier comments, which related to some extent on the medication measures -- and although I'm going to vote for the dose measures that are coming up now -- is the discussion we had in 2012 on this committee, which was to send

CMS a strong message, as I recall, about the lack of progress to develop health information infrastructure within the ESRD program with a clear roadmap to creating e-measures at some time in the foreseeable future.

And to be frank with you, we've made no progress since that recommendation we made back in 2012. So, I'm at the kind of a threshold of being concerned about those kinds of issues; hence, my vote earlier on. So, thank you, Carol.

CHAIR RAPHAEL: Okay, thank you, Lou. Thank you, Rob.

So, we're going to go on to the three measures having to do with delivered dose. And while it is categorized as encouraging further development as the staff's recommendation, I understand that we need to get clarification here in terms of the developmental stage actually that this measure is in. So, I don't know, Alan or --

MEMBER LEVITT: Yeah, I'm going to turn it right over to Joel on this.

CHAIR RAPHAEL: Okay.

MR. ANDRESS: Hi again. So, we realized last night -- and I want to thank you, Mitra, for working with us on this -- that there had been an error in the information that was submitted to you for the measures in defining the stage of development the measures were in which implied that they were just beginning development.

So, to clarify what these measures are, and this is what Andy Narva was talking about when he commented earlier. These are not new measures per se, but they are modifications of existing dialysis adequacy measures that have already been reviewed by the MAP and are NQF-endorsed -- or I should say three of the four are NQF-endorsed.

The issue at play here --- well, I'll just get to the point of it. These measures are intended to replace the existing dialysis adequacy measures in our programs. They are addressing a particular issue that's been raised

at this MAP and has been raised in public comment and the rules and at measurement development and in discussion for measure development.

Essentially, the way that four measures are designed, they partition the dialysis population for the assessment of dialysis adequacy along two axes, and those are modality and age. So you have pediatric measures and adults measures for hemodialysis and peritoneal dialysis.

And the purpose of this, of course, is to get at, with some granularity, the success at which facilities were providing dialysis care for these different groups, and to recognize that they were in some cases different standards, you know, in terms of appropriate levels of clearance by age and modality.

The consequence of this, however, is that CMS has to make a decision when it's implementing its measures about the minimum number of cases that a facility can have before it is willing to report data on that measure. In

short, if you have below that threshold, we're not going to assess you on the measure for a couple of reasons. One, there's the risk of patient identification. And, two, there's the fact that the measure may not be sufficiently reliable for the purposes of a quality program.

And what we found is that because of the way the measures are partitioned and the fact that the vast majority of dialysis patients are adult hemodialysis patients -- many facilities may have a handful of peritoneal dialysis patients, or a handful of pediatric patients, but because there weren't 11 or more, they were being systematically excluded from the QIP's assessment of dialysis adequacy. And we tried a couple of different ways to solve that without adjusting the measures through policy tools we had, and essentially hit a dead end with that.

So, at essentially the same time we were putting together the measures under consideration list that you were sent, we also began our three-year measure maintenance cycle

with NQF. And what we did was we used that period to modify the existing dialysis adequacy measures to do two things.

First, we took the two adult measures of peritoneal dialysis and hemodialysis and we simply removed the age exclusion from them. So, we included adult and pediatric patients in the same two measures. And that's what you see up here with the --- I should say actually the two bottom measures. So, delivered dose of hemodialysis above minimum, and then delivered dose of peritoneal dialysis above minimum.

And what we've done is we've essentially said with these measures, okay, it's possible that there's a difference in the dose that is to be provided in a particular group of people, but the fundamental question of the measure is, for how many of your patients are you providing dialysis adequacy, however that is defined by that patient's characteristics? And in this case primarily meaning age and modality.

So, we took those two measures and we

essentially combined both pediatric and adult patients in those measures. And then with consideration to wanting to try to include as many patients as we possibly could within the assessment of the QIP, because we didn't want to systematically exclude patients where we could avoid it, we created an overall composite measure that looks at all patients in those four original categories. And the purpose of that was to maximize both the facilities that receive a rating on dialysis adequacy, but also to maximize the number and type of patients that are contained within the QIP's assessment.

There's been a fairly consistent concern among the dialysis community that pediatric patients, and the facilities that predominantly serve them, as well as peritoneal dialysis patients, are not able to participate fully within the QIP program, and that they aren't covered within its measures. And so these measures are a direct response to that.

And, as I say, the first measure is

itself a composite of the two measures below. Now, when you received the documentation for this it indicated that the measure is still under development, but where we are with these measures is that we've completed development of the measure specifications -- or I should modification of the measure specifications -- as of September of this past year. We are at a stage where we are prepared to submit the documentation to NQF for the renal project that comes to an end in February along with a number of other measures that are also undergoing maintenance.

Our intention, ultimately, once we have feedback both from you and from NQF about these measures, is to retire the other four existing measures and replace them with these in our various quality programs.

CHAIR RAPHAEL: Okay, thank you. So, are there any other comments, Mitra, that you want to make on these three measures? Okay. Then let me just turn to Peter, who I think was still

going to be on the phone and see if he wants to make a comments as a reactor.

MR. CROOKS: Thank you. Basically, I understand that --- well, having sat on the Steering Committee for NQF for three rounds of previous renal metrics, I appreciate the changes that are being made to include pediatrics, and also understand the rationale for combining those first two to make it so that perhaps more units reach the patient threshold. And maybe also it's easier for public reporting, public understanding of the metric.

A comment I want to make for those on the panel who are not nephrologists, is that this emphasis on removing urea as being adequate dialysis is a longstanding issue and debate in nephrology. We have come a long ways, I think, in the last eight years or so. I'm trying to remember if the first round was hemo study which was an adequacy study looking at patients receiving longer dialysis, more urea removal to see if that helped outcomes.

But we appreciate, I think, more than in the past that adequate dialysis is not only removing urea as measured by Kt over V, but it's also getting to adequate volume control. It needs to take into account residual kidney function. It needs to be individualized for patients.

But, nevertheless, the idea that we still continue to need a floor for urea removal is pretty well-accepted and I think scientifically supported. So, I am in favor of seeing these measures continued, and it makes perfect sense to make sure the pediatric population, which has been relatively ignored because of small numbers, get included. So, my reaction is very positive to these metrics.

When it comes to what you'd include in a QIP, I don't know that you would want all three of these in a future QIP. Maybe the combined metric would be the one selected, but that's future work. But as they stand, I would recommend supporting all three of these.

CHAIR RAPHAEL: Okay. And just to

remind the work group that Andy indicated his support, and Tom did as well. So, let me see if there's any questions from our work group at this point. Allen?

MEMBER NISSENSON: Actually, it's a question for Joel about the testing of the composite metric. And there's a generic part to this question, which is -- because I'm sure this isn't the first time this has come up where there are approved measures that then get combined into a new measure. So, it is general and then specific about this particular one.

It seems to me that the fact that we have two measures that have been endorsed doesn't mean that combining them eliminates the need to do testing, because the combined metric is not necessarily the same as the two separate ones just added up. So, I'm just wondering how that's approached both by MAP, but also what your thoughts were, Joel, and how you've gone about that?

MR. ANDRESS: Sure. So, as part of

the measure maintenance process we also undertake to engage in the validity and reliability testing that's part of our standard measure development. In this case, because these measures are claims-based, we had access to the data and were able to conduct the testing.

We paralleled it with the testing that was done for the existing dialysis adequacy measures. Actually, I have a quick rundown of these. In terms of reliability, all three measures have inter-unit reliability of 95 percent, roughly. I think one of them is .947. But, essentially, if you're not aware, that means that 95 percent of the variability is due to between facility variation, which means the variability that you're looking at is a consequence of differences in the achievement level between facilities, and not within them, or in comparison to each other.

All the measures have very similar relationships to outcome measures that we've developed for the population, including mortality

and hospitalization, to the existing and underlying dialysis adequacy measures; that is, that greater achievement of these measures is negatively associated with higher mortality and hospitalization rates.

So, I mean, that's much of the meat of the testing. Of course, the underlying evidence for the dialysis adequacy measures is very much the same. If you look in the screens here, you'll see that we've been very careful that, for instance, with the peritoneal dialysis measure, there is a different threshold to be met for a pediatric or an adult patient. So, depending on your age, you have a different threshold to meet. But assuming you meet that threshold, you fit within the numerator.

So, in terms of what we wanted to accomplish, which was to increase the number of patients that we're assessing, in the existing measures we were capturing --- and keep in mind this is limited to Medicare patients because we're using claims data. Of the 430 pediatric PD

patients, we were capturing 95 with the old measure. We're capturing 430 with the combined measure. With the pediatric HD measure we were capturing 150 out of 483 patients. We are now capturing, I think, 482. So, the proportion of pediatric patients that we're capturing with the measure is much higher.

We've also slightly increased the number of facilities that receive ratings. Most facilities received an adult hemodialysis rating already because most facilities have enough, but there were specialty facilities that focus on peritoneal dialysis patients, or pediatric patients, who didn't receive ratings.

At this point, I believe, we were capturing, as with the data we were using for testing, out of just over 6,000 facilities, we could provide a rating for 5,965 for the overall composite measure. The numbers are a little bit smaller for the two individualized measures. One of the reasons that we've come forward with those is because they offer the opportunity of

reporting a greater deal of granularity, particularly for something like public reporting purposes where it may make sense for a patient to know if a facility is better or worse at providing peritoneal dialysis, for instance. That kind of information may be helpful for them.

