

National Quality Forum

MAP Clinician Virtual Review Meeting

Tuesday, December 14, 2021

The Workgroup met via Videoconference, at 10:00 a.m. EST, Rob Fields and Diane Padden, Co-chairs, presiding.

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 Helen Burstin, MD, MPH, MACP, Council of
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 Scott Fields, MD, MHA, OCHIN, Inc.
 William Fleischman, MD, MHS, Individual
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 Stephanie Fry, MHS, Individual Subject Matter
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 Emma Hoo, Purchaser Business Group on
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 Bret Jackson, St. Louis Area Business Health
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 Lisa McGiffert, Patient Safety Action Network
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 Amy Nguyen Howell, MD, MBA, FAAFP,
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 Donald Nichols, PhD, Genentech
 Lou Parrott, MD, PhD, Magellan Health, Inc.
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Proceedings

10:01 a.m.

Welcome and Review of Meeting Objectives

Ms. Elliott: Good morning again, everyone. We're going to go ahead and get started.

My name is Tricia Elliott. I'm the Senior Managing Director here at NQF and I'd like to welcome you to today's virtual review meeting for MAP Clinician Workgroup.

A few housekeeping reminders as we continue to convene: Please mute your computer or phone line when you are not speaking. We encourage you to turn on your video especially during the measure discussions and when speaking. Also please use the hand raise feature if you wish to provide a point or raise a question. The raise hand feature is located within the reactions button or the smiley face at the bottom of the tool bar on the pop form. There you will see an option that says raise hand when you hover over that icon. If you have the participant list open you can also hover over your name and there will be an option for raise -- that raise hand feature there as well.

Feel free to use the chat feature to communicate with the NQF host or IT support. For this meeting we'll be using Webex for presentation and discussion and we will use Poll Everywhere for voting. Please ensure you have access to both platforms.

The workgroup committee members will have received an email this morning for Poll Everywhere. Please ensure that you've received that email and able to log in to Poll Everywhere.

Next slide, please? So with that I want to welcome everyone again to the Measure Applications Partnership meeting and our Clinician Workgroup virtual review meeting, today, December 14th,

2021.

Next slide, please? I'm going to quickly review the agenda and then we'll move into some welcomes, introductions, and disclosures of interest. After that we have Michelle Schreiber on the call today who will provide some opening remarks from CMS. We'll provide an overview of the pre-rulemaking approach as well as input and an overview of the MAP Rural Health and MAP Health Equity Advisory Groups that took place last week. We'll have a discussion on Medicare Part C and D star rating measures. Then the Merit-Based Incentive Payment System, or MIPS measures. We'll have a discussion on the Shared Savings Program and we actually move that up on the agenda. That will be closer to the opening remarks from CMS. And we'll have an opportunity for public comment at then and then we'll have a summary of the day and the next days. And we'll be adjourning ideally promptly at 6:00 p.m.

Next slide, please? With that I'd like to hand things over to our Chief Executive Officer here at NQF, Dana Safran, to provide some welcoming comments.

Dana?

Dr. Safran: Thank you, Tricia.

And good morning, everybody. It is my absolute pleasure to welcome you to today's MAP Clinician Workgroup review meeting. This begins the 2021-2022 Measure Applications Partnership cycle.

NQF is honored to continue partnering with CMS and the MAP Clinician Workgroup on this very important initiative convening MAP and providing input on performance measures that are being considered by CMS for use in its public reporting and performance-based payment programs.

There really has never been a more important time for measurement in our country and this work really

is where the rubber meets the road, I would say, in terms of really considering measures that will be used in programs that have the potential to provide significant improvements on quality, outcomes, equity, and affordability in the U.S.

MAP brings together a unique multistakeholder group. Representation includes the quality measurement research and improvement field, purchasers, providers, public and community health agencies, health professionals, health plans, consumers, suppliers, and subject matter experts. And it's really through this diverse array of stakeholder voices that we work to enable the Federal Government to receive varied and thoughtful input on the measures that it's considering for final rulemaking.

I'd like to in particular highlight the work of our Rural and Health Equity Advisory Groups during their meetings last week to review the 2021 measures under consideration. The Rural Health Advisory Group has been providing critical input for several years; I believe five years, and new this year is the Health Equity Advisory Group that has shared insights on each measure's ability to identify disparities and further promote health equity. So these two groups look across the full set of measures under consideration and provide input to each of the setting-specific MAP workgroups. So we're really pleased and appreciative for the robust discussion and critical feedback that those two groups offered last week and that will be available through the conversation today.

Also I'd really like to thank our workgroup members, the federal liaisons for the time and effort that they put into MAP each year. Particular thanks to our workgroup co-chairs, Diane Padden and Rob Fields, for their leadership and for the enormous time and commitment to this work.

And finally, thanks to the members of the public

who take time to provide input during these meetings through online public comments as well. Your feedback is so very important to this process.

So looking forward tremendously to today's discussion on the 13 measures that are under consideration for the Clinician Workgroup and for the feedback that this process will provide to CMS.

With that, let me thank you all and turn it back to you, Tricia.

Ms. Elliott: Great. Thank you so much, Dana.

Next slide, please? At this time I would like to give the opportunity to Rob Fields and Diane Padden to provide some opening remarks.

Rob?

Co-Chair Fields: I'll keep mine short, but mostly just want to thank everyone for the time and dedication. It's a long day and a lot to do, but appreciate the commitment, especially lots of folks that are familiar faces year over year that continue to work on all these efforts. And I've had the privilege of serving as co-chair for three years and a participant for I think a year or two before that, and it's good to have this collective team to work on these issues with. But turn it over to Diane.

Co-Chair Padden: Thanks, Rob.

Good morning, everyone. It's my pleasure to be a co-chair here with Rob today, and I echo his comments and others'. It is an important time for us to be looking at these measures. And I too have been a part of the MAP for close to eight years now, the last two years as a co-chair. And it will be a long day, but I am very much looking forward to the discussion. Thank you.

Ms. Elliott: Excellent. Thank you both for your leadership and guidance and time for our meeting today.

Next slide? Oh, thank you, Victoria.

Next up is our disclosure of interest. So as a reminder, NQF is a non-partisan organization. Out of mutual respect for each other we kindly encourage that we make an effort to refrain from making comments, innuendos, or humor related to for example race, gender, politics, or topics that otherwise may not be considered -- may be considered inappropriate during the meeting. While we encourage discussions that are open, constructive, and collaborative, let's all be mindful of how our language and opinions may be perceived by others.

We'll combine disclosures with introductions. We'll divide the disclosures of interest into two parts because we have two types of MAP members: organizational members and subject matter experts. I'll start with the organizational members.

Organizational members represent the interests of a particular organization. We expect you to come to the table representing those interests. Because of your status as an organizational representative, we ask you only one question specific to you as an individual: We ask you to disclose if you have an interest of \$10,000 or more in an entity that is related to the work of this committee.

We'll go around the table beginning with organizational members only. I will call on anyone on the meeting who is an organizational member. When I call your organization's name, please unmute your line, state your name, your role at your organization, and anything that you wish to disclose. If you do not identify any conflicts of interest after stating your name and title, you may add I have nothing to disclose.

Okay. On the next slide, we're all set.

So first up is the American Academy of Family Physicians.

Member Mullins: Hi, this is Amy Mullins, Medical Director of Quality and Science at AAFP, and I have nothing to disclose.

Ms. Elliott: Thank you, Amy.

The American College of Cardiology.

Not hearing anyone, I'll do one more call. American College of Cardiology?

Okay. We'll circle back. American College of Radiology.

Member Seidenwurm: Hi, this is David Seidenwurm. Nothing new to disclose and it's good to be among old friends. And I think I'm the only surviving original MAP members, so it's great to be here again.

Ms. Elliott: Awesome. Thank you so much.

Blue Cross Blue Shield of Massachusetts.

Member Ying: Wei Ying. Nothing to disclose.

Ms. Elliott: And your name, please?

Member Ying: Wei Ying.

Ms. Elliott: Thank you.

Consumer's Checkbook.

Council of Medical Specialty Societies.

Member Burstin: Hey, everyone. Helen Burstin, CEO of CMSS, and I have no disclosures.

Ms. Elliott: Thank you, Helen.

Genentech, Incorporated.

Circle back. I'm not hearing anyone.

HealthPartners, Incorporated.

Member Averbeck: Good morning. This is Beth Averbeck, Senior Medical Director for Primary Care, and I have nothing to disclose.

Ms. Elliott: Thank you, Beth.

Kaiser Permanente.

Member Gozansky: Hi, this is Dr. Wendy Gozansky, Chief Quality Officer for the Colorado Permanente Medical Group, and I have nothing to disclose.

Ms. Elliott: Thank you, Wendy.

The Louise Batz Patient Safety Foundation.

I'm not hearing anything. We'll circle back.

Magellan Health, Incorporated?

Member Parrott: Hi, this is Lou Parrott with Magellan Health. I have nothing to disclose.

Ms. Elliott: Thank you. OCHIN, Incorporated?

Member Fields: Hi, this is Scott Fields. I'm the Chief Medical Officer at OCHIN and I have nothing to disclose.

Ms. Elliott: Thank you, Scott.

Patient Safety Action Network.

Member McGiffert: Hi, this is Lisa McGiffert. I am subbing for Yanlin Yu and -- for the Patient Safety Action Network and I have nothing to disclose.

Ms. Elliott: Thank you, Lisa.

Pharmacy Quality Alliance?

Member Hines: Hi, this is Lisa Hines. I'm Chief Quality and Innovation Officer at the Pharmacy Quality Alliance. PQA is the measure steward for three measures under consideration for Medicare Part D. I will recuse myself from discussion and

voting on those measures. And PQA also served as a TEP member for MUC 063, and I will recuse myself from voting and discussion on that measure.

Ms. Elliott: Okay. Thank you, Lisa. Appreciate that.

Purchaser Business Group on Health.

Member Hoo: Good morning. This is Emma Hoo. I'm the Director of Value-Based Purchasing and filling in for Rachel Brodie. No disclosures.

Ms. Elliott: Thank you.

St. Louis Area Business Health Coalition.

Member Jackson: Hi, Bret Jackson today representing the St. Louis Area Business Health Coalition, and I have no disclosures.

Ms. Elliott: Thank you.

I'm going to circle back to a few organizations we didn't hear from. Is there a representative from the American College of Cardiology?

Okay. I'll try again. The -- with the Consumer's checkbook.

Genentech, Incorporated. Do we have a representative?

Member Nichols: Can you hear me? Can you hear me now?

Ms. Elliott: Yes, we can.

Member Nichols: All right. Sorry. I was here earlier; you didn't hear me. (Audio interference) --

Ms. Elliott: Oh, you're cutting out a little bit. Is that Don, yes?

Member Nichols: Donald, yes.

Ms. Elliott: Donald. Okay. Thank you. We can hear

you now. Sorry about the audio issues there. So thank you. We got that.

And I'll circle back on the Louise Batz Patient Safety Foundation. Do we have a representative?

Okay. So if those three organizations join later, we'll have them provide a disclosure.

Next up we appreciate those disclosures from the organizations. Now we'll move onto disclosures for our subject matter experts.

Because subject matter experts sit as individuals we ask you to complete a much more detailed form regarding your professional activities. When you disclose, please do not review your résumé. Instead, we are interested in your disclosure of activities that are related to the subject matter of the workgroup's work. We are especially interested in your disclosures of grants, consulting or speaking arrangements, but only if relevant to the workgroup's work.

Just a few reminders: You sit on this group as an individual. You do not represent the interest of your employer or anyone who may have nominated you for this committee.

I also want to mention that we are not only interested in your disclosures of activities where you were paid. You may have participated as a volunteer on a committee where the work relevant to the measures reviewed by the MAP. We are looking for you to disclose those types of activities as well.

Finally, just because you disclose does not mean that you have a conflict of interest. We do oral disclosures in the spirit of openness and transparency.

Please tell us your name, what organization you're with, and if you have anything to disclose. I'll call

you name so that you can disclose.

First I'll begin with our co-chairs. Rob Fields?

Co-Chair Fields: Nothing to disclose.

Ms. Elliott: Thanks, Rob.

Diane Padden?

Co-Chair Padden: I would like to mention that I have been a part of the MACRA cost -- episode-based cost measures, as well as the patient cost measures and patient relationships, those two TEPs, none of which we'll be discussing today, but I have been involved.

Ms. Elliott: Thank you, Diane.

Our next individual subject matter expert, Nishant Anand?

Member Anand: Good morning, everybody. My name is Nishant Anand. I'm the Executive Vice President/Chief Medical Officer of BayCare Health System -- Health System-Based Data in the West Central Florida area and I have nothing to disclose.

Ms. Elliott: Thank you.

William --

Co-Chair Fields: Tricia? Sorry. This is Rob.

Ms. Elliott: Oh, go ahead.

Co-Chair Fields: Just commenting that I am actually on the TEP for MACRA, but I don't think any of the measures that we've discussed are on the docket today.

Ms. Elliott: Okay. Thanks, Rob. Appreciate that.

Next up, William Fleischman?

Member Fleischman: Hi, good morning. Will

Fleischman, Director of Quality and Safety at Hackensack Meridian Health. I have nothing to disclose

Ms. Elliott: Thank you.

Stephanie Fry?

Member Fry: Hi, good morning. Stephanie Fry, Senior Study Director at Westat, serving as an individual subject matter expert, and nothing to disclose.

Ms. Elliott: Thank you.

Amy Howell?

Member Nguyen Howell: Hi, Amy Nguyen Howell. Good morning. Chief of the Office for Provider Enhancement at Optum. Nothing to disclose.

Ms. Elliott: Thank you. And at this time I'd like to invite our Federal Government participants to introduce themselves. They are non-voting liaisons of the workgroup.

Centers for Disease Control and Prevention?

Dr. Briss: Good morning. I'm Peter Briss. I'm the Medical Director in the National Center for Chronic Disease Prevention and Health Promotion at CDC. I call David's here since the beginning, and nothing to disclose. Thanks. Over.

Ms. Elliott: Excellent. Thank you so much, Peter.

Member Seidenwurm: Hi, Peter. Glad to have another surviving alum here.

Co-Chair Fields: We have an alumni network forming. Awesome.

Next, Centers for Medicare and Medicaid Services?

Dr. Schreiber: Hi, Michelle Schreiber. You'll hear a little bit from me later, and we have a number of

people on the phone from CMS.

Ms. Elliott: Excellent. Thank you, Michelle.

Health, Resources and Services Administration.

Dr. Alemu: Hi, good morning. This is Girma from HRSA. Girma Alemu. I have nothing to disclose.

Ms. Elliott: Thank you very much.

I'd like to remind you that if you believe that you might have a conflict of interest at any time during the meeting, please speak up. You may do so in real time at the meeting, you can message any -- either of the co-chairs, or you can go to the NQF staff through the messaging or chat application.

If you believe that a fellow committee member may have a conflict of interest or is behaving in a biased manner, you may point this out during the meeting, approach the chair, or go directly to the NQF staff.

Does anyone have any questions or anything you'd like to discuss based upon the disclosures made today?

Okay. Great. Thank you so much for your cooperation and we'll be proceeding with the meeting.

So I need to introduce our workgroup staff to all of you. So myself, Tricia Elliott. I'm the Senior Managing Director here at NQF. Also on the team supporting all of the work of this project: Ivory Harding as the Manager; Ashlan Ruth as our Project Manager; Victoria Freire as our Analyst; Gus Zimmerman as our Coordinator; Joelencia LeFlore as a Coordinator; and Taroon Amin as a Consultant. So many thanks to the NQF staff for pulling together all of this information including the PA as well as meeting presentation materials.

Next slide, please? I'd also like to call out the CMS staff working with us on this project. Kim Rawlings

is our Task Order Contracting Officer Representative, and Gequincia Polk is the Indefinite Delivery/Indefinite Quantity Contracting Officer's Representative. Very much appreciate the collaboration with them and being able to achieve what we've brought to the table today.

Next slide? So the objectives for today's meeting is to review and provide input on the measures under consideration for the MAP Clinician Programs and also to identify measure gaps for the MAP clinician Programs.

Next slide? With that, I'd like to hand things over to Dr. Michelle Schreiber, who is the Deputy Director for Quality and Value at CMS, and she'll be providing some welcoming remarks to our workgroup today.

Michelle?

Dr. Schreiber: I'll sound check. Can you hear me okay?

Ms. Elliott: Yes, we can. Thank you.

CMS Opening Remarks

Dr. Schreiber: Wonderful. So greetings to everybody. This is now my third year doing these MAP meetings, I am not one of the longest survivors of you guys, but certainly it has been an absolute pleasure to be engaging in the Measure Applications Partnerships, and it's very nice to see everybody, although virtual today.

As Dana pointed out before, I extend my same thanks, both to all of you as committee members for the time and efforts that you put into this, certainly to our co-chairs Diane and Rob. You will have a lot of work keeping us all together and on time today, so thank you in advance for that.

To our NQF colleagues. Tricia, thank you for leading this today, but there are many people behind the

scenes at NQF who have done a lot of work for this. In addition there are a lot of people at CMS behind the scenes, some on the line today, who have done a lot of work, and I thank all of them, as well as the measure developers. So you'll have an opportunity perhaps to ask questions or hear a little bit more details from them as well today.

All of you have obviously gone through the past several years of COVID, and I would really like to thank each and every one of you personally, but certainly the organizations that you represent and the provider community writ large for everything that you have done to keep this country and our patients and families and communities safe during the time of COVID. So really extreme thanks for that.

And if I don't get a chance to say it at the end of the meeting, I will say it now and wish all of you a great and happy holiday season.

If I can have the next slide, please? So I know that NQF will cover this a little bit too, but I wanted to talk a little bit about the purpose of the Measure Applications Partnership because we're really very excited to hear your comments and feedback today.

This is obviously a convened group of great experts and expertise and you provide recommendations to us, CMS, about whether or not these measures that you're going to review today should be included in value-based programs. So today you will largely consider the MIPS Program, but obviously the ACO Program, as well as Medicare Parts C and D Stars Ratings. But there are a number of programs that CMS has in its value-based portfolio and the MAP weighs in on the vast majority of them, so this feedback and recommendations is re obviously very important to us.

I would point out because I have to point this out that your recommendations are strongly considered. I promise you that your recommendations have

clearly influenced CMS about measures that go into programs, or maybe don't go into programs, or that get modified, but in the end CMS does make the final decision.

This year was very exciting that not only have we had the opportunity to have these meetings, the MAP, which recommends measures for programs, but we started a new process this year where the MAP Coordinating Committee had the opportunity to make recommendations on measures to be removed from programs. Also new this year is the Equity Committee that you'll hear more about. And of course the Rural Health Committee, who weighs in on the impact to rural health.

Next slide, please? Specifically the Clinician MAP is the group who recommends measures that may potentially be included for rule-writing, particularly in PFS. Those are the physician fee services. But the programs do include MIPS, which will be the majority of what we talk about. ACO, Medicare Shared Savings Program, and the C&D. And these are a mixture of pay for reporting programs as well as pay for performance programs, and some of these measures are used to calculate -- or in public reporting on Physician Compare. Almost all of these measures actually at some point will likely become publicly reported.

Next, please? Just to share with you what are the priorities of CMS and what we are looking for as we start going into rule-writing season for 2022. The new administration has put out its CMS Strategic Priorities, which you can see are built around six pillars, the first one being to advance health equity by addressing health disparities.

Health equity is clearly at the top of the agenda for the Biden Administration and a lot of what you will hear is how this may influence equity. You'll be seeing more in rule-writing this coming year as well as we had an RFI just in this past year about ways

that CMS can start to approach equity including stratification of measures, including introducing measures that look at maybe social determinants of health. You'll be hearing some of those today as well as other ways to really address equity in the health care system.

The other pillars include: expanding access in quality and affordable care; engaging stakeholders, which is really part of what we're doing here today; driving innovation; protecting the Medicare Trust Fund so that we're sustainable for future generations; and finally within CMS fostering a positive and inclusive workforce of our own.

Next, please? There are certain key focus areas that we really are paying a lot of attention to, and you'll start again seeing measures come through around this. So obviously COVID and the public health emergency remain at the top of that agenda.

Equity, as I spoke of before. Equity including access and outcomes and referrals and patient experience.

Maternal health and safety. Some of you may have seen the Vice President's remarks on maternal safety, which is a big focus on CMS, and we have multiple initiatives going on there.

And multiple initiatives also in mental health. And these cross not just all of CMS' centers, but this is across HHS and really across government.

Resiliency and emergency preparedness clearly has come out as a topic that is extremely important. We've learned many lessons in the COVID pandemic including how we can better prepare for the future.

I want to make just one comment on safety because we did see some of the safety metrics decline during the last couple of years of COVID. CDC for example published their experience on health care-acquired infections that have gone up. We've seen similar degradations in patient safety

metrics such as falls or pressure ulcers. And really think that it's -- we need to continue to focus on and regroup around safety including not just patient safety, but workforce safety as well.

Digital transformation and the move to digital measures is an important theme because we think that this is the future of measurement.

Climate change is raising its head in terms of an important topic for HHS.

And then of course always driving towards value and value-based care.

Next slide, please? I wanted to talk just a little bit about the COVID impact to the value-based programs. And as I said before a sincere thank you to all of you and to the people who are providers across the United States.

I spoke a little bit about the trend of worsening quality and safety and a future focus of resilience. In the value-based programs, proposed and now finalized, CMS really tried to take a measured approach in terms of ensuring that we weren't penalizing either providers or organizations for things that may have been out of control. So measure suppression and other actions to limit financial impact while still preserving wherever we could appropriate public reporting because we want to maintain transparency of the data.

And obviously there have been many conversations last year, if you may recall, the COVID-19 health care personnel vaccination measures that have come to fruition and were introduced into rule-writing, and we'll be starting data collection on those already. And the health care personnel vaccine mandate that had been finalized but now of course is pending further investigation.

Next? There have been a few key enablers that we've learned and challenges for implementation of

our response to COVID. Some of the really fundamental enablers though, they're of the things that we're all familiar with: It is leadership -- leadership, culture, and governance, a focus on infection control and expertise, and local and coordinated local/regional planning.

There were many challenges including as we've all seen the underserved and vulnerable populations who were significantly affected by COVID in a disproportionate way.

We've had challenges around data reporting, which partly is one of the issues of the drive for digital measures. It's really digital data and sharing standardized digital data so that we all have access to that.

The technical assistance that was needed as well as managing multiple regions and states and organizations, and tribal and local and territorial guidance to make sure that it was cohesive and consistent. So there have been many challenges, but really many great successes, almost all at the root them through leadership, culture, governance, transformation, and people working so hard together. Thank you.

Next slide? Let me go over just MIPS a little bit that was finalized in the PFS Rule. MIPS is the program that we will certainly being a lot of consideration for measures to go into the MIPS Program today.

Finalized in the rule this year was the addition of certified social workers and certified midwives to participate in MIPS. So we now have a very robust representation of providers who may participate and are MIPS-eligible.

We set a new performance threshold at 75, which is higher than the 3 that it started at at the first year of MIPS, which was 6 years ago.

We introduced five new episode-based cost

measures, all of which have been considered by the MAP. And we also introduced in promoting interoperability the attestation to safe EHR use by the review of the SAFER guidelines.

We introduced the automatic extreme and uncontrollable circumstances, both for 2020, and we recently announced for 2021. And a reminder to all of you that 2022, this coming year, is the last year of the additional \$500 million for exceptional performance payments.

Next slide? We have also introduced the concept that you will hear more of and as we look at measures in future years the concept of MIPS Value Pathways. So rather than the extensive menu of choice of selecting from over 100 or more -- actually it's closer to 200 quality measures and 100 improvement activities. And then cost measures and promoting interoperability. We're looking actually to really put forward measure sets, measure sets that are responsive to either a specific specialty or a topic, or something that is of tremendous interest such as prevention would be a topic for a MIPS Value Pathway.

Or another topic for an MVP might be chronic conditions of care. Or you've seen several of them - - we had seven in particular that were introduced into rule-writing this year. The direction of MIPS will be around these measure sets that are integrated and coordinated and include quality that is related to improvement activity, that is related to the cost measures, and that has a foundational level, not only of promoting interoperability, but of equity as well.

We also introduced the concept of subgroup reporting. So 85 percent of clinicians currently report as part of a group. Many of those are large multi-specialty groups. Some of you are part of large multi-specialty groups. In the future we proposed subgroup reporting so that a large multi-

specialty group for example can report components of their group.

So the cardiologists may be able to report a MIPS Value Pathway separately than for example the anesthesiologists may, or that primary care may. And we want to encourage teamwork so that an MVP could be multiple specialties and multiple groups of providers who contribute to coordinated care in a specific area.

The MIPS Value Pathways will start as voluntary, but eventually -- in rule-writing we did propose the sunset of MIPS traditional in the future.

In the end we hope that this will reduce burden. There are fewer reporting requirements, measure sets that are coordinated and cohesive. And we hope that it will also provide more meaningful data not only to patients about provider performance, but also to providers about how providers are doing in areas that are meaningful and actionable to them.

Next slide, please? The ACO quality measures. I know we have representatives from the ACO to speak today. We had proposed to move to only the reporting of three electronic clinical quality measures with the sunset of a way to report in the Web Interface, but there have been concerns about data aggregation. So again we start talking about digital data and the ability to look at and report and have interoperable digital data. And we'll be working on that with the ACOs as we extended the period of time for the Web Interface as we undergo further evaluation for reporting. And we did finalize more flexibility in the final rule.

Next slide? Some potential future directions that I think you'll be hearing as the Clinician Committee again is this transition of MIPS to MIPS Value Pathways; subgroup reporting so that specialty care and specialty metrics actually take an equally important role and that they are transparent; equity

measure stratification and direct data collection as it relates to equity; digital measures; and of course the reflection of the importance of patient-reported outcome measures or patient-centered measures. All of these are directions that we are moving towards really across all of our programs, but in particular MIPS.

Next, please? So with that again I thank you. I thank you for your contributions and most of all your truly important voice -- this isn't for hospitals, this is for providers, but your truly important voice in weighing in those measures for clinicians.

Just to remind you, in the MIPS Program we are statutorily mandated to have measures for all specialties and to have cost measures that cover the vast percentage of costs that are expended by Medicare. And so as you look at the measures today you'll see those that reflect different specialties, different area of focus, starting to see measures around equity and social determinants of health. And we really look forward to your comments and recommendations on these measures moving forward.

And thank you. We look forward to your comments of the day.

And, Tricia, let me turn it back to you.

Ms. Elliott: Thank you so much, Michelle. Really appreciate those comments and overview of the clinician measures.

Before we move into the discussion on the Shared Savings Program I just wanted to give the workgroup members an opportunity to ask any questions.

Co-Chair Fields: Tricia, hey, this is Rob.

Thank you, Michelle, again for those comments. I just want to have a quick comment on the ACO

piece I think appropriately described some of the concerns that many folks have had with the eMeasures and the ECQMs in particular and the sunseting of the Web Interface.

Would add though -- I know it's been discussed in the past and because it wasn't there I would like to just have it on record to say it explicitly that there are other concerns besides data aggregation specifically on the issues of equity, which I know are really important to CMS.

And so I just think it's important to be explicit about it and put it out there and again have it on record that there is a significant concern among constituents in the ACO Program that reporting on all payer data and particular for folks like FOHCs or those that take care of a disproportionately disadvantaged and by definition difficult population not because of anything the patients have done, but just because the system makes it more difficult to close quality gaps, things like that, that it is an unintended penalty honestly for those groups to have payment mechanisms tied to quality for patients that just have trouble with access for example on cancer screenings and things like that.

So just wanted to highlight that and appreciate the presentation.

Dr. Schreiber: Thanks, Rob. And I will -- I know we have representation from the ACOs today, but I'll make sure that we carry that back. We recognize those concerns and are really trying very hard to address them through -- but as you'll see, we address them through rule-writing. But thank you so much for your comments.

Member Seidenwurm: I was wondering if you might say a word about direct contracting and where you see that going and what our role might be in performance measures for a program like that.

Dr. Schreiber: I may have to ask the folks from the

ACO to comment. And I think they're up next, so if you wouldn't mind maybe reserving your question for them.

Tricia, they're up next, aren't they?

Ms. Elliott: Yes, they are.

Dr. Schreiber: Okay. Well, if you can hold your thought and we'll let them address that one.

Ms. Elliott: Okay.

Discussion on Shared Savings Program

Ms. Slaughter: Hi, this is Sandra Slaughter from the Shared Savings Program, and I would have to reach out to my colleagues from CMMI to get some information on direct contracting. Would be happy to do that and be able to speak to that at a later date.

Member Seidenwurm: Thank you.

Dr. Schreiber: You will all recognize that CMS is the Centers -- and by -- and I emphasize plural, Centers, and that these programs do sit in different centers. So you have CCSQ, which is the Center for Clinical Standards and Quality. You have the Center for Medicare, which has that Shared Savings Program, MSSP. And some of the programs that I know many of you participate in are the CMMI, the Medicare and Medicaid Innovation Programs. And I think direct contracting sits there.

If in the future it would help to have all of us represented, I think we can have those conversations with NQF. In general those -- the CMMI measures don't come to the Measure Applications Partnership for review first. But we are truly happy to try and answer questions about these programs because you are considering the measures that are going to go into them.

Ms. Elliott: Excellent. Thank you, Michelle. That was

-- the additional information was very helpful.

I think at this point -- I don't see any other hands raised, so we'll move forward in the presentation. We're now going to shift gears into a presentation by Sandra Slaughter, who you just heard speak. And she's from the Division of Program Alignment and Communications.

So, Sandra, we'll turn things over to you. And we'll be advancing the slides for you, so just let us know when you're ready for the next slide.

Ms. Slaughter: Thank you, Tricia. And thank you for the invitation to share information about the Shared Savings Program.

Next slide, please? So today's presentation will provide a Shared Savings Program overview. I'll also discuss the Shared Savings Program alignment with the APM Performance Pathway, or APP. We'll also review the APP quality reporting options for the 2021 performance year and the reporting requirements and performance standard for the 2022 and subsequent performance years. And this slide deck also provides some details about the APP measure set for 2022 and subsequent performance years.

Next slide, please? So the Medicare Shared Savings Program is mandated by Section 3022 of the Affordable Care Act, and accountable care organizations create incentives for health care providers to work together voluntarily to coordinate care and improve quality for their patient population. So annually we assess performance on quality and financial performance, and this helps to determine shared savings or shared losses.

Next slide, please? So the quality measurement approach in the Shared Savings Program is intended to improve individual health and the health of populations, address key quality aims such as prevention, care of chronic illness, high prevalence

conditions, safety, patient and caregiver engagement, and care coordination, and align with the Quality Payment Program. So new for performance year 2021, ACOs will report via the APM Performance Pathway, or APP.

Next slide, please? So on this slide we show APP reporting for individuals, groups, and APM entities, but we will focus on ACOs. And there are two options for quality reporting. One is to report the eQMs or MIPS CQMs; which are three measures, the CAHPS for MIPS survey, and CMS calculates two administrative claims measures.

