PHYSICIAN-FOCUSED PAYMENT MODEL TECHNICAL ADVISORY COMMITTEE (PTAC)

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PUBLIC MEETING

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Virtual Meeting Via Webex

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Tuesday, September 15, 2020

PTAC MEMBERS PRESENT

JEFFREY BAILET, MD, Chair
GRACE TERRELL, MD, MMM, Vice Chair
PAUL N. CASALE, MD, MPH
LAURAN HARDIN, MSN, FAAN
ANGELO SINOPOLI, MD
BRUCE STEINWALD, MBA
JENNIFER WILER, MD, MBA

PTAC MEMBERS IN PARTIAL ATTENDANCE

JAY S. FELDSTEIN, DO
JOSHUA M. LIAO, MD, MSc
KAVITA PATEL, MD, MSHS

STAFF PRESENT

STELLA (STACE) MANDL, Office of the Assistant Secretary for Planning and Evaluation (ASPE)
AUDREY MCDOWELL, Designated Federal Officer, (DFO), ASPE
SALLY STEARNS, PhD, ASPE

CONTRACTOR STAFF PRESENT

KAREN SWIETEK, PhD, MPH, NORC at the University of Chicago

A-G-E-N-D-A

Deliberation and Voting on the Patient-Centered Oncology Payment Model (PCOP) submitted by the American Society of Clinical Oncology (ASCO)

PRT: Jennifer Wiler, MD, MBA (Lead), and Paul N. Casale, MD, MPH
Staff Lead: Stella (Stace) Mandl

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

10:00 a.m.

* CHAIR BAILET: Thank you. Good morning and welcome to this meeting of the Physician-Focused Payment [Model] Technical Advisory Committee, known as PTAC.

Welcome to members of the public, whether you're joining us via Webex, the phone, or live stream. Thank you all for your interest in our meeting today.

We extend a special thank you to stakeholders who have submitted proposed models, especially those who are participating in today's meeting.

This is PTAC's 11th public meeting that includes deliberations and voting on proposed physician-focused payment models submitted by members of the public.

Because of the coronavirus pandemic, we are holding this meeting virtually, rather than gathering in the Great Hall of the Humphrey Building.

Our goal is for a seamless virtual experience as close to an in-person PTAC

meeting as possible. That said, we appreciate your understanding in advance for any technical challenges that may arise, such as sound delays or background noise.

To echo some of what we shared at our public meeting in June, we want to thank providers, support staff, caregivers, family members, and others who are supporting patients during the pandemic.

Many PTAC stakeholders are directly involved in responding to the pandemic, and we are thankful for your service to our country. We recognize that it is a privilege to have some of you joining us today.

PTAC remains committed to having a submitter-driven process. As was mentioned in June, given that many potential submitters may be directing their time and attention to efforts related to the pandemic, anyone who is considering submitting a proposal should be aware that PTAC accepts proposals on a rolling basis. So, you do not need to worry about finishing your proposal to meet a particular deadline.

There is much to be learned about how Alternative Payment Models can facilitate provider resilience. During the pandemic, we have learned a great deal about the critical role that telehealth has played in providing access for patients and payments to providers.

There are lessons to be learned regarding the important challenges that emerge from the use of telehealth, including technical and functional challenges that can impede access to care and perpetuate disparities.

Many previous submitters have included telehealth in their proposed payment models. We have organized the agenda for tomorrow's portion of the meeting to discuss telehealth in the context of Alternative Payment Models.

The panel discussions and the public comments provided tomorrow will serve to further the depth and breadth of the Committee’s and stakeholders’ knowledge on this topic.

Next, I'm excited to welcome our three new members to the Committee. We have

Dr. Jay Feldstein, an emergency medicine physician by training. He is the President and CEO of the Philadelphia College of Osteopathic Medicine.

Welcome, Jay.

DR. FELDSTEIN: Thank you.

CHAIR BAILET: We have Ms. Lauran Hardin, a nurse by training. She is the Senior Advisor for Partnerships and Technical Assistance at the National Center for Complex Health and Social Needs, an initiative of the Camden Coalition of Healthcare Providers.

Welcome, Lauran.

MS. HARDIN: Thank you, Jeff.

CHAIR BAILET: We also have Dr. Josh Liao. An internist by training, he's the Medical Director of Payment Strategy at the University of Washington Medicine, Director of the Value and System Science Lab, and Associate Professor of Medicine at the University of Washington School of Medicine.

Welcome, Josh. And he may have stepped away, because he's recused for this morning's session.

We're thankful that they have all joined us. We welcome them to the Committee. They were appointed by the Government Accountability Office in July, and have hit the ground running by learning all things PTAC and immersing themselves in the proposals we will be deliberating and voting on today.

Now I want to update you on PTAC's work over the last few months. At our previous public meeting in June, we deliberated on two proposals, one from the University of Massachusetts Medical School, and another from the American College of Allergy, Asthma and Immunology.

We recently released our reports to the Secretary for those two proposals. And you can find those reports online.

We also released a set of questions on the For Public Comment page of the ASPE PTAC website on various topics such as current challenges in health care delivery and payment, to collect information that will serve to enhance the environmental scans that are conducted as part of our proposal review

process. We intend to post the responses we receive online.

We're grateful to our stakeholders for their engagement as we seek to improve our processes. We welcome further input on those questions at any time.

As you may know, to receive updates about these various ways to engage with our Committee, please join the PTAC listserv, which you can find on the contact page at the ASPE PTAC website.

To remind the audience, the order of activities for review of a proposal, is as follows: First, PTAC members will make disclosures of any potential conflicts of interest. We will then announce any Committee members not voting on a particular proposal.

Second, discussion of each proposal will begin with a presentation from the Preliminary Review Team or PRT, charged with conducting a preliminary review of the proposal.

After the PRT's presentation, and any initial questions from PTAC members, the

Committee looks forward to hearing comments from the proposal submitters and the public. The Committee will then deliberate on the proposal.

As deliberations conclude, I will ask the Committee whether they are ready to vote on the proposal. And if the Committee is ready, each Committee member will vote electronically on whether the proposal meets each of the Secretary's 10 criteria.

After we vote on each criterion, we will vote on an overall recommendation to the Secretary of Health and Human Services.

And finally, I will ask PTAC members to provide any specific guidance to ASPE staff on key comments that they would like included in the PTAC's report to the Secretary.

A few reminders, as we begin discussion of today's first proposal. First, if any questions arise about PTAC, please reach out to staff through the PTAC@HH.gov[1] email. Again, that email is P-T-A-C @HH.gov.

We've established this process in

1 PTAC@hhs.gov

the interest of consistency in responding to submitters and members of the public. And appreciate everyone's cooperation in using it.

I also want to underscore three things. PRT reports are reports from three PTAC members to the full PTAC and do not represent the consensus or position of PTAC.

PRT reports are not binding. The full PTAC may reach different conclusions from those contained in the PRT report.

And finally, the PRT report is not a report to the Secretary of Health and Human Services. After this meeting, PTAC will write a new report that reflects inputs from the public, as well as PTAC's deliberations and decisions today, which will then be sent to the Secretary.

PTAC's job is to provide the best possible comments and recommendations to the Secretary. And I expect that our discussions today will accomplish this goal.

I would like to thank my PTAC colleagues, all of whom give countless hours to the careful and expert review of the proposals

we receive. Thank you again for your work, and thank you to the public for participating in today's virtual meeting.

At this time, I'm going to turn over the virtual gavel, and facilitation duties to Grace, PTAC's Vice Chair, because I am part of the PRT for the proposal we are about to deliberate on.

Over to you, Grace.

*** Deliberation and Voting on The "Medical Neighborhood" Advanced Alternative Payment Model (AAPM) (Revised Version) submitted by the American College of Physicians (ACP) and the National Committee for Quality Assurance (NCQA)**

VICE CHAIR TERRELL: Thank you, Jeff. Good morning, everyone. The first proposal that we will discuss today is called The "Medical Neighborhood" Advanced Alternative Payment Model.

It's a revised proposal from the American College of Physicians and the National Committee for Quality Assurance.

*** PTAC Member Disclosures**

PTAC members, let's start the process by introducing ourselves, and at the same time read your disclosure statements on this proposal.