We wanted to get your feedback as to whether --- you know, essentially, it's a tradeoff. You capture a little bit more patients with the overall measure. You get a little more granularity in terms of quality performance for the different types of modality with the two measures. And that was one of the things that we wanted feedback from NQF and from the MAP as we're looking toward implementing these.

CHAIR RAPHAEL: Thank you, Joel. That was helpful. Sean?

MEMBER MULDOON: So, on the question of the lumpers versus the splitters, I would think that a consumer --- well, check me on this -- a consumer knows whether they're getting PD or HD. And unless performance within a given facility

has those things basically indistinguishable because they're either good or bad, I would think there would be a value of separating them so that someone could say, "I'm a PD patient, I prefer this place. Or, "I'm a HD patient, and I prefer that place."

And although none of this stuff helps for quality improvement because of the time lag, it will still force the people to solve those two different problems in presumably two different ways.

CHAIR RAPHAEL: Okay. Do I have a motion now to move for a vote? But I want to clarify something, because the way this was originally provided was to encourage continued development. Are we now changing it to conditional support? Is that correct?

MS. O'ROURKE: Yes. Could I provide some procedural clarification?

CHAIR RAPHAEL: Yes, okay.

MS. O'ROURKE: We had built this recommendation based on some old information.

But based on what Joel said, since the measures have completed testing and will be submitted to NQF in the coming month or so, it would be more appropriate to evaluate them for the fully developed measure pathway. So we would propose a conditional support pending NQF endorsement, if there's a work group member who would support that motion.

CHAIR RAPHAEL: Okay. Do I have someone who wants to move that motion of conditional support?

MEMBER LEIB: So moved.

CHAIR RAPHAEL: Okay. Second?

MEMBER STONE: Second.

CHAIR RAPHAEL: All right. Can you, Laura, we're going to do all three together, all right?

MS. IBRAGIMOVA: So, consent calendar, End Stage Renal Disease Quality Incentive Program, conditional support for delivered dose of dialysis above minimum composite score, delivered dose of hemodialysis above minimum, and

delivered dose of peritoneal dialysis above minimum.

So, do you agree with the End Stage Renal Disease Quality Incentive Program conditional support calendar? One, yes; two, no.

MEMBER DIAMOND: Carol, this is Lou here. I'm voting for conditional support, which I think is the one option.

CHAIR RAPHAEL: Okay. Thank you, Lou. And I'm assuming Carol is still on and we'll get her vote.

MS. IBRAGIMOVA: So, the results are 94 percent yes and 6 percent no.

CHAIR RAPHAEL: Okay, thank you.

All right. So, we are going to go on now to Medicare Shared Savings Program. And I believe Rabia Khan from CMS is joining us to describe this program.

MEMBER DIAMOND: So, Carol, this is Lou here. I've got to check out at around 2 o'clock.

CHAIR RAPHAEL: Okay. Thanks, Lou, for

letting us know.

MEMBER DIAMOND: Yeah.

CHAIR RAPHAEL: Rabia, are you on the line?

MS. KHAN: Yes, can you hear me?

CHAIR RAPHAEL: Yes, we can hear you. And we're looking to you to provide a brief overview of the program and the measures that we need to be considering.

MS. KHAN: Sure, thank you. So, the Medicare Shared Savings Program was established under the Affordable Care Act. And essentially it incentivizes accountable care organizations, or ACOs, to generate savings and provide high-quality care for beneficiaries.

So, under the Shared Savings Program, ACOs enter agreements with CMS, voluntarily, and then they're responsible for coordinating care and improving quality for their patient population.

We here at CMS assess the ACO performance annually on quality performance, and

then also against financial benchmarks which are used to determine shared savings.

ACOs contain a variety of providers and a key aspect of our program is that we look at the broad spectrum of care provided to beneficiaries. And we encourage ACOs to coordinate care across the different providers within their ACO, and also outside of their ACO.

Our program currently has 33 measures across four domains. And measures really range from being used as pay-for-reporting and then pay-for-performance depending on how we finalized each measure in our physician fee schedule regulation or when an ACO joined the Shared Savings Program.

So, for any ACO in their first year participating in a Shared Savings Program, all measures are pay-for-reporting. And as I mentioned before, that the 33 measures across the four domains --- the four domains include the patient caregiver experience, which is largely made up of CG-CAHPS measures. Care coordination

and patient safety. Our third domain is preventive health, and then at-risk population, which also focuses on some important clinical conditions.

So, we've recently, just an update, we've recently completed our first performance year in the program, and we had participation from 220 ACOs. And just briefly, I'm not sure if you have the list in front of you of measures that we have under consideration, but, as you can see, and I believe you're only reviewing four -- some of the measures are being reviewed at the clinician work group and hospital work group meetings -- but we're largely looking at measures that are focused on care coordination of patient care across the different providers.

We've received a lot of feedback from stakeholders, and in particular from MedPAC, that strongly encourage that we consider more outcome measures, measures that address a potentially avoidable admission or readmission. And we agree with the feedback that we've been receiving thus

far, so we feel, in addition to considering measures to meet these gaps, we also feel it's important that when we are considering measures that we're aligning with other existing CMS quality reporting programs.

So, for the measures under consideration for today's meeting, you'll see that we have four measures. There's the acute care hospitalization measure, which looks at the percentage of home health stays and which patients were admitted to an acute care hospital during the 60 days following the start of their home health stay.

Now, we put this measure on this list primarily because it fills a gap in care coordination outcome measures that we have. Although a large proportion of our measures in our current measure set are focused on physicians, whether in a group practice or individual that are participating within an ACO, and also hospital measures, we are looking to include more post-acute care measures, and

specifically moreso around care coordination outcomes.

We also have on the list, we have the antipsychotic use and persons with dementia, which is also a measure we felt addresses a gap in appropriate use of medications and patient safety.

Now, the other two measures that are on this list we've actually recently finalized in the 2015 Physician Fee Schedule rule. So we have the SNF all-cause 30-day post-discharge readmission measure, and the documentation of current medications in the medical record that were just finalized and wouldn't start being used until the 2015 reporting period.

So, again, I think this just emphasizes that, you know, we're looking for measures that address gaps in care coordination. And I guess what I would like to highlight is that we like to emphasize to ACOs that, although they are responsible for coordinating care within the ACO, we also encourage them to be working

with providers outside of their ACO for more streamlined coordinated care for their patients. So, I think that's what you would see with the measures that are on this list and what we're trying to address by considering them. I'm not sure who to turn this over to to continue the discussion, but thank you.

CHAIR RAPHAEL: Okay. Erin?

MS. O'ROURKE: Thanks, Carol. So, I wanted to just provide some details about what our preliminary analysis of these measures were. We supported all four of these through our preliminary analysis.

The first measure, you'll see, is the acute care hospitalization measure. As Rabia mentioned, this is a measure that's currently in the Home Health Quality Reporting Program, so it would help promote alignment with that program. We did not receive any public comments on this measure, but our staff analysis felt that this measure meets a critical program objective by encouraging coordination and shared

accountability and by promoting alignment across programs.

This would also address a current gap in the program of post-acute care outcomes and would address a PAC/LTC core concept of avoidable admissions. This measure is in the Affordability, Care Coordination and Hospice MAP families of measures.

The second measure is documentation of current medications in the medical record. This is one of the measures currently finalized in the MSSP program. We did not receive public comments on this measure. The preliminary analysis would be that this measure addresses a critical program objective. It would encourage coordination and shared accountability across settings. It would address the NQF's priority of safety, and this measure is included in the Dual-Eligible Beneficiaries family of measures.

The next measure is antipsychotic use in persons with dementia. We did not receive public comments on this measure. The preliminary

analysis was that this measure would address a PAC/LTC core concept and a critical program objective. This would also help promote alignment as this is another measure in the MAP Dual-Eligible family.

Finally, we have the skilled nursing facility all-cause 30-day post-discharge readmission measure. We received one public comment on this measure supporting the measure pending NQF endorsement. This measure would address a PAC/LTC core concept and it's a required measure for the SNF Value-Based Purchasing Program under the Protecting Access to Medicare Act of 2014. Use in the MSSP program would help promote alignment and shared responsibility across settings. MAP had reviewed and supported the direction of this measure concept in its 2012 pre-rulemaking. This is currently under review for endorsement and was recently finalized for use in the MSSP program.

CHAIR RAPHAEL: Erin, in regard to the documentation of current meds and antipsychotic

use in people with dementia, do these apply to all post-acute and long-term care sites and settings?

MS. GHAZINOUR: The documentation of current medication is the same measure that we just reviewed for the ESRD program and it only applies to the clinicians.

CHAIR RAPHAEL: Only applies ---

MS. GHAZINOUR: To the clinician setting. So, your question --

CHAIR RAPHAEL: No, I meant is this something we're expecting in home health care, in skilled nursing facilities, in long-term care hospitals, and inpatient rehab facilities? That's what I'm trying to ascertain.

MS. O'ROURKE: I think, as Mitra said, it's currently endorsed for the clinician level. And, Rabia, please correct me, but I believe this would be primarily addressing clinicians for the MSSP program? Could you clarify that?

MS. KHAN: Yes, so the measure would be used at the physician encounter.