Michelle spoke a little bit to option 2 earlier. Option 2 involves reporting 10 measures via the CMS Web Interface and then reporting the CAHPS for MIPS survey measures. And CMS calculates two measures using administrative claims. And as mentioned earlier we have extended the Web Interface reporting option to allow time to be able to fully report the eQMs and MIPS CQMs.

Next slide, please? So this slide shows the reporting option for Option 1 and the measures that ACOs can report via the CQM -- eQMs or MIPS CQMs: the hemoglobin A1c poor control measure, preventive care and screening for depression and follow-up plan, and controlling high blood pressure. And again the CAHPS for MIPS survey. The two administrative claims measures for 2021 are the hospital-wide, 30-day, all-cause unplanned readmission for MIPS-eligible clinician groups and the risk standardized all-cause unplanned admissions for multiple chronic conditions for ACOs.

So the next slide shows Option 2. And again this option allows ACOs to report the 10 CMS Web Interface measures. Six of the measures are displayed on this slide.

Next slide, please? So this is Option 2 continued. The remaining four CMS Web Interface measures are displayed on this slide as well as the CAHPS for

MIPS survey and the two administrative claims measures.

So next slide, please? Thank you.

So this slide describes the Shared Savings Program quality reporting requirements that we finalized for performance year 2022 and subsequent performance years. We finalized the proposed changes to the quality reporting requirements with some modifications. So first we finalized a longer transition period to all pay or quality measure reporting by extending the CMS Web Interface for performance years 2022, 2023, and 2024 for Shared Savings Program ACOs.

Specifically for performance years 2022 through 2024 in order to meet the quality reporting requirements under the Shared Savings Program an ACO must either report the 10 CMS Web Interface measures, which are listed on the slide, or the 3 eQMs/MIPS CQMs also listed on the slide, and ACO must administer the CAHPS for survey. And again CMS will calculate the two measures using administrative claims data. And based on the ACO's chosen reporting options, either the eQMs or the Web Interface measures, ACOs will be scored on six measures or 10 measures.

So for performance year 2025 and subsequent performance years, which is the second half of the slide, an ACO must report the three eQM/MIPS CQMs and administer CAHPS for MIPS survey. CMS will calculate two measures using administrative claims data. And all six measures will be included in calculating the ACO's question performance score.

So next slide, please? So on this slide we described the Shared Savings Program quality performance standard policies that we finalized for performance year 2022 and subsequent performance years. So the quality performance standard is the minimum performance level ACOs must achieve in order to be eligible to share in any savings earned, avoid

maximum shared losses under certain payments tracks, and avoid quality-related compliance actions.

So we finalized the proposed changes to the quality performance standard with modifications. And for performance years 2022 and 2023 an ACO will meet the performance -- the quality performance standard if it achieves a performance score that is equivalent to or higher than the 30th percentile across all MIPS quality performance category scores.

And this excludes entities or providers that are eligible for facility-based scoring or if the ACO reports the three eQMs/MIPS CQMs, meeting the data completeness and case minimum requirements for all three measures, and achieves a quality performance score equivalent to or higher than the 10th percentile performance benchmarks on at least one of the four outcome measures in the APP measure set and a quality performance score equivalent to or higher than the 30th percentile of the performance benchmarks on at least one of the five remaining measures in the APP measure set.

An ACO won't meet the quality performance standard if the ACO doesn't report any of the 10 Web Interface measures or any of the three eQCM/MIPS CQMs and doesn't administer CAHPS for MIPS survey.

For performance year 2024 and subsequent performance years an ACO will meet the quality performance standard if it achieves a score that is equivalent or higher than the 40th percentile across all MIPS quality performance category scores. And again, an ACO will not meet the quality performance standard if the ACO does not report any of the 10 CMS Web Interface measures while they're available or the three eQCM/MIPS CQMs and doesn't administer a CAHPS survey.

So the next two slides include tables that identify

the APP measure set for performance year 2022 and subsequent performance years. This table includes details about the number, the measure number, collection type. And as previously mentioned, ACOs have the option to report via the CMS Web Interface for 2022, 2023, and 2024 performance years only.

So next slide, please? This slide is a continuation that was the remaining measures. Thank you.

So, Tricia, I'll turn it back over to you unless there are any comments or questions.

Ms. Elliott: Great. Thank you so much, Sandra.

So we'll pause here for a moment if there's any questions that folks would like to address to Sandra.

Co-Chair Fields: Tricia, I just have a comment and a question I guess, if that's okay. This is Rob.

Thank you so much for the time and explanation of the program. I'm curious. So as I mentioned before I've been on the committee at least four years, maybe five actually this year, and I don't recall a recent time where there hasn't been a measure to discuss for any of these programs. And so I'm a little curious as to how that came about, I mean in terms of not having any measures to discuss with MSSP today and the MAP. I just don't recall that happening before.

Ms. Slaughter: Well, we aligned with the APM Performance Pathway and we were also looking at streamlining measures. So other than those two factors that have gone into our proposals for 2021 and subsequent performance years, I don't have any further comment on that.

Dr. Schreiber: Rob, it's Michelle. I think what it is is that the ACO Program is really trying to align around this small group of measures that they have already proposed. And you're right, they didn't have any new measures that they wanted to bring

forward at this time. Obviously that may be different in the future.

Co-Chair Fields: Sure. Just for a suggestion -- I know later in the agenda we're going to be talking about the social determinants measures. I would suggest that those are actually excellent ACO measures. At a population level actually it fits quite nicely with the program. Just to put it out there as - I think that my guess is that they're probably out there. Just in terms of aligning them to the right context I think is probably more the issue, because I would be shocked if there aren't appropriate measures out there to consider.

Dr. Schreiber: And you're right. Certainly in the CMMI model some of the social determinants out there are now starting to -- they're starting to look at measuring those. But we'll take this back for the SSP program, because you are right about them being very good population measures.

Co-Chair Fields: Yes. Thank you. Appreciate that, Michelle.

And then very quickly just for -- I think for folks to know, because there are other interested stakeholders I think on this committee and on the call, that the 40th percentile in slide 36 that will occur from 2024 forward -- the 40th percentile in 2019 was actually almost 96 out of 100 points. It's exceedingly high. So 20 percent of the ACOs would not qualify, would not meet the level of performance despite having a quality score of almost 96 out of 100, which is -- seems a little high from my perspective from an achievement level.

Like I get the percentile piece, but I'm not sure as designed that it needs to be intent, right? If someone is performing at 96 out of 100 points, it feels like that that's pretty good. It feels a little bit like splitting hairs at that point with pretty major financial ramifications of that decision. So just again wanted that on record as well.

Dr. Schreiber: Yes, thank you. And by the way, thank you for your comments. As I'm thinking about the conversation that we're having I think next year maybe in the orientation for the MAPs we can really spend more dedicated time going through the programs because this gets, as you're already pointing out, complicated. And how do they relate? And what measures go in which program? And where do they move around? Because I think that as this is the committee to weigh in on these measures it does help to understand the programs. And it's complex.

Co-Chair Fields: Yes. Thank you, Michelle.

Dr. Schreiber: So I will take that.

And, Tricia, maybe you can flag that. We'll take it as a to-do for the future.

Ms. Elliott: Got it. We have a couple -- or at least one hand raised now.

Lisa McGiffert, did you have a question?

Member McGiffert: Yes, thanks. I am just asking for clarification on both of these programs: the MIPS and the ACO Programs. I searched the web to try to find any kind of scores that are available to the public and I couldn't find it. So I guess my question is is there anything reported to the public about the results so far of either of these programs that shows how ACOs and clinician groups are performing?

Dr. Schreiber: Lisa, the answer to that is yes. And maybe somebody in the MIPS Team will actually put in the chat the web links to where we put out the data, certainly around MIPS.

Also I would call your attention to Physician Compare where a lot of these measures actually do get publicly reported as part of Physician Compare.

Member McGiffert: Great. I appreciate that. I'm a pretty savvy searcher for --

Dr. Schreiber: Yes, you are.

Member McGiffert: -- measures, and I am going to tell you there is nothing that comes up with MIPS, Medicare scores, ACO, nothing except the background details on what the measures have -- what measures have to be reported. So I'd appreciate that link. Thank you.

Ms. Slaughter: Hi, this is Sandra. I can put some links in the chat also. We have reported all of the measures on standards at cms.gov. I'll get the correct link for the Shared Savings Program since it began. And as Michelle said, a subset of measures is reported on Physician Compare, Care Compare for the Shared Savings Program.

Co-Chair Fields: And I'm sorry, this is --

Member McGiffert: One more question. I'm sorry. Is it -- are you sending me to a place where I can download the data, or is it actually something public-facing?

Ms. Slaughter: it is public-facing and I can put the links in the chat.

Member McGiffert: Great. Thank you.

Co-Chair Fields: Lisa, hey, this is Rob Fields. I happen to be the board chair of NAACOS. You can find all of the ACO data from the beginning of the MSSP program publicly. There are PUF files available for every single ACO, every single performance measure since the beginning of the program. The PUF files are available.

Ms. Elliott: Thanks, Rob.

And there's some additional information in the chat. Jennifer Gasperini added there's no public information on aggregate MIPS quality performance category scores and the PUF includes MSSP quality scores, but not as compared to MIPS performance, which would be helpful.

Thank you, Jennifer.

Helen Burstin, you have your hand raised?

Member Burstin: Yes, I just wanted to make a comment. Really Rob was saying much of what I was planning to say, but I do think given how important this program is, even if there aren't new measures, the ability for this group to perhaps give feedback on the measurement approach; I know that was presented to us here, would be useful.

And also with reference to the last comment, since so many of these measures are used across multiple programs, it would be very helpful to see the rates or performance across the program as to better understand for example how the measures performed differently at the individual clinician level versus the ACO level. So I guess more of a plea, Michelle, to think of this group not just about measures, but about measurement and equity and sort of those broader issues. Otherwise, we lose the opportunity to really engage in such an important program. Thank you.

Ms. Elliott: Excellent. Any other questions or comments?

I do not see any hands raised or any additional chat, so we'll continue to monitor that. So I think we'll continue to move on.

Overview of Pre-rulemaking Approach

Next slide, please? Okay. At this point I'm going to hand things over to Ivory Harding, who will be covering overview of the pre-rulemaking approach as well as the MAP voting process.

Ivory?

Ms. Harding: Thank you, Tricia.

Next slide, please? And now we will go over the preliminary analyses process.

Next slide, please? So for the preliminary analysis of measures under consideration NQF conducted a PA for each measure under consideration. The goal was to create a succinct profile of each measure to facilitate the workgroup discussions and to be used as a starting point. NQF uses a PA algorithm that will be discussed in the following slides.

Next slide, please? So here we have the MAP preliminary analysis algorithm. This was generated from the MAP selection criteria to evaluate each measure. This algorithm was approved by the MAP Coordinating Committee.

And so now we would like to orient you with the assessments, the definitions, and the outcomes. So for our first assessment we would like to focus on if the measure addresses a critical quality objective that is not adequately addressed by the measure in the program set. If it is, the measure proceeds and the review can continue. If it does not, the measure will receive a do not support. And it is important that the MAP will provide a rationale for the decision to not support, to make suggestions on how to improve the measure for a potential future support categorization.

For the second assessment the focus is on the measure to be evidence-based and either be strongly linked to outcomes or an outcome measure. If it does, the review can continue. If it does not, the measure will receive a do not support and MAP will provide a rationale for the decision to not support or make suggestions on how to improve the measure for a potential future support categorization.

In the third assessment we focus on the measure addressing a quality challenge. If it does, the review will continue. If it does not, the measure will receive a do not support and MAP will provide a rationale for the decision to not support and make suggestions on how to improve the measure for a potential

future support categorization.

Next slide, please? In the fourth assessment our focus is on the measure contributing to the efficient use of measurement resources and/or supporting alignment of measures across a program. If it does, the review continues. If it does not, the highest rating that the measure receives is do not support with potential for mitigation and MAP will provide a rationale for the decision to not support or make suggestions on how to improve the measure for a potential future support categorization.

In the fifth assessment the focus is if the measure can be feasibly reported. If it can, the review continues. If it does not, the highest rating can be do not support with potential for mitigation. MAP also provides a rationale for the decision to not support or make suggestions on how to improve the measure for a potential future support categorization.

Next slide, please? For assessment 6 the focus is on the measure being applicable to and appropriately tested for the program's intended care settings, levels of analysis, and populations. If it is, the measure can be supported or conditionally supported. If it does not, the highest rating can be conditional support. MAP may provide a rationale for the decision to not support or make suggestions on how to improve the measure for a potential future support categorization.

For assessment No. 7 the focus is if a measure is in current use, no negative unintended consequences to the patient have been identified. If no implementation issues have been identified, the measure can be supported or conditionally supported. If implementation issues are identified, the highest rating can be conditional support and MAP can also choose to not support the measure with or without potential for mitigation. MAP may provide a rationale for the decision to not support or

make suggestions on how to improve measures for potential future support categorization.

Next slide, please? We will now cover the MAP voting decision categories.

Next slide? So MAP workgroups must reach a decision for each measure. And we will now begin with the decision category, the definitions, and the evaluation criteria.

So the first decision category is support for rulemaking. The MAP supports implementation with the measure as specified. The measure is fully developed and tested in the setting where it will be applied, and meets assessments 1 through 6 of the MAP preliminary analysis algorithm. If the measure is in current use, it also meets assessment 7.

For the decision of conditional support for rulemaking MAP supports implementation of the measure as specified, but has identified certain conditions or modifications that would ideally be addressed prior to implementation. The measure meets assessments 1 through 3, but may need modifications. A designation of this decision category assumes at least one assessment 4 through 7 is not met. Ideally the modifications suggested by MAP would be made before the measure is proposed for use.

For do not support for rulemaking with potential for mitigation MAP does not support implementation of the measure as specified. MAP agrees with the importance of the measure and has suggested material changes to the measure specifications. The measure meets assessments 1 through 3, but cannot be supported currently as specified. A designation of this decision category assumes at least one assessment 4 through 7 is not met.

And lastly do not support for rulemaking. MAP does not support the measure. The measure under consideration does not meet one or more of

assessment 1 through 3.

Next slide, please? And now we will go over the MAP voting process.

Next slide? So the key voting principles. Quorum is defined as 66 percent of the voting members of the committee present virtually for live voting to take place. Quorum must be established prior to voting. The process to establish quorum is constituted of (1) taking roll call, and (2) determining if quorum is present. At this time only if a member of the committee questions the presence of a quorum is it necessary to reassess the presence of quorum.

If quorum is not established during the meeting, MAP will vote via electronic ballot after the meeting.

MAP has established a consensus threshold of greater than or equal to 60 percent of voting participants voting positively and a minimum of 60 percent of the quorum figure voting positively. Abstentions do not count in the denominator. And every measure under consideration will receive a decision.

Next slide, please? So now we will go over the voting procedure. For step 1 staff will review the preliminary analysis for each measure under consideration using the MAP selection criteria and programmatic objectives. Additionally, after a live in-meeting public commenting opportunity for all measures in the program staff will also review input from the MAP Advisory Groups and from public comments submitted to NQF during last week's online public commenting period.

For step 2 the co-chairs will ask for clarifying questions only from the workgroup including lead discussants who may have clarifying questions. Workgroup members and lead discussants shall withhold other comments at this time. Questions will be answered one at a time and measure developers will respond to the clarifying questions

on the specifications of the measure. NQF staff will respond to clarifying questions on the preliminary analysis.

Next slide, please? For step 3 voting on acceptance of the preliminary analysis decision after clarifying questions have been resolved, the co-chairs will open for a vote on accepting the preliminary analysis assessment. The vote will be framed as a yes or no vote to accept the result. If greater than or equal to 60 percent of the workgroup members vote to accept the preliminary analysis assessment, then the preliminary analysis assessment will become the workgroup recommendation.

This will be the end of the discussion of the measure and the workgroup will move on to the next measure. However, if less than 60 percent of the workgroup votes to accept the preliminary analysis assessment, further discussion will open on the measure.

Next slide, please? For step 4, discussion and voting on the MUC. If the workgroup did not vote to uphold the staff recommendation on the measure in step 3, co-chairs will open discussion and voting on the MUC. The co-chairs will first ask lead discussants to review and present their findings. The co-chairs will then open for discussion among the workgroup and workgroup members should participate in the discussion to make their opinions known. However, one should refrain from repeating points already presented by others in the interest of time.

After the discussion the co-chairs will open them up for a vote and the co-chairs will summarize major themes of the workgroup's discussion. The co-chairs will determine what decision category will be put to a vote first based on the potential consensus emerging from the discussions. If the co-chairs do not feel there is a consensus position to use to begin voting, the workgroup will take a vote on each potential decision category one at a time. The first

vote will be on support, then conditional support, then do not support with potential for mitigation, and then finally do not support.

Next slide, please? Step 5, tallying the votes. If a decision category put forward by the co-chairs receives greater than or equal to 60 percent of the votes, the motion will pass and the measure will receive that decision. If no decision category achieves greater than 60 percent to overturn the preliminary analysis, the preliminary analysis decision will stand. This will be marked by staff and noted for the Coordinating Committee's consideration.

At this time we would like to use our test question to make sure everyone has access to Poll Everywhere and is able to participate.

So for our test question please answer what region of the U.S. do you call home? The Northeast, the Midwest, the South, or the West?

Going to give everyone a few more seconds.

The test question is now closed.

Ms. Elliott: If we could hold on one second, Ivory. If we could keep it open. We are expecting at least 16 or 17, so we want to make sure that everybody is able to connect to Poll Everywhere and submit a vote. So this is for the workgroup committee members. And the link can be found in the email that was sent to the workgroup members. So we're at 16. We can --

Member Nichols: I have a question.

Ms. Elliott: Sure, go ahead.

Member Nichols: When was the email sent?

Ms. Elliott: The email was sent this morning to the workgroup members.

Member Nichols: Okay. I have -- all your emails get caught in my spam filter and they take about 12 hours to get to me, so I don't have the link.

Ms. Elliott: Okay. Let's see. Team, can we send the link in the private chat to Donald, please?

Member Fields: Once you vote does it confirm your vote or does it just sit there?

Ms. Elliott: It kind of sits there. I think it turns blue.

Member Fields: Okay. Yes, that's what it did. It just didn't confirm.

Ms. Elliott: Okay. Yes, it doesn't confirm.

Member Fields: Thank you.

Ms. Elliott: Yes. So we're just going to pause here for another minute to allow submission of a link to one of the workgroup members.

Ms. Harding: For future reference before the voting is closed if you made a mistake with a selection and would like to change your choice, just simply select the answer you prefer and it will update for you.

Ms. Elliott: Okay. Donald, the link has been sent through the private chat. Do you see it?

Member Nichols: Yes, I have it. I'm logging in now.

Ms. Elliott: Perfect.

Oh, somebody practiced changing.

Member Nichols: Now I lost it. I don't know what happened to it.

Ms. Elliott: We appreciate everybody's patience. We want to make sure that everybody is -- has the right connections to vote, and this is the best time to do it before we get into the actual votes. So thank you, everyone.

Member Nichols: Yes, thank you. I was able to vote.

Ms. Elliott: Okay. Excellent. We're at 17. Perfect. Thank you for connecting so quickly.

Okay. Ivory, I'll turn it back to you.

Ms. Harding: Okay. Thank you.

As you all can see, we will show the responses of the voting at the end and announce whether the recommendation will stand or if we need to proceed to vote on a new decision.

Ms. Elliott: Excellent. Thank you.

Ms. Harding: And the next slide, please? So now I will turn it over to Chelsea to review measures under consideration by our MAP Advisory Groups.

Ms. Lynch: Thank you so much, Ivory. I just want to make sure you can hear me okay.

Ms. Elliott: You're a little faint, Chelsea.

Ms. Lynch: Is that a little bit better?

Ms. Elliott: Yes, that's much better. Thank you.

Ms. Lynch: Okay. Perfect. No problem. Thank you.

MAP Rural Health Advisory Group and MAP Health Equity Advisory Group

And the MAP Rural Health and MAP Health Equity Advisory Groups both met last week and I'm happy to share how they provide their feedback on measures under consideration for the federal programs under the Clinician Workgroup.

Next slide? The MAP Rural Health Advisory Group is charged with providing a rural perspective on the measures under consideration to the setting-specific workgroups and to help address priority rural health issues like the challenge of low case-volumes.

Next slide? The Rural Health Advisory Group reviewed all the measures under consideration and provided feedback to all three setting-specific workgroups on the relative priority or utility of the measures in terms of access, cost, or quality issues, any data collection or reporting challenges, methodological problems when calculating the measures for small facilities, any potential unintended consequences of the measure being included, and measurement gap areas that are relevant to rural residents or providers.

In addition to this discussion the advisory group was also polled to provide a quantitative assessment of if the measure is suitable for use with rural providers within the program of interest. This polling question is a Likert scale where one is least suitable to five being most suitable.

Next slide? The MAP Health Equity Advisory Group is new this cycle. The charge of this advisory group is to provide input on the measures under consideration with a lens to measurement issues impacting health disparities and critical access hospitals. In particular they looked at how to reduce health disparities that are closely linked with social, economic, or environmental disadvantages.

Next slide? Similar to the Rural Health Advisory Group, the MAP Health Equity Advisory Group reviewed all of the measures under consideration and provided feedback to all three setting-specific workgroups. This advisory group discussed relative priority in terms of advancing health equity for all. So depending on which measure they discussed they considered things such as if the measure provides opportunities to achieve optimal health, address social determinants of health, or to reduce disparities related to social, economic, or environmental disadvantages.

Additionally, they also considered data collection and/or reporting challenges regarding health

disparities and methodological problems of calculating the measures when adjusting for health disparities. They didn't have all the data that they wanted to consider for this piece of the evaluation, so this discussion focused on what aspects and which data would be important to have access to. For example, which populations would be important to include to evaluate and adjust for disparities adequately.

They also considered any potential unintended consequences related to health disparities if the measure is included. So would including this measure in the program make disparities worse? And finally, they discussed any additional measurement gap areas relevant to health disparities and critical access hospitals.

In addition to this discussion the advisory group was also polled to provide a quantitative assessment of the potential impact on health disparities if the measure is included within the program of interest. This polling question is also Likert scaled where one is having a negative impact by increasing disparities to five having a positive impact by decreasing disparities.

Next slide? So the input from both the MAP Rural Health Advisory Group and MAP Health Equity Advisory Group is provided to the setting-specific workgroups in a couple of ways. First a summary of the discussions during their review meeting and the results of the polling question were incorporated into each MUC's preliminary analysis which were shared with each advisory group in advance of their review meetings this week.

Second, the advisory groups' discussion for each measure will also be summarized during the meeting today.

And I am happy to turn it back over to you, Tricia.

Ms. Elliott: Great. Thank you so much, Chelsea, for

covering that important information.

And just to reinforce, as Chelsea mentioned, as we present each of the measures under consideration we'll be incorporating the feedback from both the Rural Health and Health Equity Advisory Groups for each individual measure.

So I'm happy to say at this point we're running very much ahead of schedule. And we are actually going to break a little bit early for lunch and we will reconvene at 12:00 p.m. I just want to double check with the co-chairs. I know this may create some challenges for folks because that will put us almost an hour ahead of schedule for our afternoon session.

Diane and Rob, just wanted to connect with you on the timing.

Co-Chair Padden: Works for me.

Ms. Elliott: Okay.

Co-Chair Fields: Yes, I still think it's the right thing to do. I suspect that when we get into the measures, as always happens every year, we'll use that time quickly.

Ms. Elliott: Okay. So at this point it's 11:26 a.m., Eastern Time. We will break until 12:00 p.m., Eastern Time, and get started on the afternoon agenda at 12:00 p.m.

(Whereupon, the above-entitled matter went off the record at 11:26 a.m. and resumed at 12:03 p.m.)

Ms. Elliott: Okay. And we'll start by advancing the slides, please. Okay.

Next slide, please.

We're going to start with a review of programs, and the first one is Part C and D Star Ratings.

Next slide.

Medicare Part C and D Star Ratings

So the Part C and D Star Ratings Program type is Quality Payment Program and public reporting. The incentive structure is Medicare Advantage, is the public reporting and quality bonus payments, QBP. Standalone prescription drug plans is public reporting.

The program goals include providing information about plan quality and performance indicators to beneficiaries to help them make informed plan choices and incentivize high-performing plans, as a component of Part C.

The April 2018 final rule initially codified the methodology for Part C and D Star Ratings.

Next slide, please.

So this slide shares the 2022 Star Ratings Measure List divided by the meaningful measure areas. So you can see the left-hand column is healthcare priority, the meaningful measure title, and then, the number of measures within each of those. There are 38 unique measures, but 40 measures are represented here because a couple of measures are in multiple areas.

Next slide, please.

Summary of the changes for 2022 Part C and D Star Ratings.

CMS has resumed the use of the most recent data for HEDIS and CAHPS measures.

We specified the Medicare Plan Finder Price Accuracy Measure moved into 2022 Star Ratings as a new measure.

The mean resampling added to the hierarchical

clustering methodology that is used to set cut points for non-CAHPS measures to minimize the influence of outliers.

For the Part C measure, care of older adults, Functional Status Assessment, temporarily moved to the display for the 2022 and 2023 Star Ratings because NCQA made substantive changes to the measure specification.

The following measures were retired from Part C and D ratings: the Adult BMI Assessment, Appeals Auto-Forward, and Appeals Upheld.

Next slide.

The summary of the changes for Part C and D Star Ratings due to the COVID-19 public health emergency:

For the 2022 Star Ratings only, expanded the existing improvement measure hold harmless provision to all contracts at the overall and summary rating levels.

For the 2022 Star Ratings only, modified the disaster policy to remove application of the 60 percent rule and avoid the exclusion of contracts with 60 percent or more of their enrollees living in FEMA-designated individual assistance areas from calculation of the non-CAHPS measure-level cut points in calculation of the reward factor.

For the 2022 and 2023 Star Ratings, two Part C measures -- Improving or Maintaining Physical Health and Improving or Maintaining Mental Health -- are moved to the display page due to validity concerns related to the COVID-19 public health emergency.

Next slide, please.

Part C and D, the CMS high priority for future

measure consideration:

The Medicare population includes a large number of individuals and older adults with high-risk multiple chronic conditions who often receive care from multiple providers and settings, and as a result, are more likely to experience fragmented care and adverse healthcare outcomes.

Equity of care.

Functional outcomes.

Management of chronic conditions.

And prevention and treatment of opioid use disorders.

Next slide, please.

So before we begin the review of the individual measures, there's three measures in this section. It's MUC List 053, which is Concurrent Use of Opioids and Benzodiazepines; Polypharmacy: Use of Multiple Anticholinergic Medications -- sorry about that -- in Older Adults, and Polypharmacy: Use of Multiple Central Nervous System Active Medications in Older Adults. So it's MUC-053, MUC-056, and MUC-066.

Before we introduce each of these measures individually, we're going to open it up for public comment.

For public comment, you can unmute your line, raise your hand, or place an item in the chat.

Okay, I'll pause for a few more seconds to see if there's any public comment that would like to be raised on any of these three measures that I mentioned.

Okay. We'll go ahead and move to the next slide.

Was there a question?

There was a question about the preliminary analyses for public access. Those are on the NQF website, and the link has been provided in the chat.

So the first measure that we'll be discussing in this section is MUC2021-053: Concurrent Use of Opioids and Benzodiazepines.

And I might have jumped ahead. Actually, Rob, are you okay with me moving? I was supposed to touch base with you, since this is your section. Are you okay with me introducing the measure?

Co-Chair Fields: Yes. I'll have a couple of just opening comments on procedural after you're done with the preliminary analysis, but that would be great. Yes, go ahead.

Ms. Elliott: Okay. Thanks, Rob. Sorry about that. I got a little ahead of myself there.

So, once again, MUC-053, Concurrent Use of Opioids and Benzodiazepines. Description of measure: the percentage of Medicare Part D beneficiaries 18 years or older with concurrent use of prescription opioids and prescription benzodiazepines during the measurement period. The level of analysis is at the health plan level. The NQF recommendation is support for rulemaking. And we have our lead discussants listed there.

The measure falls within the chronic conditions domain. The measure was endorsed in 2018 and it has maintained endorsement.

Let's see. I just flipped forward in my notes.

The measure was discussed at the Rural Health and Health Equity Advisory Groups. The feedback or input from that Rural Health Advisory Group relative to the priority and utility, the group considered the measure to be identified as high need in the rural communities. There was no concerns for data collection, as this measure was considered to have a

low burden for data collection. There was no issues identified for calculation of the measure.

There was some discussion about unintended consequences; possible unintended consequences identified for patient populations that are excluded; concerns raised about populations that may need high doses of these medications, and concerns regarding the tapering of drugs when deprescribing.

There was a poll conducted with the group, and there is range of scores from 1 to 5, where higher is more relevant to rural care. And the average vote was 4.4.

For the MAP Health Equity Advisory Group, the measures important to measure in terms of use of opioids and benzodiazepines as it relates to minorities and underserved populations. No data collection issues identified. Calculation issues, it was noted that there is a lack of stratification identified as a priority for the measure. No other issues identified for calculation, and no unintended consequences identified.

For the polling for the Health Equity, it is a range of 1 to 5, where a higher number has greater potential for positive impact on health equity. And this measure scored an average of 3.2.

There were six public comments for this measure. Two measures were in support, that there is a measure gap and low burden for data collection. There were four comments for do not support and offered measure specification validity as a potential issue; unintended consequences of discontinuation of medications, and substantial risk for patients who need these medications.

Rob, I'll turn it back to you.

Co-Chair Fields: Great. Thank you.

Just in terms of procedure, we have, as always, a

fair number of measures, and we anticipate some meaty discussion, especially towards the end of the day. So, I'm literally pleading with folks that, if you want to validate someone else's comment or agree with it, rather than taking time out in discussion or clarifying questions, to just simply repeat what was just said, feel free to validate on the chat. I think that might be a better use of chat, so that we can move along the agenda.

And then, just as a reminder, even though most folks here have done this multiple times before, this is a two-part voting process. So, we'll have clarifying questions first and try to deal with any clarifying questions. So, things about the text of the measures, anything in the preliminary analysis that isn't quite clear or understood. But if you're trying to argue a point or things of that nature, I would really like to defer that to the real discussion portion.

So, remember, we'll ask clarifying questions; vote to agree on the preliminary recommendation or not, and then, based on that vote, then have further discussion. So, just those can be a gray line distinguishing clarifying versus more opinion types of debate-type questions. But we'd like to differentiate those two, so we can keep us moving, if that's okay.

So, I think if there are no other questions on procedure, we will, then, ask for any clarifying questions here officially.

Go ahead.

Member Nguyen Howell: Oh, hey, Rob, it's Amy for you.

Co-Chair Fields: Hey, go ahead.

Member Nguyen Howell: I wanted to, as part of my discussion, I wanted to ask the clarifying question around unintended consequences, as I was reading

through the prep materials. The measure is not intended for clinical decision-making. And I don't know if, because I believe it's at the clinician level, if folks would know that right from the start. So, I don't know if we have the developer on or anyone who could kind of answer about the unintended consequences, unintentional.