Because this meeting is virtual, I will prompt each of you. So, I'll start. My name is Grace Terrell with Eventus WholeHealth. I'm a Fellow of the American College of Physicians. I pay dues annually and participate in their continuous, continuing medical education opportunities.

I was the first NCQA Level Three Patient-Centered Medical Home in North Carolina in 2007. And in 2015 I spoke at the NCQA Quality Talks Conference but for no remuneration other than travel and lodging.

As Jeff mentioned earlier, Josh Liao has a scheduling conflict and will join the deliberation's part three. I will read his disclosure statement at this time.

I currently serve on several national ACP committees, including those related to medical quality, coding, and payment

policy. While I did not participate specifically in the creation or submission of this PFPM[2], and there are no financial conflicts of interest, a reasonable individual would view my committee involvement with ACP, and corresponding discussions about Alternative Payment Models as an inability to remain impartial. I recuse myself from the review, deliberation, and voting of this proposal.

Next is Jeff.

CHAIR BAILET: Hi, Jeff Bailet. I am the CEO of Altais. I have nothing to disclose.

VICE CHAIR TERRELL: Paul?

DR. CASALE: Paul Casale, Cardiologist, I lead population health initiatives at New York Presbyterian, Weill Cornell, and Columbia. Nothing to disclose.

VICE CHAIR TERRELL: Jay?

DR. FELDSTEIN: Hi, I'm Jay Feldstein, President and CEO of Philadelphia College of Osteopathic Medicine. And I have nothing to disclose.

2 Physician-Focused Payment Model (PFPM)

VICE CHAIR TERRELL: Lauran?

MS. HARDIN: Lauran Hardin, Senior Advisor for the National Center for Complex Health and Social Needs. I have nothing to disclose.

VICE CHAIR TERRELL: Kavita?

DR. PATEL: Hi, Kavita Patel, Brookings Institution. And I'm a dues paying member of the American College of Physicians. But outside of PTAC, have not reviewed this proposal. And I've also done work with NCQA over the years but not on this proposal.

VICE CHAIR TERRELL: Angelo?

DR. SINOPOLI: Yes, I'm a primary critical care physician and Chief Clinical Officer for Prisma Health. And I have nothing to disclose.

VICE CHAIR TERRELL: Bruce?

MR. STEINWALD: Bruce Steinwald. I'm a Health Economist in Washington, D.C. I have nothing to disclose.

VICE CHAIR TERRELL: Jennifer?

DR. WILER: Hello, I'm Jennifer Wiler, Chief Quality Officer of UCHealth Denver

Metro. I'm also a Professor of Medicine at the University of Colorado School of Medicine. And nothing to disclose.

VICE CHAIR TERRELL: Thank you, members. I would now like to turn the meeting over to the lead of the Preliminary Review Team for this proposal.

Kavita Patel will present the PRT's finding to the full PTAC.

*** Preliminary Review Team (PRT) Report to PTAC**

DR. PATEL: Great. Thank you, Grace. And if we can go ahead and advance the slide. I just want to make sure I acknowledge the other members of the PRT, Dr. Sinopoli and Dr. Bailet.

And just also want to acknowledge that as Grace mentioned, this was a revised proposal. And we had had participation in the past from previous PTAC members, just to acknowledge that in addition to Dr. Bailet, Harold Miller participated in that very first review.

And wanted to thank everyone for

being a part of that. Next slide.

So, we're just going to go over kind of the basics of the PRT and the proposal overview. A summary of our Preliminary Review Team's assessment with some issues and our evaluation. Next slide.

And as just a reminder, this is standard, the Preliminary Review Team composition. So, we are assigned two to three, in our case, three PTAC members, with myself serving as the lead.

And the PRT identifies if we need clarifying information from the submitter. All of this is in public record. So, any additional documents are available to anyone watching or listening to this webinar.

But, then we as a PRT can determine if there is any initial feedback on a proposal, as well as after reviewing the proposal and materials assembled by ASPE and other public comments that were received, we prepare a report of our findings, which are also available to the public, and posted on the PTAC website if people need a place to find them.

The PRT report is not binding on PTAC members, including the PRT members, by the way. So, the PTAC itself, including the PRT members, might reach different conclusions from those contained in the Preliminary Review Team report.

The key word there is preliminary. And just a way for framing the discussion. Next slide.

All right. So, in order to just do a little bit of background, we wanted to offer, this was a -- I really wanted to thank the submitters, as well as those of you that did provide public comments.

And again, just the ability to, as an example for anybody interested in submitting a proposal to PTAC, this was a case where, I think, the initial feedback that had been afforded to us by regulations and authority was able to help to really refine this proposal and bring it to what we are presenting today.

Rather than read the slides, and I know there are people just listening on the phone, I'm going to hit the highlights so that

we have a sense of what this model involved.

The five-year, multi-payer pilot program that builds on a current CMMI[3] program, the Comprehensive Primary Care Plus, CPC+, and the Primary Care First model, which has not started, but is slated to begin in 2021, and it incorporates the NCQA's guidelines developed on patient-centered specialty practices.

The MNM as we're going to try to refer to it, Medical Neighborhood Model, MNM, is really designed to address two key issues: the dearth of current specialty advanced payment models, and really this poor intersection between primary care and specialist referral coordination. So, I think you've got a good exemplar of specialists and primary care physicians on the PTAC composition. But, it was really helpful to hear perspectives from physicians and public comment to this point.

Submitter proposes that the MNM be piloted in a subset of CPC+ or PCF[4] regions once they are initiated, with enough specialties so

3 Center for Medicare & Medicaid Innovation (CMMI)
4 Primary Care First (PCF)

that there's kind of a high value and high volume electronic quality measures that can be used to actually monitor the MNM.

And because of this need to start with certain specialties, the submitter proposes, but it's not binding, cardiology, infectious diseases, and neurology as potential initial pilots.

So, the APM entity, the goals are as stated, to improve Medicare -- to improve care for Medicare beneficiaries with multiple chronic conditions through the better coordination of specialty and primary care.

And the APM entity would be specialty practices that have achieved in NCQA, PCSP, Primary -- sorry, Patient-Centered Specialty Care Practices. This is my acronym test recognition. Next slide.

And eligibility for this, there we go. Sorry, I'm trying not to read off the screen and just go by my notes.

But, the eligibility for this targeted beneficiaries would be eligible for attribution in this with multiple chronic

conditions that include the specific conditions on which the model focused. For example, with some of those initial proposal specialties.

The payment would be one of two tracks for which the entity could choose from. Track one would be a regular fee-for-service payment track.

While track two would be reduced fee-for-service, set a 25 percent reduction in fee-for-service, but in exchange for quarterly prospective payments that are risk-adjusted.

Performance measures, as mentioned again, it's the NCQA PCSP recognition program, which has an incredible comprehensive, detailed set of existing quality measures that have been validated.

And the focus on those measures does include everything from utilization, behavioral health, patient reported outcomes, experience, and care coordination. Next slide.

Core elements of the MNM program. There are three really critical core components. And this will vary a bit depending on that payment track that an entity chooses.

There's a care coordination fee where all participants would receive a monthly per beneficiary fee to support the care delivery investments, as well as a potential kind of add-on performance-based payment on spending relative to a benchmark that's risk-adjusted for quality and utilization metrics as well.

Then there's a performance-based payment adjustment where all participants would also receive a performance-based payment. But, it depends -- based on spending relative to a benchmark. This is for both tracks one and two.

And then the next, third kind of major component is really for people who choose that track two of reduced fee-for-service.

So, it would be a comprehensive specialty care payment. And that's a quarterly prospective payment based on estimates of anticipated or prospective Medicare fee schedule spending.

So, I've just -- that's some of what we can go into. But again, there's a deep, a

rich set of background and materials related to this in the public viewing folder.

All participating specialty practice will get a risk and geographic adjustment, non-visit based, per beneficiary per month care coordination fee on -- attributed patients.

The care coordination fee as I referenced in one of the three domains, is risk-adjusted at the population level to account for intensity of care management services. Next slide.

And then attribution, which is obviously incredibly important to this model, occurs in three steps. First, all referral requests from a CPC. Remember, there are people who are kind of, if you will, nested or centered in CPC+ or PCF practices.

All referral requests from CPC+ or PCF, kind of primary care physicians are pre-screened to ensure that there is an appropriate specialty visit. This is to mitigate unintended consequences.