CHAIR RAPHAEL: I don't really understand how that would be translated. So, can you explain how that would work in a home care setting and how that would work in a skilled nursing facility setting?

MS. KHAN: So, the way that we are using it, this measure actually is used in the Physician Quality Reporting System, and we're using it in the same manner as they are for their program. So it's at each physician encounter. And I don't think this is applying to home health or SNF, is it?

CHAIR RAPHAEL: Sorry. So, I'm trying to understand why this work group is considering these measures, because in a home care setting, and Peg can jump in here, we're going to generally have a nurse who is the care manager who's going to be doing the assessment, the care planning, the monitoring, doing the medication reconciliation. And I'm not sure, you know, and it probably varies by skilled nursing facility in terms of who would be doing the assessment, and

care planning, and medication review. It might be someone else in an inpatient rehab facility. So I don't really understand why this work group is considering these measures. Alan?

MEMBER LEVITT: Rabia, was this your decision or did the NQF divide it this way?

MS. KHAN: So, I believe the decision was to divide some of the measures across the different work groups that they felt were applicable. This was a measure considered for PQRS and as our alignment with that program we finalized it. I can't speak to why this was included for this work group to review. I know at the hospital work group we came across the same issue as some of the measures are also being considered for PQRS in alignment with that program that we moved for clinician work group review. I'm not sure if --- I mean, I leave it to NQF and the MAP to decide whether you feel this measure needs to be reviewed here or at the clinician work group on Monday.

CHAIR RAPHAEL: Helen, what are your

thoughts?

DR. BURSTIN: Just briefly, we actually had centralized review of the entire MSSP program done; actually, I did a good portion of it. It then got ferreted out to the work groups we thought might want to add additional input. It'll still go to the Coordinating Committee, who's actually the ultimate group for these measures because it does cross settings. So, some of these logically because they're about home care and dementia seemed like they would fit here, was really the logic of just getting your input before it goes to the Coordinating Committee. But, again, it still a measure at the level of an ACO, not a clinician, not home care, et cetera.

MEMBER LEVITT: Yes, if I can make a comment. I mean, I think the impact, once again this standardization across settings, we may, you know, for patients with multiple chronic conditions, the frail, elderly patient, there needs to be a place to start really looking at these types of patients. And perhaps, you know,

that's something to think about, is that a mission that a committee such as our's wants to take on.

CHAIR RAPHAEL: I think that for the population that we generally take care of, in either post-actue or long-term care, these are important areas. You know, the rate of rehospitalizations, the ability to improve medication compliance, and the validity of the medication regimen. The people with dementia are going to be a very key group in our population, so this really applies. But what I'm trying to understand is this is reported at the ACO level, and then it's up to the ACO to determine how its component partners kind of capture and report this data, I assume.

MS. KHAN: Yes, we report all the results at an ACO level to the ACOs.

CHAIR RAPHAEL: Okay. Are there other questions or comments on this? Peg?

MEMBER TERRY: It's an interesting point whether home care really today cares for a

lot of dementia patients. In fact, they don't. It's very interesting. I think it's changing. It's a different population from what I --- from the data I've looked at, where it's more in SNFs and other post-actue settings, but I think it's a big question in my mind whether home care would have at this point because of what happens quickly, their short stays, whatever, in home care to really address or be able to manage these kinds of issues with the multiple physician population they deal with. So, I just --- it's an interesting way to look at it. I've never thought about it before, but I think it's certainly a concern.

CHAIR RAPHAEL: Thank you. Sean?

MEMBER MULDOON: So, some clarification. You're an ACO that has two SNFs in your network, one has everyone on antipsychotics, another one has none. So, your ACO then receives a piece of data that says on average your ACO patients have, you know, that simple example, 50 percent. So, how does that help the --- what

additional --- I guess that provides --- is the idea that the subscriber might want to know that, but the ACO already does.

MS. KHAN: So, this is Rabia. What --- and I just want to be clear we're still sticking to documentation of current medications in the medical record. Correct?

MEMBER MULDOON: Fine.

MS. KHAN: So, the way this measure is going to be reported, we provide --- I mean, ACOs will be submitting data to CMS through our web interface, and we would identify for them the encounters in which they would report to us, whether it's been documented at that visit or at that encounter, what the current medications are in the medical record.

MEMBER MULDOON: But an ACO does not do the encounter; the ACO has a network of providers who do the encounter.

MS. KHAN: Right.

CHAIR RAPHAEL: Right.

MS. KHAN: Yes.

CHAIR RAPHAEL: Right. So, it's incumbent upon the ACO to figure out how it will collect and aggregate this information and report on it.

MS. KHAN: So, they report it to CMS via our G-Pro web interface, and they have to go through consecutive beneficiaries, so we provide them with a list of --- based on our assignment sampling approach identifying beneficiaries and providers that are assigned to the ACO who would be --- who they would report on over the course of an eight-week period. So, that's how we would be collecting the data in the future on that measure.

CHAIR RAPHAEL: Okay. Dianna?

MEMBER REELY: I'm curious why the acute care hospitalization measure would be different than the acute care hospitalization measure for Medicare that's currently being reported, which is a rehospitalization within 30 days of the hospital discharge.

The concern from Providence on the

West Coast are our home health length of stay is much shorter than the first 60-day episode. And I didn't see that the exclusion would be a patient who was discharged from home health services in the ACO model before their 60-day episode was up, so you could have a 21-day length of stay, and then have the remainder of the time where, you know, there could be a home health or an ACO penalty if the patient was rehospitalized.

MEMBER LEVITT: Rabia, this is the old measure. Right, the existing measure?

MS. KHAN: This is the existing measure that's being used.

MEMBER LEVITT: Right. Right. So, the advantage of this measure ---

MEMBER REELY: Not the existing measure.

MEMBER LEVITT: The measure that is still under NQF endorsement is not this measure; this measure is the existing measure that's on Home Health Compare already. It's 60-day for the episode; it's not a readmission measure, it's a

hospitalization measure because it includes all home health patients whether or not they have recently been discharged from the hospital. They could have been referred by a physician or a nurse practitioner into home health care.

CHAIR RAPHAEL: Okay. Peg?

MEMBER TERRY: So, I have a question about that. I know this is the old measure that exists today, and we'll have a new measure in January for 30 days, but my question is okay, so these patients --- it's a 60-day measure. You discharge a patient in 30 days, they're not with you. Everybody knows about this measure and how it works, but these are not patients coming from the hospital. These are not readmissions. It doesn't totally make sense to me if you're holding the ACO Shared Savings Account responsible and you're saying it aligns with the home care measure, that doesn't quite align with the home care measure.

The 30-day one is patients who are discharged from the hospital, and that's how they

capture that. That is a different measure, the one that --- the new one in January. The 60-day is all patients, you're right, and it's through the whole 60 days, but many of these patients don't come from the hospital, probably the majority. So, I'm not sure how the thinking is. I just don't understand it, and so maybe you could help me.

MS. KHAN: So, with the Shared Saving Program, we're focused on trying to address more avoidable admissions, or potentially avoidable admissions, or even readmissions. I know there's the other readmission measure that's going through the endorsement process, but in this instance we're really focused on preventing a patient from being hospitalized.

I understand that, you know, the patient is not being discharged from the hospital and then being readmitted, but in terms of coordinating care, if we can prevent the patient from being admitted into the hospital in the first place, that is sort of our goal with

introducing more potentially avoidable admission measures into our measure set.

But as far as the different types of providers that make up ACOs, it's not solely just hospitals or individual physicians or group practices. We also do have post-actue care facilities, and we are noticing even with the first performance year -- and this is why we've introduced the SNF readmission measure -- is that there is significant savings being generated around coordination with post-actue care facilities. So, we want to be sure that, you know, we're also looking at the quality of care being provided.

So, with this measure, and I cannot say off the top of my head how many ACOs have a home health provider as among their participants, participating providers, but I can say that like from our analysis with the SNF readmission measure, we have seen that for 2014 out of the 338 ACOs that we have, we have about 189 SNFs that are participating within an ACO. So, we are

trying to identify measures that we think will help promote primary care and coordination amongst the different providers, so that's why we're considering the existing hospitalization measure here.

CHAIR RAPHAEL: I think that we should all be aware that in ACOs they're finding that a certain percentage, a significant percentage, of course, are attributable to post-actue care, so this is a very important part of the continuum for ACOs.

Now, I think the issue becomes if you admit someone from the community who has congestive heart failure, and then, you know, the question is if it's pneumonia or UTI, could you have prevented a hospitalization? But then if it's a stroke, you know, it's a different situation, so I think it just really --- there are some things that are preventable. I'd feel better if this sort of had a sensitivity kind of part of it that, you know, preventable hospitalizations rather than hospitalizations per

se. But anyway, Tom?

MEMBER VON STERNBERG: I cannot speak for the 186 ACOs, but I happen to actually represent two very excited integrated care systems that are involved in the ACO world. I will tell you these group of measures are absolutely in line with what the ACOs expect to be measured on. They are also absolutely in line with the expectation of signaling, too, either with existing in-system partners or contracted partners around simply paying attention to the aspect heightening the awareness to home care nurses about their role in identifying potential risks of hospitalization period. That language and that conversation at the home care level, which I have with my teams now, again, is not that that home care agency says boy, this pneumonia couldn't be prevented, and this stroke could have been. It isn't down to that parsing.