MR. SHIRLEY: This is Ben Shirley with PQA. I'm happy to jump in quickly, I think if that's all right with you.

Co-Chair Fields: Yes, please go ahead.

MR. SHIRLEY: So, I think one key point there is that this is not a clinician-level measure. So, this is being evaluated --

Member Nguyen Howell: Oh, it's not? Okay.

MR. SHIRLEY: Correct, yes. So, the Part C and D Star Ratings are health plan level. So, this is going to be exactly as you said. It's a population-level, health plan-level measure that is not intended to guide those individual decision-making processes for individual clinicians.

Member Parrott: But, Ben, would that apply --

Member Nguyen Howell: Great. And then --

Member Parrott: Oh, go ahead.

Member Nguyen Howell: Oh, no, go ahead. Go ahead.

Member Parrott: I was just going to say, would that imply, then, that maybe we would expect a basal level of concurrent use? I'm not sure what that level is, but, you know, the idea is that, hopefully, everybody achieves that basal level, because maybe some people at a clinical level do need both. We just want to prevent excessive use. So, is that kind of the spirit? I'm just trying to check in with that.

MR. SHIRLEY: Yes, you pretty much hit the nail on the head. So, with this measure, right, and a lot of medication safety-type measures, we're not necessarily, or we're not looking for a rate of zero percent, because, we you just mentioned, there are going to be rare instances where the balance of risks and benefits associated with concurrent prescribing of these medications is such that it's indicated. But we want to emphasize, you know, between the CDC Class A recommendation and the FDA black box. We know that that's going to be on the rare side. We know there's a lot of risk associated with these.

And exactly as you've said, Lou, there is some baseline amount of concurrent prescribing we would expect. When you look at the performance information included in the submission and in the PA packets, we're seeing average rates of around 20 percent, with some plans going up to 40, 50 percent of individuals on opioids also on benzodiazepines, which we think is certainly representative of a serious concern and room for improvement. So, I think you laid it out very well.

Co-Chair Fields: If we can ask, there are a couple of questions -- and I'm just going to in the spirit of moving us along here -- about the denominator. So, for this part of the discussion, has there been any response to the denominator concerns raised in the preliminary analysis? And if not, if we don't have any answer to that, then defer further discussion on denominators on the discussion portion.

MR. SHIRLEY: Yes, I'm happy to just provide a response. I think that the concern about the denominators, it was raised in public comment by BCBS Massachusetts.

So, the purpose of creating a denominator of individuals who receive opioids, right, the denominator for this measure is individuals with two fails on unique dates of service, released 15-day

supply.

The goal is to ensure that the denominator is going to be composed of individuals who are at risk for the numerator event, which is concurrent use of opioids and benzodiazepines.

So, when you think about that, it's creating a much more targeted measure and denominator for plans to be able to use versus just the measure that says our denominator is the entire population, and the numerator is, then, going to be those with concurrent prescribing. That's going to be a much smaller rate and it's going to be harder to sort of hone in on those at risk.

So, I think I want to clarify that reducing opioid prescribing in general, which was mentioned in the BCBS MA comment, that would reduce the size of the denominator, but that doesn't actually inherently increase a measure rate. The rate would still be, again, just reflective of those individuals who are on opioids, and thus, are at risk of concurrent prescribing of benzodiazepines as well, who actually are seeing that concurrent prescribing.

So, the effects of general opioid deprescribing on the rate would actually depend on whether the patient who is no longer receiving opioids was also receiving benzodiazepines or not. Just reducing the denominator of a measure doesn't actually inherently change the rates. It will depend on whether or not that individual was numerator- or denominator-compliant to start with.

So, I'll just say that I think this is not an uncommon construction for these types of measures. I know other opioid measures used in Part D on the display page are actually harmonized with this specific denominator.

But just to be clear, the lower rate is a better rate. We are looking for a lower score on this measure, representing lower concurrent prescribing of opioids

and benzodiazepines.

Hopefully, that was able to clarify. Let me know if there's anything else I can provide.

Co-Chair Fields: From Helen or Wendy, does that help? Or any other clarifications on the denominator issue?

Member Burstin: Yes, this is Helen. Thanks for that. That's helpful, although I am still left with the basic question that, if you, in fact, shrink your denominator and you don't change your numerator, it does change the rate.

So, if your overall strategy is to decrease opioids, then, I am still left seeing the logic of the Blue Cross comment, unless you can assure me there's something in the measure calculation that we're missing.

MR. SHIRLEY: Again, I'm not sure how much more I can provide. I mean, individuals leaving the denominator would increase the measure rate if they were not also in the numerator. So, when you're deprescribing, there is a proportion of those you deprescribe that are less in the numerator. Then, it may affect the measure by driving it down to some extent.

I think that our concerns about this at the population health-plan-level are not too high. I think that this is also sort of a methodology that has been used in several measures in the Part D program, at least from a display perspective. And I don't think that we've seen concerns about this before in that setting. So, I think that that gives us some level of comfort.

Co-Chair Fields: I think, related, the comment I think deserves discussion in this part of the group and clarifying, because I think, Ben, you mentioned that the intent is not necessarily to go to zero because of the relatively or significantly uncommon

-- i.e., maybe rare -- instance where that's indicated.

But Koryn raises a good point -- and maybe this is a CMS question, actually -- in the way the measures are actually executed, like the way they're acted upon at the health plan level, it's usually, unless there's a benchmark target, which it doesn't sound like there is, then it would be either zero or it's fairly binary, in other words.

So, I'm trying to figure out how that actually gets executed. I think Koryn brings up a great point.

MR. SHIRLEY: Yes. So, to that point -- and I know the Part D team is on as well -- the Star Ratings for each of these measures actually has a whole methodology for how they approach what they call cut points (audio interference) --

Co-Chair Fields: Wait, Ben, we lost you. There we go. Sorry.

MR. SHIRLEY: Oh, sorry about that. Can you hear me?

Co-Chair Fields: We lost you right before cut points, I think is what you were about to say.

MR. SHIRLEY: Okay. Okay, yes. So, essentially, the Star Ratings Program -- and again, I'll let the Part D team jump in, if they want to, since they are the experts -- but they do have a scoring methodology that establishes cut points, which are, essentially, benchmarks for different Star Ratings, which are actually based on clusters of plan performance.

So, the CMS program is sort of creating those based off of the distribution of performance. So, I think that that actually makes a lot of sense because, when we think about there being some natural -- I think it was referred to as the basal rate of prescribing -- that would be reflected in the Star Ratings cut points.

But I'm going to pause before I get too far into the Part D methodology and let them just in, if they want to.

Member Parrott: Would that mean that what we're voting here, they about have to do with how to measure this, and the separate discussion about what success means, based on the cut points, and so forth?

MR. SHIRLEY: Correct.

Member Parrott: Okay.

MR. SHIRLEY: That's my understanding.

Co-Chair Fields: Anyone from Medicare care to comment?

Dr. Cho: Yes, this is Taemi from CMS Part D.

So, Ben is correct; we have cut points. They're not a predetermined threshold or predetermined set. They, basically, run the measure throughout the measurement year, and then, once we receive all the rates, then we have a contractor that does all this algorithm methodology to determine those cut points. And each cut point is very specific for each measure. So, there's no benchmark that we use.

Co-Chair Fields: Okay. It sounds like folks are going to have to make a decision, when they vote, in terms of -- Koryn, I see your additional comment in the chat -- but in terms of folks are going to have to decide in terms of their implications of the measure on the plans based on this. And it doesn't sound like the methodology in terms of determining the cut points are certainly there.

The issue of denominator I think deserves one more clarifying comment, because it looks like the denominator -- I think the concern about the rate in the chat, and as Helen commented as well, making potentially worse over time, would be true if the denominator were just those Medicare beneficiaries

on opioids. But, if I am reading this correctly, the denominator is all Medicare Part D beneficiaries 18 and older, and then, it's just the overall rate of concurrent use. So, as you reduce concurrent use, that rate should, actually, decrease, not increase. Do I have the numerators and denominators correct?

MR. SHIRLEY: So, the denominator is inclusive of individuals with two or more claims on different dates of service for opioids with at least 15 days' supply.

Co-Chair Fields: Aw, okay.

MR. SHIRLEY: With the idea being that you're working from a population at risk.

Co-Chair Fields: Yes, got you. Okay, got it.

MR. SHIRLEY: Sure.

Member Parrott: One other clarifying denominator question, and maybe it's just a caveat to understand for the measure. So, even the goal is to measure concurrent use of both drugs, you're starting with just one, opioids, and then, seeing, out of that, how many end up getting benzos as well. We're not measuring the reverse, correct?

So, you could imagine that there are people who may be on benzos to start, and then, they end up with an opioid prescription. They could, in the end, look like the same population, but they would not be captured here, technically, because we're starting the denominator with opioids. Is that accurate? I'm just trying to, again, get denominator clarification.

MR. SHIRLEY: Yes, so that is accurate. This was sort of developed as part of a suite of opioid measures. Therefore, the denominator is harmonized with those other opioid measures.

I think it's important to understand that, if

someone, even if we have the reverse denominator, essentially, if someone still hits the amount of concurrent use needed for the denominator, they would still be in the measure, right, because they would still have those opioid fills necessary to be in the denominator. So, from that perspective, it does work both ways, but you're correct that those individual fills on the denominator side for benzodiazepines are not included, and that was from a harmonization perspective.

Member Parrott: Thanks.

Co-Chair Fields: Ben, one more question on as the measure was being developed. Will Fleischman made a comment here in terms of using a two-claim criteria versus a days covered. I think there's a very good example that he puts in the chat about how you might miss folks that, potentially, you might argue are at higher risk with intermittent prescriptions as opposed to more consistent prescriptions. So, I wonder if you have any comment on the rationale behind that.

MR. SHIRLEY: Yes. So, I think that there's sort of two parts to this, right, though? The concurrent use requires both a number of claims and a number of days' supply cumulatively over the course of the year, right? You need two fills for each of the medications we're talking about, and they need to overlap for 30 or more cumulative days, based on the dates of service and days' supply on the prescription claims for those. And the reason for it requiring two claims, I think there is a great example of about one 30-day Rx for benzos, and how that could hit the denominator.

This really was sort of a consensus decision. POA follows a consensus-based measure development process that incorporates feedback from plans, as well as clinicians and all the different stakeholder groups.

But, really, there was concern about the

actionability of this measure from quality improvement and programmatic perspective, where, off of just one fill, the plan could now be in the numerator and there's no way to get out of it, right? So, with two fills, you're giving a chance for the plan to intervene, to communicate, to put an edit in place, or use whatever utilization review tools they have available to sort of try to make sure that this is a case where it's absolutely necessary, right? Or if it's not, to at least try to make everyone aware of that or provide education, et cetera. So, essentially, that's an actionability piece.

And then, the 30 days, again, was a consensus decision. Seven days was also considered. We did sensitivity analyses. We looked at various thresholds. Ultimately, 30 was something that the group and some external subject matter experts as well agreed represented sort of a high level of concurrent use and a high level of actionability. There was some concern, again, that just seven days might be very easy for a person for to sort of hit that and the plan not have a chance to intervene.

Hopefully, that's helpful.

Co-Chair Fields: I think that is.

So, I think, based on the comments in the chat, just procedurally, because, again, we'll have more time for discussion. So, the first vote is to whether or not we support the NQF recommendation for rulemaking. So, I think I'd like to move us there, anticipating -- well, we'll see. We'll see what the vote casts. But further discussion on any denominator issue, anything, we can have at this next section. But I think to be able to move us, I'd like to proceed with the initial vote on supporting the NQF recommendation or not. And then, if not, we move into further discussion.

MR. SHIRLEY: And can I make one last, quick, clarifying comment, Rob?

Co-Chair Fields: Please.

MR. SHIRLEY: Yes, I appreciate it.

I think, also, just from a contextual perspective, it's important to understand that this measure is not going to stand alone, and it's the only thing that Part D is doing about opioids, right? Part D has a robust monitoring system, the opioid monitoring system, and a combination of utilization reviews that plans are required to do, and tracking the safety reports, et cetera.

So, I just want to make sure that these sort of concerns I seem to be seeing, that overprescribing, we need a companion measure, Part D is spending a lot of time and effort tracking prescribing of these sorts of substances in the Part D program. And so, this is part of a larger suite of interventions that the program is using. It's one tool in the toolbox. So, I just want to make sure we have that context.

Co-Chair Fields: Yes.

MR. SHIRLEY: I'm sorry, go ahead.

Co-Chair Fields: Super helpful. Thank you.

Okay. All right. So, if the staff is ready, I'd like to have us move forward with that initial vote.

So, to be really clear for the group, especially for folks that may be new, we are simply voting as to whether or not we support the NQF recommendation that is currently support for rulemaking. If you are not supportive, you vote no, and then, we go to further discussion with the broader group. Everyone clear on that point? It's a two-part voting mechanism here.

All right. So, I will turn it over to the team.

Ms. Harding: Voting is now open for MUC2021-053: Concurrent Use of opioids and benzodiazepines for the Medicare Part C and D Star Ratings Program.

Do you vote to support the staff recommendation as the Work Group recommendation?

Ms. Elliott: And on this measure, we're looking for 16 votes.

Co-Chair Fields: There we go.

Ms. Harding: We will now view the responses.

Nine members voted yes and seven members voted no for MUC2021-053.

Ms. Elliott: Okay. So, this represents 56 percent, which is not the threshold of 60. So, we move to the next step, Rob?

Co-Chair Fields: Right. All right. So, we will move on to further discussion. So, we will start with the lead discussants to review and present their findings. And we have two lead discussants of Magellan Health and Amy Nguyen Howell.

I don't know who wants to go first. Obviously, Amy is here. I think I heard a representative from Magellan on the intros. But I don't know who wants to start. Amy, do you want to start, since I know you're here?

Member Nguyen Howell: Yes. Sure, I'll start. Where should I start?

So we discussed the denominator. I mean, so this is a process measure for Part C and D, as we discussed. Several disciplines are covered with this. It's a high-priority measure. It covers chronic conditions. It has been endorsed by NQF. There is no eCQM measure for it. It does align with the Medicaid CMIT 5887.

I think, while there was a really robust discussion on the denominator, I think -- and I don't want to take us down that rabbit hole -- so, what I found in reading the measure is that there is high reliability testing for the measure. There is face validity for it.

And there's a low burden of data collection as well.

I did want to kind of point out that it poses, I think, a health plan issue, based on the discussion that we already had. From the provider perspective, I don't think there is much of an issue there.

I will bring out or raise, one of the questions I had that we didn't get to was this measure is not risk-adjusted, nor does it capture any SDOH components in the risk adjustment model. And I think that's an opportunity for the measure, given what it's supposed to measure, concurrent use of opioids and benzodiazepines, and the population in which it's capturing.

So, while I think the roll score was appropriate, and the health equity score was kind of in the middle, I do think that's an opportunity for measurement development.

So, I'll pause here.

Co-Chair Fields: Thanks, Amy.

Member Parrott: This is Lou with Magellan. I was also chiming in earlier as well.

And I agree with the things that Amy mentioned, and wondering what Ben mentioned earlier about this being one of a suite of measures, you know, it may be helpful to kind of have some explanation or declaration of this measure to explain its kind of role in the suite. That might help answer some of the questions that have been coming up. And some of those might be the things that Amy just mentioned. I'm not sure of some of those other aspects that could be addressed through the other suite of measures. So, just some other ways to think about how to position this for explanation.

MR. SHIRLEY: So, I'm happy to jump in just on a couple of these. And again, I think -- well, I'll go first on the risk adjustment piece.

Totally agree on the interest around SDOH, the interest in potential stratification. I think, looking at risk adjustment specifically -- so, generally, process measures are not risk-adjusted. That's sort of the position of most of the quality authorities, since the measured entity generally has control over the process that is being measured. Risk adjustment really, typically, is trying to account for factors that are going to be outside of the measured entity's control that are influencing the rates, particularly of outcome measures or maybe intermediate outcome measures.

So, during development, regardless of measure type, PQA does always consider risk adjustments. We always look at the potential appropriateness, but, for this measure, there really was no sort of suggestion that risk adjustment was necessary or appropriate.

And I'll add that this measure was actually re-evaluated and re-endorsed by NOF in the past few months. And those committees did not raise this, this sort of appropriateness of risk adjustment, either.

I think that stratification is a great question that's something that PQA is very interested in across all our measures. I want to sort of highlight that I think the stratification of rate reporting, in general, is also very much sort of in the purview of program stewards. You know, as developers, we can certainly make recommendations about how the measure is reported, but, at the end of the day, thinking about sort of the Part D program, it is also in many ways up to them how they want to report the measures that are in their program.

So, I'll say that this is something that we're actively looking at, the stratification. I think it's something that most stewards are thinking about, as we heard on the equity meeting. But you're correct that it's not currently in place. But that is something that

we're considering, both internally and something that we like to collaborate or correspond with the Part D team on as well.

And then, there was the other point on the suite of opioid measures. So, I can just speak to the measures briefly.

So, there are other opioid measures used in the Part D program looking at prescribing of opioids chronically in persons without cancer at high dosages or for multiple providers. Those are both NQF-endorsed measures that the MAP, actually, in previous years has supported for rulemaking.

That being said, there is sort of this larger universe of opioid utilization review, management, policy that I am not personally an expert. I don't know if anyone on Part D -- I don't want to put anyone on the spot -- has a brief overview of systems like the OMS, et cetera, but there is sort of a robust level of review around controlled substances like opioids in the program. This is, certainly, not the only measuring stick for these types of medications.

Co-Chair Fields: Thank you.

Dr. Cho: Hi. This is Taemi from Part D.

So, as Ben said, we do have a lot of different tools within Part D. We do have the three measures that Ben described for display. We have the OHD OMP, and we also have the initial prescribing, along with the concurrent use of opioids and benzodiazepines.

Along with those measures, we also have safety edits for opioids at the pharmacy level. So, when patients get a prescription, then there are certain checks that the pharmacy will do before a prescription is given to a patient.

We also have the Opioid Overutilization Monitoring System and the Drug Management Program. And

so, basically, if a bene meets a certain threshold with their opioid MNE, then we'll send information on those benes to the different contracts, and the contracts would start doing their investigation and looking into them, calling the doctors or looking to see if the opioid amounts are appropriate or not.

And we also have our complaints, our complaint system, our tracking module. And so, we also monitor all the complaints that we may receive from beneficiaries regarding their opioids; if they have an access issue. If they just have any issues in getting their medication, we'll be able to also track that.

And so, there are a lot of safeguards and protections, so that we ensure that beneficiaries do get access to their medications, and at the same time, monitoring to make sure that prescriptions for opioids are appropriate as well.

Co-Chair Fields: Thank you.

I'm trying to figure out for the Committee -- so, we had a fair number of folks that, obviously, supported it for rulemaking. I mean, I don't imagine that will change based on this discussion.

For the others, just a reminder of the three other categories. There is conditional support for rulemaking, and then, there are two do not support categories, one with potential for mitigation and the one just not supportive at all.

I'm trying to get the temperature of, you know, gauge the temperature of the group, especially those that were not supportive of the recommendation. If we're more on the conditional support and what those conditions might be -- or are we just more squarely on the do not support bucket? I wonder.

So, at least I know your comments on the chat; you wanted more discussion. So, that's what we're doing now. Anyplace you want the discussion to go

to help get clarity?

Member McGiffert: No, the discussion has been very helpful. Thank you.

Co-Chair Fields: Yes.

Any other missing gaps for the group here?

Member Parrott: This is Lou again. I just wanted to get another kind of clarifying aspect.

Co-Chair Fields: Please.

Member Parrott: So, this measure would be all based on claims, correct? So, any self-pay prescription fills for either the opiates that led somebody to the denominator or self-pay for the benzos that could lead you in the numerator, those would be out of scope, and then, kind of invisible to this measure, even though, like through an PDMP, the prescribers should be being aware of those things. That's how I'm envisioning this from what I've read so far. I'm just trying to clarify if that's accurate.

MR. SHIRLEY: That is correct. This is sort of a universal shortcoming of (audio interference) pull out what the program has. I guess I would just add that I think that it would be accurate to say they're really not included programmatically, right, because those fills that are cash, the Part D plans really don't have any visibility ability to act upon them, et cetera. So, this is using the Part D claims as a data source to align with that being the program in which it's used.

But you're correct that, like all claims-based measures, we are, unfortunately, limited in our ability to see what's going on when patients (audio interference).

Member Parrott: And that aligns with your prior answer. This is a health plan measure. It's not at the provider level.

MR. SHIRLEY: Correct.

Member Nguyen Howell: Hey, Rob?

Co-Chair Fields: Yes?

Member Nguyen Howell: I just want to take the liberty, as one of the lead discussants, to just say, for the record, this doesn't affect the voting per se, but I do encourage the measure developer and other measure developers around opioids and benzos that, if we're truly going to move the dial in this country -- and if CMS is listening -- for this population, we do need to look at outcome measures and to take into consideration SDOH and other population health determinants, if we really want to truly improve the outcomes, the health outcomes of our patients on this.

Co-Chair Fields: Thank you.

Member Anand: Rob, this is Nishant.

I had two questions, Ben. I think you've said this well and I commend you for focusing on this issue.

So, one is, how do we prevent the exclusion of management of acute pain issues? So, I can imagine -- I know you had emergency medicine and you had some of the acute specialties listed in there -- you could imagine situations, back pain, chronic back pain, as a simple example. You come in one month; you come in three months later; you come in six months later. It's combination of opioids and benzos. How do we make sure that the -- I'm sure you all thought about it -- but how do we make sure that we don't undertreat acute pain?

MR. SHIRLEY: Yes, it's a great question. And really, this is where both sort of the two-claim piece and the threshold for concurrent use comes in. Again, I think I mentioned there is thought maybe we could use seven days as this threshold. But it's sort of exactly what you mentioned. What we want to avoid

is drawing people in based off of one-time, short-term, acute medication use.

So, you really have to have two unique claims on unique dates of service for both the opioids and the benzodiazepines, and have those overlap two or more, right, for 30 cumulative days. So, if someone has a very high number of acute situations, it is possible that that would trigger it, but, again, I think that's where it's important to recognize that this is not a denominator of 30, like a clinician measure. We're talking hundreds of thousands of patients. And as a population measure, we anticipate that to be pretty limited. We're confident that this construction is really going to focus on the people we're trying to focus on.

Member Anand: Got it. That's helpful because, again, if you had 7 or 15, I think it would worry. So, 30 days makes sense.

MR. SHIRLEY: Okay.

Member Anand: And then, to Amy's question, have you all looked at tying it to an outcome, such as admission or some sort of -- you know, admission to a hospital or some sort of adverse event that they had, as a fall, as a claim?

MR. SHIRLEY: Yes. It's like a great question. So, actually, we did look at this pretty recently. When we went back to NQF, we did provide some empirical validity analysis that we've done tying, essentially, health-plan-level rates on this measure to how they perform on -- we, essentially, put together a composite of ED visits due to opioid- and benzodiazepine-related events, et cetera, et cetera, injuries, harms.

And we did see that there was correlation, such that -- I can't remember the exact coefficients off the top of my head, but it passed NQF's evaluation of validity. So, we did see that there was a significant relationship between plans' performance on this and

the amount of their members that are experiencing these harms we know are associated with them.

Member Anand: Okay. Thank you.

Co-Chair Fields: I'm wondering if --

Member Gozansky: Quick question.

Co-Chair Fields: Question? Well, yes, go ahead.

Scott, I'm going to tee up, and you can start thinking about it after this next question.

I understand that you want some definition, a greater definition, on both the numerator and denominator. If you can be thinking in the next couple of minutes about what more specific -- be specific on those, what you need relative to what's in the measure spec or the prelim analysis, that would be helpful. So, that way, we can determine how best to vote. Because if we vote yes, either by conditional support or with mitigation, it's helpful to give specific recommendations. So if you can be thinking about that?

And I don't know who wanted to ask a question. There was somebody that said something. I don't see it.

Member Gozansky: Hi. Wendee Gozansky. I had my hand up.

So, I think one of the things I just want to clarify is my understanding is we're talking about this for the Star Ratings. And so, when we talk about the suite and what the other measures are currently within the Star Ratings, I think that's part of my concern, is, you know, if this is the one opioid-benzo measure, would we be better off having a more generic measure that gets at the baseline prescribing, or so forth? So, I think that's what I'm trying to understand.

MR. SHIRLEY: Yes. So, I think that what I'll provide

there -- and, you know, I also think, to some extent, the three measures that are included in the Stars Rating, so it's sort of a CMS question.

But this panel previously recommended use of opioids chronically, I mentioned, in high dose and from multiple prescribers. So, those measures have not been implemented in the Stars yet, but they've been recommended by MAP, right? They're on the table.

So, I think there are a lot of different ways to think about the different combinations, the constellations of measures that could go into the Stars, but I don't want to presume the role of the MAP, right? But we're just trying to think, for each of these measures, are they appropriate, understanding that we don't have total control over all the other measures that might surround them?

Does that make sense?

Member Gozansky: Yes, it makes sense, and I think maybe that's part of the -- that's part of my concern, is, you know, if they have three measures to choose from, if we approve this as is and they have three measures, then they could choose this as the single measure, rather than one of the others that actually may be more appropriate from a broad population health perspective.

Co-Chair Fields: And that's true, and unfortunately, we have to accept that lack of control. But I think, to Amy's point in the chat, I think to some degree we have to assume best-use case because, mostly, our job is to look at the measure as part of the suite available, and not to -- I totally get it.

Wendee, I think you're totally right; I think that's a concern for everybody. We have to have faith in those administering the program that they will use, they will take these comments and considerations and use a suite of measures appropriately. But, to some degree, that's a separate decision than our

recommendation to include it in the suite of measures or not, although that creates discomfort, as I can appreciate for sure.

Scott, I'm going to come back to you and see if you have any additional details, because they would inform the potential vote.

Member Fields: Oh, I appreciated all the comments that have occurred. I voted for this because I think the idea behind it is good to have as part of the suite. So, that's why I voted for it.

But I do have concerns, much of which has already been discussed, about the denominator and numerator. And the numerator, I don't like the fact that the focus is on opiates followed by benzos, as opposed to benzos followed by opiates. You know, that's a pretty major exclusion, if you will, from the numerator, and the same sort of issues in the denominator that have already been mentioned.

So, that's my point. I think the heart's in the right place. I think it should be part of the program, but I just don't really like the definitions at the moment.

MR. SHIRLEY: And I can jump in just to clarify that the order of the opiates and benzodiazepines actually is not going to matter for an individual that's going to hit the numerator. So, this is going to look across the full measurement year, right, and if someone has 30 days of concurrent use of opiates and benzodiazepines, right, they're in the numerator; by definition, they're also in the denominator because the denominator is based on just the opiate half. So, if you received, you know, benzo fills earlier on in the year, and then, you received concurrent use of these two medications, you would still be in the measure because over the course of the year you would still satisfy the criteria for both.

Does that make sense?

Member Fields: I hear you, yes.

Member Parrott: So, this measure is not, doesn't march through time. It looks for a base of opioids, and then, it looks backwards and forwards for any overlapping benzo claim for the numerator hit. Is that accurate?

MR. SHIRLEY: Correct. So, it's within Part D generally and in the specification of the measure. We're looking retrospectively at a measurement year.

Member Parrott: That does help clarify. I had been thinking of it in temporal fashion. You just explained that it is different than that. Because you look for the opioid piece first, and then, you look both ways, if there's an overlapping benzo hit.

MR. SHIRLEY: Correct.

Member Parrott: Yes.

Co-Chair Fields: Ben, this is kind of perhaps a dumb question, but I'm curious as to why taking that approach on the denominator of having the base be those that have been prescribed opioids, as opposed to just doing an overall rate of concomitant use. I'm confused by that.

Because it seems like what you're really trying to target here, you're not trying to adjudicate or provide any sort of measurement on use of benzos and opioids, which have their own risks independent of each other, right, in this population, in a Medicare population. But you're really trying to target the concomitant use, and I'm just confused as to why not just do an overall rate. And it would really resolve some of the denominator issues. There must have been a thought process behind that. I'm just trying to understand it. And I think the Committee might like that as well.

MR. SHIRLEY: Yes. So when you say, overall rate,

you're just thinking --

Co-Chair Fields: Like all Part D beneficiaries over 18, right?

MR. SHIRLEY: Yes, yes. Sure. So I think that, first of all, it's important to understand that this measure, right, is developed as part of a suite of measures with some of those that we just mentioned, right, high-dose, multiple providers.

And the PQA, you know, sort of following CMS and the others' recommendations for measurement, we're trying to harmonize those as much as possible, which means that having a consistent denominator is going to be beneficial. So, that is part of the reason.

But I think, even beyond that harmonization piece, the goal still was to sort of establish a denominator that is individuals who are at risk for this intervention, which, then, allows health plans to look at it and look at these people who are at risk, and then, make more targeted interventions, or whatever may be necessary to improve on the measure.

I think that, again, the thought that general deprescribing of opioids would harm this measure is sort of contingent on the thought that the people you're deprescribing, right, would be differentially on opioids and benzodiazepines over time, right? Because the assumption is that everyone who falls out of the denominator, that only increases the measure rate if the person was not also in the denominator -- or if they were in the numerator. So, again, I need a Venn diagram.

Essentially, we don't really anticipate in practice at the population level this effect on the rates. And just to circle back to your question, it was both for harmonization with other opioid measures and based on establishing a denominator of those at

risk, rather than a broader denominator.

Co-Chair Fields: Yes. So, in other words, if someone were on both benzos and opioids and hit the numerator, if you remove either one of those because somehow the measure changed their behavior, and you were educated -- you educated yourself on the risk, et cetera, et cetera, either way, those folks would be removed because they're no longer -- either they're not on either one of those or both. So, either way, they would just be removed out of the calculation altogether?

MR. SHIRLEY: Yes. I'll caveat that this is hard to talk about without a whiteboard.

Co-Chair Fields: Yes, a whiteboard.

MR. SHIRLEY: But I think I follow what you're saying.

Co-Chair Fields: Right. Yes, yes.

Okay. So, my sense of where we are -- and it only makes a difference in the order in which we vote, to save time. So, we could go through all three votes in the remaining categories and spend a lot of time, run a poll everywhere. Or we could start with the one that, judging by the conversation, I think where we are.

So, I think where we are is conditional support for rulemaking, as opposed to do not support. So, we're going to put that for a vote first and see where we land.

Ideally, it would be helpful to have a little bit more of a sense on what the conditions are. I'm hearing perhaps more clarification on the numerator and denominator, although what I'm hearing from Ben is, a couple of the concerns were, you know, the order of how we identify the denominator probably doesn't matter. And again, if folks are using both, they're going to end up there, anyway, regardless of

how you start the target population, because it's concomitant use over a period of time. So, the logic will end up being inclusive, regardless. I think that addresses that concern.

And then, the other concern about, you know, if you reduce opiate use, somehow that would increase your rate. But what you're saying, also, is that, effectively, if you remove one of the meds because you've realigned your thinking around the management of this issue, then they'll end up dropping out anyway, because they're no longer concomitant use. So, they'll be out of the numerator and the denominator just by definition.