Second, if the specialist is uncertain whether a visit is necessary, because

they need more information, an optional e-consultation is conducted to determine whether an in-person visit is appropriate.

I think all of us in this that are practicing in light of COVID, can see how this is probably a lot easier than we would have anticipated than in prior days.

Third, a patient for whom a visit is determined to be necessary, has an office visit with the specialist. Next slide.

And then just to go over, we -- yeah, there we go, sorry. Summary of our PRT review. I think this is record setting.

I'm one of the original PTAC members. And I can't recall a time when we had both unanimity and just not -- unanimity across the PRT, but unanimity in our conclusions.

I'm not going to read this to you, because every single criteria specified by the Secretary of our 10 criteria, unanimously we felt met the criterion.

So, this is something of a -- I -- Grace might correct me, or Jeff is one of the PRT members. But, I can't recall something

that was, had this degree of agreement. Next slide.

But that's not to say, here's where I get to be bad cop to some degree. Not in a bad way. But, just to say our unanimity didn't mean that there weren't some key issues that we identified.

So, we wanted to make sure that, you know, there was an incredible importance in having this grounded in the CPC+ and PCF programs. But there are reasons for which many providers don't have those opportunities.

And we want to, you know, just encourage the PTAC to consider that we brought this up and discussed it.

And then we also think that this Medical Neighborhood Model is an important approach. And that this could really be kind of a game changer if you will.

It's what some of us have always thought of as last mile in patient care, with improving care within and between specialty practices, to avoid unnecessary care.

But we do think that in order to

make sure that this has a high of a probability of successful execution and implementation, that there may need to be some refinements. That you know, obviously the submitters were bound both by page requirements and just time constraints.

So there are -- you know, clearly if this were to go forward as the PRT felt it should, that we thought that there needed to be refinement.

And that goes everywhere from some of the details on attribution to payment to risk adjustment, to consideration, for example, of requirements around specialty measures. Next slide.

The other things that we, and I touched on some of the key aspects that we thought needed to be developed further.

So, I'll say that despite some of those issues that we do feel need refinement and further discussion and deliberation beyond kind of the PTAC, we thought the MNM proposal itself gave sufficient framework and mechanism to justify the considerations that are

unanimity and, you know, kind of all the 10 criteria.

And that we thought that, you know, a special APM in and of itself could not achieve like a threshold of large savings for model development and implementation. For example, an infectious disease APM potentially, or a neurology APM in and of itself.

But, that having this model that allows for kind of potentially a hub and spoke with primary care and specialties, as is kind of consistent and common in regular practice, that we felt like this was why the MNM model really was -- it's why we voted the way we did.

And then if this is, and I think the key here is that the ACP and NCQA really proposes this as a pilot. So, they proposed it as a pilot with kind of initial strategy for those three specialties, cardiology, neurology, and infectious diseases.

And that, if that were to be defined, executed, and potentially piloted, that then there could be an opportunity for additional specialties. Next slide.

And then just to go through, I'm again, not for the sake of reading, but highlights on this.

That the Criterion 1, which was one of our high-priority criterion around scope, that this proposal we felt unanimously met the criterion because it did provide an opportunity for more people to participate in APMs, particularly specialties who might not have an opportunity otherwise. And it leverages two existing, at least two existing CMMI APMs.

We don't know if the referral volumes to some of the specialty practices from these primary care groups that are in CPC+ and PCF might be large enough. So, that was something that we brought up.

And that we also know that if there are specialty practices who do not have NCQA PCSP recognition, which is proprietary and not open source, that that could be -- that could be a barrier in joining easily. Next slide.

Scope -- Criterion 2, which was also high priority, quality and cost. It calls for the -- again, felt unanimously the PRT, that it

met this criterion.

And that at no additional cost that we thought that this could improve quality. It really uses existing evidence-based measures.

And one thing that might, because of the proprietary nature of the PCSP, there may be a consideration for an alternative approach to achieve those same domains and measures.

And one thing we just wanted to, the submitter kind of proposes that CMS[5] really kind of helped with quality, clinical quality improvement through regular performance feedback to participants, including meaningful benchmarks, so that you can compare yourself to others, as well as kind of a control group.

But we think that because of the model's increased payments, it may be difficult to offset some of this through downstream savings. So, just to the point of cost that we think that there's again, more work that could be done on the suggested two tracks.

But in terms of meeting the criterion, we felt that it did. And also

5 Centers for Medicare & Medicaid Services (CMS)

wanted to acknowledge some of the difficulty potentially with model overlap with people who are in CPC+ or MSSP[6] programs, ACO's[7] et cetera. Go ahead and next slide.

The third criterion, also a high-priority one, payment methodology. We touched on some of the issues that need to be further addressed if the PTAC moves this on beyond this process.

But it does -- we did feel unanimously that this addressed a pretty important challenge of how to adjust for specialty -- specialist time for appropriate referrals, kind of for necessary care, including the necessary time and coordination with primary care physicians to incentivize kind of that appropriate both, appropriate initial and subsequent referrals, as well as closing the loop on referrals when you no longer need specialty care.

And that without really having, again, we think that some of the attribution methodology could be used further in discussion

6 Medicare Shared Savings Program (MSSP)
7 Accountable Care Organizations (ACOs)

and refinement. But we felt like it was sufficient, in fact, met the criteria in a way that we thought hand off between providers.

We thought that handoffs, especially if there were duplicates, shared savings payments could be problematic. But we think this could also be dealt with through thinking through a little bit further on the attribution and payment methodology.

We also, the model expects that if you are a specialist participating in this model, that you'll use that care coordination fee for infrastructure investment. It might be technology. It might be further care coordination staff.

But the CPC+ model already includes those care management fees. And just a, the published literature to date has not shown cost savings from those care coordination fees.

Another issue that we brought up with the downside risk is not incorporated into this proposal. Track two does have that reduced fee-for-service payment, which especially for many providers, because it's a

reduced fee-for-service payment within a quarterly prospective payment, that one could argue that in some way that is a bit of downside risk.

But again, there's not kind of what's been seen in previous APMs with the direct downside risk tracked.

Half of -- and then finally, half of the performance-based payment benchmark would be based on regional spending. And there is a methodology to include that payment -- to include that payment to be risk-adjusted.

But, it would -- that benchmark itself could be very difficult to define under a general formula to serve as kind of the counterfactual spending target.

Meaning, it’s comparisons of potentially apples to oranges with regard to a benchmark based on regional spending that is risk-adjusted and finding kind of even in a control group, how to compare that.

And that's also come up with previous models. So, but given all those areas, we still felt that this was, again,

going to the top point, an incredibly valuable payment methodology to address this kind of last mile between coordination of primary care and specialties. Next slide.

Fourth criterion, value over volume, felt that, unanimously felt that this met the criterion because if this is done correctly, and attribution payment, risk adjustment quality measures, that this really is intended to reduce inappropriate use of specialty referral.

Or even the kind of downstream or upstream duplicate testing and diagnostics that can happen when trying to coordinate primary care and specialty care. It does allow the specialist to kind of select quality measures which could lead to cherry picking.

So, we wanted to just flag that. And again, this is, I think, a point for consideration if this were to move into what we recommend into the pilot phase as suggested by the submitter.

And it will be, all of this is kind of contingent, you know, everything is linked

to the payment methodology being further detailed, attribution methodology being refined, and making sure that the true intention, the adequate coordination between specialist and primary care really does happen.

But we felt that because the submitters had suggested an initial set of specialties in a smaller, what we call, pilot phase, there's an opportunity to refine these issues. Next slide.

Criterion 5, flexibility. This again, the initial phase, which is described as a pilot phase, after that period of time, whatever that might be, there is a recommendation to allow it for multiple specialties.

Which we thought could be an incredibly flexible model. And also, it involves potentially the door to be opened for specialists to benefit from these kinds of one-time consultations and ongoing collaborations with primary care practices.

The submitters did suggest that the proposed model could be expanded over time,

basically to any specialty that has a sufficient, like kind of high-value electronic, clinical quality measures and referrals form CPC+ or PCF practices.

But we noted, the PRT noted that small practices, small specialty practices in particular might find the PCSP recognition itself from the NCQA, a bit too costly and burdensome. Which is why we bought up some of the potential for alternatives to that, or at least consideration.