The dementia measure of antipsychotics is an overuse measure, and it's a global overuse measure. Similar to readmission, the rate should

not be zero. Readmission from home care or from hospitals should not be zero. Antipsychotic use for patients with dementia does happen, not at the rate of 25 percent, is not what we expect to have as normal.

So, I think each of this I think resonates well. I struggle with the 60 versus 30 because I think that's a bit confusing. I'm not necessarily committed to saying can't go forward on either, or one versus the other, but they are all very consistent with what the ACOs signed up for. And that their learning curve of --- they didn't know they had to have relationships with SNFs. Their readmission rates are higher. These people bought SNFs. Their readmission rates are lower. So, I don't feel much heartburn about this.

CHAIR RAPHAEL: Okay, that's very good to hear, Tom. All right. Marc?

MEMBER VON STERNBERG: I'm from Minnesota.

MEMBER LEIB: I'm glad that these

resonate with you and that may be tempering some of my comments. The only one I have an issue with and it's only a minor quibble is the first one, the admitted to an acute care facility during the 60 days following the start. I'm wondering if that measure might discourage attempted use of home health prior to an admission -- this is not a readmission, so you want to keep someone out of the hospital, but a certain percentage of those people are going to get worse no matter what you do in the home health setting and will end up hospitalized. But this measure of how many of them get hospitalized may, in fact, discourage the use of home health prior to hospitalization to try to keep someone out. And I'm not sure how to word it in a way that would temper that.

MEMBER VON STERNBERG: I guess I would only quickly comment that going from the level of ACO measurement and system design to the point of care of Dr. X in the office, I will absolutely tell you that my experience being the doctor in the office across the room from someone who needs

home care or not, I do not think physicians at the individual patient level are at all capable of that kind of calculation from their supervisor doc saying don't order home care, or put them in, or what have you.

I just don't think that point of care physicians are at that level of ability to distinguish. In fact, they don't want to be. In fact, many of these docs are seeing an ACO patient, and then at 2:30 they're seeing an Aetna Medicare patient, and then at 4:00 they're seeing a Medicare Advantage patient from Cigna. So, I think that's just another part of the process to be aware of.

CHAIR RAPHAEL: Okay. Clarke?

MEMBER ROSS: So, I wanted to speak in favor of the two medication measures, and the first one. Just to emphasize, the duals work group is predominantly focused on the consumer and beneficiary, what is best for them. And the clinician group is predominantly focused on physicians and how you practice medicine. And

they both conclude that in order to practice medicine in the best standard, when you prescribe a medication or change the dose, you should know what the other medications are. And this is just one of those little vehicles to get to that basic point where physicians, and consumers, and beneficiaries agree, so I would hope the group could be comfortable with that.

And then I wanted to reinforce Tom's point. It's a lot more complicated point, but we have an OIG report and a GAO report on the misuse of antipsychotics particularly in skilled nursing facilities, and what are we going to do about it? And this is an effort to try to address a very glaring and documented problem throughout the country. So, those two observations from the duals group.

CHAIR RAPHAEL: All right. Sean?

MEMBER MULDOON: I'm talking about the admission rate from home care and the readmission from SNFs. Check me on this, if you are in an ACO, you're in the ACO metric denominator. You

are not in the fee-for-service denominator. Right?

CHAIR RAPHAEL: Let me ask CMS on that. Rabia?

MS. KHAN: Yes, you would be a part of the ACO denominator.

MEMBER MULDOON: And not part of the fee-for-service denominator. That has ---

MS. KHAN: No.

MEMBER LEVITT: Sean, I'll get back to you, but I think it's just they're not included, nor is like Medicare Advantage. I think it's fee-for-service, but I'll get back to you separately on it.

MEMBER MULDOON: Well, make sure it is, because that keeps Marc's problem from being a big problem. Because if you're in an ACO, you're going to use a home care visit as a way to stave off a short-term visit, knowing that it's risky for them. And you don't want to penalize that home care agency or that SNF from trying to prevent a short-term admission. So, if they're

separate, we're okay on that. If they're together, then you're going to have a conflict of interest between what the ACO wants the SNF to do, and the SNF putting themself out at risk because they're taking someone that has a high probability of being admitted.

CHAIR RAPHAEL: Okay. And I know there are always attribution issues that underlie this as well, but we won't go there. Dianna?

MEMBER REELY: My comment is you can be, I believe, a home care organization, let's say, that is in an ACO, and also seeing fee-for-service or Medicare patients. Right? You've got a business that you're running, it doesn't matter. So, my question is with --- going back to the acute care hospitalization measure here -- I just want to make sure I understand this. Why would it not be the same measure that we'll be going forward with in 2015 for the 30-day readmissions because, again, we get back to the burden on organizations to collect and report data two different ways. We've got 30 days for non-ACO

patients, and 60 days for ACO patients, if I'm interpreting this correctly. So, the question is, am I?

CHAIR RAPHAEL: All right. Alan or Rabia?

MEMBER LEVITT: I just wanted to point out again the readmission measures are claims-based measures, so they would not add increased burden to providers.

MEMBER REELY: I don't think that's true because we said earlier from the provider standpoint, like with the annual reporting that we talked about earlier with ESRD I believe it was, there's still a lot of work that the providers go through. I can speak for Providence as an organization because we're collecting the same data concurrently, not to wait for the public reporting or the claims-based reporting. So, the concept that there isn't increased work I don't think is necessarily --- isn't true from our perspective as a provider, just to state that.

DR. HITTLE: Excuse me. This is David Hittle, one of the measure developers for home health.

CHAIR RAPHAEL: Yes?

DR. HITTLE: And the claims-based measure that's described here is the one that's currently being reported, not the one that's coming up for --- to be implemented in 2015. This is a hospitalization measure as opposed to a rehospitalization measure, and it is based strictly on the Medicare claims that are submitted by the home health provider in order to identify a home health care episode, and then they match those to hospital claims in order to determine whether or not there's been a subsequent ---

CHAIR RAPHAEL: All right. Peg?

MEMBER TERRY: So, I understand it's a 60-day. I have to bring back another issue that I discussed before. The claims-based admission or readmission data in my opinion does not take into account, and I'm saying this for the record

because we had a long conversation about this at the last meeting. Some of the factors that really account for patients in home care going back into the hospital, lives alone, does not have a care provider, and some of these factors are very important. And I think particularly for some of the dually eligible patients they are increased factors, so I just want to get that on the table again. I know it hasn't --- I don't believe it's changed, but I think it's an important thought when you're looking at ACOs because now it's taking on a different look, in my opinion, now that it's going to be part of an ACO concern, or interest, or measure.

CHAIR RAPHAEL: Okay. With that, let me see, are there any other comments on this? Yes, Robyn?

MEMBER GRANT: First, just real briefly kind of for the record, as well, I just wanted to express my continued concern about the SNF readmission measure being a disincentive to hospitalization. But I just wanted to speak very

strongly in support of the antipsychotic use in patients with dementia.

CHAIR RAPHAEL: Talk a little louder.

MEMBER GRANT: Oh, I'm sorry. I just wanted to speak very strongly in support of the measure for antipsychotic use in persons with dementia. As we know, it is a terrible problem in nursing homes, it's about one in about 20 percent I think of residents now are still on these medications, but we can't get at this if we just look at one setting. It really does need to --- we need to look at it across settings. And this is a step, I think, toward doing that so that we could look at this problem holistically and solve it that way.

CHAIR RAPHAEL: I'd like to ask the group if anyone wants to pull out any of these four that are now all having a recommendation of support? All right. If not, do I have a motion to support these four recommendations as part of the Medicare Shared Savings Program? Okay, a second? All right, Roger.

So now, Laura, we are ready.

MS. IBRAGIMOVA: So, consent calendar Medicare Shared Savings Program for PCT/LTC setting support acute care hospitalization risk-adjusted measure, documentation of current medications in the medical record measure, antipsychotic use in persons with dementia measure, and skilled nursing facility all-cause 30-day post discharge readmission measure. Do you agree with the Medicare Shared Savings Program support calendar? One, yes; two, no.

CHAIR RAPHAEL: Lou dropped out so did we remove him from the base? Okay.

MS. IBRAGIMOVA: So, we have --- the results are 100 percent yes, and zero percent no.

CHAIR RAPHAEL: Okay, very good. Thank you. All right. Thank you, Rabia.

So, we are going to go on to our pre-rulemaking measure on the consideration for home health quality reporting. And, Erin, are you going to provide a brief overview of this, the staff's preliminary analysis? Oh, long-term care

hospital, hang on. Oh, all right, hold on. I must have missed that. Thank you. I did. All right. Going on to long-term care hospital. And I think, let's see, Erin, you are going to start. All right.

MS. O'ROURKE: Yes. So, we have one measure under consideration for the long-term care hospital quality reporting program. This is a paper reporting and public reporting program. For Fiscal Year 2014 and for each year after LTCHs must submit data on quality measures to CMS to receive the full payment update. Failure to report this data will result in a 2 percent reduction in their annual payment update.

The data must be made publicly available with LTCH providers having an opportunity to review it prior to its release. And there's been no date specified to begin public reporting of this data.

The goal of the program is furnishing extended medical care to individuals with clinically complex problems such as multiple

acute or chronic conditions needing hospital-level care for relatively extended periods of greater than 25 days.