So, it's sort of the same issue. It's like, once you remove one, they're out of the measure -- of the numerator for sure. So, that should address that concern. So, I think we got all the clarifications we need.

Anyone else have thoughts on what other conditions? Would it be helpful to have more examples perhaps in the measure spec? I don't know if that's a thing, but, certainly, in the comments I think we've reflect all the examples.

Member Parrott: This is Lou.

One of the things I'm just wondering -- I don't know if it's possible -- but it sounds like the discussion is kind of hypothesizing different rules that would, for instance, expand the denominator, and so forth. But, in fact, if this has been being measured for a couple of years now, I don't know if data could be rerun to show, hey, if we do the theoretically change in the definition, it doesn't really make much difference, for instance, which is I think perhaps maybe what we're hearing. But maybe we're not all privy to seeing that.

So, perhaps part of the revision in the future would be to help describe the different gatings and how we arrived at this one. But I'm just wondering if that

could be evidence that I think people are asking about here, that maybe we just weren't prepared to talk about and display.

Co-Chair Fields: Right. And to Amy's point, we can't specifically change the measure specs for this. So, we can ask for rationales as to why the specs exist.

But I think what you're asking for is really just a request for the program to continually evaluate this measure over time. Is that what I'm hearing in terms of the cut points and how it affects numerators and denominators over time?

Member Parrott: Yes, I think that that's accurate as well. And my prior question was around the cut points being separate from this voting scenario, which is my understanding. We're not voting on cut points. We're just voting on a metric. Somehow later, there will be a discussion about like what it means to meet the measure.

Co-Chair Fields: Correct. That's right.

All right. So, we're going to start with the voting on conditional support, but --

Member Burstin: I'm sorry, Rob, just quickly --

Co-Chair Fields: Tricia, you were saying maybe we can -- oh, sorry, go ahead, Helen.

Member Burstin: Just two quick comments.

I agree with the prior point about sort of monitoring for unintended consequences; in particular, keeping an eye on the elements of the numerator and the denominator to see over time if, in fact, the opioid rates go down, if that measure has any unintended consequences.

But, secondly, since we're going to talk about the next two measures, which are not yet NQF-endorsed, maybe when those two measures come forward to NQF, they could actually look at these as

a suite, and really help us, you know, really on the implementation side understand how these come together as a package, and again, think through the issues around unintended consequences.

Thanks.

Co-Chair Fields: Thanks, Helen.

Tricia, just a matter of procedure. So, there was a private message, but I think I'd like to ask it publicly, because I actually don't know the answer to this.

I don't know that I've ever been in a situation where we can go back and start with just support for rulemaking. So, if I could go back to the initial voting, since we don't have really specific conditions, frankly, I guess we have the ability to do that? Is that what I'm hearing?

Ms. Elliott: Correct. That first vote opens it up for more discussion, if folks aren't comfortable with the initial, you know, the public comment and the clarifying questions. So, it gave us the opportunity to ask more questions. But we can start with support for rulemaking.

Co-Chair Fields: Okay. That's very helpful because I didn't know we could do that.

So, if we could actually start there, that would be great. We were close last time. I think we had good discussion. I think if we go and open up the vote for support for rulemaking, which was the initial recommendation from the NQF team, and go from there?

Ms. Harding: Voting is now open for MUC2021-053: Concurrent Use of Opioids and Benzodiazepines for the Medicare Part C and D Star Ratings Program.

Do you vote support for rulemaking?

Co-Chair Fields: All right. We have our 16.

Ms. Harding: Voting is now closed for MUC2021-053, and the responses are as follows:

Thirteen members voted yes and three members voted no. And that brings us to 81 percent. So, the Work Group is in support for rulemaking for this measure.

Co-Chair Fields: Great. All right. We will move to MUC2021-056 and ask the team to review the preliminary analysis.

Ms. Elliott: Great. Thank you. This is Tricia.

This measure, as Rob mentioned, MUC-056, Polypharmacy: Use of Multiple Anticholinergic Medications in Older Adults. This description is the percentage of Medicare Part D beneficiaries 65 years of age or older with concurrent use of two or more of the unique ACH medications during the measurement period. Level of analysis is health plan. NOF recommendation is conditional support for rulemaking. The lead discussants are listed there. I wanted to also let you know the chronic conditions is the domain for this measure.

I'm going to share now the Rural Health and Health Equity.

So, from the Rural Health Advisory Group, the relative priority or utility of the measure: this measure was suggested to be relevant to the older rural residents. Concerns raised regarding the included medications; for example, prescribed versus over-the-counter medications. Data collection is at the health plan level, which does not present any additional burden for rural providers. There are no issues identified with the calculations, and for unintended consequences, concerns were raised regarding deprescribing appropriately.

Once again, the range of 1 to 5 for polling for this group. Higher is better. The average for this particular measure was 4.0.

For the Health Equity Advisory Group, the measure was considered to be an important polypharmacy related to patient safety. No issues identified with data collection. Calculation issues: lack of stratification was identified as a priority for this measure. No other issues identified, and no unintended consequences.

The range, again, for polling with this group was a higher number has greater potential for positive impact on health equity. The measure scored at 3.2.

For this particular measure, there were three comments.

One was in support of the measure; that it addresses safety, including the overall use of medications. And the non-support comments included penalizing the measured entity in a scenario by shrinking the measure denominator, as well as beneficiaries having limited safe and efficacious therapies, and some questions about the adequacy of exclusions.

Co-Chair Fields: All right. Thanks, Tricia.

So, as before, we will open it up for any clarifying questions, again, on either the text of the measure spec, the numerator/denominator, any clarifying questions. And then, we'll move to a vote, and pending that, we'll have further discussions.

Clarifying questions?

Member Gozansky: A quick question. I guess I'm wondering if somebody can speak to the reliability on this measure is a little bit lower. It's still over .7. Any explanation as to why that is?

MR. SHIRLEY: This is Ben.

I don't think that I can provide a specific answer. I believe the scores were .77 for Medicare Advantage prescription drug plans, being one line of business, and .82 in the PDP. I'm doing that from memory,

but those are well above the .7 threshold currently used by NQF, and that's a threshold that is in some ways -- if you listen to the SMP, it's possible the threshold will be even lower. So, no, I don't think we have a specific factor we can point to that would make this less reliable than the others, but we still view those as very reliable and well beyond what NQF would typically look for in their criteria.

Co-Chair Fields: Any other clarifying questions? We'll move to the first vote, if not.

And, Tricia, I'm sorry, maybe I do have -- I have a clarifying question. So, the conditions by which the prelim analysis would approve this, or could support it, were what exactly?

Ms. Elliott: NQF endorsement.

Co-Chair Fields: Okay. Just pending NQF endorsement. So, that's it? Okay.

All right. If there are no other clarifying questions, we'll -- two more seconds here -- we'll to a vote to accept the recommendation or not, and then, move to discussion, if not.

So, all right, let's go ahead and move to that vote.

Ms. Harding: Voting is now open for MUC2021-056: Polypharmacy: Use of Multiple Anticholinergic Medications in Older Adults for the Part C and D Program.

Do you vote to support the staff recommendation as the Work Group recommendation?

Co-Chair Fields: Are we still looking for 16 on this one?

Ms. Elliott: Correct.

Co-Chair Fields: We need one more.

I guess it reminds me, folks, if you have to step away for a while, if you can let the NQF team know? So, that way, we don't wait for you indefinitely for a vote.

Anyone having trouble?

What do you think, Tricia?

Ms. Elliott: Yes, I think we can go ahead and close it because we have one recusal on this measure. So, we have the votes, yes.

Co-Chair Fields: Oh, okay. Okay. Fine.

Ms. Harding: Voting is now closed for MUC2021-056, and the results are as follows:

Twelve members voted yes and three members voted no. And that brings us to 80 percent.

Co-Chair Fields: Excellent. I appreciate everyone's support on this one.

So, we'll move to the next measure. Tricia, I'll turn it over to you for the prelim analysis.

Ms. Elliott: Okay. I'm catching up with my notes here.

The next measure is MUC2021-066: Polypharmacy: Use of Multiple Central Nervous System, Active Medications in Older Adults. The description is the percentage of Medicare Part D beneficiaries 65 years of age or older with concurrent use of three or more unique central nervous system active medications during the measurement period. The level of analysis is at the health plan level. The NQF recommendation is conditional support for rulemaking. The domain is chronic conditions. It has not been submitted for endorsement as of yet.

The Rural Health Advisory Group input: the relative priority is that this measure was suggested to be an important area for geriatric populations and rural

communities.

Concerns were raised regarding the data capture of medication use in nursing homes. There was some discussion about short-stay versus long-stay patients.

There is no calculation issues identified and no unintended consequences identified.

The average scoring from the rural health perspective was 3.9.

The MAP Health Equity Advisory Group provided input stating measure is important to address for patient safety. Important impact on institutionalized people with disabilities. No data collection issues identified. There is mention of a lack of stratification as a priority for this measure. Unintended consequences, the Advisory Group noted that hospice patients and seizure diagnoses excluded to reduce unintended consequences.

The scoring for this measure from the health equity perspective was 3.2.

There were two comments, public comments, received about the measure. Both were not in support. And some of the comments related to the fundamental threat to the measure validity in terms of some of the specifications, and there was concern about implementing this measure in the Star Ratings at this time could have negative consequences for patients, and had additional comments about exclusions that could result in beneficiaries having limited safe and efficacious therapeutic alternatives for treatment like pain management.

Those are the comments.

Co-Chair Fields: Great. Thank you.

Any clarifying questions from the Committee?

Member Gozansky: Question. So, I am somewhat surprised that bipolar disorder was not potentially an exclusion, like seizure disorder. Was that something considered or looked at?

MR. SHIRLEY: So the seizure disorder one was actually specifically added sort of in response to some updates to the underlying evidence, the Beers Criteria around addition of antiepileptics to this sort (audio interference) CNS active medications, where (audio interference) more of them represents this (audio interference).

And so the idea with that one really was just that there are these existing persons with stable treatment, and we don't want to have any situation where we're incentivizing people to change that for the sake of this measure.

I am actually not aware that bipolar was considered in the same way by the panels that developed and updated the measure. That doesn't mean that it's not something that we can potentially look in the future. We do have a standard process by which we evaluate emerging evidence and new potential exclusions, and certainly, add them, as appropriate, as we did with the epilepsy or seizure disorder exclusion.

So, I think I can say that that hasn't been considered yet, but we're certainly happy to take that back and consider it in the future.

Member Ying: I have a question, clarification question. So, for the opiate measure that we discussed earlier, there was mention that Part C and Part D programs, or CMS in general, has a suite of measures to monitor the overuse of the opioids to start with.

So, I just wonder for this measure, because the starting point are the patients who are already prescribed by the type of medication, even though the numerator is, again, concurrent multiple use. Is

there any indication of either underuse or overuse of the drug to start with, basically, the denominator population?

MR. SHIRLEY: So, I'm not aware of a monitoring system similar to the ones that Part D described for opiates for these types of agents specifically. I know that health plans and PDMs and those participating in the Part D program have all sorts of tools they use to review the utilization of the drugs that they use, presumably, for things, including overuse and including underuse.

But I don't think that I can sort of speak to a universal Part D approach to that in the way that it is for opioids. I think that opioids, obviously, are a particular priority area with all of this. Thus, the infrastructure around that. But I don't know that I can speak to it specifically for these medication classes.

Is that helpful?

Member Parrott: I don't know if this was the same question just asked, but this is what I thought was going to be asked. Given the opioid measure had exclusions of cancer diagnosis, sickle cell, and so forth, are we saying that opioid use, opioid prescribing counts as CMS active? And if so, wouldn't those be part of the exclusions for this poly-CNS measure as well, just like the consideration described before around bipolar, given that patients with bipolar who may be well-controlled might be on an anticonvulsant, just like someone with seizures?

MR. SHIRLEY: Yes. So, that's a great question.

So, the exclusions, typically, when we're developing them, at least the original sort of genesis of the exclusions is typically from the clinical guidelines or evidence on which the measure is based. So, the COB measure was really coming from the CDC Guideline on Opioid Prescribing for Chronic Pain,

which is out of scope for those groups that we just mentioned.

Individuals with sickle cell disease, individuals with cancer, and those in hospice, right? So, those individuals are excluded because the recommendations related to them -- for example, around concurrent use of opioids and benzodiazepines -- are out of scope.

This measure is actually not based on that guideline. It's based on supporting evidence, as well as, primarily, on the AGS guidelines. So, those guidelines do not sort of call out those exclusions. So, those exclusions might not be directly relevant to this measure, which is based on the AGS Beers Criteria, in the same way that they are relevant to the specific recommendations from the CDC Guideline on which the COB measure is based.

Additionally, it's true that opioids are one of the number of CMS active classes included in this drug, but there are several other classes as well. So, there may be patients that are not on opioids for which it would be in scope.

But I think the primary answer is that those individuals are excluded from the opioid measure because they are out of scope from the underlying guidelines, while they are not out of scope for the guidelines on which this measure is based.

Co-Chair Fields: Any other clarifying questions before we move to a vote on the recommendation?

Member Averbeck: Yes.

Ms. Elliott: We have a hand raised, Rob. Beth.

Member Averbeck: Yes. Thank you.

So, Beth Averbeck from Health Partners.

Just a question, a clarifying question, and a consideration. I know this hasn't gone through the

endorsement process, and it would be around dementia with agitation or delirium, and having those diagnoses considered.

And then, as far as unintended consequences, especially for patients in long-term care, I think, potentially, the safety of the staff, if you have someone with dementia with agitation.

So, those are just things I think to keep in mind. I think, in general, this is a great direction. There may be an opportunity to further define some exclusions.

Thank you.

MR. SHIRLEY: Yes, we appreciate that as well. I think, as I said to the other one, we're always looking for ways that these measures can be refined and honed over time. Exclusions are frequently a way that that happens. So, we absolutely continue to review recommendations, look at them in light of the evidence that we have, and certainly have and do make alterations to our measures over time, including when they are implemented.

Co-Chair Fields: Just a warning. I don't know what Diane's screen looks like, but I can only see six boxes at a time. So, if you have your hand raised and I don't see you, I'm sure the NQF staff will help me, but don't let me keep moving forward without hearing your voice. So, just unmute and say something if we're not catching you. So, I apologize.

Ms. Elliott: Yes, we will help monitor that, Rob. Thanks.

Co-Chair Fields: Okay. Any more clarifying comments? Otherwise, we'll move to a vote on the recommendation.

Going once, going twice.

All right. We will move to a vote for whether or not

to support the NQF recommendation of conditional support for rulemaking.

Ms. Harding: Voting is now open for MUC2021-066: Polypharmacy: Use of Multiple Central Nervous System - Active Medications in Older Adults for the Part C and D Program.

Do you vote to support the staff recommendation as the Work Group recommendation?

Co-Chair Fields: Tricia, is anybody recusing themselves for this one?

Ms. Elliott: Yes, there's one recusal.

Co-Chair Fields: Okay. One more. There we go.

Ms. Elliott: And there is just a quick question in the chat. The condition is NQF endorsement, correct, Lisa.

Co-Chair Fields: I thought it was -- oh, yes, right. Okay. Yes, that's right.

All right. You're good?

Ms. Elliott: We're good. Please close the vote.

Ms. Harding: Okay. Voting is now closed for MUC2021-066, and the results are as follows:

Eleven members voted yes; seven members voted no. And that brings us to 73 percent.

Co-Chair Fields: Great. Thank you to the group.

I think we're, actually, like almost an hour ahead of schedule. Do I have that right?

Ms. Elliott: Yes. We do have on the schedule to take a break. So, I would encourage -- we're at 1:25. And let's see. I'm suggesting a 15-minute break, and that puts us at 1:40, which still keeps us an hour ahead of schedule currently.

Co-Chair Fields: Great.

Ms. Elliott: Is that amenable, Rob and Diane? We'll start at 1:40?

Co-Chair Fields: Helen's asking whether or not we need another break, or whether we should keep going. And can we move the break? Is that possible? I don't know how this is going.

Ms. Elliott: Yes, we can keep going and wait and break either partway through the next set of measures or after the next measures. Either way is fine.

Do you want to keep going? Everybody good?

Co-Chair Fields: Is anyone opposed to just continuing to go for right now? I'm with Helen; it sort of feels like we need --

Ms. Elliott: Okay. It sounds like keep going is the consensus. So, we'll keep going.

Co-Chair Fields: I don't hear any opposed, and we've got more agreed.

Ms. Elliott: Okay.

Co-Chair Fields: And our impromptu poll everywhere tells us --

Ms. Elliott: Our impromptu chat poll.

Okay. So, we're moving into the MIPS measure.

Next slide, please.

Merit-based Incentive Payment System (MIPS) Measures

So, the Merit-Based Incentive Payment System, the program type is a Quality Payment Program. The incentive structure is pay for performance.

There are four connected performance categories

that affect a clinician's payment adjustment. Each performance category is scored independently and has a specific weight.

The MIPS performance categories and finalized 2021 weights include: quality at 45 percent; promoting interoperability at 25 percent; improvement activities, 15 percent; cost, 15 percent. The final score, or 100 percent, will be the basis for the MIPS payment adjustment assessed for MIPS-eligible clinicians.

The program goals for MIPS include:

Improved quality of patient care and outcomes for Medicare fee-for service;

Reward clinicians for innovative patient care;

And drive fundamental movement toward value in health care.

Next slide, please.

The 2021 MIPS current measures divided by the meaningful measure areas are displayed on the screen; includes:

The healthcare priority of effective prevention and treatment;

Making care safer;

Communication and care coordination;

Making care affordable;

And the person and family engagement.

For a total of 209 measures.

Next.

The MIPS-CMS high priority for future measure consideration.

MIPS has a priority focus on:

Outcome measures;

Includes outcomes, intermediate outcomes, and patient-reported outcome.

Outcome measures show how a healthcare service or intervention influences the health status of patients.

Person or family. Reported experiences of being engaged as an active member of the healthcare team and in collaborative partnership with providers and provider organizations.

And population health. Health behaviors and outcomes of a broad group of individuals, including the distribution of such outcomes affected by the contextual factors within the group.

Also, measures that provide new measure options within a topped-out specialty area.

Reduce reporting burden. This includes digital quality measures, administrative claims measures, and measures that align across programs.

The capture of relevant specialty clinicians. Focus on patient-centered care and include the patient voice.

Reflect the quality of a group's overall health and well-being, including access to care; coordination of care, and community services, health behaviors; preventative care screening, and utilization of healthcare services.

Addresses behavioral health, and support for health equity.

Next slide, please.

Cost measures address needs in MIPS.

Currently, MIPS has 20 cost measures. Eighteen are episode-based cost measures for specific procedures

and acute conditions. Two population-based cost measures that assess the overall cost of care.

As required by statute, CMS has developed five novel cost measures. These were selected to address measurement gaps and meaningful measures priorities. Development process has included extensive expert stakeholder input through TEP, clinician subject matter expert panels, patient and family voice, and national field testing.

These five new measures would allow more clinicians to be measured by episode-based measures and support MIPS Value Pathway development.

Next slide.

The measure framework focuses on capturing clinician role in care. The measures are constructed using the same framework as other cost measures reviewed by MAP in previous years.

The procedure: melanoma resection and colon and rectal resection.

Acute inpatient medical condition is sepsis.

Chronic condition measures use a familiar framework.

Shares elements from other episode-based measures and NQF 3575 TPCC. The attribution requires two visits to identify the start of clinician-patient relationship.

Features to account for chronic condition management were developed with stakeholder input through multiple meetings over an 18-month period. Costs measured for at least one year to reflect the ongoing nature of care and encourage care coordination.

And tailored to capture care specific to the management of diabetes and asthma/COPD. These

stratify patient cohorts into smaller groups, including only clinically-related costs; accounts for risk factors specific to that condition.

Next slide.

So, we'll be moving into a section to discuss eight MIPS quality measures.

Next slide, please.

The 2021 current MIPS measures divided by the meaningful use areas. I think we shared this slide already with the health priorities and the number of measures. So, we'll move to the next slide.

So, here we have public comment for the MIPS measures under consideration. So, here's where we have eight measures on the MUC List this year to discuss. So, the eight measures are:

MUC-125: Psoriasis - Improvement in Patient-reported Itch Severity.

Muc-135: Dermatitis - Improvement in Patient-reported Itch Severity.

MUC-063: Care Goal Achievement Following a Total Hip Arthroplasty or Total Knee Arthroplasty.

MUC-107: Clinician-Level and Clinician Group-Level Total Hip Arthroplasty and/or Total Knee Arthroplasty. Patient-Reported Outcome-Based Performance measure.

MUC-090: Kidney Health Evaluation.

MUC-127: Adult Kidney Disease: Angiotensin Converting Enzyme Inhibitor or Angiotensin Receptor Blocker Therapy, ACE and ARB.

MUC-105: Mismatch Repair or Microsatellite Instability Biomarker Testing Status in Colorectal Carcinoma, Endometrial, Gastroesophageal, or Small Bowel Carcinoma.

And the eighth one, MUC-058: Appropriate Intervention of Immune-Related Diarrhea and/or Colitis in Patients Treated with Immune Checkpoint Inhibitors.

So, we will pause here for public comments on any of the eight measures that we will be discussing.

Work Group members and members of the public can raise their hands or type comments in the chat function or unmute themselves for this public comment.

Okay. I'm checking the chat and raised hand feature.

Okay. Diane, I'll check in with you, as we pause for an additional moment for public comment before we move into introducing each individual measure.

Co-Chair Padden: Okay. Thanks, Tricia.

I'm taking the lead on these next eight measures. And as Rob began with the previous measures, we want to make sure that all of your questions are answered or clarifying comments. And then, we will continue with the same process that we used earlier.

So, we're hopeful, now that we've got a good rhythm going, we can move through these and make sure everything is clear and your comments are heard. And we'll try to capture them both by the raised hand as well as chat. So, between Rob, myself, and Tricia, and the other NQF staff, we want to make sure that we do address all of your concerns.

And I think we're ready to get started then, unless we have public comment.

Ms. Elliott: Great. I'm not seeing any hands raised or anything in the chat. So, I think we are good to move forward.

Next slide, please.

Okay. The first measure up for discussion in this section is the MUC-125: Psoriasis - Improvement in Patient-Reported Itch Severity.

So, the description of this measure is the percentage of patients aged 18 years and older with a diagnosis of psoriasis where, at an initial index visit, have a patient-reported itch severity assessment performed, a score greater than or equal to 4, and who achieve a score reduction of two or more points at a follow-up visit.

The level of analysis is clinician. The NQF recommendation is conditional support for rulemaking, pending NQF endorsement. This measure falls in the chronic conditions domain.

I'll highlight the Rural Health and Health Equity input.

So, the relative priority of the measure for rural health, the measure was noted to be relevant to rural providers. However, there were concerns about the prevalence of psoriasis in rural communities.

No data collection issues were identified. There were concerns expressed regarding the low population and case minimums for individual providers.

Also, concerns were noted for how low population sizes for individual providers in rural communities would translate to the statistical methods used by the developer.

There were no unintended consequences identified.

And the polling range, or the average of the poll, was 4.1. Five is the highest, and higher is more relevant to rural.

For MAP Health Equity, the relevant priority, the Health Equity Advisory Group noted that psoriasis is

an important clinical topic. Since this is a self-reported measure, data collection may be a problem for disadvantaged populations due to language and cultural barriers, as well as access issues.

This measure does require two assessments, and the response rates may drop among disadvantaged populations, resulting in selection bias in the measure performance.

The Advisory Group recommended this measure be stratified to assess performance based on population subgroups.

And some unintended consequences were: disparity in diagnoses was identified as a potential issue, and response bias was identified as a potential issue.

The average poll was 2.7, where 5 is the highest, and the higher number has greater potential for a positive impact on health equity.

There were no public comments submitted for this measure.

Co-Chair Padden: Thank you, Tricia.

Are there any clarifying questions?

I'm not seeing any comments.

Member Averbeck: Diane, this is Beth. I wonder if I could just make a comment. I was one of the lead discussant reviewers.

Co-Chair Padden: Sure.

Member Averbeck: But I wonder just as far as from the disparity aspect around the barriers to responding to this, I think any of the patient-reported outcomes would potentially have that. So, I appreciate it being mentioned for this. But I think of our depression remission response also could have some of those same things. So, I think it may just be a theme that we want to keep in mind for

any type of patient-reported outcome.

Thank you.

Co-Chair Padden: Thank you, Beth.

Ms. Elliott: And we have a hand raised from Wei Ying.

Member Ying: Sure. Just a clarification question. So, for the baseline starting point, baseline score, it is not going to be adjusted for this two-point reduction, right? Because, similar to the depression remission and response, what we noticed is that those patients who started very high, meaning very severe, it's relatively easier for them to have some level of reduction versus someone at the borderline to have the same magnitude of the reduction. So, I just wonder, for this measure, is the baseline performance taken into consideration in some way, or it doesn't matter?

Co-Chair Padden: Do you know, Tricia, if we have the developer?

Ms. Elliott: Yes, Diane, I was just going to check to see if we have the developer on the line for this measure.

MS. CARTER: Yes. Hi. My name is Stephanie Carter with AAD, and was a developer with this measure.

So, in regards to your question, this was taken into account. So, a minimum score is needed to be put into the denominator. So, this is mostly looking at patients with moderate to severe psoriasis with a score of 4 or higher. So, that was done to kind of take into account looking at those moderate-to-severe patients, and where the reduction the itch would be most meaningful.

Co-Chair Padden: Did that help answer your question, Wei?

Member Ying: Yes. I think the answer is that there

is no differentiation between moderate versus severe symptom to start with. You are, basically, for all the patients that scored at least a 4 score to start with, you are looking for at least a two-point reduction during the follow-up period.

Member Averbeck: I think the difference between -- so, this is Beth -- the difference between this one and the depression, the depression looks at a percent and this one looks at an absolute.

Member Ying: Great. Thanks.

Co-Chair Padden: Are there any other questions?

Ms. Elliott: Emma Hoo has her hand raised, I believe.

Member Hoo: Hi. This is Emma Hoo.

I just wanted to add in some general comments. As a purchase organization, we are supportive of advancing patient-reported outcomes in this category of services and, broadly, in the autoimmune space. On the macro level, purchasers are seeing significant cost increases as part of the overall treatment.

And to the extent that these types of measures allow for management of the treatment and management to outcomes, I think, from a purchaser perspective, that despite some of the concerns on the Equity Committee, to operationalize this allows for more adaptive treatment, based on patient-reported information, and ultimately, not only improves outcomes, but has the opportunity to mitigate cost, both from the purchaser perspective and patient out-of-pocket.

Co-Chair Padden: Thank you, Emma.

All right. I'm not seeing any other questions.

Nothing in the chat. No other raised hands. Tricia, do you see anything else? Oh, there might be one

more coming up.

This is from CMS.

Ms. Elliott: Right. So, we'll read this.

Michelle commented the comment regarding challenges of responding to PROs, patient-reported outcomes, for certain populations was discussed extensively in the Equity Committee, who did note that there should be future consideration for any PRO of outlying wage and cultural issues as to how that may impact reporting.

So, thank you, Michelle.

And, Diane, if it's okay with you, because we are running ahead of schedule, before we go into the vote, I'd like to pause one more time for public comment as well, to offer that opportunity in case folks are joining as we go along here.

So, great. So, we'll pause just for a second here before we move into voting.

Okay. I don't see any other hands raised or hear anyone coming off of mute. One more glance, and no other items in the chat.

So, Diane, I'll turn it back to you.

Co-Chair Padden: Okay. So, I think, then, we would be ready for the vote.

And as a reminder, the preliminary analysis that we'll be voting on is conditional support, pending NQF endorsement.

Ms. Harding: Stephanie, did you have a question before we voted?

MS. CARTER: I just had a comment. Thank you. That was in regards to the comment posted in the chat.

And during that equity meeting, there were

comments in regards to language. And I just wanted to note that, with this measure, at least one of the tools that can be used to assess itch in patients, it is validated across a number of different languages. So, I just wanted to note that.

Thank you.

Ms. Harding: Thank you.

Okay. Voting is now open for MUC2021-125: Psoriasis - Improvement in Patient-Reported Itch Severity for the MIPS program.

Do you vote to support the staff recommendation as the Work Group recommendation?

Co-Chair Padden: Looks like we have 16.

Ms. Harding: Okay. Voting is now closed for MUC2021-125, and the results are as follows:

Seventeen members voted yes to uphold the staff recommendation as the Work Group recommendation, at 100 percent.

Co-Chair Padden: Okay. Looks like we got a vote in at the last second there, Ivory.

Ms. Harding: Yes. Thank you.

Co-Chair Padden: Okay. Thank you.

Okay. Tricia, we'll go to the next measure.

Ms. Elliott: Yes. Thank you, Diane.

The next measure up is MUC-135: Dermatitis - Improvement in Patient-Reported Itch Severity.

The description of the measure is the percentage of patients aged 18 years and older with a diagnosis of dermatitis where at an initial or index visit have a patient-reported itch severity assessment performed, with a score greater than or equal to 4, and who achieve a score reduction of two or more

points at a follow-up visit.

The level of analysis is clinician. NQF's recommendation from the preliminary analysis is conditional support for rulemaking, pending endorsement.

And the comments from the Rural Health Advisory Group. There are no concerns raised for this measure relative to priority or utility. No issues identified for data collection or calculation. And none were identified for unintended consequences. And the average score was 4.3.

For the MAP Health Equity Advisory Group, the relative priority and utility. The Health Equity Advisory Group noted that dermatitis is an important clinical topic. Since this is a self-reported measure, data collection may be a problem for disadvantaged populations due to language and cultural barriers, as well as access issues.

The measure does require two assessments, and the response rates may drop among a disadvantaged population, resulting in selection bias in the measure performance.

The Advisory Group recommended this measure be stratified to assess performance based on the population subgroups.

And unintended consequences, the disparity in diagnoses was identified as a potential issue. Response bias was identified as a potential issue as well.

The average polling was 2.8.

And there were no public comments received online for this measure.

Co-Chair Padden: Thank you, Tricia.

Any clarifying questions or comments?

And I see that Stephanie, the developer, has remained on the line as well.

Member McGiffert: This is Lisa McGiffert.

I sat in on the Health Equity Committee, and just kind of wanted to -- my impression with that 2.8 score is that most of them didn't feel like it would have any impact on disparities one way or the other. I might be corrected, but that's sort of what I got from that meeting.

Ms. Elliott: Lisa, this is Tricia. I would agree because the 3 score is kind of a neutral score. So, it's just below that neutral score in terms of the scale of 1 to 5.

Co-Chair Padden: Thank you for sharing that, Lisa.

Any other questions?

Do our lead discussants have anything they would like to add prior to going to a vote?

Member Burstin: It's Helen. I'll just note it's great to see another PRO after years of talking about it.

Member Nguyen Howell: I didn't have anything to add, Diane. Thank you.

Co-Chair Padden: Great.

Okay. I'm going to look one more time for a hand.

I'm not seeing any. Nothing in the chat.

So, can we go to a vote?

Ms. Elliott: Just double-checking your assessment there, Diane, and I'm not seeing any other.