And the volume of patients in smaller practices might also be insufficient in small and rural set -- small urban settings and smaller rural settings. Next slide.

Criterion 6, the ability to be evaluated. Submitter acknowledged in their proposal the recommendation of an independent third party evaluator. Which is generally now considered standard practice for most CMS type models.

But the submitters had some nice recommendations around the kind of targets for these evaluations, including the data sources.

We noticed, we noted also that again, there's a lot of dependency on sufficient volume.

And we thought that maybe that there needed to be at least 100 patients to, you know, attributed to the entity, to trigger those monthly care coordination fee payments. But, it's not necessarily clear from the proposal if there is a statistical calculation based on, you know, entity size, et cetera.

So, we're not sure if this kind of number of 100 is one, appropriate, but number two, sufficient or attainable by participating practices. Next slide.

[Criterion 7] Integration and care coordination, also again, unanimous agreement. But this met the criteria, because this is essentially the goal of the program, to encourage greater coordination of care.

And while just at one issue that we discussed at the PRT, it doesn't necessarily go through the how to or the steps that a specialty practice needs to undertake to improve care coordination. Next slide.

Criterion 8, patient choice. This

model did not restrict patient choice of specialty care.

And it would, that -- we noted that the participating practices being part of a PCSP should result in greater access to specialty care because of this anticipated helpful reduction in inappropriate referrals and inappropriate visits.

But again, the process for attribution of patients could be a challenge. And that's why reinforcing the submitters' suggestion to have a pilot, was one of the reasons that we felt very comfortable unanimously agreeing for this criterion as well. Next slide.

Criterion 9, patient safety. There are multiple, what I would call, checks and balances on maintaining patient safety. And again, I think the NCQA's PCSP model has a very rich set of measures that are dedicated to the domain of patient safety and patient-centered outcomes, with monitoring and suggested for the MNM model.

Everything from CAHPS[8] surveys on electronic quality measures, and also using administrative claims, Medicare claims, as well as multi -- commercial payer claims on quality and utilization.

But, it's not entirely clear, this concept of an e-consult, while it might be a little bit more kind of inoculated during an era of COVID, not entirely sure how we would have kind of a standardized, you know, consult, e-consult appropriateness of care. So, we just wanted to flag that. Next slide.

Final criterion, health information technology. You can tell, there is a rich set of what I'll call electronic-based processes. That this would require everything from using just the basic certified EHRT[9], which was one of our, you know, subpoints for this criterion. And also having multiple options for sharing and reporting data, data entry into EMRs[10] designed really to hopefully reduce administrative burden on providers.

8 Consumer Assessment of Healthcare Providers and Systems (CAHPS)
9 electronic health record technology (EHRT)
10 electronic medical record (EMR)

And there could be, you know, the requirement would be uniform kind of electronic data exchange standards so that there's not as much of this interoperability kind of between EMR negotiating.

And there are -- but given all that, there is acknowledgment that some even certified electronic health record technologies might not actually be able to do that.

And there might need to be some of that infrastructure investment. It usually gets put on the practices to actually improve coordination.

So we, the -- and this is in our further, this is in our PRT report. But we just wanted to kind of make sure that while there's so much importance put on data exchange that it's not coming at the undue kind of, where it's disproportionate burden to the participants. And next slide.

So, that concludes our presentation from the PRT. I'm going to stop here and ask, I mentioned, I've got Jeff and Angelo who were my copilots on this journey. And of course,

the amazing ASPE staff and NORC staff.

But, I'll ask maybe Jeff, start with you, any additional comments? Things that we -- things that I missed to flag? Or things you want to just emphasize?

CHAIR BAILET: No, thanks. That was a great job summarizing the work on our committee and the proposal.

Two comments I would make. One is I complement the proposal submitters for their diligence and stick-to-itiveness that they revised their proposal. They -- we had a rich discussion with them, and the revised proposal reflects a lot of the learnings from that initial exchange.

The second thing is, I think that one of the key issues that you touched on could be that this proposal really does two things. It creates an interface.

It addresses an interface between the specialty and primary care community that really can drive up costs and impinge quality, because it really gets to this transition between making an appropriate referral to a

specialist and ensuring that all of the information, including the need to refer the patient to a specialist, is done on the front end.

And that coordination is critically important. And it's been clear that when that breaks down, it drives up costs and it impugns quality. So, that's critical.

And the other comment I'll make is that these proposals still, as you've suggested, and the submitters acknowledged, Kavita, they're imperfect. They're not complete.

But this, we felt this proposal creates a broad enough framework to break through what we've been looking for in several of the evaluations. It creates a forum for specialists to participate in Alternative Payment Models.

And think that the framework is sufficient in coordination with CMMI and CMS that it will hopefully serve as a framework that can actually be constructed for Alternative Payment Models for specialists.

And it goes in with select specialties in neurology and cardiology and infectious disease. It goes in at a level where there's a -- it allows for testing, but it also is robust enough that I think the framework coming out of that could be offered to many other specialties.

So, thank you.

DR. PATEL: Great. Thanks, Jeff. Angelo, any comments to add? Things to highlight?

DR. SINOPOLI: Just a few short things. So, first of all, Kavita did an excellent job describing this proposal and all the details involved, and captured the PRT sentiments regarding this.

I do think it's significant that the PRT had unanimous positive evaluation of all the criteria for this proposal. So, I think that is significant.

I think that as a specialist, you know, I reiterate too that these are real issues. And I see them every day with patients being referred.

And we've seen patients and having inadequate data, so either it's a waste of a visit, or you wind up repeating studies that didn't need to be repeated. So, it is a significant cost and quality issue that needs to be addressed.

I think it's also significant, as Kavita and Jeff pointed out, there are a lot of areas where there were concerns or questions about how this proposal might be further developed and further refined. We think there's a lot of opportunity to make this a more effective model.

But, I think the things that really drove my decisions around this is that this is a proposal that gets specialists involved in these APMs. And really the intent is to get the specialists and primary care doctors coordinated are together in a better way.

And I think the other issue that made me feel more comfortable with this, is from the onset they describe this as a pilot. So, it's not that it's necessarily being pushed forward as a permanent or Alternative Payment

Model.

But, they realize that this needs to be piloted, some things worked out, evaluated, and then potentially scaled down the road. Thank you.

DR. PATEL: Great. And Grace, I'll ask now if we want the full PTAC to ask any questions of us, the PRT, before we get to –

*** Clarifying Questions from PTAC to PRT**

VICE CHAIR TERRELL: Yes. So, just to remind everybody, these are for clarifying questions. Details about the actual proposal itself, you have the opportunity to once the submitters have had a chance to comment.

So, we will do this through our process of who is raising their hand. And I believe that I see that Bruce's hand is raised. Is that correct?

MR. STEINWALD: Yes. This is a test. I guess my question is, since this is a resubmission, what are the major ways in which this proposal differs from its predecessor?

DR. PATEL: I can go through, we had

a, just out of fairness of the fact that not all of the current PRT was not involved, Angelo was not part of that first deliberation.

I would say that our initial feedback really was to further refine the payment method -- it was all the domains that we had flagged for, honestly, querying questions and further collaboration.

So, attribution, payment methodology, clarification on measures. And including, I think this concept of a pilot with an initial phase rollout.

So, just in general they strengthened and added the (audio interference) -- kind of what we felt like was necessary detail. Remember, we weren't giving them technical feedback. It was just initial feedback based on that proposal.

That being said, I would just ask the full PTAC to really judge it based on what you see in front of you. And not necessarily worry as much about the first deliberation.

I really more just wanted to acknowledge that this was something that was

revised. And that we had had a member of PTAC who was on that first PRT, who's not here.

MR. STEINWALD: Okay. Thank you.

VICE CHAIR TERRELL: So, I believe that Jennifer Wiler is next with her hand raised.

DR. WILER: Thanks for the excellent summary of a really comprehensive model. And so appreciate the comments.

I'd like to hear a little bit more about the PRT's opinion regarding no downside risk in this model. And how you thought about that in the context of a high-priority characteristic.

You commented on it. But just wanted to give a little bit more space to hear more about that.

DR. PATEL: Yeah. I'll go ahead and start. I mean, and I think this might be where even though we were unanimous in our, kind of our voting, we each probably have different reasons for what this means.