So, again, we have the one measure under consideration for this program as VTE prophylaxis. This is the same measure we considered earlier for IRFs. The staff had a preliminary analysis that we conditionally support this measure pending appropriate expansion and testing of the measure to address the LTCH setting. This measure addresses the NQF's priority of safer care and is relevant to the priority of LTCHs. Venous thromboembolism has an annual incidence of approximately 900,000 cases of which 300,000 are fatal. AHRQ has noted the appropriate use of preventative measures has a potential for reducing the incidence of VTE and improving patient safety. Use of this measure would promote alignment across programs because it is used in other acute care program settings such as the IQR program. This measure is not ready for implementation as it needs further

testing for this setting before it could be used in the program.

CHAIR RAPHAEL: So, is the major condition having to do with testing it in LTCHs? It's been used in other sites, but it has not been tested in the long-term care hospitals.

MS. O'ROURKE: Yes, this is currently used in acute care hospitals, so the recommendation would be to just ensure it could also be used accurately in LTCHs.

CHAIR RAPHAEL: All right. Okay. CMS?

MEMBER LEVITT: I just wanted to say once again --- well, first of all, Charles Padgett who's lead in LTCHs has also come up to the table. But we would be looking at this measure similarly to the IRF measure and see, you know, if it needed to be respecified, so to speak, in terms of special population of the LTCH patients.

CHAIR RAPHAEL: Okay. Are there any questions? Sean?

MEMBER MULDOON: Just remind me about

the ICU exclusion, is that the ICU at the referring hospital, or the ICU in the long-term care hospital?

MEMBER LEVITT: Charles can answer.

MR. PADGETT: Charles, can you speak a little louder, please?

MR. PADGETT: I believe it's the ICU in the referring hospital.

MEMBER LEVITT: This is the acute hospital. This is the same measure that we were talking about earlier. We're taking the hospital measure and we're going to be, you know, looking at it and moving it into the LTCH setting. So, once again, Sean, we'll work to look at the LTCH setting and see, you know, what the VTE prophylaxis guidelines and recommendations are, and adjust specifications, you know, as such.

MEMBER MULDOON: Well, I mean, conceptually this is perfectly fine. The glitch will be that there will probably be more people for whom prophylaxis was considered but not chosen, and that's a chart extract. So, to some

degree, you know, we'll be grading our own paper on that one.

CHAIR RAPHAEL: All right. Jennifer?

MEMBER THOMAS: Just clarification from a standpoint of settings. A long-term care hospital does not infer nursing home. Correct?

CHAIR RAPHAEL: Right.

MEMBER THOMAS: And since the duration is longer here, I just want to throw out the idea of unintended consequences here if we start using some of the newer oral anticoagulants because of the issues of persons that miss doses; hospital stays are about three, four, five days, you're not going to capture a lot of this, but in this setting will have a longer stay likely. And stopping those medications even for a day can actually cause an embolic event because of pro -- become a pro-coagulant type state, so just throw that out there for --

CHAIR RAPHAEL: Okay. Debra?

MEMBER THOMAS: Consideration for testing.

MEMBER SALIBA: My comment is also related to the length of stay and the fact that anticoagulation may not be appropriate for every person in LTCHs. And it's not clearly defined in any guidelines right now what to do with people that are sort of between the acute care hospital and the long stay, the people that are in that little post-actue care window. How much you anticoagulate and for how long is very unclear. And it's sort of a patient by patient decision to look at risk factors, prognosis. It's a much more complex decision than it is in the hospital where it's pro forma for most people.

CHAIR RAPHAEL: Okay. Pam?

MEMBER ROBERTS: Just two clarifications. One, this measure is just that you document that you looked at it. It doesn't say you have to have given it. Correct?

MR. PADGETT: Yes, that's correct.

MEMBER ROBERTS: And then my other question, this would be anybody that's admitted to the LTCH regardless if they're in the ICU in

the LTCH or wherever. Is that correct?

MR. PADGETT: Correct.

CHAIR RAPHAEL: Okay.

MR. PADGETT: I mean, the measure that we're looking at, I mean, right here that's being considered today, is the acute care hospital measure. And what we're saying is that, you know, while it's under review today for LTCHs, that CMS would consider all of these --- take all of these considerations under advisement and if we need to respecify the measure to some degree to make it more appropriate for the LTCH setting, we would certainly do that.

CHAIR RAPHAEL: All right. Any other comments or questions? If not, I'm going to move this to accept the recommendation for conditional support. Do I have a motion to move that? Second? Okay. Laura?

MS. IBRAGIMOVA: Consent calendar long-term care hospital quality reporting program for conditional support venous thromboembolism prophylaxis. Do you agree with the long-term care

hospital quality reporting program conditional support calendar? One, yes; two, no. We're going to have to vote again.

CHAIR RAPHAEL: Okay. All right. We are going to vote again. Should we do it right now?

MS. IBRAGIMOVA: Yes, you can vote. So, the results are 94 percent yes, and 6 percent no.

CHAIR RAPHAEL: Okay. All right, thank you. Then we've met the 60 percent requirement. And now we're going to go on to home health quality. Erin?

MS. O'ROURKE: I apologize, I misspoke on the LTCH program.

CHAIR RAPHAEL: Oh, we do.

MS. O'ROURKE: And we've got two measures under development that we need to do discuss. Apologies, I was trying to let you all go a little early.

CHAIR RAPHAEL: All right.

MS. O'ROURKE: So, we have two measures under consideration for this program, or these

measures are still under development. We gave them a preliminary analysis that we would encourage continued development.

The first measure is compliance with ventilator process elements during the LTCH stay. This measure addresses an important safety priority for LTCHs. It's estimated that 25 percent of ventilated patients in LTCH acquire ventilator-associated pneumonia, and there's evidence for interventions developed to decrease incidence of ventilator-associated pneumonia and improve ventilator care. VAP and BAE are associated with substantial morbidity, mortality, and excess health care costs, so we would encourage further development of this measure.

We did receive one public comment on this measure. The commentor was supportive of the measure pending NQF endorsement. The commentor noted that currently available modes of invasive mechanical ventilation encourage patient spontaneous breathing and promote liberation from mechanical ventilation contributing to successful

spontaneous breathing trials.

The next measure is ventilation weaning liberation rate. This measure addresses an important safety priority for LTCHs. MedPAC estimates that 16 percent of LTCH patients use ventilator services. Weaning is the process of decreasing the amount of support a patient receives from the ventilator, and successful weaning is associated with decreased morbidity, mortality, and resource use.

We received three public comments on this measure. The comments were mixed on this measure. Commentors noted that measuring the rate of weans in a health care facility is good conceptually; however, this particular measure is not useful for differentiating among LTCHs because it is not risk-adjusted. However, the definition of weaning is fairly strong because it does not include partial weans. The commentor noted their concern that this is a self-reported measure for which the reporting tool has not been defined.

CHAIR RAPHAEL: Okay. Are there questions or comments on these two measures? Sean?

MEMBER MULDOON: I was on the subgroup that did all this, so I have fairly intimate knowledge of it. We went round and round on the wean rate, which we would generally support with the recognition that, you know, you're either going to be precise or accurate. You can't be both on one of these things, and that's why we did not choose to do a partial wean. And we did not allow the hospital to determine, with very few exceptions, what category of patient was unweanable. So, you're just going to have to live with that and we'll either have that discussion again here, or you'll just have to kind of believe that we vetted it as well as we could, and had to call it one way or another, and called in both of those ways.

It will penalize the hospitals who take the riskiest patients. And it will favorably impact those who take COPD exacerbations.

CHAIR RAPHAEL: All right. Any comments from CMS on this?

MEMBER LEVITT: Charles, did you want to say anything?

MR. PADGETT: Yes, sure. So, as Sean said, we --- you know, the TEP when we met with them did go round and round on these measures. I just wanted to make a few comments regarding the public comments that were made regarding this. And one, about the lack of risk adjustment. You know, this was certainly discussed by the TEP and it was certainly advisable that we risk-adjust this measure, but there's very little data out there right now to inform this particular risk-adjustment. And the cities that are available are very small in scope, or look at one or two hospitals and the data is just simply not generalizable to the larger LTCH population. So, that's something we still are struggling with and looking at, but we understand that it is very important to this measure, and we will work towards getting there.

And then, secondly, I believe there was a comment regarding how this measure was to be reported. And I just wanted to make it known that this measure would be collected using the LTCH care data set that's currently in existence for use in the LTCH setting. And it's currently how LTCHs report their quality data, their assessment data to CMS.

CHAIR RAPHAEL: All right. Any other comments here? If not, this was recommended for encourage continued development. Do I have a motion to move toward a vote on that? Second? All right, Laura?

MS. IBRAGIMOVA: So, consent calendar long-term care hospital quality reporting program, encourage continued development, compliance with ventilator process elements during LTCH stay measure, and ventilator weaning rate measure. Do you agree with the long-term care hospital quality reporting program encourage further development calendar? One, yes; two, no. And the results are 94 percent yes, and 6 percent

no.

CHAIR RAPHAEL: Okay. All right. Now, we're going to go on to home health quality reporting. And, Erin, you're going to give us again a brief overview of the program and your analysis and recommendation.