And similar to the last measure, I would just like to pause and offer a public comment as well, since we are running ahead of schedule and folks have joined with interest in this particular measure.

Okay. I think we are good, Diane, if you want to call for the vote.

Co-Chair Padden: Okay. We will call for a vote.

And as a reminder, the preliminary analysis for NQF was conditional support, pending NQF endorsement.

Ms. Harding: And the voting is now open for MUC2021-135: Dermatitis - Improvement in the Patient-Reported Itch Severity for the MIPS program.

Do you vote to support the staff recommendation as the Work Group recommendation?

Okay. Voting is now closed for MUC2021-135, and the results are as follows:

Seventeen members voted yes to support the staff recommendation as the Work Group recommendation. And that is 100 percent.

Co-Chair Padden: Thank you.

Okay. Moving along, is everybody okay?

Ms. Elliott: Diane, it's Tricia.

We're getting some messages from Work Group members that need to step away at 2:00 p.m., some for as long as 30 minutes.

So, I'm looking ahead with the next measure. I'm wondering if we want to squeeze in a break here, since we do know that there's several people that need to be absent for half an hour. So, I just wanted to get your and Rob's input, and maybe Michelle or Kim from CMS.

If we pause until 2:30 before we start the next total hip and knee measures, if we pause until 2:30, we are still 35 minutes ahead of schedule.

Co-Chair Padden: That would be fine with me. I was going to ask if we needed to take a break. So, it

was perfect.

Ms. Elliott: Yes. And because we do have Committee members that need to step away for that time, it might work.

Rob, any concerns?

Co-Chair Fields: No concerns.

Can I ask like, what do we need for a quorum?

Ms. Elliott: The Committee was 20; quorum is 66 percent. So, if I'm doing the math right, we need 13 for a quorum.

Co-Chair Fields: Okay. Yes, it will be pretty tight. So, we probably need to take a break anyway.

Ms. Elliott: Okay.

Michelle or Kim, is a break okay on your end as well, if you guys are on the line?

Dr. Schreiber: No scheduling issues --

Ms. Elliott: I'm sorry?

Dr. Schreiber: I have no concerns.

Kim, do we have any scheduling issues?

MS. RAWLINGS: No, I don't think so. I think we're fine.

Dr. Schreiber: Yes. Thanks for asking.

Ms. Elliott: Yes. Because we'll still be a little bit ahead of schedule, and then, on track to get to the social determinants or social drivers of health measures at the time that we hoped to.

So, excellent.

Okay. Thank you all.

(Whereupon, the above-entitled matter went off the

record at 1:54 p.m. and resumed at 2:32 p.m.)

Ms. Elliott: Diane, are you okay if I get started?

Co-Chair Padden: Yeah, we're all set.

Ms. Elliott: Okay. Excellent. So the measure up for discussion next is MUC 063, Care Goal Achievement Following a Total Hip Arthroplasty or Total Knee Arthroplasty.

The description of the measure is the percentage of adult patients 18 years and older who had an elective primary total hip arthroplasty or total knee arthroplasty during the performance period and who completed both the pre- and post-surgical care goal achievement survey and demonstrated that 75 percent or more of the patient's expectations from surgery were met or exceeded.

The pre- and post-surgical surveys assess the patient's main goals and expectations, i.e., pain, physical function, and quality of life, before surgery and the degree to which the expectations were met or exceeded after surgery.

The measure will be reported at two risk-adjusted rates stratified by total hip arthroplasty and total knee arthroplasty.

The level of analysis is clinician and group. NQF recommendation is do not support for rulemaking.

And I would like to share next the feedback from the MAP Rural Health Advisory Group. The relative priority, a concern was raised regarding patient expectations related to goal achievement. Patients from rural communities may have different expectations from surgery than the general population.

With regard to data collection, the data collection tools of paper versus electronic health record were discussed. And it was expressed that the paper tool would be more common in rural communities.

A concern was raised regarding a calculation issue of risk adjustment for BMI and the impact on rural communities.

And concerns were raised about patient selection in rural settings as a potential unintended negative consequence for the measure and should be monitored. The average voting poll there was 3.6. For the Health Equity Advisory Group, they deemed this important, excuse me, patient-reported outcome measure. Challenges were identified with the completion of both pre- and post-surveys due to the loss to follow up for disadvantaged populations.

The Advisory Group recommended this measure be stratified to assess performance based on population subgroups.

It was noted the measure is risk-adjusted by age, gender, BMI, but no details on other risk adjustment factors such as the socioeconomic status measures or elements. The developer noted that measure is not stratified by race, ethnicity, or other factors.

The Advisory Group also noted that there is a disparity as to who receives total hip arthroplasty and total knee arthroplasty and who has access to the surgery. This disparity and use of this measure could foster further patient selection.

It was noted that the denominator may not include populations who are unable to return for the post-survey. The polling average was 2.6.

For this particular measure, we did receive four comments. Two were positive in support of the measure. And two were not in support of the measure.

In terms of the not in support, a data collection burden was noted, and data collection for the practice, hospital. And patient must be adequately addressed, and any measure considered for MIPS

must be feasible, reliable, and valid.

The comments in support included the measure focuses on the patient goals and whether they were achieved by the medical intervention. And the other support was being able to define value based on what matters to the patient in the support of the measures that way.

That's it for comments, Diane.

Co-Chair Padden: Okay. Thanks, Tricia. Do we have any clarifying questions, comments? Would either of our lead discussants like to add a comment? I see Stephanie.

Member Hoo: Hi, this is Emma Hoo. I would like to pose a question to the developers around what efforts are in place to continue to develop this measure and to build out more volume in terms of reporting and testing.

Ms. Elliott: Ronen --

Co-Chair Padden: Ronen --

Ms. Elliott: -- it's hard to hear you.

Dr. Rozenblum: Can you hear me now?

Ms. Elliott: That is a little bit better.

Dr. Rozenblum: Okay. So, first, thank you for giving us the opportunity to discuss our measure. I will try to address, you know, some of the concerns and the question.

So, as mentioned, the measure was fully developed and tested using comprehensive qualitative and quantitative methods. Actually, this measure was sponsored by CMS. And we are continuing to be sponsored now with a no-cost extension to the questions that were asked now.

I will touch a little bit about, you know, the next

phase in our ability to add additional clinician groups.

We tested this measure in a real-use case scenario using Epic in six clinician groups. What you see is that three clinician groups in the testing for the people that reviewed the testing is the ones that met the benchmark.

Both the pre- and post-survey were programmed and implemented into existing PROMs programs and were assigned to total hip and total knee patients, which I liked from our perspective the feasibility and use of our measure.

Somebody mentioned in terms of the rule, you know, basically our ability to test the measure in EHR and paper. So it's important to mention that we tested our measure in mixed methods both on EHR using Epic in real environment, as I mentioned, and in paper base and didn't show any differences. So there is not disadvantages.

And actually, the measure is very simple in terms of the algorithm, in terms of the scoring. It could be used also in paper.

As I mentioned, you know, in terms of the qualitative interviews and focus groups with patients, providers, and peers, which we did the comprehensive work, which really highlighted the value and the need for this measure.

And in terms of the burden, because you mentioned burden, we actually did, as part of the qualitative assessment and specifically cognitive testing, testing to show to assess the burden. And basically this suggested there's minimal burden.

It actually took them two to three minutes. And the patient and provider really didn't think that it's adding any additional significant burden in terms of that.

Quantitative testing showed mixed results, and as mentioned by the SMP, and it's mainly because of the small sample size.

It's important to mention also that because we worked with the CMS and it was sponsored by the CMS, the research methodology, findings, including the measure testing level, which is a clinician group level, were supported and vetted by measure experts, patient providers, and staff members, including public, you know, public comments.

Now, I don't think it was mentioned, but one of the SMP main concerns was regarding the reliability and validity issues related to small sample size.

And this is something that we would like, when we acknowledge basically the issues raised by the NQF SMP regarding the small sample size and its effect on the finding, we do believe that the outcome of reliability and validity of testing of this PRO-PM should be assessing the context of new PROMs and PRO-PM because we cannot leverage from existing PROMs and registries, so we have to test our measure.

As I mentioned, we implemented and incorporated our measure into existing, you know, PROMs platform where we collected pre- and post- paired data sets. So, basically, for us to expand our efforts and to do that will take many years basically.

And as mentioned by the committees and based on the qualitative, you know, assessment, this is a very important, you know, measure that is aligned with the goals of CMS basically that really promotes patient-centered care and enabled -- personalized and aligned with patient goals and more importantly fills a gap. But I do mention that there is not currently any care goal achievement PRO-PM in orthopedic.

So we would like, if possible, for this working group to consider this in the context of new PROMs and

PRO-PM.

My last point here, and I can talk about other issues that some of them you raised, is the decision of the preliminary analysis and decision of this working group, which we respect, not to support our rulemaking.

If you look at what we received from your analysis, out of the seven, six criterias of basically passing the measure, the first five evaluation criteria were passed by this committee.

And the only one that didn't pass is basically number six. Number seven is not applicable because it's about current use measure.

So we appreciate if the working group will assess again their decision and consider conditional support or something else, because basically out of the seven criterias, only one did not pass. And that's it.

And I think somebody mentioned about on the rule that basically suggests that there might be, you know, anticipated biases in rural places.

Actually, we think the other way around, because really there is some population that really suffer from providers not paying attention or attentive to their goals and expectations. And in some cases, it's in rural places.

And in terms of biases selection, biases, we are not anticipating selection bias because the measure is actually assessing expectation against, patient expectation against them, you know, addressing expectation not against other populations, so, which really promote communication between providers and patients about unrealistic expectations. That's it. So we're not anticipating any selection bias.

Co-Chair Padden: Thank you, Ronen.

MS. SINGLETON: This is Stephanie Singleton. I also worked on the project with Dr. Rozenblum. And I

heard someone kind of ask a question about continuing to gather more information.

And currently, even though the contract period ended, we're actually still collecting data at Partners. We're still collecting across those six clinician sites.

And so we continue to gather more and more data in the test environment, which -- and I feel a little silly calling it a test environment because it's real time. It's being implemented in Epic and is going to all the patients who are scheduled for hip and knee replacements who meet the measure specification criteria.

It's actually been added into the current musculoskeletal survey group that Partners is deploying. So, in addition to our measure, it's not a separate thing. It's actually been kind of streamlined into their PROMs collection process as it is.

So those patients are getting our measures, as well as PROMIS Global Health, the HOOS-PS, and the KOOS-PS, and their other kind of patient-reported outcome measure collection instruments.

Co-Chair Padden: Thank you, Stephanie.

Member Fry: Stephanie, curious if there is any thought about possibly collecting outside of the six sites just in terms of having data from a broader cross section of the population, you know, kind of broader geography, you know, population base, that sort of thing. Or is the current collection going to be strictly the existing six sites?

Dr. Rozenblum: So this is Ronen. We are aiming to expand the effort. But --

Member Fry: Yeah.

Dr. Rozenblum: -- going back to my -- so definitely we're aiming to expand the efforts. But because this

PRO-PM is based on a new PROM, we need to implement that in other places. And we have communication with other places.

But basically, it's a perspective. You cannot use the registry or any other existing data. So this, as I mentioned, this will take a lot of time, which it makes sense completely.

But, you know, CMS is really promoting the right to do that patient-centered care. And this is in the heart of patient-centered care, being attentive to the patient needs, concern, you know, and trying to improve communication around goals and expectations.

So our worries, we think based on measure experts and people that are working with us really, you know, these people, that what we have now, it might be sufficient for a committee like you to make a decision.

Although we acknowledge that some of the reliability and validity is not sufficient because of the small sample size. But it should be a context -- I think there is something here, a case for you guys to consider when it's coming to new PROMs and PRO-PM that have to do that prospectively.

But to your question, we definitely are aiming to expand the efforts.

Member Fry: Thank you. That's really helpful. And I would just note quickly that I think it's really important to call this out as an interesting measure looking at patient experience because it looks at patient goals as compared to just, you know, functional outcomes or different things.

And so, you know, as someone who has built a career around patient experience measurement, I am thrilled to see this on the docket for consideration and a reasonable way to approach it.

The very small cell sizes and kind of inability to look at, you know, what would that mean if you expanded it and, you know, reliability and validity and, you know, should there be risk adjustment for, you know, race, ethnicity, SES, different things, you know, I worry that maybe it's a factor of, because it's a small cell size because it's a small geographic area, that we mightn't know all the right information about how to do this really well yet.

At the same time, I would be heartbroken to see something that moves so clearly in the direction of patient experience measurement in a really patient-centric way kind of cast aside. So I throw it for other questions before we carry on.

MS. SINGLETON: Thank you for that.

Dr. Rozenblum: Thank you for that. And if I may just address, because you mentioned risk adjustment and somebody else at the beginning mentioned one of the concerns.

So we identify and decided to risk adjust for age, gender, BMI based on comprehensive work, on lit review and basically other existing measures. So most of the measures out there in orthopedic take into consideration age, gender, and BMI.

But when it's coming to care goal achievement, you know, which is not assessed as you mentioned, Stephanie, just physical activity and function, the suggestion of measure developers that we worked with in patients, advisors, and providers is not to add race and ethnicity. This data was, you know, we had access to this data. So we made the formal decision now not to include that.

Member Fry: And I wonder if goals vary enough by race, ethnicity, SES, or other things, you know, rurality, that those are things that we really need to dig into. So that's just something that sort of floated around in my mind as I was looking at the characteristics and knowing that patient experience

often varies by race and ethnicity, that, you know, that's sort of baked into expectations that they may look different.

So that was something that occurred to me. And I know you are well underway and maybe many more questions yet to answer.

Co-Chair Padden: Great. Thank you. We have some questions. Emma Hoo?

Member Hoo: Hi. And if I may just procedurally sort of take my discussant hat off for a moment and also disclose that we, PBGH in the past had worked on orthopedic PROMs and working with researchers at Stanford found significant correlation around patient experience and higher rates of satisfaction for individuals that were engaged in shared decision making, which this measure supports in capturing that care goal achievement and setting expectations for time and effort required for rehab and, you know, other components of post-surgical care.

And while that work did not result in PROMs development, you know, recognizing that there, you know, is a whole body of research that supports the use of care goal achievement as part of our measurement process, you know, does move the patient-centered strategy forward.

And then, you know, secondarily, in full disclosure, PBGH was also a CMS MACRA grant recipient and, you know, fully recognized that the data collection was challenged during this COVID environment and that, you know, as Stephanie mentions, you know, having that conditional support with the opportunity to flush out the data and run some of the reliability and validity testing, you know, would be valuable insofar as -- you know, as, you know, we see the volumes for surgeries, you know, start going back up again, it seems like there are substantial opportunity to build out a better understanding of how this measure functions. Thanks.

Co-Chair Padden: Thank you, Emma. We have a comment from Lisa in the chat. And if you would like to address that to the group to --

Member McGiffert: That was just a comment saying how important these kinds of measures have, and I agree with what has been said before.

I did have a question about the role of the registry in this. Is the fact that you're reporting it through a registry going to restrict who participates, what gets seen by the public?

Issues like that always come up for me with, when registries are involved. Can you address what the role of the registry is?

Dr. Rozenblum: This is Ronen, but I would like also Stephanie to weigh in.

So maybe it's my fault that I confuse you. We are not using any registry. So it's a completely new PROMs and PRO-PM, which is not existing. And we are not aiming for the time being to be added or to use a registry. But, Stephanie, maybe you want to add --

Member McGiffert: I was just reading from the paper. And it says how is the measure expected to be reported to the program --

MS. SINGLETON: Right.

Member McGiffert: -- through the clinical quality measure registry. Is that a CMS registry?

MS. SINGLETON: Well, so it's funny. So it actually, the reporting has changed a little bit from like the time when we first got this grant.

It was at one point if a clinician group had I believe 25 or more clinicians reporting then they used one platform. If they were 25 or under, they were able to submit their data, you know, on an Excel spreadsheet. And I think CMS has been working

hard to kind of streamline the reporting back to MIPS process.

And so I know that right now AAOS has been doing a lot of reporting out for clinician groups, especially for those providers who are submitting for the AJRR and for the CJR.

So I think at this point one of the things that we kind of put in our submission is that based on what we are collecting and given the ease of use of the measure itself, meaning the calculations that need to be done, it's only eight questions, so, and it's a pretty standardized orthopedic scoring algorithm, that there should be some flexibility depending on kind of what the CMS requirement is based on the clinician group size.

And so I think it really depends on what those next steps look like with regard to what MIPS is requiring, the tool that is used for how clinician groups report out the data.

Member McGiffert: Okay. I just want to make sure I understand what you said. I think you said that for some physicians the, they are reporting to the registry and the registry is reporting to CMS, correct?

MS. SINGLETON: That is how it has been done in the past. There are also third-party vendors, like OBERD and a couple of others, that also act as that kind of link between a clinician group and MIPS.

They've suddenly realized that reporting is real and it's here and it's here to stay. So they've built that into their platforms.

So, for instance, if I'm a smaller size practice and I want to submit my data and I'm already using OBERD as my PROMs platform instead of perhaps an EHR, which is totally plausible, then OBERD might be submitting that data to MIPS on my behalf.

It really kind of depends on the size of the practice and what is already being kind of in place and the collection and then the size of the practice.

Member McGiffert: Okay. Thank you very much.

MS. SINGLETON: Sure.

Dr. Rozenblum: But, Lisa, just to make sure, so our measure is not just dependent on registry. It's completely --

Member McGiffert: Got it.

Dr. Rozenblum: This is very important.

Member McGiffert: Yeah, so I got that. Thank you very much.

Co-Chair Padden: Okay. I'm going to try and get us back to any clarifying questions on the measure, and so we can get a little closer to a possible vote.

I'm going to ask, Lou in the chat had a question, which directs directly to the vote, about what the specific reasons were for the NQF recommendation not to support. Can someone help us with that?

Ms. Elliott: Yes, Diane, this is Tricia. I can address that.

So the reason we put that forth in the preliminary analysis is the measure did not pass our NQF scientific methods panel for sufficient reliability and validity of the measure specifications.

Co-Chair Padden: Okay. So our first vote would still be for a yes/no on a do not support, correct?

Ms. Elliott: Correct. So a yes would mean that there's agreement with the recommendation to not support. A no would open it up for further discussion and potential other recommendation categories.

Co-Chair Padden: Okay.

Dr. Rozenblum: This is Ronen. Just if I may in this just said what I mentioned like ten minutes ago.

So, when we, you know, starting the day, you mentioned kind of the metrics how you assess. And basically you had seven criteria, just again mentioning that we will be happy to get this clarification.

Out of the six -- one is not applicable. Out of the six criteria of, you know, for you guys to vote, five were, met the -- basically you endorse and pass. And only one, number six, didn't pass.

So this, you have in the beginning of the day kind of a formula which measures should be passed or, you know, be considered under a conditional support or some.

MS. SINGLETON: It's just a little bit confusing kind of the disconnect between kind of the two. And so we're just trying to understand that a little bit better.

Ms. Elliott: This is Tricia at NQF. Was that Stephanie Singleton asking the question?

MS. SINGLETON: Yeah. Just again, as Ronen had said, you know, in the preliminary ask that you sent out, based on the criteria, just to us anyway, it looks like, oh okay, well, we met the criteria for certain milestones. And then, obviously, we realize with our small sample size, you know, and the reliability didn't meet that.

But it was just a little bit confusing the way it's laid out on the chart, because when we look at it, it looks like, oh well, maybe we should be in a different category based on those responses. So maybe we're just not looking --

Ms. Elliott: Right.

MS. SINGLETON: -- at it from the correct order of how it's being done.

Ms. Elliott: So the preliminary analysis includes a lot of those details, Stephanie, and the -- because this meeting is not to endorse a measure.

MS. SINGLETON: Right.

Ms. Elliott: But we inform this group of the status of where it was at. And because of the impact of the SMP committee decision and then how the criteria are laid out for the voting categories here, that's where we landed --

MS. SINGLETON: I see.

Ms. Elliott: -- in the preliminary analysis.

MS. SINGLETON: Got it.

Ms. Elliott: So the process here now is we look at the recommendation made out of the preliminary analysis, and that is do not support. So the committee will decide yes or no to move forward with that recommendation.

MS. SINGLETON: Okay.

Ms. Elliott: If it's a no on the recommendation, then further voting will occur.

MS. SINGLETON: Okay. That makes sense. Thank you.

Ms. Elliott: Yep. But this is separate from the endorsement piece.

MS. SINGLETON: Got it. Okay. That makes good sense. Thank you. I appreciate it.

Co-Chair Padden: Thank you. I think we're ready to go to the vote then, Ivory.

Ms. Harding: Okay. Thank you, Diane. Voting is now open for MUC2021-063, Care Goal Achievement Following a THA or a TKA for the MIPS program. Do you vote to support the staff recommendation as the work group recommendation?

Ms. Elliott: And just for everybody's information, we should get to 14 votes here. We do have a recusal.

Ms. Harding: Okay. Voting is now closed for MUC2021-063. And the responses are as follows. Ten members voted yes and four members voted no with a percentage of seventy-one percent. So the work group has voted to support the staff recommendation as a work group recommendation.

Co-Chair Padden: Okay. Thank you, everyone. And we will move on to the next measure, Tricia.

Ms. Elliott: Yes. Thank you, Diane.

The next measure is MUC 107, Clinician-Level and Clinician Group-Level Total Hip Arthroplasty and/or Total Knee Arthroplasty Patient-Reported Outcome-Based Performance Measure, PRO-PM.

The measure will estimate at clinician and clinician group level risk standardized improvement rate for patient-reported outcomes, PROs, following elective primary THA/TKA for Medicare Fee-For-Service patients 65 years of age or older, substantial clinical benefit.

Improvement will be measured by the change in score on the joint-specific patient-reported outcome measure instruments -- PROM measures or PROM instruments -- measuring hip or knee pain and functioning from the preoperative assessment, which is data collected 90 to 0 days before surgery, to the postoperative assessment, data collected 300 to 425 days following surgery.

Level of analysis is the clinician and group, and the NQF recommendation from the preliminary analysis is conditional support for rulemaking. I'll now share the Rural Health and Health Equity comments.

Rural Health -- the measure was noted to be applicable to rural providers. Concerns were raised regarding the challenge of obtaining high response

rates for follow-up, as rural providers with resource limitations may be specifically challenged.

Concerns raised regarding the calculation of the average or the changed score of the measure was noted for a calculation issue. Concerns were raised regarding lessened recovery for patients due to the physical, manual occupations in rural communities.

The average whole score there was 3.3. MAP Health Equity Advisory Group input included the measure looks at a threshold level of improvement. With data collection, challenge with collecting data pre-op and post-op due to complexity and access barriers for certain populations of patients, for example, non-English-speaking patients.

Burden to collect data will likely be distributed unevenly across practices. Lack of stratification was identified as a priority for this measure, particularly stratification for language -- potential selection bias of the population, as well, for calculation. The Health Equity Advisory Group noted a concern that the measure may benefit practices that serve more English-speaking, less socially disadvantaged patients for whom administering these measures are easier.

The whole range for the score is 2.6, and there was two comments for this measure. Both were not in support, and both spoke to the data collection burden of the measure. And those are the comments.

Co-Chair Padden: Tricia, I just sent you a message. There's a couple comments in reference to the last vote on quorum.

Ms. Elliott: Sure. Let me double-check. So the quorum --

Co-Chair Fields: I thought quorum and --

(Simultaneous speaking.)

Co-Chair Fields: -- percent needed to vote were two different criteria, right? We have quorum present, and we need --

Ms. Elliott: Yes.

(Simultaneous speaking.)

Co-Chair Fields: -- percent of the voting members. Those are two different things.

Ms. Elliott: Correct. So we have quorum present, and on that particular measure, we had one recusal. So that's why the vote went through with 14.

Co-Chair Padden: All right. Thank you for clarifying.

Ms. Elliott: Mm-hmm. Sorry. I didn't see that question while I was --

Co-Chair Padden: You were busy, right?

Ms. Elliott: -- checking the comments here, so --

(Simultaneous speaking.)

Co-Chair Padden: -- together here. Okay. Now we're going to regroup. I just wanted to be sure we were moving in the right direction if we had to take a step back.

So any questions, clarifying questions, on this particular measure? And the recommendation is conditional support pending NQF, correct?

Ms. Elliott: Correct.

We do have a hand raised that I can see, Diane, Nishant Anand.

Co-Chair Padden: Okay. Must be --

(Simultaneous speaking.)

Member Anand: Just a question on this one. So 300 to 425 days -- I was looking through the reports,

and the providers, the surgeons and CJR, completed it. But, you know, I -- just one clarification. That's a pretty precise area. So are we going to be able to collect it in that time frame?

And I don't know -- people who originally did this measure, were they able to get a good sample size of folks? Because I can imagine there's a pretty significant drop-off as you go that far into the future.

Co-Chair Padden: Who would be able to answer that question?

Dr. Balestracci: Hi. This is Dr. Katie Balestracci. I am representing the measure developer. If that helps, I can speak to that.

Co-Chair Padden: Yes.

Dr. Balestracci: Wonderful. Thank you. So, yes, this is -- the data used to develop and test this measure, as you noted, were collected through the CMMI's CJR program.

The 310- to 425-day follow-up is our recommendation based on really significant stakeholder input, particularly from clinicians and surgeons, noting the propensity to have a one-year post-op follow-up visit with patients and that having a two-month window on either side of that appointment would allow for optimal capture of PRO data in order to calculate this measure.

In CJR, as posted in the final rule, the data collection window was the equivalent of 9 to 12 months versus this 10 to 14. There was a drop-off in collection from the pre-op window, and one of the reasons for this recommendation is that some of that was thought to be that -- for scheduling purposes or a cancelled appointment or a missed post-op appointment, that the collection of the post-operative data were being hampered by the one-year collection cutoff.

So the expectation is this shift in the post-op window would in fact enhance postoperative data collection and increase the response with both pre- and post-op data.

Member Anand: Thanks. Just one final question on that, Katie. So there was --

Dr. Balestracci: Sure.

Member Anand: -- a subsequent visit at that 300 to 425 days. Was there a subsequent office visit at that time in order to collect data, or was there navigators or someone who called the patients to get those --

(Simultaneous speaking.)

Dr. Balestracci: It was -- yeah, thank you for that question. The providers and hospitals -- because, as those on the call may know, the CJR program was initially put -- this voluntary PRO collection was initially put in place for hospital collection because we do have an NQF-endorsed hip/knee PRO-PM on which this measure is respecified.

But the follow-up -- the pre-op and the post-op can be collected in a number of ways, and our understanding from hospitals is that a number of options were considered by particular providers, so that some may have been collected during office visits.

And the hope is that the timing of the preoperative and postoperative windows certainly supports that type of collection. But some providers did use other methods of collection: phone, electronic, et cetera.

Member Anand: Thank you.

Co-Chair Padden: Are there any other questions, comments?

Lou has got something in the chat.

Lou, do you want to ask your question?

Okay. I'll ask it for him. I don't see him. His comment that you may see -- the importance of PROs -- also, does this measure or other similar measures in the suite of measures capture any objective provider-measured outcomes for comparison as well?

Dr. Balestracci: Again -- Dr. Balestracci -- this is a patient-reported outcome measure, so this particular measure does in fact reflect patient report of their own pain and functioning preoperatively and postoperatively.

For these particular metrics, we actually think that the patient report is the most valuable and that patients are best able to, in fact, report on their own functioning and pain.

CMS does have a suite of measures that include a complications measure that looks at complications up to 90 days post-elective primary THA/TKA. So there are some other measures that are not necessarily provider-reported but are measuring other metrics related to this particular procedure.

Co-Chair Padden: Thank you.

Lou, did that answer your question?

And we also have a comment from Lisa, who is also from the measure developer.

A comment from Wei -- specific 20-point, 22-point increase cut point is based on test data or literature review?

Dr. Balestracci: So the substantial clinical benefit thresholds, which are these 22- and 20-point increases from preoperative to postoperative data, are those that were tested and validated by Stephen Lyman and his colleagues, who developed the HOOS JR and the KOOS JR.

They are anchored in patient report following a hip/knee procedure, and his work included patient interviews. So there was a great deal of anchoring in patient experience when the substantial clinical threshold was identified and calculated.

In addition, we as measure developers did test these increases along with other potential increases in our data and found these to be the best choice for this measure, both because they reflected substantial change but also identified variation among clinician and clinician groups, which is certainly one of the targets for a measure like this to identify and then provide incentives for improvement following the surgery.

Co-Chair Padden: Thank you. Okay. I'm not seeing anything else in the chat. I do not see any other hands.

Tricia and Rob, any other hands? Nothing in the chat?

Ms. Elliott: Correct. Again, I'm not seeing either.

Co-Chair Padden: Okay.

Dr. Balestracci: May I -- if I may, I did hear something in the introduction, perhaps a comment coming from the Rural MAP, and if I misunderstood, please forgive me. But it sounded like there was a reference to an average. I do want to make sure that Committee members are clear that the improvement threshold for this measure is in fact the substantial clinical benefit change in point increase.

We heard back from stakeholders that this approach versus an average change approach was far preferable because it could identify patients who did improve and did not improve, and that an average could obscure a provider that had mostly average outcomes for their patients versus one that might have some that did really well but some that did, in

fact, really poorly.

And the other, we believe, important aspect of this threshold change is that it actually de-incentivizes providers from not choosing to perform surgery on patients with greater severity at baseline. In other words, patients with more severity at baseline have a greater opportunity statistically for meeting the improvement threshold.

So it really continues to encourage surgeons to consider all patients, but particularly those most severe at baseline.

Co-Chair Padden: Thanks.

Okay. I think that we're ready to move to a vote. And, as a reminder, the preliminary analysis was conditional support for rulemaking.

Ivory?

Member Mullins: Thank you.

Voting is now open for MUC2021-107, Clinician Level and Clinician Group-Level THA and/or TKA PRO-PM for the MIPS Program. Do you vote to support the staff recommendation as the Work Group recommendation?

Co-Chair Padden: And how many will we be expecting? Fifteen?

Ms. Harding: Yes, at least 15.

Ms. Elliott: Fifteen at a minimum. There are no recusals this time.

Ms. Harding: Okay. Voting is now closed for MUC2021-107, and the results are as follows: 16 members voted yes to support the staff recommendation as the Work Group recommendation, or 100 percent.

Co-Chair Padden: Okay. Thank you.

All right. Move along. Tricia for the next one?

Ms. Elliott: Excellent. We'll just wait a moment here for the slide.

Okay. If we can -- there we go. Oh, 90. Yep.

So our next measure up is MUC2021-090, Kidney Health Evaluation. The description of the measure is the percentage of patients aged 18 to 75 years with a diagnosis of diabetes who received a kidney health evaluation defined by the estimated glomerular filtration rate and urine albumin-creatinine ratio within the 12-month measurement period.

The level of analysis is clinician and group. NWF recommendation is conditional support for rulemaking. And I have the Rural Health comments to share with the group.

The Rural Health Group felt that the goal of the measure is important. The Rural Health Work Group expressed concern on whether rural providers would be able to report the measure due to the difficulties obtaining the data and lack of lab capacity in rural settings to complete the testing.