I will say that having now studied probably every Alternative Payment Model known

to mankind, I have not seen yet a model that has initial downside risk.

When you have a model that has incredible implementation, execution, attribution, risk adjustment, quality measurement, that having kind of an initial downside risk immediately, often we have now counter -- example after example where it has very little uptake and in some ways kind of sets model participants up to fail.

So, I will say that my viewpoint on not having some sort of downside risk is a potential flag. It was really more of that I think we're going to face the need to not have models that just look like they're handing out coordination fees without any accountability.

Having said all that, I think that this model has such a tremendous amount of measures, accountability, evaluation, feedback, benchmarking, that I wasn't as concerned about it.

So, that's my opinion. I'm sure Jeff and Angelo have different kind of maybe perspectives.

VICE CHAIR TERRELL: And I see that Angelo's hand is up now.

DR. SINOPOLI: Yes, thank you. So, I would agree with Kavita's evaluation of that. I think this is being viewed as a pilot. And there's a lot of issues to be worked out.

And so I think putting participants and downside risk as we're trying to work, or they're trying to work through the nuances of what makes this model work better, I think would prevent a lot of people from participating.

And so I think at some point as we move forward, I would expect that this would have downside risk. But, probably not until a little more refinement when the model gets accomplished.

CHAIR BAILET: Kavita, this is Jeff, I agree with your assessment and Angelo's. I am looking at it and viewing it the same way. Thank you.

VICE CHAIR TERRELL: Any questions? I'm not seeing other hands right now. I'll give it a minute or second or two just to make

sure.

Okay. Well, hearing none, let's -- all right, let's go ahead and have the proposal submitters join us.

We have four representatives from the ACP, and three from the NCQA joining us via Webex. If you guys will introduce yourselves.

I know you want to make some opening comments, which we're going to limit to 10 minutes. That's all together with all of you.

And then we're going to open it up for questions. And so, I am going to thank you guys for being here.

So, first one I believe is from the ACP, Shari Erickson, Vice President of Governmental Affairs in Medical Practice for American College of Physicians.

Are the submitters on there yet?

*** Submitter's Statement**

MS. ERICKSON: Thank you. Yes. Would you like me to go ahead and make opening remarks? Or would you like me to, or us to interview ourselves first?

VICE CHAIR TERRELL: Yes. If you

could just introduce yourselves. So, there's so many of you, I didn't know you were going to introduce, you know, individual folks. Or whether you're just going to go on one by one.

But, you were the first on the list.

MS. ERICKSON: Great. Thank you. I appreciate the introduction. You already mentioned my title, Vice President of Governmental Affairs in Medical Practice at the ACP.

I'll actually defer to my colleagues to each introduce themselves on the webinar. So, Brian Outland, if you could go next.

DR. OUTLAND: Yes. I am Brian Outland. I'm the Director of Regulatory Affairs at the American College of Physicians agency.

VICE CHAIR TERRELL: And I believe Amir --

MS. ERICKSON: And next up, Amir, Amir Qaseem. Dr. Qaseem?

Perhaps he's not on as a presenter yet. So, Suzanne Joy, could you introduce yourself, please?

MS. JOY: Yes. Hi everyone. My name is Suzanne Joy. I'm on the ACP Regulatory Affairs team. And I work heavily in the quality-based payment world.

So, I'm very excited to be here. And I appreciate the opportunity, thank you.

MS. ERICKSON: Thanks, Suzanne. And then also Samantha Tierney, if you could introduce yourself, please?

MS. TIERNEY: Yes. Hi everyone. Good morning. I'm Samantha Tierney. I'm a Senior Scientist with the Clinical Policy team.

VICE CHAIR TERRELL: Okay. So thanks for the ACP. Anyone else from your team?

DR. BARR: Hi. This is Michael Barr. I'm the Executive Vice President for Policy Measurement and Research at NCQA.

Thank you, Grace. And let me let Joe Castiglione introduce himself, as well as Paul Cotton.

MR. CASTIGLIONE: Hi there. Joe Castiglione. I work in Strategic Initiatives for NCQA. Thank you.

DR. BARR: Paul Cotton, are you there?

I know he's struggling between two meetings, so he might join us later. Back over to Shari. Thank you, Grace.

VICE CHAIR TERRELL: Okay. And I believe now you're going to have, Shari, you're going to go the first five minutes and then Michael, the second five for your presentations.

So, we look forward to hearing what you have to say.

MS. ERICKSON: Great. Thank you, Grace. Really appreciate the opportunity to present our model and appreciate the hearing from PTAC, as well as our PRT team.

It's been a great opportunity to provide input along the way. And approvals of submissions of our model. And so we look forward to hearing from the PTAC, answering your questions, and seeing this through the process.

So, the teams at the American College of Physicians and NCQA have been

actively collaborating to develop something we believe will be a meaningful opportunity for specialty care internists and other physicians to engage in value-based payment efforts.

I believe this model offers an on-ramp to Advanced APMs that can apply to multiple specialties. And is not limited to any one type of clinical condition.

The American College of Physicians represents 163,000 internal medicine physicians, about half of our membership. All are sub-specialists.

So, I mean, there's a lot of collaboration that goes on within our own membership, as well as our members with other specialties.

We started down this road 10 years ago when we published our policy paper titled, the patient-centered medical home neighbor, the interface of the patient-centered medical home with specialty and sub-specialty practices.

Unfortunately since that time, there is still limited opportunities for specialty practices to engage with their primary care

colleagues in a manner that appropriately rewards both for excellent care.

Therefore, this payment model has been created in a manner that builds off successes of the Comprehensive Primary Care Plus model, and the upcoming Primary Care First model. And engages specialty clinicians with primary care partners to transform into medical neighborhoods.

This is, as Dr. Patel mentioned, a five-year multi-payer pilot that would operate in a CPC+ and Primary Care First region.

The main focus of this model is on improving patient care, particularly those with multiple chronic conditions.

It does that in a few different ways. First by ensuring that practices meet advanced standards that are intended to improve primary care and specialty practice coordination.

Eighty percent of serious medical errors involve simple miscommunication during handoff between clinicians, according to research. Additionally, referral issues can

lead to a high severity of harm in 83 percent of cases.

The model also includes a unique prescreening step to cut down on unnecessary specialty visits. This saves time and money for everyone.

And eventually, we believe we've reduced specialty wait times, thus improving access for patients. Eighty percent of all specialty referrals are inappropriately, are inappropriate with medically unnecessary or with the wrong specialty.

And nearly half of all specialty care appointments are routine follow-up appointments, some of which can be delivered at the primary care setting with the same or better quality outcomes.

And additionally, this model utilizes high validity performance metrics that hold clinicians accountable and incentivizes better outcomes, patient experience, and efficient resource utilization.

All participating clinicians must meet national average to share an in

performance-based payment adjustment. And unlike other models, higher performance score, the more of this payment performance-based payment adjustment they can retain.

The key is that payment structure that supports these adjustments, which was discussed earlier. There is a per member per month care coordination fee that's intended to support meeting advanced practice transformation standards and better care coordination with primary care partners to include patient outcomes.

We believe this is important for stability. And something we've learned, I think, particularly given the impact on practices, and who are participating largely in fee-for-service environment within this pandemic.

Performance-based payment adjustment is the second component of the payment model. It holds clinicians accountable and incentivizes meeting robust quality and financial targets based on high-value performance metrics.

This payment features several risk options, a choice of the symmetric savings and loss rate of zero to two percent. And those who choose higher levels are intended to qualify as we advance examples with them.

And finally, there's an optional perspective payment for those that choose track two, which we call the comprehensive specialty care payment, by exchange to reduce fee-for-service payments. And this was discussed earlier.

I also want to hit on a few of the model strengths. And the needs that it addresses. And we believe that this model can reduce administrative burden by encouraging the adoption of certified electronic health records and electronic clinical quality measures.

The measures are also intended to be aligned across payers, which is a significant burden for practices today. And we anticipate labor flexibility such as reducing prior authorizations et cetera that can also reduce administrative burden within the practices.

We believe this is a fully scalable

model. It is multi-payer. It aligns incentives across the payers.

We can apply it to a broad range of specialties. It also aligns with a planned transition to admit value pathways, or MVPs[11] within a quality payment program that are planned to be implemented in the coming year.