MS. O'ROURKE: Yes. So, the home health quality reporting program is a pay-for-reporting program with a public reporting element. Medicare certified home health agencies are required to collect and submit the OASIS data set. The OASIS is a group of data elements that represent core items of comprehensive assessment for an adult home care patient and form the basis for measuring patient outcomes for purpose of outcome-based quality improvement.

Home health agencies meet their quality data reporting requirements through the submission of OASIS assessments and home health CAHPS. Home health agencies that do not submit data will receive a 2 percentage point reduction in their annual home health market basket

percentage increase. Subsets of the quality measures generated from OASIS are reported on the Home Health Compare website which provides information about the quality of care provided by home health agencies across the country.

The goal of the program is to --- the CMS had adopted the mission of the Institute of Medicine, which has defined quality as having the following properties or domains: effectiveness, efficiency, equity, patient-centeredness, safety, and timeliness.

So, we have one measure under consideration for the home health quality reporting program. A percent of patients with pressure ulcers that are new or worsened. This measure had a preliminary analysis of conditional support, was conditional support pending further development and NQF endorsement of the measure. This measure addresses a PCT/LTC core concept, and will be a required measurement domain under the IMPACT Act. This measure promotes alignment as it is harmonized with NQF Number 678, percent

of residents or patients with pressure ulcers that are new or worsened, which is included in the SNF, LTCH, and IRF settings.

We received one public comment on this measure. The public commentor supported this measure pending NQF endorsement, and noted that currently available remote patient monitoring technologies are equipped with sensors that detect patient position and movement, and notify caregivers of the need to reposition the patient in order to reduce pressure which may contribute to the development of pressure ulcers.

CHAIR RAPHAEL: Does anyone from CMS want to speak to this? Alan?

MEMBER LEVITT: I'll just make a couple of comments. First of all, the data element that we are looking for for this measure will start to be collected. OASIS-C1 begins January 2015, and so the data elements for this will start then.

Second thing interesting about this measure is including the --- we've included actually in this measure slough and eschar, which

have not previously been included in our other pressure ulcer measures, so just to note that.

CHAIR RAPHAEL: Are there comments or questions on this? Peg?

MEMBER THOMAS: So, I have a comment on the exclusion criteria for this measure. And I've spent a lot of my time looking at patients who do not --- their wounds do not improve, a lot of data. And we have found one of the reasons that patients don't get better is that they're dying, so the patient is transferred to a hospice. That, to me, would be a very helpful exclusion measure to put in there; not just death, but that they are being --- they are moving, they are going to a hospice, so I think that those patients, obviously, don't get better.

My second question, of course, gets back to risk adjustment. And this is the kind of patient that really relies on the support of a family. Home care and helping wounds get better or improving wounds, it's critical to have adequate risk adjustment because it's critical to

have family members available, or a caregiver available. It's not like an institutional setting, so I just wanted to make that point.

I don't know what the criteria are included in the risk adjustment calculations, but I think we've really got to include something along the lines of caregiver availability as a factor. That's my only other comment.

CHAIR RAPHAEL: Okay, thank you. Art?

MEMBER STONE: I'm sorry. I just wanted to mirror what was just said on the risk assessment, what factors were brought into that? And there are many things that are coming out of particularly the acute hospitals that are never-events on their side, but are major events on the home health side, and they're not accounted for. And it could present a huge problem over the period of time as this begins to develop a little further.

MEMBER LEVITT: Would anyone like to comment on the phone?

DR. NUCCIO: This is Gene Nuccio

calling from the University of Colorado. We are the contractor that developed the measure and do the risk adjustment on all of the OASIS-based measures. This measure, as Alan pointed out, is not yet being collected because the data set is not available, and it won't be available until January 1st. However, I can tell you that historically we have about five percent of our home health population has pressure ulcers at stage two or higher, only five percent of our patients. And approximately two percent of the patients have stage one pressure ulcers. So this is not a very large population or group that we do this measure for. However, I can tell you that for the other approximately 40 home health outcomes that are OASIS-based, virtually all of them make use of patient ---excuse me, caregiver variables as part of the prediction model used for risk adjustment.

We have several items on the OASIS data set that get to both if a caregiver is available and if a caregiver is knowledgeable and

willing to participate in the care of the patient. So, we do quite clearly recognize those for the other prediction models and would anticipate that this model, when built, will also include that variable. It will certainly be tested as part of about 400 potential risk factors that are used in the testing and the development of prediction models.

CHAIR RAPHAEL: Okay.

MEMBER WINSTEL: This is Lisa Winstel with the Caregiver Action Network. I'd like to have a comment.

CHAIR RAPHAEL: Sure, go ahead.

MEMBER WINSTEL: In that last comment when you were talking about caregiver variables, were you referring to the paid home health caregiver, or were you talking about the family caregiver being available, knowledgeable, and willing?

DR. NUCCIO: We're talking --- hi, this is Gene Nuccio, again. We're talking about the family member primarily, although it could be a

paid member. But, in fact, the item, data item 2102 in the OASIS data set specifically excludes the agency, the home health agency staff from that.

So, for example, we have the types of assistance broken out into ADL assistance, IADL assistance, medication administration, medical procedures and treatment, management of equipment, supervision and safety, and advocacy and facilitation. So there are seven dimensions. And across each of those dimensions, the caregiver could provide assistance. Currently, the caregiver could be judged to provide assistance if training was provided. We do have a column for the caregiver, not likely or unclear, and as well as assistance is needed but no caregiver is available.

So, it's a very large grid of 35 particular elements that discriminates what sorts of care that the patient could be receiving.

CHAIR RAPHAEL: Just one --- go ahead, Lisa.

MEMBER WINSTEL: It sounds like a very comprehensive grid, and I'm very sorry I'm not there. I know it's awkward to comment on the phone, and I apologize. But I maybe missed this, who is doing the assessment of the caregiver?

DR. NUCCIO: The nurse or the physical therapist who is completing the OASIS at the time of admission or, that is, start of care or resumption of care.

CHAIR RAPHAEL: Is that required that there be an assessment of the caregiver's preparedness and capacity to perform the tasks that are needed?

DR. NUCCIO: That is a data item within the OASIS instrument, and so it would be required.

CHAIR RAPHAEL: Go ahead, Lisa, back to you.

MEMBER WINSTEL: Sorry. But so I understand correctly, that is not --- at this moment that is not required. Correct? Caregiver assessments?

DR. NUCCIO: The caregiver item is currently used on the OASIS-C instrument, and it's just numbered slightly different because we've collapsed two categories. We used to have six functional categories of the caregiver and we collapsed it to five based on our data analysis of the current data. So, under the current instrument, it's Item M2100.

CHAIR RAPHAEL: Okay. Sean, you ---oh, Lisa, do you want to say anything more?

MEMBER WINSTEL: I might but I'm okay right now. Thank you.

CHAIR RAPHAEL: Okay. Sean?

MEMBER MULDOON: Yeah, I want to do a concise summary of why I don't like this measurement at all. It's basically two basic reasons. It's the first measurement for whom the behavior we're trying to modify is not that of an employee. And second of all, it's the first measurement for whom it does not apply to 19 out of 20 recipients. And put together, I would propose that there's a better place to put

effort.

DR. HITTLE: I actually need to clarify that. This is David Hittle from the University of Colorado. The measure itself, the denominator for the development of a new or worsened pressure ulcer is not the people who come in with a pressure ulcer, it is everybody who may or may not --- who comes into the home care --- who is treated by the home care agency. And, so, what we're looking at is whether at the end of the home health care episode of care, when they're discharged from home health care back to the community, whether or not they have developed a pressure ulcer during that episode of care.

MEMBER MULDOON: Okay. So, the 19 out of 20 doesn't count, but the vast majority of home health recipients, I would think, are not bed- or chair-bound. Well, whatever the --- I think the direction of the comment stands. And then the one about employee is just the way it is. I would think we go someplace else.

CHAIR RAPHAEL: All right. I'm going to

go to Clarke.

MEMBER ROSS: I wanted to react to Sean's comments. Christopher Reeve, you probably all know from Superman, died of an infected pressure ulcer. He had a personalized attendant, he had a loving wife, and in the best of circumstances, people with paralysis get ulcers and die. And people live in the community who are paralyzed, but one of the biggest fears for my engagement with United Spinal, and the Christopher & Dana Reeve Foundation, and the folks who are paralyzed is the fear that this ulcer, any little red spot on their body, they instantly fear because it could become an ulcer, and it could be infected, and they could die like Christopher Reeve. So this numbers game, I think we have to look at the consequence of not detecting an ulcer, not the numbers of who might have an ulcer. Thank you.

CHAIR RAPHAEL: Okay. Alan?

MEMBER LEVITT: Sean, I appreciate your comments. The IMPACT Act, one of the

measures in the IMPACT Act is skin integrity and changes in skin integrity. And this will need to be looked at within the home health setting by, if I look at my timeline, January 1st, 2017. So, statutorily we are asked to do this as well, irrespective of any other reason.

CHAIR RAPHAEL: Okay, Liz?

MEMBER PALENA HALL: I just want to point out there are some health IT standards around pressure ulcers, and I encourage the Workgroup to look at those in relation to whatever transpires out of this.

CHAIR RAPHAEL: Robyn?

MEMBER GRANT: First of all, I wanted to support what Clarke said. I think it shouldn't just be a numbers game, because each and every one of those pressure ulcers is really critical when you think about who it's effecting.