No issues were identified for calculation or unintended consequences, and the polling average was 3.5. For Health Equity, the measure was noted to be an important clinical topic. Robust discussion occurred regarding a new CKD-EPI eGFR equation that does not include race. It's considered use of raceless eGFR estimation equation.

The Advisory Group strongly supported the use of the raceless eGFR estimation equation. No calculation issues and no unintended consequences were identified. There was four public comments received on this measure. Three were in support, and one was does not support but with mitigation.

And let me just double-check my notes here. The

concern with the mitigation was concern with the overall Cohen's kappa agreement rates of none to slight for the numerator and exclusion and additional testing. So that was the major comment there. The rest were in support of the measure.

Those are the comments, Diane.

Co-Chair Padden: Okay. Thanks.

All right. Any questions -- clarifying questions/comments from the group?

Do either of our lead discussants have anything they would like to share with the group?

Member Fields: I would just comment that this has already been accepted by HEDIS and is already being used by that group. So it would be consistent with what's already being used.

Co-Chair Padden: Thank you.

Member Mullins: Yeah. I would add to that, and I would say that it's being considered also in the Core Quality Measure Collaborative to be added to the PCMH/ACO set and is already being used by health plans.

Co-Chair Padden: Thank you, Amy.

Any questions? Any other comments?

Okay. There is one comment in the box. The American Society of Nephrology Quality Committee is in support of this measure.

Thank you. Okay. I'm going to look one time for hands.

Member McGiffert: The recommendation is, please?

Co-Chair Padden: That is conditional support for rulemaking pending NQF endorsement.

Member McGiffert: Thank you.

Co-Chair Padden: Okay, Tricia. Ivory, I think we're ready for a vote.

Ms. Harding: Okay. Thank you.

Voting is now open for MUC2021-090, Kidney Health Evaluation for the MIPS Program. Do you vote to support the staff recommendation as the Work Group recommendation?

Okay. Voting is now closed for MUC2021-090, and the results are as follows: 16 members voted yes in support of holding the staff recommendation as the Work Group recommendation. Thank you -- or 100 percent.

Co-Chair Padden: Thank you. We'll give the staff a little time to get the next slide up as we move to the next measure.

Tricia?

Ms. Elliott: Okay. Thank you, Diane.

The next measure is MUC2021-127, Adult Kidney Disease: Angiotensin Converting Enzyme Inhibitor or Angiotensin Receptor Blocker Therapy.

The description of the measure is percentage of patients aged 18 years and older with a diagnosis of CKD Stages 1 through 5 not receiving renal replacement therapy and proteinuria who were prescribed ACE inhibitor or ARB therapy within a 12-month period.

The level of analysis is the clinician and group. The NQF recommendation is support for rulemaking. And I will now share the Rural Health Advisory Group input.

The measure was suggested to be important for the rural communities, and opportunities for improvement do exist. Data collection issues -- none were identified. In terms of calculation issues,

concerns were raised that lower patient volume in rural settings may impact the reliability/validity of the measure. And no unintended consequences were identified. The polling average was 41.

The MAP Health Equity Advisory Group input includes the Advisory Group noted the importance of this clinical area and relative low performance among disadvantaged populations. There is a gap in care, and this is an important intervention that is evidence-based.

There were concerns expressed related to the data collection burden. It is more burdensome since it requires some chart detail to understand exclusions, and providers with fewer resources may struggle. There was no calculation issues identified, and concerns expressed over access to care as an unintended consequence as well as concern expressed regarding the exasperation of disparities. The average polling rate was 31.

There was two comments received regarding this measure, and both comments were in support of the measure.

Co-Chair Padden: Thank you.

Any questions, clarifying questions? Any comments from the Committee?

Do either of our lead discussants have anything they would like to share with the group?

Member Hines: This is Lisa Hines. I do not have concerns with this measure and agree with the NQF recommendation.

Co-Chair Padden: Thank you.

We have a comment in the chat box. The National Kidney Foundation supports this measure.

Member Fleischman: I have a question. The concern that was raised about some of this being a burden

on providers -- from reading the measure, I can't think of things that cannot be electronically extracted in terms of diagnoses to supportive conclusions and so on.

What is the -- yeah, I don't know if the discussants or the measure developers can clarify what might be burdensome on providers.

(Simultaneous speaking.)

Ms. Elliott: This is -- sorry. This is Tricia, and that comment came out, I believe, as part of health equity. So I was just looking through my notes.

From their perspective, in reviewing the measure, they were saying it does require some chart detail to understand the exclusions. So I'm not sure if the developer is online and can speak to that.

If the -- Renal Physician Association is the measure developer. Are they on the line?

MS. BECKRICH: I am. Sorry. It just took me a moment to get unmuted.

Ms. Elliott: No problem. Go ahead.

MS. BECKRICH: So we do agree with the previous speaker that said that they thought the elements of the measure could be collected electronically. And we were a little unclear during the discussion last week about why those reviewers thought it might be more burdensome than some of the other measures.

The exclusions, we think, are pretty straightforward. So I think that these are things that could be programmed to be captured electronically and would not require some sort of extensive chart review by the provider.

Co-Chair Padden: Thank you, Amy.

Any additional comments or questions?

Seeing no hands, no chat questions or comments, we will move to the vote, which is to support for rulemaking.

Ivory?

Ms. Harding: Thank you.

Voting is now open for MUC2021-127, Adult Kidney Disease ACE Inhibitor or ARB Therapy for the MIPS Program. Do you vote to support the staff recommendation as the Work Group recommendation?

Okay. The voting is now closed for MUC2021-127, and the results are as follows: 16 members voted yes, which gives us 100 percent for the Committee support of the staff recommendation to move forward as a Work Group recommendation. Thank you.

Co-Chair Padden: Okay.

Ms. Elliott: Next measure?

Co-Chair Padden: We're ready.

Ms. Elliott: All right. Here we go. MUC2021-105, Mismatch Repair or Microsatellite Instability, MSI, Biomarker Testing Status in Colorectal Carcinoma, Endometrial, Gastroesophageal, or Small Bowel Carcinoma.

So the description is the percentage of surgical pathology reports for primary colorectal, endometrial, gastroesophageal, or small bowel carcinoma biopsy or resection that contained impression or conclusion or recommendation for testing of mismatched repair, MMR, by immunohistochemistry, the biomarkers MLH1, MSH2, MSH6, and PMS2, or microsatellite instability, MSI, by DNA-based testing status or both.

Level of analysis is clinician, group. NQF

recommendation is conditional support for rulemaking. And I will now share the Rural Health and the Health Equity comments.

The Rural Health Group provided the following input. This measure was suggested to be important and relevant to the rural communities, as rural patients may be less likely to receive this care or tests. Concern was raised regarding data availability for rural providers. No calculation issues were identified.

The measure may stimulate the availability of these tests in rural settings. That was listed as an unintended consequence but could be a positive consequence. The average poll from this group is 3.6.

With regard to the Health Equity Advisory Group, the Health Equity Group noted that disparities exist in access to this testing. Access to cancer care is an issue, as well as ongoing treatment/support is an important equity concern.

Data collection issues were noted as lack of stratification was identified as a priority for this measure. No calculation issues identified, and no unintended consequences. The average polling for this measure was 2.7.

There were 16 public comments for this measure, and all comments were supportive. Some of the themes that came out of those 16 comments were improved outcomes, improved screening, and low burden because the data is from the pathology reports.

Co-Chair Padden: Thank you, Tricia.

Ms. Elliott: Mm-hmm.

Co-Chair Padden: Any clarifying questions/comments from the MAP Committee?

Member Fleischman: So I see that there's some

mention that some EHRs are electronically extracting this information, which tells me that others are not. So it just doesn't seem to be low burden to me. It's not an electronic measure, or it's not an ECQM.

It's relatively small. At least by the time the measure description was written, there were, I think, 6 practices, 11 clinicians total, submitting information to the Pathology Registry. So it hasn't been well tested.

The question I have is how broadly can this be expanded, or how easily can other practices and clinicians adopt this without using stuff like natural language processing and so on to process these pathology reports to figure out if this testing was done?

Dr. Cardona: I can address that.

Co-Chair Padden: Yes. Go ahead.

Dr. Cardona: My name's Dr. Cardona. I'm a pathologist at Duke, and I'm here representing the College of American Pathologists. So, since the time that we wrote the measure and the submission, we are definitely well on track on getting over 20 practices reporting on the measure.

So we're very hopeful that we would get an intra-reporting year benchmark for this year. And the way that they're submitting the data, there's three different options. So we do have some practices that have a direct feed into their laboratory information system. We have some that do a poll in which they run a report, extract the data into an Excel, and upload it to the registry.

And then we do have a smaller subset that do manual entry. And it really is dependent on the practice and their overall volume for the various measures on which of those three modalities they

choose.

Co-Chair Padden: Thank you.

Did that answer your question?

Member Fleischman: So I'll follow up on one other partially asked -- so the biomarker testing or mismatch repair, which was framed in the description as a comment, is really -- they are discrete events that should generally be recorded as a lab test in claims, billing, so on, that could -- I could imagine any large system could adopt this by way of referring to discrete tests or claims or line items within the lab management system. Right?

Dr. Cardona: I wish it was that simple, but unfortunately, for example, immunohistochemistry is a generic 88342 CPT code, which could be any immunohistochemistry. So it could have been CDX2, ER, estrogen receptor, progesterone -- it could be anything.

It wouldn't be specific to any of those for immunohistochemical biomarkers, and same thing for PCR testing. So, unfortunately, the CPT code data is not granular enough for us to just pull it off of that.

Member Fleischman: But, beyond CPT code data, you mentioned the systems that do have it connected to their lab management system. Beyond claims --

(Simultaneous speaking.)

Dr. Cardona: -- language.

Member Fleischman: So it is NLP. Okay. There is no way to connect -- because that's an added function/technology that most systems don't have at the moment. There is no way to connect beyond -- not claims, but in Epic or any EHR order, there's nothing specific for this subcategory of immunochemistry testing?

Dr. Cardona: Depending on the EMR or laboratory information system, which we call LIS -- so, unfortunately, every LIS is different in their capability and how granular that ordering system is.

So, for places like where I'm located, I could pull that data because it's all electronic ordering. In a lot of our smaller rural-setting community hospitals, that's not the case.

Member Fleischman: Right. And sorry if we're getting into the weeds here, but for example, Epic Beaker, is that what you use in -- I'm just thinking of the scope of this. How broadly can this be adopted, with the caveat that -- right, smaller places won't be able to potentially use this measure initially because of burden?

Dr. Cardona: Yes. So Epic Beaker, absolutely. What you're describing, we could run that report and pull exactly every single MLH1, MSH2, et cetera, order that we placed. Same thing with MSI/PCR testing because we do have it down to the discrete orderable.

But the people that are using this measure for the purposes of MIPS aren't people in big academic centers, really, because they're usually in the APMs. So, yes, I think that this could be a broad quality measure for more than just MIPS, but for right now, the people that would be using it for MIPS, it would be probably less likely the case that they would have that discrete orderable information.

But the natural language processing that we're using now is working for those practices that have selected to do that work up front as far as the mapping.

Co-Chair Padden: Thank you.

Any other questions?

Member Gozansky: Yeah, I have a question. This is

Wendy Gozansky. So I'm not clear: why would this not lead to overuse, potentially?

Dr. Cardona: I guess I would question what would you define as overutilization? So, if you are limiting it to these cancer types, which is what the guideline recommends, then you would be doing proper utilization because this would not only dictate potential immune checkpoint therapy utilization but also the benefit of Lynch syndrome screening.

Member Gozansky: And can I clarify the guideline has been published?

Dr. Cardona: So we have our original 2016 guideline that first included just colorectal cancer. The CAP, along with the American Molecular Pathology Association, ASCO, and patient advocacy groups are working on the next iteration that includes the other cancer types that we've included here.

Endometrial carcinoma -- I think that recommendation came out -- I believe it's 2018 or so. It's just the new iteration of the guidelines now includes gastroesophageal as well as the small bowel.

(Simultaneous speaking.)

Member Fleischman: Oh. Sorry.

Co-Chair Padden: Go ahead.

Member Fleischman: So, following up on that, assuming the guideline is -- essentially recommends what is listed here, if an organization would test every patient in the denominator, they would be following the guidelines. They would be 100 percent guideline concordant, if you will.

Dr. Cardona: Correct. Now, one caveat to that is that this measure does not require testing. It says that either you've done the testing, or at a minimum, the pathologist has put in their

recommendation language. Because of various reasons we got during feedback on the measure, small community practices may not have access to the testing readily, or their local physicians, because of cost concerns, said that they don't want it to be a blanket thing.

So, I mean, I think you could argue that that needs to be discussion between the pathology group and the clinicians to say, well, this is what the guidelines recommend. But at a minimum, we felt that if the pathologist would put in the documentation of this is recommended, now that patients have access to reports, they could also be part of that discussion with their clinicians to ensure that the testing is being done.

Co-Chair Padden: So we have the developer here with us.

Colleen, please.

MS. SKAU: Hi. Just to clarify really quickly since this came up, to the point about the use of the measure, the original number that was submitted back in May was low because this is the first year of use of this measure. So, honestly, we were still onboarding practices.

We currently have 27 practices that are reporting data for this measure. Nine of those practices are doing it directly from their laboratory information system. So they -- you know, basically no human intervention is necessary.

So we do have fairly high confidence that even practices that are small private practices, just one or two pathologists, are able to submit data on this measure in whatever of the three forms that Dr. Cardona described.

Co-Chair Padden: Thank you.

Member Fleischman: So you could get around -- if I

was a pathology group, I could just implement a smart phrase or a default statement in the impression that says, consider testing for -- consider mismatch repair/microsatellite instability testing, and that would satisfy the measure. That would get me into the numerator.

Dr. Cardona: That is correct.

Co-Chair Padden: Great. We have another hand.

Wei?

Member Ying: Sure. My question is mainly on the underlying, quote unquote, case mix. So, because -- as you mentioned, the guideline on the colorectal cancer screening came first, and then in '18, there's another set. And the new one that's to be released is on the GI front.

And I think I saw in the preliminary analysis there is a trending -- there are some difference in terms of guideline compliance by the underlying clinical condition. So I wonder whether you looked at the case mix distribution among the pathologists that covered or participated in your field test. And do you see whether the underlying case mix actually has anything to do with the overall performance?

Co-Chair Padden: Is your question for the developer?

Member Ying: Yes.

Dr. Cardona: So not so much variability in the performance. I think it's more of a reflection on the incidence of those cancer types, where colorectal obviously is the most common of that group, followed by endometrial, and then gastroesophageal and then small bowel being the least common of the cancer types.

So (audio interference) are what's driving the denominator in the practices that are using the measure now is colorectal cancer followed by

endometrial. The other ones really haven't impacted performance simply because the N is so small.

Member Ying: Right. And so, then, if -- my assumption from your comment earlier, then, you don't foresee that case mix is going to change much from group to group, from doctor to doctor, or from time to time? So the colorectal will always be dominant, and the other ones will be very minimal.

Dr. Cardona: Correct.

Member Ying: Okay. And another question is -- on the field test, I remember seeing about 51 physicians participated, but there was no -- at least on what I have seen, there was no minimum requirement on how many patients each provider served/had to report on to be included in the test.

So do you have a range, how many patients per provider actually was being looked at?

Dr. Cardona: Colleen, do you have that number?

MS. SKAU: I don't know the range in front of me. We included any clinician that saw at least one case of this. We did not have a cutoff. I could look up the range if you're interested in that.

Member Ying: Yeah, the reason I'm interested in that is actually related to my previous comment, totally understanding that in general, colorectal cancer should be the one dominant. But, again, because there is a different release of the timeline, the more mature condition, probably, the physicians usually have a little bit more percentage in their patient panel; their performance probably is better.

So those providers have more gastroesophageal or small bowel cancer patients because the guideline is still to be released. So, at least for the first couple years, if those physicians have a relatively heavier percentage of their panel in those clinical categories, their performance may seem to be

worse than other physicians. But that's just a mere reflection of their underlying case mix.

Dr. Cardona: That's a great point. And I think we're also biased by the people that are using the measure now are using it through our registry, in which they get the information like this is why we're doing it, and this is the evidence to support it. And they change their practice quite quickly.

Pathologists don't like to be short of 100 percent, we've found. So -- but once it's out in the public domain, hopefully -- I think that you have a very valid point because now it's all comers, not just those potentially using the registry.

So, in that situation, I'm hopeful that the guideline will be released. When we submitted this to you guys, we were told that the guideline was supposed to be published this fall. That is a completely separate arm of the CAP, and we're separate for a reason. So I honestly don't know all the backstory as to what the delay has been in the publication, but we're hopeful that it's literally going to be any day now.

So, hopefully, that -- once this becomes public measure -- has already been released and becomes more standard practice to include the new cancer types.

MS. SKAU: Yeah. I'll also note, to your point, we had a separate measure that just dealt with MMR/MSI testing in colorectal cancer because that recommendation has been available for several years, and a separate measure that just dealt with MMR/MSI testing and endometrial cancer.

So we previously had those as sort of freestanding measures. And over the course of use of those measures, we did see an increase in performance, but they were by no means 100 percent. So, even though the colorectal cancer recommendations for universal testing of colorectal cancer have been out

for several years, per the previous version of this measure, pathologists were not at 100 percent with that.

So we do still think that there is room for improvement in that, and your point is well taken that it is going to somewhat depend on case mix. But it's not likely if you're seeing colorectal cancer patients only that you're automatically going to be at 100 percent.

Member Ying: Great. Point well taken. I think my main concern that -- or even a question, not even a concern. I was just curious that whether you guys -- whether the developer has looked at the case mix, because when you look at the real identity that the case mix is not even a reliable measure, still, the case mix is not part of that consideration.

It can be very reliable based on just a numerical value, but if you have not looked at the case mix of the participating pathologists, I would recommend you do that just to see whether it's actually caused some -- just artificial inflation or deflation of the performance.

Co-Chair Padden: Okay --

Dr. Cardona: Yeah, I think that's a great point. And the registry would allow the practice to drill down, down to the case level, if there are any pieces where they're not meeting the measure. And so we could look at that. We just haven't done it for the people that are reporting currently.

Co-Chair Padden: Thank you. We're going to try to get back to the specific question here. I appreciate the in-depth discussion.

Any additional questions related to this measure before we go to a vote, for clarity?

Will?

Member Fleischman: One more. What is conditional

support here? It says pending deliberations of the evidence. Who is going to deliberate and evaluate the evidence?

Co-Chair Padden: This is conditional support -- it's the separate -- correct, Tricia -- from NQF.

Ms. Elliott: Correct. This should -- let me just double-check here. I think that should actually read -- oh, that we're awaiting the guidelines to be released, as the developer stated.

Member Fleischman: Okay. So not the strength of evidence provided? So it's pending the guidelines essentially agreeing with the measure.

Ms. Elliott: Correct.

Member McGiffert: And so this is not NQF-endorsed either, and that's not part of the condition.

Co-Chair Padden: Okay.

(Simultaneous speaking.)

Member McGiffert: Is that correct?

Ms. Elliott: That could be part of the condition, but right now, because of the timing of the evidence, we were going to have that as the initial condition for this recommendation.

Member McGiffert: So, once the guidelines are out, then that would -- if we voted yes, it would go directly to CMS for rulemaking.

Ms. Elliott: Well, it goes to the Coordinating Committee, and they would reflect on the discussions we've had here and the recommendations made from this group.

Member McGiffert: Got it.

Ms. Elliott: And we should -- to clarify, too, we should probably add the condition of NQF endorsement, as well, as we've done on other

measures. But we called out this evidence piece because we're waiting on what the developer spoke of.

Member McGiffert: And I think that would be a good idea.

Ms. Elliott: So maybe we could clarify to say NQF endorsement and pending review of the guidelines, kind of a combined condition, if the Co-Chairs agree.

Co-Chair Padden: That sounds agreeable to me.

Co-Chair Fields: Yeah, that makes sense.

Co-Chair Padden: Okay. So, Ivory, we will call the vote. And, as Tricia just helped us to clarify, you're voting on the preliminary analysis, conditional support pending NQF endorsement as well as the release of the guidelines.

Ms. Elliott: And, just to note, Diane, Helen makes a great point, too. Evidence is part of the endorsement, so we could probably collapse that in and say that it's pending NQF endorsement just for clarity.

Member McGiffert: I want to make another statement about this being a process measure, not an outcome measure, and that the priorities for these programs -- my understanding is for them to be outcome measures, and it would pose some questions for me as to whether we should be spending our time on these.

Co-Chair Padden: Okay. That comment is noted, as this is being recorded. So we will have that in place as well.

Ms. Harding: Okay. Are we ready to move forward with the vote, Diane?

Co-Chair Padden: Yes. The poll is up. I see we've got people already voting.

Ms. Harding: Okay. The vote is now open for MUC2021-105, MMR or MSI Biomarker Testing Status in Colorectal Carcinoma, Endometrial, Gastroesophageal, or Small Bowel Carcinoma for the MIPS Program.

Do you vote to support the staff recommendation as the Work Group recommendation?

So it looks like everyone has voted already. The voting is now closed for MUC2021-105, and the responses are as follows: 14 members voted yes, and three members voted no, with a percentage of 82 percent. So the Committee voted to uphold and support the staff recommendation as the Work Group recommendation. Thank you.

Co-Chair Padden: Thank you.

Okay, Tricia.

Ms. Elliott: Okay. Thank you.

The next measure is MUC2021-058, Appropriate Intervention of Immune-Related Diarrhea and/or Colitis in Patients Treated with Immune Checkpoint Inhibitors.

The description is the percentage of patients age 18 years and older with a diagnosis of cancer on immune checkpoint inhibitor therapy and grade 2 or above diarrhea and/or grade 2 or above colitis who have immune checkpoint inhibitor therapy held and corticosteroids or immunosuppressants prescribed or administered.

The level of analysis is clinician or group. NQF recommendation is conditional support for rulemaking, and the condition being NQF endorsement.

The MAP Rural Health Advisory Group input includes the following. The context of the measure was suggested to be appropriate for rural providers and geared towards outpatient for the rural populations.

For data collection, concern was raised for the data availability for grading, as it would be in progress notes and would require chart abstraction. Integration of data from multiple patient care sites was noted as a concern as well. There was no calculation issues or unintended consequences. The polling average was 3.2.

For the MAP Health Equity Advisory input, no major equity implications were identified, either positive or negative. This measure may have a small denominator was a data collection concern. And there's no calculation or unintended consequences identified. The average poll for this for the Health Equity Group was 3.4.

There was five comments that we received, all in support of the measure. And many of the measures spoke to improve patient quality of life and the general support of the measure.

Co-Chair Padden: Thank you.

Any clarifying questions or comments from the Committee?

Member Fleischman: This is extremely niche. But my main concern is clinicians don't generally document somebody with grade 2 diarrhea or grade 3 diarrhea. The patient has diarrhea. Same goes for colitis. People don't generally document that. As such, how easy will this be to actually measure?

Dr. Pai: Hi. This is Sara Pai from Mass General Hospital. I was representing Sid C., who's the measure developer. You know, with immunotherapy, there's increasing use of immunotherapy across the country, and we're hoping that immunotherapy continues to gain access outside of major academic centers.

And as part of that increasing trend, we want to make sure that the immunotherapy is safely administered. So this is really a measure for medical

oncologists, where they would be assessing for any adverse events or effects prior to the next administration of immunotherapeutic drug.

And as part of the routine assessment of patients in that oncology visit, assessing for frequency of diarrhea as a side effect would be something that would be typically documented in the clinic note or progress note.

Member Averbeck: This is Beth Averbeck. I was one of the lead discussants, so I spent a little time actually looking it up clinically. And there is a definition of grade 2 and -- as far as reporting. So I think there is some opportunity to say, if this is what the definition is, the measure could be done. It looks like it has been tested already.

Member Fleischman: There might be the a definition, but what I'm saying is -- so, first of all, not everyone shows up in the Med Onc -- in the Hem Onc office. If this patient's on a checkpoint inhibitor -- and I'm in the emergency department and I see plenty of patients on these drugs.

And so if they show up with GI issues -- colitis and diarrhea are very common. We see this very commonly. Those visits will count as well, I would think.

Dr. Pai: Well, this is an outpatient measure, and it's really -- the measure is trying to see whether the medical oncologist would be able to hold the next dose of treatment. So, if they were to be admitted, that wouldn't be counted.

Member Averbeck: Yeah, and I think in reading through -- I mean, it seems like the intent of the measure is to try and identify and intervene early enough that it would prevent people from having diarrhea that's significant enough that they would seek emergency or urgency evaluation.

Member Fleischman: But most -- sorry. Most

patients -- I think my camera's having -- many patients with abdominal pain -- colitis commonly will give you diarrhea, fever, abdominal pain.

These patients are nearly -- well, I'm not going to say universally, but very commonly referred to the emergency department. And many of them are discharged home after an evaluation. Does that count, or is any kind of ED inpatient visit excluded from measurement?

Dr. Pai: Well, I think with -- you know, I'm not going to speak for other chemotherapeutic agents and associated GI effects that are not related to the drug. Certainly, with immunotherapy, though, assessing for frequency of diarrhea is an important measure or metric to be able to catch it early.

So, again, this is an outpatient assessment prior to next dosing. It's really, as stated before, trying to prevent that patient having to go to the emergency room. And once they get admitted, this is not included, as this is no longer a measure that would be measured.

Member Fleischman: No, I understand that. I'm still unclear about how -- is this something that's built in -- for example, for the places where this has been used, this is built into the regular office assessment with a table where you document number of times of diarrhea and so on?

Dr. Pai: Exactly. I mean, this is common questions for any oncologist administering the immunotherapy in terms of, you know, are you experiencing any diarrhea? Are you experiencing any cough? Routine laboratories are assessed for autoimmunity/autoimmune diseases. So --

Member Fleischman: And this is then submitted -- or how would this be reported, then? Is it structured in a way to be able to be electronically extracted, or is it chart abstraction, manual chart abstraction?

Dr. Pai: It would be through progress reports, but during the coding, if they were to put in diarrhea or colitis, it could be captured in that way as well.

Member Fleischman: But the problem is that grading system. That's not electronic, right?

Dr. Pai: Right. So the grade 2 would have to be extraction from the progress notes.

Member Fleischman: So you essentially have to abstract this measure -- manually abstract the measure, because you can get the colitis charts and all the diarrhea charts, but then you have to see which ones meet the measure.

Dr. Pai: Mm-hmm. Correct.

Co-Chair Padden: There is a comment. Helen has provided a comment in the chat box as well.

Would you like to speak, Helen?

Member Burstin: Sure. I was just pointing out that, again, this is not your garden-variety patients with diarrhea. These are patients on immunotherapy for cancer. So it's a pretty targeted population who are pretty high risk.

If you read through the comments from the cancer and the GI communities, they found it really important because these patients are so high risk. So, true, it may be a little work to collect it, but it's not on everybody. It's a pretty small population that's at pretty high risk. And, I mean, I'm swayed by the degree of support from that broad community who takes care of these patients. Thanks.

Member Fleischman: Yeah. And, to be clear, when we see them in the emergency department, we actually get these huge pop-ups and sirens that go off that tell us to really look closely at these patients. So, no, I definitely understand the importance of these, that these can be deadly for

this group of patients.

I'm just interested in how this will actually be broadly applicable -- not applicable, what the burden is for cancer centers, like we have in our system, to be able to adopt this kind of measure. Thanks.

Co-Chair Padden: Thank you.

Any other comments or questions?

I'm not seeing any other hands. Tricia, do you see any other hands? Rob?

Ms. Elliott: No hands raised.

Co-Chair Padden: Okay. So I believe, then, we can go to Ivory for a vote.

Ms. Harding: Thank you.

Voting is now open for MUC2021-058, Appropriate Intervention of Immune-Related Diarrhea and/or Colitis in Patients Treated with Immune Checkpoint Inhibitors for the MIPS Program.

Do you vote to support the staff recommendation as the Work Group recommendation?

Okay. Voting is now closed for MUC2021-058, and the results are as follows: 16 members voted yes. One member voted no. And this gives us a percentage of 94 percent, with the Committee voting to uphold the staff recommendation as the Work Group recommendation.

Co-Chair Padden: Thank you.

I think at this time I'm passing it back to you, Trish.

Ms. Elliott: Yes. And, actually, we're going to pause and just take a five-minute break. We have measure developers and other folks lined up for the next discussion that will be available at 4:15, so we didn't want to open public comment until 4:15.

So the next two measures up for discussion are the cross-cutting measures of MUC 134, Screen Positive Rate for Social Drivers of health, and 136, Screening for Social Drivers of Health.

So we will take a five-minute break. My laptop clock says 4:10, so we'll reconvene right at 4:15. So a quick bio-break for everybody. Thank you.

(Whereupon, the above-entitled matter went off the record at 4:10 p.m. and resumed at 4:16 p.m.)

Cross Cutting Measures

Co-Chair Fields: All right, great. So I -- I believe -- sorry -- as soon as I say that, my notes went away.

I believe, just if I recall, we're going to start with public comment section, correct? So we'll take a few minutes for public comment on the two measures on the whole domain, excuse me, which is more on the social determinants of health.

Ms. Elliott: Correct. So if we could advance the slides, please, and start the recording. Okay, the recording has resumed. If we can go to the next slide, please.

So these two measures are part of the Merit Based Incentive Payment System, MIPS. We've reviewed these slides earlier in the day, but just as a refresher, the program type is a quality payment program. The incentive structure does include pay for performance. Therefore, connected performance categories that affect the clinicians' payment adjustments, those categories are quality, promoting interoperability, improvement activities, and costs. And the program goals are listed there at the bottom.

So our next slide, please.

And so we're going to -- Rob, if you can open it for public comment.

Co-Chair Fields: So we'll take a few minutes if folks have any comments they want to make.

Now I will say in advance we did receive many, many comments in advance so I anticipate that will be the case here this evening and if folks, again, have already restated -- some folks have already stated their point. If you just want to document your public comment instead of repeating the same issue, it might make good use of the chat so we can have it documented and still move the agenda along.

Ms. Elliott: Great. And we'd like to call on Dr. Gary Price to open the public -- or to offer a public comment, please.

Dr. Price, can you hear us okay? If you are talking, you are on mute, Dr. Price.

Dr. Price: Can you hear me now?

Ms. Elliott: Yes, we can.

Dr. Price: Sorry about that. I am Gary Price, an attending surgeon and Clinical Professor of Surgery at Yale New Haven Hospital and past President of the Connecticut State Medical Society.

I'm also a Board Member and current President of the Physicians Foundation which is directed by physicians from 21 state and county medical societies across the country from Honolulu to Hanover and all regions in between. We are the major developer for MUC2021-136, Social Driver of Health Screening Rates and MUC2021-134, Social Drivers of Health Screen Positive Rate.

In COVID-19's wake, food insecurity, housing instability, and other social drivers of health have reached unprecedented levels and revealed massive racial disparities. Yet, despite the well-documented impact of social drivers of health on health

outcomes and cost and their disproportionate impacts on communities of color, there are still no drivers of health measures in any federal healthcare payment or quality program.