And additionally, I want to note that this promotes the use of telehealth through e-consults and virtual check-ins. I think the current pandemic has shed light on the importance of telehealth, which I believe the PTAC will be discussing tomorrow, to providing ongoing care to patients when and where they need it in the safest manner possible.

So, even when the pandemic wanes at some point, the delivery system, I believe, will be forever changed due to what we're learning now.

And telehealth will be a key component of that evolved system. Therefore, models such as ours that promotes the use of

11 Merit-Based Incentive Payment System [MIPS] Value Pathways

multiple modalities of care, is critical.

So, at this time I'll turn it over to Dr. Michael Barr with NCQA to continue to discuss our model. Michael?

DR. BARR: Well, thank you, Shari. Let me add my gratitude for the opportunity to discuss this proposal with the Committee.

And thank you to the PRT for your initial review. It helped us immensely with the resubmission. I don't think we can underestimate your feedback, and thank you.

As Shari outlined, we were really proud of the collaboration between ACP and NCQA. And I'm especially thankful for the opportunity to work with Shari.

We -- she and I previously collaborated when I was on the staff at ACP, to help bring the patient-centered medical home policy to life. And it's been great to gather our respective teams around this effort to create an Advanced APM proposal for specialists.

Now, this is a unique collaboration between a leading medical professional society

and NCQA, but it's not the first time that ACP and NCQA collaborated.

In fact, when I was at ACP, we worked with NCQA to develop the first PCMH[12] direct mission program. And that was an effort spurred on by the response of employers and insurers to the PCMH concept.

We wanted to know which practices were adhering to the attributes of the medical home so that they could consider paying those practices differently. That same approach is applied to the patient-centered medical home neighbor policy referenced by Shari.

Just as the first PCMH recognition program was built to support the need for employees and peers to differentiate primary care practices, the patient-centered specialty practice program, a key component of our proposal today was created by NCQA with input from ACP and other key stakeholders.

In fact, the policies that underline this proposal, as well as the payment model and recognition program, were all developed with

12 patient-centered medical home (PCMH)

and from our key subject matter experts, and Committees at our respective organizations.

We believe that the entry point to this payment model should not be based on attestation. But demonstration of key attributes provides assurance that practices are ready to take accountability with a robust coordination, communication, and most importantly, effective care this model is designed to promote.

Unlike NCQA's native PCSP program, which does not require the submission of electronic clinical quality measures, this proposal specifically requires electronic quality measure reporting. And in other words, PCSP recognition is the foundation that measures the assessment and the payment model, the motivation to continuously improve.

And with respect to the measures, we believe a course that a cross-cutting measure supplemented by specialty-specific, or condition-specific measures within the specialty of interest, would help curtail cherry picking. And alignments across

participating practices which involve specialty, will facilitate analysis and benchmarking.

The proposal relies upon electronic reporting exclusively in order to minimize burden and leverage the rich clinical ability in electronic health records – specialty-specific registries and other electronic sources.

Since the PCSP program is essential, let me spend a bit more time describing it in some detail. It is the only national program of its type, and along with the PCMH program, the PCSP is recognized as an improvement activity in the CMS quality payment program. And it's the only, the PCSP is the only MACRA[13]-approved specialty practice recognition program.

Now, what does it include? It includes seven ranges, and I'll go through them quickly to highlight some key practice attributes that align very well with the purposes of this model.

13 Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)

First, a team-based care and practice organization. It's the practice up to, set up to succeed in terms of defined roles, responsibilities training, and communication, and team-based care.

It doesn't involved patients and families, or practice governance or stakeholder committees.

Initial referral management, does the practice coordinate with primary and referring clinicians? Does it set expectations for information sharing and close referrals?

Knowing and managing your patients, does the practice capture and analyze information about the community it serves? Provide culturally and linguistically appropriate services?

Adjust medication management and safety within the practice and through coordination of referring clinicians? Does it use clinical decision support to help guide care?

Patient-centered access and continuity. Does the practice assure the

appropriate levels of care are accessible, for example to help avoid emergency department utilization?

Plan and manage care, does the practice do risk assessments and consider the needs of patients when developing care plans in coordination with them?

Care coordination and care transitions, including management to secondary referrals, tracking and file for diagnostic test result, and so on.

And then performance measurements and quality improvements. Essentially is this a practice of a culture of data-driven performance improvement and clinical quality and patient experience metrics, and to engage the staff, patients, families, and care givers in those efforts?

Now, we understand the concern that small practices might have challenges with the PCMH PCSP program. However, let me just say the average size of an NCQA PCSP site is five clinicians.

So, we anticipate that small

practice sites will be able to actively participate in the MNM. In fact, small practices might actually have an advantage over large ones.

Once they commit to do the work, there aren't multiple levels of approval to secure. And changes can be implemented reasonably quickly if the practice is prepared to act.

There are over 530 sites and greater than 3,100 clinicians recognized by NCQA, including specialists in cardiology, neurology, hematology, endocrinology, pulmonary medicine, rheumatology, gastroenterology, infectious disease neurology, and some non-internal medicine specialties, including orthopedics, urology, dermatology, and obstetrics and gynecology.

This demonstrates that the PCSP is sufficiently flexible to accommodate a variety of medical specialties, and surgical specialists, and this is a key strength of the MNM because it is scalable to additional specialties which lack meaningful robust

opportunities.

And of course, the CPC+ and Primary Care First participants naturally make excellent partners in the medical neighborhood. Many of these practices are themselves recognized as NCQA PCSP mixed practices and have complementary care coordination process in place.

In closing, in 2006 when ACP released the advanced medical home paper, it reinvigorated the concept of primary care as the foundation for better health care system.

However, we knew then as we know now, that primary care alone cannot improve quality and reduce costs. The ACP medical home neighbor policy was recognition of that fact.

And here we are now with the chance to link primary care with specialty care in a robust test of the premise that by working together, they will be more effective at improving care for people, reducing harm, and wringing out unwarranted variability and inefficiencies that add tremendous costs to our health care system.

On behalf of ACP and NCQA, let me say that we are committed to work on the issues that were identified by your review. And thank you very much for the opportunity to speak today.

VICE CHAIR TERRELL: Thank you both, Shari and Michael.

I am now going, at this point, to open it up for my colleagues who would like to ask some questions. Again, since we're in a virtual format, I will be calling on each of my colleagues who have indicated that they have a question or comment.

Each of the Committee's questions will be directed to Shari Erickson for ACP and Dr. Michael Barr for the NCQA, who will determine who from each of their teams will provide the response.

In the event that one or more Committee members provides comments relating to the proposal without directing the specific question to the submitter, please notify PTAC staff if someone from ACP/NCQA team would like to provide a response, and the Chair or the

Vice Chair, in this case, will give you an opportunity to share your response.

So I am going to give my colleagues a moment to see what, to put up their hands, then I will start calling on folks. If you don't put up your hands, I've got some questions.

Okay. Well, I'm going to start then while my colleagues are thinking about -- or am I missing somebody here?

DR. CASALE: I have my hand up. It's Paul.

VICE CHAIR TERRELL: Oh, there it is. Got it, got it. Paul does. And now I see Lauran's. Okay. There must be a little lag here. Well, Paul, I'll start with you. And then we'll go to Lauran.

DR. CASALE: Great. Thank you. And thank you for those comments. They were very helpful.

Just a couple of questions, two questions, one is -- and I appreciate the advantages of the PCSP recognition program and no doubt. And you commented that it was

essential to the model.

One of the concerns at least we've heard from CMMI in the past, and we've seen other models with sort of proprietary either software or pieces to it where clinicians have to pay to participate. And CMMI in the past has been reluctant to consider that.

And I know in the questions that the PRT had asked you was, you know, can you participate in this without being part of the recognition program?

And at least in the answer what I saw was highlighting the advantages of the program, which I understand. But I wasn't sure if I saw a clear answer as to whether you could participate without being part of the recognition program.

DR. BARR: I will take that. Thank you. And then, Shari, feel free to comment.

I think it's, from our experience with the PCMH and so far with the specialty practice program, as I said, I don't think, we don't think attestation is simply saying a practice is doing something that's going to be

sufficient for us to put accountability on the practices.