But I have a question. Under the exclusions, I'm not sure I'm understanding correctly. It says, "episodes of care ending with a transfer to an inpatient setting." So, would

that mean that if somebody were at home and getting home health services, they developed a severe pressure ulcer, stage four, it was so bad they had to go to the hospital, that that wouldn't be counted? I'm concerned I'm missing something here, because if that ----

DR. HITTLE: This is David from the University of Colorado again. That is actually an artifact of the data collection method because when they leave the care of the home health care agency, with an ordinary discharge, the clinician comes out and does a discharge assessment on them. If somebody is unexpectedly transferred to an inpatient facility --- well, if they end up going to an inpatient facility, the home healthcare clinician does not have the opportunity to go out there to assess their clinical status. And, therefore, we simply don't have the data because they weren't able to make a visit out there for the assessment and collect the OASIS assessment data.

And that's a shortcoming with just

about all of the OASIS-based outcomes, but unfortunately it's just a part of the nature of the data collection process.

CHAIR RAPHAEL: Okay. Art?

MEMBER STONE: Again, I just want to make sure that in the assessment -- and I realize we're using the OASIS assessment process -- but that varies in somewhat -- and I'm not sure we're collecting the same thing of apples to apples and oranges to oranges to make sure that we are collecting the appropriate data. And I strongly recommend there is something added to that for palliative care and people in their end stages of living, because that can skew the whole thing completely in where we are and what we're trying to prove, because those ulcers are not going to heal.

DR. HITTLE: We are able to --- there is an item, at the time of discharge, there is a question as to their discharge destination, and admission to hospice is one of those criteria, because they can't really be getting the home

health benefit and the hospice benefit at the same time. So, they end up being discharged from the home healthcare, sometimes to the same provider because a lot of home care agencies are also hospices. But it's a different provider number because it's a hospice.

So, at any rate, when they're discharged we do have the information that they've been discharged to hospice, and it would be possible, therefore, to have the exclusion that I believe Dr. Terry mentioned.

CHAIR RAPHAEL: Bruce?

MEMBER LEFF: Yeah, I just want to pick up Art's banner. You know, there are a number of folks who are in home-based primary care types of programs who never make it to hospice because they don't want to change providers, who are quite disabled and you're in a situation where you're choosing between treating or relieving pressure and actually causing pain and discomfort by doing so. So sometimes those are in conflict, and patient preferences need to

guide. So, you know, the notion of trying to find some sort of exclusion for people who are at that stage, I think is important.

CHAIR RAPHAEL: All right. Peg?

MEMBER THOMAS: So, it would be great to be able to capture that data, truly. Just two points. Of course, diabetes is an issue for these patients, and I'm sure it'll be part of the risk adjustment. But the other thing I just want to mention to the person on the call, Lisa, that the new proposed COP does have a lot of requirements that the home health agency work and train, and that there's evidence that you're training caregivers to care for patients; although, it is not there today in that explicit state. And that's still under review; just wanted to mention that.

CHAIR RAPHAEL: Okay.

MEMBER WINSTEL: Thank you. That's actually I think what I was getting to. And while I'm speaking, I do have a question. I want to pose a scenario to make sure I'm understanding

this proposed rule correctly.

If we have a family caregiver caring for a loved one and then home health comes into the home, the family caregiver is there 24/7, the home health aide is not. Pressure ulcers develop and worsen. Does this that we are considering then in some perverse way encourage home health to, for want of a better word, blame the family caregiver for that pressure ulcer, since the family caregiver is the one who is there around the clock? And how would we capture that? I'm just worried about an unintended consequence.

CHAIR RAPHAEL: Does anyone on the phone want to respond to that?

DR. HITTLE: This is David Hittle from the University of Colorado again. I'm not sure that the measure --- I mean, the measure simply says whether or not --- you know, simply indicates whether or not a new or worsened pressure ulcer had developed. There isn't any assignment of responsibility or way that we could --- in terms of whether that came from the

caregiver's limitations or from the home health agency's limitations.

There is, certainly, the fact that we do collect the information on the caregiver's involvement in care and what their availability is. But I don't think that really is an assignment of responsibility for the outcome one way or the other. Obviously, if they have less caregiver availability that's probably an indicator that they're more at risk of having some decline in their health status, but there really isn't any assignment of blame or responsibility there.

CHAIR RAPHAEL: All right. Any other questions or comments?

MEMBER LEVITT: Gene, are you talking about Item M2110 in the new OASIS?

DR. NUCCIO: Yes.

MEMBER LEVITT: Okay.

DR. NUCCIO: And that was ---

MEMBER LEVITT: Mitra, I did send the OASIS to you, if anyone wanted to see it. Oh,

you sent it out, so it's on page 22. If everyone looks at page 22 on the top, they can see the item that is being referred to.

CHAIR RAPHAEL: All right. Are there any other comments or questions on this? All right. What is recommended is conditional support, so do I have a motion to move to a vote on that? All right. Second?

Okay. Any more discussion? All right. If not, Laura?

MS. IBRAGIMOVA: Consent calendar, Home Health Quality Reporting Program for conditional support, percent of patients with pressure ulcers that are new or worsened. Do you agree with the Home Health Quality Reporting Program conditional support calendar? One, yes; two, no.

We're going to have to vote again. Sorry.

CHAIR RAPHAEL: Okay. And do we have Lisa's vote?

MS. IBRAGIMOVA: Yes.

CHAIR RAPHAEL: Okay. And is Carol

still on? Okay, good.

MS. IBRAGIMOVA: And the results are 72 percent yes, and 28 percent no.

CHAIR RAPHAEL: All right, thank you.

All right. So, now the last thing we're going to consider today is the Hospice Quality Reporting Program, where I believe we do not have any measures that are under consideration. I think what we wanted to hear from the Workgroup are, based on where we are today, what additional priority measurement areas do we recommend and what could we import from PAC/long-term care programs into the hospice QRP and vice versa?

But is there a way of kind of giving us a rundown of where we are in hospice, so that we all have a common understanding?

MS. O'ROURKE: Sure. So, Alan, please jump in if I get anything wrong. So, right now the Hospice QRP, which is used to collect data to calculate six NQF-endorsed measures, and one modified NQF measure. They're Number 1617,

patients treated with an opioid who are given a bowel regimen. NQF Number 1634, pain screening; NQF Number 1637, pain assessment; NQF 1638, dyspnea treatment; NQF 1639, dyspnea screening; and NQF 1641, treatment preferences. And a modified version of NQF 1647, beliefs or values addressed if desired by the patient.

MAP has made some previous recommendations around this program, including that the program should include measures addressing concepts such as goal attainment, patient engagement, care coordination, depression, the role of the caregiver, and a timely referral to hospice.

Some future directions of the program that MAP had noted that we would like to see were to develop an outcome measure addressing pain and selecting measures that address care coordination, communication, timeliness/responsiveness of care, and access to the healthcare team on a 24-hour basis.

CHAIR RAPHAEL: Okay. Carol, do you

want to say anything on this?

MEMBER SPENCE: Yeah. Are we limited just to the Hospice Quality Reporting Program? Because the fact that there is going to be, starting in January, a experience of care measure survey -- and I think there's eight measures that are going to be calculated from the results of that survey -- round out the picture a good deal.

But if our focus is just on the reporting program, which right now is the hospice item set, we can do that, too. I just think people need to know that information from that survey is also going to be part of what hospices are required to do related to quality measurement.

CHAIR RAPHAEL: Carol, could you just clarify that survey?

MEMBER SPENCE: Well, it's going to be part of the CAHPS family of surveys, so it's going to go --- but what makes it unique, because it's hospice, it's going to be sent out to family caregivers. So it's not a patient survey, it's a

bereaved family caregiver survey.

And for those --- anybody --- I don't know who's around the table -- is at all familiar --- Peg, you might be -- with the family evaluation of care survey that NHPCO has had out there for over 10 years, there's a lot of similarities. But it goes to the caregiver and it asks questions both about the care that the patient received and some of the care that the family caregiver received. Keep in mind that the unit of care for hospice is the patient and the family, so it does address some of the family care, as well as patient care.

CHAIR RAPHAEL: Okay. All right. So, let me see if there are other comments. Alan?

MEMBER LEVITT: Yeah. Originally, this actually was not on the agenda because there was no measure, and I had actually asked to put this on because we actually do very much value your opinion. There's a new lead in our program, Michelle Brazil, who's sitting back there who's very engaged and really wants to hear from the

post-acute care community and the hospice community as to what we can do with this program. So that's why we're here.

CHAIR RAPHAEL: So, just sort of stepping back and recalling our conversations, I mean, we were very much focused on pain management and the outcomes since managing pain is such a critical element in high-quality hospice care and just continued focus on alleviating suffering.

And then we also were very focused on what we called access and responsiveness, and just sort of the continued issues around how late people often come to hospice, and whether or not there's anything we can do to give people the choice and the opportunity at an earlier point to participate in hospice no matter what decision they make. Because I think all of us who work in this field know that we still haven't moved the needle on when people tend to come into the hospice program, if you look at the mean and the medians.

And then the last thing was just this really important element of service of having members of the team be available around the clock, because I think we all know that, you know, the terrors and the problems tend to come in the middle of the night and that this is one service where having access to the team quickly in the middle of the night or on the weekends is so terribly important.