On behalf of physicians across the country, we believe this is untenable. We submitted these first number social drivers of health measures to address CMS's commitment to address the standard measurement gap for social and economic determinants, as well as the MIPS program's commitment to advance health equity.

Ahead of today's discussion we wanted to speak to two key issues. First, these two social drivers of health measures are interrelated. Each of these measures was extensively tested with over a million patients in 600 plus clinical sites including in-patient, emergency department, and primary care via the CMMI Accountable Health Communities Model.

This testing relied on both screening beneficiaries and the results of that screening, the two measures under discussion today. Of course, it is not possible to test or validate any type of screening tool without knowing the results of the screen.

The second issue is that these foundational social grabbers of health measures do not at this point require that providers act on the findings from the screen. The concern is the screening without acting on the results could frustrate patients and providers. We agree. But empirical evidence from the extensive testing of social needs screening completed to date indicates that providers will, in fact, act on the screening results even if not required to do so. For example, in CMMI's comprehensive primary care plus model, 1200 of the practices were not required to screen for social needs. But the vast majority did so anyway.

Most importantly, 93 percent of the physicians in these practices reported taking action on these

social drivers of health screening results including linking patients to community resources without any requirement that they do so.

Ultimately, today's review of these two measures comes down to leadership. These two social drivers of health measures have now been tested for five years in an existing CMMI model across hundreds of clinical sites, have undergone independent review to assess their psychometric properties, and have driven significant, pragmatic learning about how to collect and use social drivers of health screening data.

We anticipate that the measure should and will be improved over time. But we also recognize that as with all measures in the federal payment and quality frameworks, we must begin using, learning, and improving them.

We appreciate the MAP's consideration of these measures, the only patient level equity measures under review this cycle, and urge to support both of them for rulemaking.

Thank you very much for the opportunity to speak to you today.

Co-Chair Fields: Thank you, Dr. Price.

Ms. Elliott: We have some hands raised, Rob. First up, we have Andrew Morris-Singer and then Kathleen Conroy.

Co-Chair Fields: Great. Andrew.

Dr. Morris- Singer: Thank you so much for the opportunity to speak. I'd like to build on the comments by Dr. Price.

I'm Dr. Andrew Morris-Singer. I'm a primary care physician also Co-Director of the Morris-Singer Foundation, Founder of Primary Care Progress, and also faculty of Harvard Medical School and Oregon Health and Science University.

I, too, want to strongly urge the MAP to recommend both of these social determinants of health measures. We on the front lines of healthcare know that building strong relationships with our patients, addressing clinician burnout, especially physician burnout, achieving better health for all, and reducing healthcare costs depend on our recognizing the reality of our patients' lives, those critical co-morbidities such as food insecurity or housing instability that have only escalated in the context of COVID-19.

It's past time for these two measures, especially as we physicians continue to witness the profound impact of this pandemic, the physical, the psychological, economic well-being of our patients. Dr. Price highlighted how we have evidence that shows that providers will choose to screen their patients and will act on those results even without these measures being in place.

And I'm going to add one other thing to that, that our foundation supports a range of programs that work directly with clinicians and administrators all over the country. And we do focus groups. We do surveys. And again and again, when we've asked the clinicians what matters most to them in their roles as healthcare practitioners, they regularly tell us without a doubt that clinicians are hungry for measures like these two proposed ones that help shift the practice of medicine from the normal litany of required measures to measuring what matters for health. And this is not just an issue of the health of the population. This is about burnout of the clinician population and we're losing clinicians at an exponential rate at this point. So this is about an existential crisis amongst the profession.

So I strongly encourage the MAP to recommend both of these social determinants of health measures to recognize for the first time in the federal payment model the thousands of physicians and other healthcare providers who work every day

to understand what their patients need to be healthy and to address these needs. And I appreciate your consideration. Thank you.

Co-Chair Fields: Thank you, Andrew.

Kathleen.

Dr. Conroy: Hi. My name is Kathleen Conroy. I'm a pediatrician and the Clinical Chief of Primary Care at Boston Children's Hospital.

Today, I'm speaking as an individual clinician in support of these measures and I bring a deep experience in implementing screening for social determinants of health.

At my own practice where we serve about 22,000 children, we've been formally and universally screening for social determinants of health for over a decade. Like many pediatricians, we adopted this practice because of the overwhelming evidence that screening is both acceptable to families, but also helps facilitate connection to needed social resources like housing programs or SNAP benefits which themselves are associated with positive impacts on children's health.

Just like screening for depression or anxiety, screening for and addressing social determinants of health has become a standard part of our clinical program.

But more recently in 2018, the Massachusetts Medicaid Program introduced two quality measures through its current 1115 waiver that are really, really identical to the measure we're talking about today. Although we were already screening in my practice, the need to examine our findings across the population rather than at the individual level allowed us a few important things. First of all, it helped us to understand who in our population was most likely to have needs and how these needs were changing over time. And then interestingly,

whether our systems of screening and response to these needs were themselves unintentionally inequitable. And so this knowledge has become the foundation for both disparities focused quality improvement programs in our system and also as the impetus for creation of new community partnerships to better address the needs of certain populations.

And so I've also, as others have said before me saying that I think 134 and 136 need to be implemented together.

I'll also offer that Massachusetts similarly did not initially require navigation to resources. And this allowed healthcare organizations the opportunity to build their response systems after initially understanding families' needs and it's allowed us the time to build the data system to record the social need responses delivered to families. So in my own system, we recognize that we were actually under documenting our response work we were doing with families once needs were identified and have improved this in anticipation of needing to ultimately report positive responses to screen.

So as a pediatrician who screens hundreds of adult caregivers for unmet social needs yearly, I strongly endorse the creation of federal social needs screening measures. Thanks.

Co-Chair Fields: Thank you, Kathleen. I think we had Richard Thomason next.

MR. THOMASON: Thank you. So I'm Richard Thomason and I'm Policy Director for Blue Shield of California Foundation which supports lasting and equitable solutions to make California the healthiest state and end domestic violence. The Foundation strongly supports both these measures, 136 and 134, and we urge the MAP to do the same.

As you've heard, thousands of clinical practices across the country are already conducting SDOH

screening to identify patients' unmet social needs including the half dozen CMMI models, but without the benefit of any formal quality measures, guidance, or tools from CMS.

As evidenced in the momentum for these measures across the health sector, it's imperative that we begin to implement social driver of health measures in the federal payment program, especially in the wake of deep health inequities revealed by our response to COVID.

It's particularly essentially that both of these SDOH measures move forward this cycle, given that these measures have been demonstrated to effectively identify disproportionate screen positive rates in racial and ethnic minorities through the AHC model. It's crucial from an equity perspective to move forward the SDOH measure that recognizes providers for reporting the screen positive rate. To reward screening, but not reporting of the screen positive rates would mask these disparities and risk exacerbating inequities.

So don't let the perfect be the enemy of the good. These measures do not dictate a specific screening tool, but do require that whatever tool is used align with the measure. This pragmatic approach will keep the focus on collecting baseline data while supporting flexibility in the field in linear terms.

The MAP's opportunity today is to support moving the first ever SDOH measures into practice to enable this kind of learning and improvement over time. The data collected and learning from these foundational measures will be critical to improve the measure, to set appropriate performance targets, and to be thoughtful in developing the next set of measures focused on ensuring patients get the resources they need to be healthy. So we urge the work group to recommend both these measures. Thank you.

Co-Chair Fields: Thank you, Richard. Joseph Valenti

is next.

Dr. Valenti: Thank you very much. My name is Dr. Joseph Valenti. I'm a practicing gynecologist in North Texas. I work in a practice that sees both low- and middle-income patients and takes all sorts of insurance including Medicare and Medicaid.

We have seen so many issues with social determinants and patient compliance and rather than be too much a policy wonk because I sit on both the Texas Medical Association Board of Trustees and the Physicians Foundation Board, I'd like to just -- a couple brief anecdotes. A mother delivers a child. The child is insulin- dependent. The child is admitted to the Intensive Care Unit with sugars in the 600s. The mother is accused by Child Protective Services of endangering the child. The mother says I'm giving insulin. I'm giving the insulin that's supposed to be given. I don't know what's going on. And a \$20,000 admission to the ICU could have been thwarted had anyone informed the mother that the insulin had to be refrigerated, but she doesn't have a \$200 refrigerator.

These sorts of anecdotes are happening in our healthcare system every day and they are a shame and a moral injury to both physicians and patients and we need to start screening these patients for their needs. When a \$200 refrigerator can obviate the need for a \$20,000 ICU admission and a CPS investigation into a mother that's really trying, but simply doesn't own a refrigerator, this is something that really drives home the need for these measures.

We have other cases of patients who are presenting very late due to inability to get care and eventually have to sign up for Medicaid which in Texas pays 63 cents on the dollar in Medicare and we're seeing patients come in with eight pound uteri with Stage 4 uterine cancers all because they didn't have access to care and are just not able to access the system.

So these sorts of anecdotes I found odd that they're happening every day and they're real and they're happening in doctors' offices and we want to take care of patients, but we need some measures to start screening patients to find out what they really need and what their real stressors and obstacles to care are.

So I speak strongly in favor of these measures and these are real anecdotes I'm relating to you and we see these on a regular basis. So this is happening all over the country and we need to start getting on these issues. And this is a way to start. Thank you for your time.

Co-Chair Fields: Thank you so much. Amy Smith.

Dr. Smith: Hi. Thank you so much for letting me speak. My name is Dr. Amy Smith. I'm a primary care physician practicing at the Cambridge Health Alliance in Cambridge, Massachusetts. And I just want to say many of the comments that have already been said I really strongly agree with.

I want to urge the MAP to recommend both these measures as well.

For the past decade, I've been deeply involved in efforts at my healthcare institution and along with other healthcare systems in Massachusetts to screen patients for the social drivers of health. I have extensive experience designing and implementing SDOH screening and navigation protocols at scale and have published on these efforts.

It is clear that food insecurity, for example, is not just a social factor, but a clinical comorbidity that impacts quality care and drives health disparities. During COVID, SDOH screening has become only more critical to support our patients and to mitigate the frustration and burnout among primary care providers as we try to address the barriers to health and well-being for our patients.

Yet, we do so now without the benefit of any SDOH measures and any federal payment program including MIPS. It is untenable for our federal payment programs to continue to exclude those factors that we know is around 80 percent of health outcomes in our patient population.

At CHA, we've been screening patients consistently in primary care sites across our healthcare system for more than five years. In doing so, we have found that 27 percent of our patients screen positive for food insecurity. And at some of our clinical sites, we found the rates close to 40 to 50 percent. This crucial data about our patient population, exactly the kind of foundational data that these SDOH measures will provide, then allowed us to design an electronic active referral to a community-based organization to help connect patients in order to support their needs.

My fellow providers confirm that this approach is not only feasible in a busy primary care setting, but help relieve moral injury by allowing us to identify the needs that interfere with improved health and help us provide better care to our patients.

And from the perspective of a physician who like thousands of others across the country, is absolutely committed to serving patient populations that often face these challenges. These first ever federal SDOH measures are essential to recognize practices like mine that are trying to tackle these issues already.

So I strongly urge, along with everybody else who has spoken, the MAP to recommend both of these measures to recognize for the first time in a federal payment model the thousands of physicians and other healthcare providers who are committed to addressing these issues for their patients. Thank you so much for letting me speak.

Co-Chair Fields: Thank you. Ron Wyatt.

Dr. Wyatt: Hi. This is Ron Wyatt. Thank you for letting me speak. Let me start this way, a few years back, there was an outbreak of tuberculosis in the Black Belt in Alabama. Harper's wrote a piece on it and described it as a place where healthcare won't go. That's where I grew up.

I'm an internist in practice for 25 years in FQHC in St. Louis and Huntsville, Alabama. I'm here representing the voices of the people that I grew up with and people that I've encountered along the way.

Currently, I am involved with five equity collaboratives across the country that include Blue Cross of Massachusetts, Blue Cross of Illinois, Kansas City Foundation, Providence Healthcare System, ACGME Equity Matters Initiative. So I'm going to bring that experience with what I'm about to say.

And what I will say when I look at the measures I will call them a good start. But they will remain a pebble in my shoe until I can take it out because what you've already heard is what this is really about and I understand the necessary process of psychometric testing and kappa statistics and harmonization and things that we do as we develop measures.

But it's about us. And us, you've heard some of that already. Us is the single mom on the south side of Chicago that has to take a bus, and a train, and a bus to Page County for a \$12:50 an hour job working 36 hours a week that she's got to get then at the end of the day to get her children home and make sure that she has enough money to feed them or to pick up an inhaler. Unfortunately, in some cases, that mom has to choose between an inhaler and food for her children. And if she's got to get the inhaler, how she lives in a pharmacy desert that she's got to navigate through while the kids are at home, possibly alone.

So when I think about social determinants of health and social drivers of health and honestly, I stopped using those words a decade ago. But what we have created are populations of people that have been dehumanized, devalued, have been under resourced, have been marginalized, pushed to the side, they have become invisible. Therefore, they become disposable.

What happens then is what I call the stuff that kills us, the stuff that harms us, the stuff that causes trauma and suffering. Before coming on this call, there was a piece in New York about the mortality rate of Black and Brown women being eight times that of White women. The fact is maternal mortality rate for Black women has been twice that for White women for over a hundred years.

So we have to think about these measures in terms of who this impacts, who comes first. Next is then why when we think about measurement. And part of that why is biased stereotypes, institutional structured racism, the lack of structural competency, the lack of structural ability, the weakness in our ability to react and respond to the needs of the people that we say we serve.

And we've come to a point where this matter now has to be put into what I will call patient safety. And I'm a patient safety expert, that's my day job, of forcing functions. So what I see here are forcing functions to say to people what has been called moral issues is a moral failure if we don't continue to advocate and push to measure and to either reward or not the people, places, and I think Dr. Valenti mentioned, leadership that has so far failed to react to what's being called social drivers of health.

So what we need to do through these drivers as we move forward is actions that will make people visible, that will make people in the center and not at the margins, that will move people from being

disposable to indisposable for the children to come.

I will go back to my friend there at Boston Children's. Underneath this is how we address childhood poverty and the trauma of childhood poverty.

So we need to think about as we look at these metrics how they can be advanced, how they can be refined, how they can be sustained, and how they can be reinforced or in fact, forced. So I stated there is an urgency to this. There is an urgency of right now and when I look at these measures what I see is hope. I don't see solutions. I see hope.

So my hope then is that these measures be the minimum beginning of a sea change in addressing the stuff that's killing Black and Brown people in this country. So I thank you and I'll stop there.

Co-Chair Fields: Thanks, Ron. William Lawrence is next.

Dr. Lawrence: Good afternoon. Are you able to hear me?

Co-Chair Fields: We can.

Dr. Lawrence: Yes, thank you. My name is William Lawrence, general practice physician in North Carolina. Thank you for the opportunity to speak.

The COVID pandemic, amongst other things, has exposed longstanding racial and economic injustices embedded in our healthcare system, just this last year renewed commitment to improve health equity and address the social drivers of health that account for 80 percent of health outcomes and have a disproportionate impact on communities of color. These include stable and affordable housing, healthy food, reliable income, interpersonal safety amongst other things.

Despite the well-documented impact of social drivers of health on health outcomes and costs and

their impact on people of color, there is still no approved standardized SDOH measures in any of our CMS programs. Absent such measures, CMS cannot realize its pledge to collect more robust drivers of health data to move the needle on health equity and address its stated measurement gaps to develop and implement measures that reflect social and economic determinants.

Physicians and other healthcare providers have called on CMS to create standardized patient level SDOH measures going beyond just socio-economic status and dual status, recognizing that these factors drive physician burnout and impact providers caring for affected patients via the increase financial risk, the lower MIPS scores, et cetera.

Moreover, the growing number of CMS innovation center models such as the Accountable Health Communities and Comprehensive Primary Care Plus Model have screened for social determinants of health and acted on the results across millions of Medicare and Medicaid beneficiaries and thousands of inpatient and outpatient clinical settings across the country. They have done so, however, without the benefit of standardized SDOH measures or screening tools from CMS. As a result, we believe CMS cannot systematically compare or use that data effectively.

The proposed social drivers of health measures have been effectively implemented into AHC over five years across the one plus million CMS beneficiaries and 600 clinical sites and multiple practice settings across the country. As documented in the AHC evaluation, these measures reliably identify number one, beneficiaries with one plus health related social need, high costs, and high use beneficiaries, and racial and ethnic disparities. The AHC screening results have also been used to understand the impact of screen positive patients on total Medicare fee-for-service expenditures, inpatient admissions,

admissions for ambulatory care physical condition, unplanned 30-day readmissions, and emergency room visits. The AHC screening tool used to generate the measures has been psychometrically tested on both the item and the tool level and it's demonstrated reliability and concurrent and predictive validity supporting its use in the healthcare setting. This includes comparison with other screening tools producing high kappa statistics, as well as adequate sensitivity and specificity.

We believe the social driver of health screen positive rate measure recognizes clinical sites for reporting the results of the screen in the social drivers of health screening rate measure. Given the disproportionate impact of SDOH and people of color, this measure recognizes providers for reporting the screen positive rate for their patients as well as the basis for identifying racial and ethnic disparities in SDOH that, in turn, fuel disparities and health outcomes.

The baseline data collected via SDOH screen positive rate measure will be essential to inform the next round of CMS social determinants of health measures focused on navigation and successful resource connections for patients. Given the variability and the prevalence of SDOH across geography and patient populations, as well as clinical site capabilities to provide patient navigation, the staging of introducing SDOH measures into the federal quality frameworks is critical. Thank you for allowing me to speak.

Co-Chair Fields: Absolutely. Thank you. Karen Smith, you're next and will be the last of this section of public comment. I don't see any more hands in order for us to get to voting. So Karen, please.

Dr. Smith: Thank you very much. I'm Karen Smith. I'm a family physician, 29 years' service in rural

Hoke Count as an independent physician.

I'm also considered to be an early adopter of EHR. EHR for us includes the efficiency in which we were able to provide access to care for people in our community, a community that is 55 percent minority. And we have certainly practiced throughout the 29 years of dealing with social determinants of health that has had impact on the health and the care that we're able to provide.

Now I can tell you I was most pleased as we were going through meaningful use. I was actually one of those providers who was pleased as we were going through MIPS and the opportunity to participate with the ACO organizations. And why was I so pleased? Because the work that I had done with the Office of the National Coordinator made us recognize that the gathering of data and technology was going to make a difference in terms of how we managed the care and managed the lives of the patients that we take care of. And for us to have the absence of the social determinants of health, to have the tool kit, to actually be able to see and quantify what are the true needs of the people that we care for, so that could go ahead and further develop five projects and programs that would assist them.

As we continue to leave out these measures and not be able to quantify, then how in the world do we know if we're effective? How do we know if we're making a difference? How do we know if we're seeing any success at all? Isn't that the whole basis for having meaningful use data? And so this does need to be included. And we want to make sure that it's included in a way in which we can affect the change.

Our practice is also currently working on equity oriented primary care, allowing us to redesign healthcare for equity. We need data and we need to make sure that that data has been collected in a

way in which CMS has typically done. And so that's what I do and support and hope that this will move forward because if we are truly going to have impact on population health management, we need to have that information.

So I've heard my colleagues already speak, don't want to repeat what has been done. But I did want to reiterate that it is being used even at the level of where I practice as an independent rural physician and the data matters. And we need this information if we are truly going to effect the change for the populations that we care for. Thank you so much and certainly look forward to a positive outcome.

Co-Chair Fields: Karen, thank you. By the way, Karen, I was in Asheville, North Carolina for years and I remember you very well in early -- as a family doc myself in North Carolina and your leadership, so good to see you here.

All right, I think we are ready, Tricia, for the preliminary analysis on 134.

Ms. Elliott: Correct. Could we have the next slide, please?

Dr. Walker: I raised my hand at the last minute. Is it possible for me to provide comment?

Co-Chair Fields: We had really so that Karen would be the last one.

Dr. Walker: That's fine, that's fine. That's all right.

Co-Chair Fields: Thank you.

Ms. Elliott: Great, thank you.

So, we are introducing MUC-134: Screen Positive Rate for Social Drivers of Health, and providing the preliminary analysis overview.

The description, the percent of beneficiaries 18 years and older who screen positive for food

insecurity, housing instability, transportation problems, utility help needs, or interpersonal safety.

The level of analysis includes clinician, group, facility, other, beneficiary, and population.

The NQF recommendation was do not support for rulemaking. And, a little bit more insight into that.

So, this measure assesses the percentage of patients who screen positive for the health related social needs. It would be the first in MIPS to specifically address screening for health equity, which is consistent with both the program goals, and a meaningful measures priority.

However, the same concept would be better addressed by alternative approaches that do not present potential, unintended consequences, and show stronger correlation with outcomes.

The measure ultimately seeks to bridge patients screen positive for health related social needs, with community navigation services, and an individualized action plan from a beneficiary to resolve HRSNs identified by the screening.

However, the screening measure does not contain any data or requirements to guarantee this follow-up.

While most physician practices do not screen for all five social needs identified in the measure, the measure has not been tested for reliability or validity. And, the measure logic driving quality improvement is unclear.

I also want to share the rural health advisory input that we received last week. From the rural health perspective, this measure was suggested to be applicable to rural communities.

And, concerns were raised regarding standardized datasets, and data collection for the social determinants of health.

The developer responded that since the screening is standardized, then the positive indicator would also be standardized.

The calculation, no issues were identified there.

In terms of unintended consequences, there was some discussion on what the impact of the measure on payment to providers.

Concerns were raised regarding the capture of a positive screen, without the appropriate resources available to support the patient needs.

The polling average score for rural health was 3.5.

MAP health equity comments included, this social driver measures important as this is one of the first measures considered for federal programs.

Issue was raised as to how the results of the measure correlate to quality of care for this measure.

Data collection issues were shared as follows. Without standardization, there are concerns for variability of the measure to be able to compare across programs, or entities. For example, some screens may include unmet behavioral health needs, where others may not.

Results may not be comparable over time. There is no calculation issues identified, and facilities with resources will potentially capture more needs in a disproportionate fashion and thus, results of this measure maybe difficult to interpret.

The average polling score for this measure was 3.7.

We also received very robust public comment during the public comment period submitted to NQF. There was a total of 45 public comments received.

Overall, 29 of those 45 public comments were in support of the measure, and 16 were non-support

or presented challenges, or concerns.

The themes for supporting, we've heard many of those already today form our public comment period. The equity achievable by addressing social determinants of health, it's laying a good foundation for social determinants.

There's a sentiment that significant impact on health disparities, that they're the start the standardized approach. It builds links to community services.

There is support with concerns regarding the implementation, and there was a sentiment that benefits do outweigh the burden.

One other thing I'd like to point out on the support side is support for the use of Z codes. So, several public comments mentioned the use of Z codes.

With regard to non-support for this measure, some of the items pointed out included burden of collecting and reporting this measure. Not outcomes based. The comment being what happens after screening.

The disincentive to treat patients with high social needs was identified as a concern. The measure not supported by evidence.

Absence of resources and tools. We must be able to connect the patient to the services.

And, a comment was made to increase the measure beyond just 18 plus, to include those under the age of 18.

And, there were comments on the concern side regarding that the harm outweighs the benefit.

Rob, I'll turn it back to you.

Co-Chair Fields: Great, thank you.

So, now is normally the time when we would ask clarifying questions. So, we've got a few in the chat already, but, yes. So, let's start with the first one.

So, there was a question about do we foresee one standardized tool, or different questions. But I believe the measure, and I guess I don't know if the, either stewards are here, but I assume they are.

But my understanding is that it specifies domains --

(Simultaneous speaking.)

MS. ONIE: Yes, we're on the line.

Co-Chair Fields: -- within the specific tool. Is that correct?

MS. ONIE: Yes, this is Rebecca Onie, I'm on the line with Rocco Perla, we're the technical advisers to the measure developer.

Co-Chair Fields: Great, thank you.

MR. PERLA: I can take that question if that's helpful, on the standardization of the tool.

Co-Chair Fields: Yes, please.

MR. PERLA: So, I think as you pointed out, and as other comments pointed out, the measure is the standard. So, any tool that would be used for reporting must be aligned with the measure.

So, as many of the public comments submitted before us here today indicated, clinical practices have been clear that they value the flexibility in being able to select the specific SDOH screening tools that they're using.

And, the measure developer took that feedback based on their own review and analysis of the industry, and provided their focus on the measure, without recommending imposing that a specific tool

be used, which didn't seem like the most expeditious, or appropriate route to take at this moment in time.

In the future, CMS may decide to recommend a standard tool. But at this moment, the primary focus is on collecting some baseline data, to understand where folks are so that we can begin to build this into the federal requirements around measurement.

Co-Chair Fields: Great, thank you.

And, there was a follow-up question on is, on the interval requirement for the screening. And, assuming if we can answer that for both 134 and 136, it might be helpful because I might anticipate some questions for the next one if they're different.

MR. PERLA: And, Rob, by intervals you mean the regularity in which the data would be collected and reported?

Co-Chair Fields: Correct, yes, or the screening. Yes, the data is collected at the practice level, yes.

MR. PERLA: I would defer to our colleagues at CMS on that, partly because they are the ones that are going to be influencing kind of, how that plays out.

Co-Chair Fields: Anyone from CMS?

MS. ONIE: It's Michelle. Somebody else is one? Go ahead.

Ms. Elliott: Yes, sorry, Michelle. I was just going to clarify the question that I saw in the chat, that I think Rob was referring to.

It says what is the screening interval for this measure to be numerator compliant? Is it annually, every two years, or other?

So what --

(Simultaneous speaking.)

Ms. Elliott: I'm not sure if it's for you, Michelle, or for Rocco. Sorry to interrupt.

MS. ONIE: I think it may be for Rocco.

Co-Chair Fields: Why don't I just ask Rocco if you defer to the CMS.

MR. PERLA: From a perspective of a measure developer --

(Simultaneous speaking.)

MS. ONIE: If it were CMS generally, it would be annual if it's in the MIPS Program. MIPS measures are reported on an annual basis.

Co-Chair Fields: Great, thank you.

Member Fleischman: So, I'm not sure why we're discussing this one before 136, because this is actually a child measure of, of the parent measure, which is the actual screen.

And, full disclosure, Rocco, and Rebecca and I, did have a discussion yesterday about this.

So, 136 is the actual screening measure, and that is the percent of patients seen, well, annually, as Michelle pointed out, that you actually performed a screen on. This is not really a measure, it's actually a data point that comes out of 136.

So, I'm a bit confused about why this is presented as a measure. It's really a data point that comes out of the next measure, which is the true measure, which is an actual process.

So, I think this should simply be looped, or lumped in with 136, and be the data, part of the data that's reported in addition to the actual percent screened, to report the actual screen positive rate.

It should be a component of that as opposed to

being its own measure.

Co-Chair Fields: Thanks for that.

And, Amy, I see your comments in the chat and not to seem disrespectful, but I think in terms of clarifying measures, I want to get us to a vote on do not support, or not.

If there are any other clarifying questions, and then we can get to discussion?

Ms. Elliott: I see a hand raised by Emma Hoo, Rob.

Co-Chair Fields: Thank you. Emma, go ahead.

Member Hoo: One of the questions I have in this context of screening positive is definitions around follow up frequency, you know, similar to the way you know, PHQ2 or PHQ9 measure is structured, and sort of the expectation of follow up within a specific period.

And, I wondered if that was part of the future consideration in designing this set of measures.

MR. PERLA: I can speak to that, Rob, if that's helpful.

Co-Chair Fields: Please, go ahead, yes, go ahead.

MR. PERLA: It's a great question.

So, for MIPS, the measure just to make clear to folks, is a optional measure first. You could opt into this as part of a 40 percent quality weighting.

And, the measure developer has recommended that this be a pay for reporting measure, so that the focus is on reporting baseline data, in order to enable future measures that would then focus on the percent of patients that receive navigation, and the percent that received a closed loop referral services.

Those four measures come directly from the

Accountable Health Community's pilot. So, all of the data, the evidence, the second measure testing that was done through AHC, is what we are using as the foundation for the measure.

And, then also just to speak to Will's point around the two measures. Again, the screen, the percent of beneficiaries screened and the screen positive rate, are two of the measures that have been implemented over five years, and across AHC.

So, we, the measure developer is excited to think about those subsequent measures and subsequent cycles. But at this moment in time given that it's a new measure, we wanted to encourage reporting of the data and minimize any barriers to do so.

Co-Chair Fields: Yes, I think that speaks to --

(Simultaneous speaking.)

Member Hoo: And --

Co-Chair Fields: -- the comments and the. I'm sorry, go ahead, please. Go ahead, Emma.

Member Hoo: Yes, I just also had a follow-up question, but go ahead.

Co-Chair Fields: No, no, go ahead while you're on.

Member Hoo: Yes, my second question is, and it may be more applicable to 136, is that I note the absence of social isolation you know, in the set of domains that are listed here. And, that would of course, go back to the overall screening.

But in terms of screening positive, you know, the experience in certainly commercial populations, is identifying individuals who have had a change of circumstance that may affect caregiver support, that might affect marital status, and so on, that are triggers for other issues.

MR. PERLA: Great question, Emma. I'll just say

really quickly on that, the measure developer really wanted to adhere to the AHC measure.

So, these measures are the ones that have been applied to the model for over the past five years.

The five core domains that were identified are the ones that are actually pulled from AHC. There is no question to a lot of the public comment that was made today, that we can start to sort of revisit that in the future.

But initially, we wanted to make sure that we were as aligned as we could be, with the actual measures that have been used in practice.

Co-Chair Fields: So, I'm just going to sort of summarize some of the stuff in the chat, and I see that we have three hands raised.

And, so I will take some prerogative thought to say that if it is not a clarifying question, I'm going to move us to a, we're going to pause it and come back to it in discussion.

But there is, the summary in the chat I think is helpful for clarification because there was a comment that this is a pay for reporting sort of measure.

But Michelle, and maybe I'll ask you to unmute since you have your hand raised also, first made a comment about MIPS measures are pay for performance by definition.

So, if you can clarify that, that would be helpful. Because I think the point that's raised in the chat about you know, if you're in a community with high needs, you're going to screen positive at a higher rate, right?

So, then the measurement becomes a little tricky. So, if you could help clarify that, that would be helpful.

Dr. Schreiber: I'm happy to do that.

So, by definition, any measure that's in the MIPS program is considered a pay for performance measure, because measures go into the calculation of MIPS performance.

On rare occasion, maybe it can be given zero points, but frankly, there is no history of us having done that before.

And, as opposed to like, the hospital programs that you're probably familiar with, like the IQR program where it is pay for reporting for a while before it moves into a payment program, that's not an option in MIPS.

Now that being said, in this particular case as Rocco already pointed out, the MIPS program has an extensive number of measures we've already seen.

There's over 200 quality measures in the MIPS program. And, so these would be optional for clinicians who wish to do that until and unless at some point in time, CMS wanted to change its approach to measures in the MIPS program and require some, or build some into future MVPs as requirements around equity or part of the foundational level.