It's, you know, people think they're doing things. But unless they demonstrate that, they're not consistently applying the attributes of what we would like to see to justify the payment model.

Now, does it have to be the PCSP program from NCQA? That's a valid question. I think that's the only program out there that's been MACRA-approved.

So, going with that, obviously, we have a direct interest as NCQA. But the cost of the actual license to their program is far less than the rule that a practice would need to do to actually adhere to the principles and drive towards the model we're trying to encourage.

And the payments from this model wouldn't offset any direct costs in the licensing of the recognition program. And furthering the pilot of both ACP and NCQA agrees to discount the fees significantly in order to help promote the model.

And if another model exists and somebody wants to develop another recognition program, I suppose the Committee could take that and CMMI could take that and see if that's an equivalent.

Shari, do you have anything you want to add to that?

MS. ERICKSON: No, I really don't have anything to add to that. I think that answered the question.

DR. CASALE: Great. I had just one other question, Grace, which was, you know, a specialist, in terms of engaging specialists and models, the current one is really the BPCI[14] Advanced.

And, you know, as you probably know, last week CMMI announced the move in model year four to sort of these episode service lines. And they've signaled that after the, in 2023 their intent is to make those mandatory, potentially.

Is there any barrier for specialists to participate in BPCI A, as well as with the

14 Bundled Payments for Care Improvement (BPCI)

Medical Neighborhood Model?

MS. ERICKSON: I think that I'll ask Suzanne Joy on our team to answer that.

MS. JOY: Sure. I think that's a really great point. And I think that model overlap is certainly going to (audio interference) not only for our model but for, you know, as (audio interference).

And I think the general answer to those questions is that you have to look at the incentives of whether there are going to be differing incentives.

So ours is a benchmark style model. And we do think that there is an added advantage to having a benchmark style model. And that's why we can see, for instance, that the MSSP model can overlap with CPC+ that is allowed. But CPC+, for instance, cannot overlap with other more similar models.

So, in regards to that question, I think we have to take a deeper look. But, you know, they do seem at face kind of different incentives for slightly different activities.

The MNM is specifically to

incentivize coordination across settings with primary care clinicians. So we certainly think there would be room to still separately incentivize, you know, efficiencies further within the confines of the specialty practice.

So I wouldn't say that we will in that specific instance specifically preclude it. But it's certainly worth taking a closer look. And that's kind of where I would put that. It sort of depends on the (audio interference) side of the models. And I'm happy to answer any additional questions.

DR. CASALE: Great. Thank you. Thanks, Grace.

VICE CHAIR TERRELL: Thanks. Lauran, you had some questions, ma'am.

MS. HARDIN: Thank you so much for this innovative and comprehensive proposal.

I'm curious if you could articulate a little bit deeper, what is the difference -- what difference do you anticipate occurring in care coordination that is not already being incentivized under the CPC+ model outside of that initial primary care to specialist

consult?

MS. ERICKSON: So I will start with that briefly. And then I think I'll defer to my colleagues, either to Brian or to Suzanne, to see if they'd like to add anything, as well as my colleagues at NCQA.

So the CPC+ model, as you're aware, is focused on the primary care practices themselves. And it certainly does incentivize and through their requirements to work with their specialty colleagues. But the specialty colleagues themselves are not as engaged in that model directly.

So this model really offers an opportunity to build on the CPC+ model, as well as the forthcoming Primary Care First model in a way that actively engages the primary, or the specialty care practices and incentivizes them and rewards them, quite frankly, for engaging in a meaningful care coordination agreement with the primary care practice.

So I'll jump over to Suzanne, who I think may have more to add on this. And then I'd also like to see if our NCQA colleagues

would like to add more as well given the recognition program that's engaged with this model for specialty practices.

MS. JOY: Sure. Thanks, Shari. Just to add on to what you said, which I think is a really good point, you know, with CPC+ it specifically says that it's geared towards primary care physicians.

So, even though I think it's great that specialists are engaged in the model and often participating in care coordination agreements, they don't have formal recognition in that model.

And they also importantly, therefore, do not have the necessary funding to uphold a lot of these care coordination activities, you know, which do cost money. And so that's where we really see our model entering and supplementing that.

And I'll also add that, you know, they are also able to participate in MSSP ACOs and other models as well. But again, you know, while they are allowed to share in those, shared savings of those models, it's not

required or guaranteed.

And so MedPAC actually in their report specifically called this out as an issue. And they're seeing some specialty practices leave because they don't have sort of that financial investment in the model. So we really think that's critical and really a gap that our model aims to address.

And just to add to that, one other point is that we certainly think there's a lot of evidence of room for improvement. At this point, only half of referring clinicians have any idea that their patient even actually sees a specialist. That's a problem. But it also gives us a lot of room to improve in that area.

And so we think that building on these models and further improving the coordination between these settings and giving specialty practices an actual financial accountability is really the key to this model.

MS. ERICKSON: And also I believe Brian Outland wanted to comment on this as well. And then we'll see if our colleagues at NCQA would like to add anything more.

DR. OUTLAND: Yes. And also one of the things that was actually intentionally built into this model is a triage of every referral that comes to the specialty clinicians. So they will triage every referral. And then they will see where the best services can be provided for each patient that comes to them.

So it may be that then they can go talk back to the primary care physician and coordinate their care without having to bring them into the office, freeing up time for them to take care of their more initial patients that are sicker and those who they actually need to see.

So it frees up their time and also gives them more communication back with every referral that comes to them, rather than just sending the patient back saying, you know, we don't need to see you or we don't have the appropriate information. But it allows them to have that open communication back and forth with the primary care clinician that refers every patient to them.

MS. ERICKSON: Thank you, Brian. I think that was an important point to add on. Michael or Joe, do you have anything to add as well from the NCQA perspective?

DR. BARR: No, I think you answered the question completely.

MR. CASTIGLIONE: I agree.

MS. ERICKSON: Thank you.

VICE CHAIR TERRELL: I don't see right now any of the rest of my colleagues with their hands up on my participant list here. But I had a question or really sort of a, it's a perspective on this.

I've practiced medicine long enough that I remember the bad old days when we were all on paper. And when I made a referral as an intern to a specialty practice, we went through some sort of insurance process. There was all this stuff that I would fax over. And then the patient would see the specialist. And I would get back most of the time a very thoughtful dictated response from my specialist colleagues that I referred to.

But it was a messy process. It was

hard to ever understand after the very first consult visit what was going on in the long run.

And when we went to electronic medical records, as bad as they were across the many things that had to change and all the things we've complained about, one thing that got better, because I was part of the multispecialty practice, was internal referrals.

That information was seamless. And it was much easier to refer that information to my colleagues. And they had the ability to see the information.

But there became some continuity for those colleagues of mine that were specialists I referred to that were not part of my multispecialty group, because it wasn't necessarily connected in a way that was easily able to transfer the records.

That's a long preamble to say that, as I was listening today, I was thinking of all the benefits that this model can do and very much support the idea not only of medical hall

but medical neighborhood.

But I would very specifically want to understand, as someone who advocates for integrative care and multispecialty medical groups in many situations, whether this is a model that is much more specific for solo practices or independent practices, or whether you see this as being something that could be coordinated across the type of specialty practices, whether it was part of an integrated group, a health system, or just solo.

Is this for small solo practices or can others participate, and does it change if that's the case?

DR. BARR: Grace, this is Michael. I'll take it. And I'm sure Shari and the ACP team have some additional comments.

First, thanks for your comments. And I haven't practiced in a few years. And I did previously. Your experience mirrored mine.

I didn't work in an integrative system. But I had good colleagues who were able to complete notes and share them back with me and made my job as an internist much easier.

And I've tried to make their job easier by providing complete notes and with the actual question I wanted the specialist to answer.

I think this model is trying to drive us towards that goal again and really focus on the patient, their narratives, the needs of the patient as he or she moves through the system, whether that's a solo practitioner referring to a large specialty practice as part of an integrated system or sort of affiliated with one or vice versa, where a specialist is, you know, a large internal medicine group is looking for the local specialist.

This model is flexible enough to allow and promote good care in both of those cases. And the referrals should be, I'll use the word healthier in the context that the information transferred is more complete.

And the patients may not be healthier, because you want to send the folks who need to be seen by the specialist and the specialist coordination.