So, those just come from our practice experience in terms of directions that we thought we needed to move. But I am very open to kind of new members of our Workgroup or others who want to add anything to the kind of areas that we really felt were remaining gaps.

MEMBER WINSTEL: This is Lisa Winstel at Caregiver Action Network, and I applaud your prioritization, especially around access and responsiveness. I think that having lack of access, or lack of response, is one of the greatest causes of stress to family caregivers at those times. And I would also like to add maybe

access and responsiveness not just during the course of hospice, but at intake, as well.

CHAIR RAPHAEL: Okay. And we now have up on the board -- I don't know how many of you can see it easily -- but sort of looking at our core concepts and looking at nursing homes, home health, long-term care hospitals, the inpatient rehab facilities, ESRD, and hospice, how are we doing in regard to our core concepts?

And interestingly enough, home health has the highest number. I think nursing homes are probably second. And the smallest number is in the hospice column. So, there is experience of care, and there is establishment of patient family caregiver goals. There isn't anything on mental health, interestingly enough, nor shared decisionmaking, which is hard to understand.

So, I think we still, even in terms of our core concepts, have some room to strengthen the hospice QRP.

All right. Any other comments?

Anything that you would like to say as

our CMS new lead here?

MS. BRAZIL: Can everybody hear me? We did take into consideration all of the stakeholder priorities, particularly with our technical evaluation panel that we had in the summer right before I came on board, but also the NQF and MAP high priority consideration areas. Even the media we're taking into consideration. As many of you know, the Washington Post articles and the IOM report on "Dying in America."

So, our top priorities right now that we're currently researching is the pain outcome measure as our number one, but also those areas on the access, responsiveness, and timeliness of care specifically measures the timeliness and responsiveness to care and access to a health care team on a 24-hour basis with a goal of providing timely and appropriate intervention. Because as you just mentioned, after-hours care is very critical.

We're also looking at possibly a composite measure, and we're not quite sure just

yet, but on communication, access to care and care coordination, and looking at the access and availability of services, communication as it relates to caregiver, patient education and support, even avoiding unwanted treatments, unnecessary hospital and ED admissions, and implementing patient, family, and caregiver goals.

The care coordination piece might be a little bit more difficult because you're talking about a measure that would cross multiple settings, but we are currently doing our research on that, as well, to see what would be feasible for the program.

CHAIR RAPHAEL: You know, I think the ED one is particularly challenging, and others can certainly weigh in. But, you know, you work very, very closely with the family to tell them do not panic, if anything happens, call someone from the hospice team. And then you still find that when something happens, you know, bleeding, the family panics, calls 911, the ambulance

comes, the person ends up in the ED, the ED doesn't know that the person is in hospice or has really had an advanced directive with certain instructions and starts the aggressive sort of therapies all over again. So, I find that a particularly challenging area of practice.

That being said, you are focusing on the areas that matter to us. Michelle, would it be possible to get out to our work group the IOM report? I think they would find that very helpful and informative. I don't think we have seen that as a work group.

MS. BRAZIL: Okay. I'd be happy to send it to everybody.

CHAIR RAPHAEL: Okay, great. All right. Any other thoughts on this area? If not, I'm going to ---

MEMBER SPENCE: Carol, this is Carol. I'm just going to just beat the very same drum that I continually do I think at each meeting. And, you know, CMS is making a huge step by including that --- having that survey, that post-

death survey. But that survey, you know, you're still dependent on a response rate for a survey. And while I think it is a great measure, or data source for measures, and certainly, you know, we've supported exactly that thing for many, many years, I think family needs to be included in some of the process and chart-based measures also.

So, I'm not saying it's --- it's not really an addition to the things that Michelle has said and the priorities that this group has talked about. It's just that that family piece needs to be included as we're talking about measure development in the specific measures, just to keep in mind patient and family are the unit of care for hospice.

It's a tough concept because we're the only ones that have it stated. It should be, they should be included, of course, across other providers, but it is a stated unit of care for hospice, and so that we're held responsible, should be held responsible for inclusion of

family. And I think sometimes the specific focus on family, while it's always in the background, it can be something that slips aside, so I really would like to see it highlighted with quality measures.

CHAIR RAPHAEL: Thank you, Carol. I'm going to now turn to public comment and see, Cathy, our operator, if we have anyone from the public that wants to make a comment?

OPERATOR: Okay. At this time to make a public comment, please press *1.

There are no public comments at this time.

CHAIR RAPHAEL: Okay. Then we are going to have a summary of the day, of what we have accomplished today. Mitra, do you want to run that down for us?

MS. GHAZINOUR: Sure. So, we have put up this table that should be familiar to most of you. This is called PAC/LTC Core Concepts By Programs. And so it demonstrates the core concepts that have been addressed in the PAC/LTC

programs. So far as of to-date, today we added the avoidable admissions core concept that the measure for the skilled nursing facility value-based purchasing to this table. However, there are still gaps, other core concepts that have not currently being addressed across programs, such as advanced care planning and treatment, adverse drug events, establishment of patient, family, caregiver goals, experience of care, inappropriate medicine use, shared decisionmaking and transition planning, they remain as gaps.

These are high priority measurement areas across all PAC/LTC programs. Currently we don't have any measures to address these core concepts.

I just wanted to show that this is our progress, and we still have a way to go. Just wanted to get your thoughts.

CHAIR RAPHAEL: Okay. And in terms of what we did today, can you just give us a rundown? We know that on ESRD we're coming in with no recommendation. In all the other cases

we are coming in with a recommendation from MAP. Is that correct?

MS. GHAZINOUR: Yes. For ESRD, I think we supported conditionally the three measures that we initially thought that they were under development. So, we have a recommendation for those measures. However, we don't have a recommendation for the first four measures that we are asking the Coordinating Committee to review. For the other programs, we have recommendations.

CHAIR RAPHAEL: Okay. So, before we all depart, which should be fairly soon, Erin, I don't know if you wanted to just give us a couple of minutes on something that is really, really important. There was a big program, I think, on all the news channels this morning about a study in the UK actually on antibiotic overuse. And I think we have an action team. So, if you could just give us a couple of minutes before we conclude?

MS. O'ROURKE: Thank you very much,

Carol. So, I wanted to bring up an issue, as Carol mentioned, that's been in the news lately and was a focus area at the recent MAP Hospital Workgroup meeting, that as we're putting increased attention on infection rates, there's a potential unintended consequence of a lack of antibiotic stewardship, if you will, and a continuing problem that we could see more sewer bugs developing. So we wanted to highlight the work of the NQF Antibiotic Stewardship Action Team that's working to promote the stewardship in this area, sorry. And we're fortunate enough to be joined by Wendy Prins, who is leading this work.

MS. PRINS: Well, I've also been here all day because I immensely enjoy the topic of long-term care and post-acute care. But thank you, Erin and Carol, for bringing this up.

I just wanted to raise this as we've been doing a lot of work and thinking about the hospital setting and ambulatory care around the issue of antibiotic stewardship. And we had a

meeting in November to bring together a small group of stakeholders, NQF members to start to focus on this area.

And I think we'd be interested in maybe if you have any comments or want to talk with me separately afterwards if you have any thoughts about how this might be addressed in the post-acute or long-term care setting particularly. As we know, a lot of people get discharged from the hospital on antibiotics and are there processes in place or programs, or stewardship programs in the post-acute setting that we should know about, learn about, and try to integrate into this work? Because we recognize that it's certainly something that is not just isolated in the hospital setting or with physicians. There are a lot of others who could play a role, so --- oh, Bruce. Yes?

MEMBER LEFF: Thanks, Wendy. So, I could tell you I have colleagues at Hopkins who have developed antibiotic stewardship programs both for hospital and for nursing home settings.

So if you'd like me to help you make contact, feel free to drop me an email. I'd be happy to do that.

MS. PRINS: Yeah. I would love to, thank you.

CHAIR RAPHAEL: Tom?

MEMBER VON STERNBERG: The Medicare QIO in Minnesota, Stratis Health, is right now in the early phases of a statewide collaborative with nursing homes to reduce antibiotic use. I mean, if you need contacts, I can get them to you, but it's been about a year so far they've been working on it.

MS. PRINS: Okay. And I know this is something that's sort of in some of the scope, the new scope of work for the QIOs. Right?

CHAIR RAPHAEL: Yeah. Okay. Bruce, go ahead.

MEMBER LEFF: Yeah, I would just say, you know, another thing to think about with something like that is, you know, we tend to think about our traditional approaches, but for

something of that sort, I think thinking about large supply chain types of situations; so, for instance, the Premier Hospitals, which there are about 2,000 Premier Hospitals, they --- it's quality improvement, and they have the supply chain. So those kinds of organizations are in a position to really influence how things like antibiotics get moved out into the world.

CHAIR RAPHAEL: Good point. Good point. All right. Thank you, Wendy.

MS. PRINS: Thank you.

CHAIR RAPHAEL: And my thanks to all of you, I mean, for really a very productive session. And I just think that we have a group that brings a lot of complementary skills and experience to our deliberations. So, thank you so much. And safe travels to everyone, and a good holiday.

(Whereupon, the above-entitled matter went off the record at 3:10 p.m.)

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C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: MAP Post-Acute Care/Long-Term Care

Before: NQF

Date: 12-12-14

Place: Washington, DC

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

Neal R. Gross

Court Reporter