But I just wanted to clarify that the nuances of the program, they can't be just pay for reporting.

Co-Chair Fields: And, that's important right, just to be clear for the group and folks that are in the public that may not be familiar with this.

With this voting, is specifically for voting this measure to be included in the MIPS program specifically.

We could make a comment for the record, that it may have a better home in a different program for that reason, but that is not what we're voting on.

So, just to be really clear for everyone in the group.

MR. PERLA: And Rob, I apologize because I think I just may have misspoke or confused folks.

So, when the measure developer talks about reporting, it's reporting the data that would be the performance.

So, it's not like the requirements that they have to lower food insecurity in their community as an --

(Simultaneous speaking.)

Dr. Schreiber: Correct.

MR. PERLA: -- outcome measure.

So, I just want to make sure I clarify.

Dr. Schreiber: Yes, no, you're absolutely right. The measure here would be whether or not you're doing the screening, right?

Co-Chair Fields: Well, no, it's a screen --

(Simultaneous speaking.)

Co-Chair Fields: -- rate.

MR. PERLA: No.

Dr. Schreiber: Yes.

Co-Chair Fields: So, that's different than, I mean yes, I would agree --

(Simultaneous speaking.)

Dr. Schreiber: Yes.

Co-Chair Fields: -- that was 136, but this measure specifically --

Dr. Schreiber: No, you're right, it's the positivity.

Co-Chair Fields: Right, exactly. So, if you're in a

high needs community, you're going to have a higher score, and then how to evaluate that in MIPS becomes very tricky, right?

So, I'm going to ask, we have Scott Fields was next, and please, just to distinguish, we need to have two votes on this.

So, if it's not a clarifying question, if I could ask you to pause and I'll call on you next when we go into discussion.

Same with Nishant, if it's clarifying on the specs of the measure, that would be great. Otherwise, pause if you don't mind.

So, Scott, go ahead.

Member Fields: 5:06:51 then because the way I read it is that the, the performance is on reporting what your positive rate is.

It's not whether it's high or low, but the fact that you report is the indicator. And, you can be paid based on the performance of reporting.

Is that accurate?

Dr. Schreiber: That is accurate.

Member Fields: So, on that basis, I would just say that this is a tremendous step in the right direction, of a step-wise process that we've gone through at OCHIN quite honestly.

We've used national guidelines built out, social determinants of health indicators, done the screening of over a million screens in our system, and have developed social services resource locators to assist in clinicians getting to resources to actually help patients.

And, now we're beginning to see the outcomes of that. And, unless we get down this pathway, we will never make a dent in what is a huge issue for our

patient community.

So, I'm supportive. Thank you.

Co-Chair Fields: Thanks.

Unfortunately, though, I think I am now confused again, and I'm sure if that's happening to me, it's happening to others.

So, it feels like what was just stated, is actually the opposite of what was just said a second ago.

So, the difference between 134 and 136 is that this is a screen positive rate. You're measuring the rate.

So, if you can tell me if you have two organizations that are reporting, one with reporting 70 percent food insecurity, another 50, are those weighted the same in the context of MIPS?

Dr. Schreiber: Another case we are actually looking to see that you have done a positivity rate.

So, the intent here is not to say that one organization is quote, worse, unquote, than another because they have higher risk needs.

The intent is to see that organizations have actually looked at their positivity rate. They have assessed their positivity rate; they've screened; they've assessed their positivity rate.

Because really, how can you address the issue if you don't know a) if you haven't screened, and b) if you don't know or understand your positivity rate.

Co-Chair Fields: Understood. I think for the trouble with the committee based on all the comments is that there's a confluence here of 134 and 136.

And, if we're assessing what's the best way of getting to that very point, I think that's what the committee's struggling with, is my sense.

MR. PERLA: Rob, maybe I can just --

(Simultaneous speaking.)

Member Fields: I would argue that they're different. They're different, and that's the whole point.

One of them is that you do the screen; and the other is that you look at the data and note the positivity.

And, you will end up noticing the positivity in different areas, and then you will develop resource locators to help with it.

It is a process of which we now are acting on potentially, two steps in the process. And --

(Simultaneous speaking.)

MR. PERLA: Understood.

Co-Chair Fields: But Scott, like so thinking about the depression measures as a reasonable corollary.

We don't have a measure to screen for depression, and then also a measure that measures the positivity rate of depression among those screens.

We just, because it doesn't quite make sense and it's sort of confusing. So, if you're --

(Simultaneous speaking.)

MR. PERLA: I mean --

Co-Chair Fields: -- acting on the depression measure.

MR. PERLA: Yes, I mean just to maybe to help clarify this.

So, I think we're all now understand that 136 is the percent of beneficiaries that are screened in a practice, in a panel, in a hospital, what have you. 134 is the percent that screen positive.

Again, those are the measures that have been

implemented across 600 plus clinical sites. And, it's been really helpful to understand what percent of the population is actually being screened.

You could have a very high percent screen positive rate, but have sampled a very small percentage of the population. And, so it's really important to understand that.

And, I think to the comment that was made by Scott, really beginning to understand where are folks, where are folks having trouble screening.

Part of what AHC was intended to do was understand could we, could screening be implemented on a wide scale, across a number of different practice types, e.g., inpatient, behavioral health, primary care.

So, the act of screening, and being able to screen a significant portion of the population, is a really important activity.

And, then being able to act on the data generated through the either positive or negative findings.

Co-Chair Fields: Don't disagree with any of that.

I think the confusion you're seeing is that we have other measures that are, have similar aims for whatever they're screening for. And, do not have two different measures.

I think that's, I'm just trying to reflect the confusion that's clearly being generated in the chat, and the committee right now.

So, I think in order to move us for further discussion, I would like to kind of just vote on this, on the recommendation for NQF. So, then we can move to broader open discussion, just from a process standpoint.

And, if anyone wants to, if anyone's intensely opposed to doing that on the committee, please

unmute and tell me now.

But I think I would like to move us in that direction, so we can continue in more open discussion.

Member Fleischman: Can I just do, sorry, one clarifying thing because this is really bugging me and it sounds like its bugging you, too, because it makes no sense. We're getting conflicting information.

The measure here then, is not really the measure of how you're going to measure an organization's performance on this measure, is whether they calculate and report their screen positive rate.

It's not how they're performing in terms of what percent of their, of the people they screen are positive, it's whether they actually report the screen positive rate.

So, that the numerator and denominator are just not well written, if that's the case.

Dr. Schreiber: It would be the screen, it would be that they are calculating and reporting a screen positive rate.

Look, CMS would not ever want to penalize an organization for a high positivity rate. That runs counter to what it is that we're trying to accomplish, okay?

What we are seeking to do is to engage clinicians and screen for social determinants, and to look at their rates so that they can act on it.

And, I think it's the beginning of a series of either other measures, or a composite, or a suite of measures, that obviously will come.

Have you implemented a plan around that? What are your plans? And, eventually outcomes measures about how these patients do.

Co-Chair Fields: Okay, thank you for that.

Let's go ahead and move to a vote, and what we're voting on is to support the NQF recommendation of do not support for rulemaking.

And, so if you vote yes, then you are agreeing with that recommendation. So, you are agreeing to not support.

And, if you vote no, then we will continue discussion for some of the other categories.

So, if we can move to that vote, please.

Ms. Harding: Voting is now open for MUC2021-134: Screen Positive Rate for Social Drivers of Health for the MIPS Program.

Do you vote to support the staff recommendation as the workgroup recommendation?

Ms. Elliott: We have 17, Ivory.

Ms. Harding: Okay. Voting is now closed for MUC2021-134. Six members voted yes, and 11 members voted no.

So, the workgroup did not vote to support the staff recommendation as the workgroup recommendation.

And, that came to 35 percent.

Co-Chair Fields: Okay, so now we can start open discussion. I think we had, after Scott we had Nishant? I'm sorry if I'm not saying your name correctly, but I think --

(Simultaneous speaking.)

Member Anand: You have it correct, Rob, thank you.

Yes, I think that part of the reason why I was, now that I have clarity on this, I do think that 136,

you're going to have to do that in order to get to the 134 measure on there.

Part of the reason why I voted against the recommendation of the staff, is because you actually have to, you have to start to do something at some point, in order to figure out what the resources are.

So, one of the things I heard from the feedback is if you find something, then you've got to do something about it.

But I'm not sure how we're going to be able to determine that there's issues going on with food insecurity with some of these transportation issues, unless we start to screen that.

So, again, I think they're both interrelated with this but the screening positive, if it's just reporting a positive rate, you know, if 100 people are screened, 50, or sorry, if there's 100 people, 50 are screened, 25 end up being positive, then at least we know that in those five domains that there's an issue with it.

So, that was just the rationale behind it.

But as I've been working in population health for most of my career, I just don't know how to address the issues that we need to, and change healthcare unless we start to do more of the screening effort.

I fully agree it's not perfect, but I think it's a good start. And, as you explained and clarified the numerator and denominator, I think it makes a lot more sense to me, so thank you for the opportunity to speak.

Co-Chair Fields: Can I say first, the CMS colleagues, you know, often when we have other, again I go back to the depression measure, which is in structure, fairly similar.

So, broad based screening, no one, I don't think

anyone on this committee is arguing that we shouldn't be screening.

But I think, someone can correct me in the chat if I'm wrong about that, but I think everyone is fully supportive of the concept of screening, and being aware of the results and acting on them. I think we're simply trying to evaluate the measure in this program.

And, so as a matter of process, when we do depression measures in the past and report on those, we often report the number of the PHQ9.

So, the difference between a PHQ9 of one versus 10, or 15, or whatever. To get to the same outcome that it sounds like you're trying to get to with the positivity, right?

Like, you both in that one measure, you've documented that you have screened, and you've documented a result.

I am curious from our CMS colleagues, if there's any way on the program side, to structure this so that, such that you can get to a similar outcome without creating a measure that, I mean as it's just even in this committee, is obviously pretty confusing.

And, I imagine with the greater population, will continue to be that way.

Dr. Schreiber: I think what you're asking us is that in a way, can we combine the measure for example, into one where it's --

(Simultaneous speaking.)

Co-Chair Fields: Correct.

Dr. Schreiber: -- kind of like what you're talking about.

Co-Chair Fields: Yes. If not in the measure itself, but in the program process to some degree.

Dr. Schreiber: Yes, in the program process, we would have to go back and have a conversation about it.

For the MUC and MAP consideration because it came through as two separate measures, we couldn't have unless we, because it would have been you know, a substantive change.

And, we would have had to go back and reset the clock, and resubmit a new and different kind of measure to the MUC.

And, so whether or not we can do this within the program about how you assign points, or how it's reported, I think those are places where we could do that.

Member Anand: Also, just as a follow up to my comment, Rob, and I don't know if this is where you're going.

At some level, you have to know what's positive, too. So, is there an opportunity, it's probably not going to be on this version, but if we're going to find an opportunity of food insecurity, aggregating the data is where it's powerful as a community, as nation, to be able to say food insecurity's our problem.

If it's positive, I'm not sure if it's food insecurity, if it's transportation, if it's housing, if it's safety, or whatever tool that they're using at that time.

So, I agree that these two could probably combine into one. I think we also made that comment eloquently before.

You have to screen, and then you can say it's positive.

The challenge is I think the true intent of this, and this is where some of the public comment was, is you have to identify what the problem is that's coming positive.

And, it doesn't have to be at the specific, but at the category level. So again, food insecurity, housing, would now give us some information that would more meet the intent, just as you're thinking about it for the future.

Co-Chair Fields: And, totally agree.

And, I think there was a comment here from I think Wendy's comment reflect that as well, you know, that it's more about the next one.

But I think there's an assumption that when you report on 136, you would report results, not just yes/no for the same, and get to the same outcome.

Just looking at the chat here. I think there was a question about will compensation be calculated based on the differences in scores.

And, I think that certainly it sounds like what you're saying is not on the, there would be a quality calculation based on the rate of screenings reported, but not on the actual number.

Just to clarify.

Dr. Schreiber: That's correct. I mean, penalizing somebody because they have a high score again, runs counter to I think what we're trying to promote in equity.

Co-Chair Fields: And, Wendy, you want to unmute? I saw your hand raised.

Member Gozansky: Yes, I guess I'm wondering whether do we have the potential to be talking about sort of a, do not support with potential for mitigation for this 134, so that the mitigation recommendation would be that you actually would also, would also include the percent screened?

So, the percent positive out of the percent screened, as a way to combine these two.

Because I do, I mean I think we all want to endorse screening, and we need to know who's screening positive for what.

So, I'm just I'm looking for some way to enable us to get to an outcome.

Co-Chair Fields: Yes, I think that's a good point. I'm going to, and Wendy I'll come back to that in one second. I just want to clarify something for Lisa on the chat.

So, the process now is just like the other measures. For instance, we voted to not agree with the recommendation from the NQF team.

We have this discussion that we're having now, and they will re-vote, with actually all four options still on the table, as was clarified earlier. So, we can go back to all four.

MR. PERLA: Rob, can I just, can I say one thing? Because I think this is really important. I just --

(Simultaneous speaking.)

Member McGiffert: That doesn't really answer my question either. Go ahead.

Co-Chair Fields: Okay.

MR. PERLA: My concern from the perspective of the measure developer, is that these measures have been tested and validated in a CMS program.

If this process is going to be about science, evidence and practice, I think the conversation we're having now needs to reference the evidence, and what was done.

I'm really uncomfortable about moving away from that and now proposing a new measure, when it is inconsistent with how the measure was developed, how it's been tested, how it's been validated. It feels inconsistent with the MAP process.

So, I just want to raise that concern from the perspective of the measure developer.

Co-Chair Fields: Thank you.

Lisa --

(Simultaneous speaking.)

Member McGiffert: No, I was just, I meant to ask. So, if we voted the NQF recommendation, then what happens then? It goes nowhere, is what my interpretation is. And, I don't think we really want to do that.

So, I guess I would like to explore more about the mitigating condition that we could add maybe that they're not, is there a way we can say they're not merged, but they're paired with each other?

Co-Chair Fields: I don't know that we could actually do that. I'm looking for help from the NQF team.

I mean, if one recommendation, from going back Wendy's comment is, we could do a do not, we have all the options available to us.

But one potential option is a do not support for rulemaking with mitigation, and the mitigating factor I don't know if we could have that be that it's paired.

We would want to be, we could have a mitigating factor be what Wendy suggested, which is that it's a reporting on not just the positivity rate, but the total number screened, and those that were positive out of that. So essentially, that in effect combines the two.

Which maybe we get to the same thing, I guess, if we have them in combination.

I don't know from the NQF team if a mitigating factor would be, again, Rocco, I'm thinking about your point so as to not to change the measure. But

we could suggest that they be paired to get to the objective that CMS wants.

Which is to get a sense of general screening, and the rate of positivity. Without having to change the specs of the measure, which is a whole other, which is not really something we can do.

MR. PERLA: From the perspective of the measure developer, having them paired, I think would be great. If that means that they're not being changed or modified, but actually just viewed together.

Because I think they have to be viewed together. You need to screen, in order to determine who's screen positive. I think that's a point that we have all come to.

Depending on what paired would mean, I think we would be open to that. It would seem fine.

Co-Chair Fields: Okay. So, one option is to then change the recommendation and say conditional support, and the conditional support would be that they are paired.

We haven't even voted on 136 yet, but you know, I suspect that one will be easier than 134 based on the comments.

But does that sound like a place to start? If not, we can keep voting. We have to vote on all four categories. But unless anyone's grossly opposed, I think that's where we should start.

Emma Hoo, please?

Member Hoo: I wanted to clarify that reporting the positives would entail positive in any one category, not a hierarchy about reporting positive in three or two, or you know, what portion in each segment.

Co-Chair Fields: So the question is is it a positive rate?

Member Hoo: Is it additive across all five domains, or is there some segmentation around reporting in each of the categories, or leveling around two or more categories?

MR. PERLA: Rob, I can clarify that if that's okay.

Co-Chair Fields: Yes, please.

MR. PERLA: So, the percent of beneficiaries screened for the five core drivers of health would be an and.

So, the screening again, consisting with we have a health communities pilot, would be to screen for all five core social needs.

The reporting about the screen positive rate could be done in a number of different ways. One of the ways that AHC, one of their main metrics is the percent of beneficiaries that screen positive for at least one related, health related social need.

And, then that could also be evaluated through different types of positive indicators, you know, at the local level.

But that's how the measures are being broken down.

Co-Chair Fields: Great, thank you.

So, there's movement in the chat to consider actually voting on 136 first. But maybe Emma, if you can clarify for me.

I'm not sure how that helps us because if, even if we vote for 136, I'm not sure how it changes everyone's opinions on 134.

Member Hoo: I think you just had a bit more clarify that you're actually talking about pairing it with something.

So, I think my guess is 136 will be easier, and then

I think you could return to this question of how this measure relates to 136.

Co-Chair Fields: I hear you.

There's also the issue that Amy raised, which is if these are optional measures, they get selected, the ideal pairing probably doesn't really fly, certainly in MIPS, because you can choose individual measures, so.

Okay. So, Tricia, I don't know what your thoughts are about if we can fairly quickly go to 136. I suspect that will go fairly quickly. It's worth a shot.

Ms. Elliott: Sure. If the committee would like to go in that direction, we'll pause this discussion here, and circle back for the final vote. I'm fine with that.

Co-Chair Fields: Okay.

Ms. Elliott: Okay.

Co-Chair Fields: Because I know we've got to move based on other stuff left.

Ms. Elliott: Okay, so we'll go to 136. I'll introduce the measure.

136 is Screening for Social Drivers of Health, percent of beneficiaries 18 years and older screened for food insecurity, housing and stability, transportation problems, utility help needs, and interpersonal safety.

Level of analysis similar to 134, it's clinician group, facility, other, beneficiary, and population.

And, the NQF recommendation here is conditional support for rulemaking pending NQF endorsement.

The rural health and health equity comments I will highlight. Rural health, the measure was suggested to be applicable to the rural communities. Concerns raised regarding standardized data sets, and data

collection for the social determinants.

However, the advisory group agreed that it is important to start the standard collection of this information. The developer commented that by introducing this measure into CMS programs, it will help drive standardization.

No calculation issues. Concerns were raised regarding the capture of the positive screening without appropriate resources available to support the patient needs.

The health equity group. The social driver measure is important, as this is one of the first measures considered for federal programs. Screening is important to advance equity.

Need to ensure alignment regarding data capture and standardization, such as the CMS SDOH Z codes, would provide consistent standards. Lack of fully developed federal data standard is holding back major investments and data systems for SDOH.

This measure is particularly important, useful to stratify by disability from the health equity group once again, and patient provider frustrations and concerns about having to screen without having robust options, such as community resources, care navigators, et cetera, to address the positive responses.

There was very robust public comment for this measure as well, with 50 public comments coming in to NQF. Thirty-four were in support of the measure, 16 were not supportive.

And, just a few highlights. No follow up interventions on the non-support side, and wanting an outcome measure. Consider flexible tools, and let's see, data collection burden was identified as well.

I think all the support comments have been discussed over the course of our PCR, so.

Co-Chair Fields: Great, thank you, Tricia.

So any clarifying questions on this one? Otherwise, and if there are, great, and if there aren't, then we'll move to a vote to the NQF recommendation.

There's a question, does this measure pay for reporting or pay for performance? And, it's a program question.

Anyone from CMS want to comment? And, I imagine that could change over time. So, whatever happens now may change, but.

Anyone from CMS? Michelle, anybody?

Dr. Schreiber: I would expect here that screening equals performance. So, the higher the percentage of patients that are screened, the better your performance.

Co-Chair Fields: Right, okay.

Right, good point, Helen, sorry, yes, that was right.

Okay, so it's a MIPS program. This is the MIPS program so it's all pay for performance. Good point, so.

Any other clarifying comments? Otherwise, we'll move to a vote.

Ms. Elliott: No hands raised, Rob.

Co-Chair Fields: Okay. All right, well let's go ahead and vote on the NQF recommendation for conditional support for rulemaking.

If you're in support of this recommendation, that is what we're voting on now.

Let's go ahead and do that.

Ms. Harding: Voting is now open for MUC2021-136: Screening for Social Drivers of Health for the MIPS Program.

Do you vote to support the staff recommendation as the workgroup recommendation?

Three more seconds.

Okay, voting is now closed for MUC2021-136, and the results are as follows. Fifteen committee members voted yes, and one committee member voted no.

Co-Chair Fields: Great.

Ms. Harding: Which brings us to a percentage of 94 percent.

So, the workgroup voted to support the staff recommendation as a workgroup recommendation.

Co-Chair Fields: Great. Thanks to the committee.

So, we have now approved a recommendation to include screening in the MIPS Program.

So, now we'll go back to 134. And, to review the understanding with this measure. This is a MIPS measure.

The performance here is not the number who screen positive, to be clear. The performance here is the fact that you are reporting a number. That you are reporting anything it sounds like. Rocco, Michelle, that's what I'm understanding.

It's not that you had 70 percent of folks insecure, food insecure versus 60, it's that you reported any positivity, or any rate on food insecurity.

MR. PERLA: Correct, that's correct.

Co-Chair Fields: So, it's a little more, it's not paper reporting in the way we think about it in the MSSP Program. But it certainly it's not exactly pay for

performance in the same way we normally think about it either, so.

MR. PERLA: That's right.

Member McGiffert: Can I ask a clarifying question?

Co-Chair Fields: Please, yes. At this point, we're back to open discussion, so go for it.

Member McGiffert: Okay. So, the measure would be, it wouldn't be yes/no that you reported positivity, but you would report a percentage of positivity. You would have to do that to meet the measure, right?

Or could you say, is that correct? I guess I should stop there.

MR. PERLA: That's correct.

Member McGiffert: Okay.

(Simultaneous speaking.)

Co-Chair Fields: Any --

Member Anand: Just another clarifying.

That's all you have to do is report a percent on this one, the other one you actually have to screen more people. The denominator on this one could be much smaller, is that correct?

It's just all you're reporting is I screened two people, one was positive, the other one I have 100 people, I screened 50 of them.

Am I interpreting the distinction between the two correctly?

MR. PERLA: That's the distinction in theory, that could happen. That would be possible.

Co-Chair Fields: And then I think just for summarizing just and we probably can move to a

vote here pretty quickly, because I'm not seeing a ton of other comments.

So, Michelle, you clarified earlier that these -- when -- obviously since MIPS has a ton of optional measures, folks could potentially choose this one, as opposed to 136, or just choose 136 potentially, depending on I mean obviously their option at that point.

Dr. Schreiber: Or depending on how it gets structured in the program.

Co-Chair Fields: Okay, so I'm not seeing anything else either in the chat, and I don't see any other hands raised.

So, I'm going to, given the time, I'm going to move us to a vote. The question is which one?

So, I'm actually going to change it in terms of which one we put up first, trying to see which we hit the lottery here and save some time.

We'll do, we'll start with conditional support for rulemaking similar to the last one. I don't know in terms of the conditions that that would be, I don't believe these are NQF endorsed, or are they?

Ms. Elliott: No.

MR. PERLA: They have not been submitted at this point, Rob.

Co-Chair Fields: Okay, and that was true for the last one as well, which that was a condition, correct?

MR. PERLA: Correct.

Ms. Elliott: Correct.

Co-Chair Fields: Yes, so we would make this measure same as 136, which is conditional support for rulemaking.

If we could start the vote there, if that's okay with

everyone here?

Ms. Elliott: So, are you, Rob, this is Tricia. Just to clarify, are you proposing the condition be NQF endorsement?

Co-Chair Fields: Correct, yes, I'm sorry.

Ms. Elliott: Okay.

Co-Chair Fields: And, then if that doesn't fly, we'll go to the next category. But let's start there.

Ms. Elliott: Okay, the team is pulling up the right vote.

Co-Chair Fields: Yes, thank you. Trying to take the temperature of the group here.

Ms. Harding: The voting is now open for MUC2021-134: Screen Positive Rate for Social Drivers of Health for the MIPS Program.

Do you vote conditional support for rulemaking?

Co-Chair Fields: All right, we've got 17.

Ms. Harding: Okay, the voting is now closed for MUC2021-134.

And, the results are 11 members voted yes, six members voted no.

Co-Chair Fields: I believe that gets us --

(Simultaneous speaking.)

Ms. Harding: And, that gave us 65 percent.

Co-Chair Fields: All right.

Ms. Elliott: We're done.

Co-Chair Fields: All right, so conditional support for MUC.

Thank you to the committee, and appreciate the

discussions, a lively discussion. That's good. It gets to better outcomes that way, so appreciate everyone's input.

Ms. Elliott: Excellent.

Opportunity for Public Comment

So we now have an opportunity, it's the end of our meeting, and so we open it up for public comment.

As a reminder, to comment you could raise your hand, unmute yourself, or post a message in the chat.

Jennifer Gasperini, did you want to make a comment? I saw you asking in the chat.

MS. GASPERINI: I did, thank you. Can you hear me?

Ms. Elliott: Yes, we can.

MS. GASPERINI: Okay, great.

I just wanted to be on record saying that, first of all, I'm Jennifer Gasperini, with the National Association of ACOs, NAACOS.

And, for a couple of years now, we've been advocating for these types of measures that look at social determinants of health, and others like it.

And, would like to see such a measure applied at the ACO level. We think that is a good fit, and think perhaps even a better fit maybe than the MIPS programs.

So, we just wanted to provide those comments today.

I also wanted to make a comment that the days at home measure was originally discussed a couple of years ago, as potentially being included in the MSSP in rulemaking, and was not raised today.

So, I just wanted to ask a question about why that was, as well.

Ms. Elliott: Thank you.

Any other public comments? Once again, you can raise your hand, post in the chat, or come off mute.

Co-Chair Fields: Tricia, just a question here. So, we're not asking folks to respond necessarily, like when there is a question from the public? I just want to.

Ms. Elliott: No.

Co-Chair Fields: Okay, thank you.

Dr. Price: I wonder if I might just briefly thank all of you for the time and really careful thought you've put into these measures on behalf of the foundation.

And, also like to thank all of those who supported these measures going forward, and I look forward to the work we can all do to make the healthcare in our country better as we pursue them.

But thank you all very much.

Ms. Elliott: Thank you, Dr. Price.

Co-Chair Fields: I would just say Tricia, that as Jennifer said, I just says in the public comment section not necessarily as Chair, but I do think that these conversations on those last two measures would have been infinitely easier in the context of a MSSP program.

It's just the way the structure of the program is at that level. There's a paper reporting structure. There's just a thousand things that are easier about doing these types of broad level metrics.

And, I know if folks aren't used to this process, it's a little bit challenging to reconcile the passion around

the measure, and matching it to the right program. And, those are fundamentally two different things.

And, so how it gets administered is important. And, not because the measure isn't important, but that so a lot of the tension you're sort of feeling I think reflects, I think a lot of folks, a lot of the folks represented on the committee, in trying to reconcile those two things.

Ms. Elliott: Helen, did you want to share your comment that you placed in chat?

Member Burstin: No, just agreeing with Rob.

Ms. Elliott: Okay.

Member Burstin: I think the population level fits really well with MSSP.

Ms. Elliott: Perfect, thank you.

We'll pause for another minute or two, just to make sure we gather any other public comment.

I'm not seeing any hands raised.

And, Michelle, did you want to make your comment, or I can read it?

So Michelle states that MSSP program is working to align with MIPS measures, so this will be a topic we bring back to them. So, thank you.

Okay, so at this point, I'd like to Rob, if it's okay we'll move forward.

I think we paused and received some public comment, so we can move forward to wrapping up.

So if I could --

(Simultaneous speaking.)

Ms. Elliott: -- okay. Next slide is there already.

So we'll summarize the next steps, Victoria, I think, I believe that's you. And, then we'll circle back to the Co-Chairs to close out the meeting for us.

MS. FREIRE: Thank you, Tricia.

Summary of Day and Next Steps

Okay, I will go over the MAP pre-rulemaking approach.

As you can see right now, we're in December with the MUC list being released December 1, and our clinician meeting being over today.

We have hospital and the post-acute care long, post-acute care long-term care workgroup meetings happening this week.

And, then in late January the MAP coordinating committee virtual meeting, to finalize recommendations. With the final report going to HHS CMS by February 1.

And, then in March, the pre-rulemaking report, which is published.

There's a timeline of upcoming events. There will be a second public commenting period on workgroup recommendations from December 30 through January 13.

Like I mentioned, the coordinating committee virtual review meeting will be January 19, and then the final recommendation to CMS by February 1.

Ms. Elliott: Great, thank you so much, Victoria.

So, if I can hand it back to Rob and Diane, for any closing comments?

Co-Chair Fields: I'll just reiterate my thank you to CMS and the team, for being so helpful.

The measure stewards, I think it was very helpful at different times in the meeting today to get, keep us

moving and clarify issues that the committee had, questions the committee had.

And, of course, for the committee to spending all the time in reviewing all the measures and the data. It's a lot of effort, and to try to do the right thing.

And, so greatly appreciated.

Will also comment that it is a, perhaps a small step not to use like, not to go all the way to the full cliché here, the full quote, but it's an important one.

I think it's certainly a flag planting for this group, and for quality measurement in general, to move into the realm of social drivers of health.

So, I am thankful to have been here for it. So it's great, we're moving in the right direction. A lot to do, but right direction.

Diane?

Co-Chair Padden: I see Michelle's hand up. I'll defer to you for a minute, Michelle.

Dr. Schreiber: I was going to wait and come after you guys.

Co-Chair Padden: Okay.

I'll just make one small, two comments.

Echo Rob's thanking the NQF staff and CMS, for doing this incredible work. Because, and it always comes right before the holidays. So, I know you're all scrunched trying to get it all, all these meetings in and get all the work done.

And, then thank the MAP committee as well, for the discussion, the good questions, and really you're attentiveness. Because it's not easy to sit in a virtual room for eight hours, as we all have done today.

So, I do appreciate your attentiveness, and asking

really great questions so we can move the needle.

Thank you.

Ms. Elliott: Michelle?

Dr. Schreiber: On behalf of CMS, I actually just wanted to take the opportunity for us to really thank the Co-Chairs. You guys did a wonderful job kind of you know, moving the conversations along.

To all of the committee members, your insights have really have been wonderful, and we've learned a lot, and it will help influence how we use measures in our programs. What measures we use in our programs.

To the measure developers, who supported their measures today and were able to answer questions.

And, of course, to the NQF staff who we work with closely on this.

And, so again, on behalf of CMS to all of you, our great thanks and wishes for happy holidays.

Ms. Elliott: Thank you so much.

So, very generous thank you to Rob and Diane from the NQF team, and leading us through this. And, thank you Michelle, for your kind words.

On behalf of the NQF staff, I want to thank everyone as well. Phenomenal day; lot of excellent discussion. And, also kudos to the team behind the scenes.

All of those running the polling, creating the slides, putting all the PAs together. It definitely takes a village to pull a lot of these details together.

So, we very much appreciate everybody's time and energy to devote to this, these important topics.

Adjourn

And, with that, we, for the record, we are ending at 5:49 p.m. and I wish everyone a very happy holiday season.

Thank you all.

(Whereupon, the above-entitled matter went off the record at 5:49 p.m.)