But that whole relationship around sort of the information sharing and

coordination is healthier. And that creates efficiencies in and of itself. And that's what we hope to achieve through this model. Shari, ACP, other comments?

MS. ERICKSON: Sure. I think that's absolutely right, Michael.

And I guess I would just want to reiterate what Brian spoke about before is this pre-screening that I think is unique in this model that really allows the opportunity for advanced coordination between the specialist and the primary care physician so that we're certain that that referral is appropriate and that there is, you know, an expectation from the specialist when they see that patient that they will have the information that they need and that they will be able to provide the services that they need to provide to that patient.

So I think that, and I think getting at this issue that, the idea of this prescreening, it also really allows that specialist, as Michael was saying, to be certain that they are seeing the patients that

they need to be seeing and that it will actually free up, I believe, access to that specialist for the patients that need to see them the most.

And I think that that is a real meaningful outcome I hope that this model could provide and ensure also the ongoing discussion and collaboration between that specialist and the primary care clinician over the course of treatment for that patient so that we're sure that they really do know what's happening between, you know, with that patient over the long term, so, you know, and that coordination and communication is there as it's established through a care coordination agreement and the infrastructure that they both, that both practices put into place through their work to achieve, a primary care practice to achieve the standards that they need to achieve to be a CPC+ practice or a Primary Care First practice, or if this were to expand, you know, a PCMH practice more broadly and that specialty practice, you know, as they put into place those standards, to be, you know, a patient-

centered specialty practice.

So I'll stop there. I don't know if any of my other colleagues from ACP have anything else to add.

MS. JOY: And I'll just add quickly to those great points that I think another key factor of our model that makes it achievable and attractive to small practices is the scaled risk and the fact that they can select their own level of symmetrical risk, because we've heard from our members. They know this is a commonly cited problem that one of the biggest barriers to small practices joining APMs are really high levels of static, you know, immobile risk.

And so I think the fact that our model starts where the practices feel comfortable and offers them opportunities certainly to take on more risk in exchange for more reward, there is that incentive to build towards that. But it's not required from day one.

And I think that's really important to get small practices on board and help them

feel comfortable with the model and attract them.

VICE CHAIR TERRELL: Thank you. I don't see any other hands raised right now. I want to just confirm from my colleagues, if they have any further questions. Somebody can certainly shout out if I'm missing them.

Hearing none, let's go to the public comment period.

*** Public Comments**

And we've got two people that have signed up today to speak from the public on this proposal. And I just want to make sure I've got my list here. I believe that the first person on the list is Sandy Marks from the American Medical Association.

MS. MARKS: Thank you, Dr. Terrell. Good morning. I'm Sandy Marks. And I'm making comments on behalf of the American Medical Association. (Audio interference [The AMA strongly supports the Medical Neighborhood Advanced APM proposal]) from the American College of Physicians and the National Committee for Quality Assurance. And we urge

PTAC to recommend it to the Secretary for implementation.

The proposal cites (audio interference [data from multiple sources]) indicating the magnitude of the problem with poor coordination between specialists and primary care physicians.

As many as half of referring primary care physicians have no idea if their patients ever actually see the specialist to whom they are referred. Specialists report receiving referral information for only about 35 percent of referred patients.

These gaps in communication lead to delays in care, inappropriate care, and errors, all of which could be prevented with the coordinated medical neighborhood approach described in this proposal.

We think it is also important to recognize that existing APMs, such as Accountable Care Organizations, have not fixed this problem nor have the existing Medicare Medical Home models.

Existing models and the forthcoming

Primary Care First model can provide much needed support to primary care physicians, but they have not been effective in supporting the specialists on whom patients depend to treat and manage complex conditions.

The Medical Neighborhood Model is scalable and can accommodate a variety of specialties. And we appreciate that it is starting with three key specialties, cardiology, neurology, and infectious disease.

Our current experience with COVID-19 has provided many physicians with experience in e-consults. And it reinforces the advantages of their inclusion in this model as an option.

Pre-screening through e-consults can avoid treatment delays that occur when patients are initially referred (audio interference [to the wrong type of specialist and allow more urgent cases to be quickly identified and seen by the specialist. A chief criticism of the fee-for-service system and an accurate one is that it promotes]) fragmentation in care.

Patients tell us that what is for their entire (audio interference [to

collaborate on and implement their treatment plan]) seamlessly instead of having to start from square one with each physician that they see. The Medical Neighborhood Model can repair this fragmented system. Thank you.

VICE CHAIR TERRELL: Thank you, Sandy. Our next commenter from the public is Leslie Kociemba from the American Academy of Neurology.

MS. KOCIEMBA: Good morning. On behalf of the American Academy of Neurology, I wanted to share our support for this Medical Neighborhood Model and reiterate some of the areas we find particularly important related to it today.

Neurologists have struggled to participate meaningfully in Alternative Payment Models on neurology-specific items beyond stroke. And we believe the opportunity to use various neurology measures in the Medical Neighborhood Model would be critical and relevant for neurologists in a PCSP practice.

So, to echo some of the PRT's feedback and as noted several times today, we

believe this not only relates to neurology but is highly scalable to various specialties to participate where they may not have been able to meaningfully participate in APMs in the past.

On that same note, we support the multi-payer structure of the model as it formally engages specialists in financial outcomes. Neurologists participate in care coordination activities often. But as noted by ACP staff, they are oftentimes not paid for this work, as that goes towards primary care specialists instead of specialists.

We also strongly support the model's flexible risk options with the opportunity to take on more risk over time. We have a lot of small and solo neurology practices that often struggle to visualize how they might be able to participate in value-based care models and Alternative Payment Models. And so we find the flexibility options to be critical for engaging different practice types.

We also support many of the specific care coordination elements in the model,

especially the pre-screening process and optional e-consultation, to resolve cases that don't require an appointment with a specialist.

These elements not only enhance communication and consultation with primary care and specialty practices, but they value patients' time, as noted earlier, reduce unnecessary delay to treatment and waiting times for more urgent cases that are especially relevant now in the landscape of COVID and telehealth.

We appreciate the opportunity to share our support and thoughts on this and look forward to continued collaboration in the future.

VICE CHAIR TERRELL: Thank you very much for your comments.

Now I'm going to ask if there are anybody else from the public that would like to comment at this time. PTAC, Amy is monitoring and can let people in through the operator.

The other thing that I just got a note from PTAC is apparently we did not make it clear earlier that if anybody has any specific

questions regarding this process or this particular model that they can reach out specifically to ptac@hhs.gov.

All right. I've got a message that there's no other public comments. So it's time for the Committee to begin getting ready for voting.

But before we do that, I want to just ask my colleagues, do they have any other comments or discussion before we get into the voting? I'll just give them a minute.

*** Voting**

Okay. Hearing none, first, as our colleagues know, we vote on the proposal individually as whether it meets each of the 10 criteria. The member votes roll down until a simple majority has been reached.

A vote of 1 or 2 means does not meet, 3 and 4 means meets, 5 and 6 means meets and deserves priority. And the asterisk means not applicable.

After we vote on all 10 criteria, we will proceed to vote on our overall recommendation to the Secretary. We will use

the voting categories and process that we've been using since December 2018. We designed these more descriptive categories to better reflect our deliberations for the Secretary.

First, we will vote using the following three categories: not recommended for implementation as a physician-focused payment model, recommended, and referred for other attention by HHS.

We need to achieve a two-thirds majority of votes for one of these three categories. If the two-thirds majority votes to recommend the proposal, then we vote on a subset of categories to determine the final overall recommendation to the Secretary.

The second vote uses the following four sub-categories: the proposal substantially meets the Secretary's criteria for PFPMs, PTAC recommends implementing the proposal as a payment model; number two, PTAC recommends further developing and implementing the proposal as a payment model as specified in PTAC comments; or number three, PTAC recommends testing the proposal as specified in PTAC

comments to inform payment model development; or finally, PTAC recommends implementing the proposal as part of an existing or planned CMMI model.

And then we would need two-thirds majority for one of these four categories.

* **Criterion 1**

So now it's time for us to vote on the first criteria, scope, which is considered a high-priority item. We appreciate your patience, again, as we get each member connected to the mobile technology for this voting session.

(Pause.)

CHAIR BAILET: Grace, while folks are voting, I just thought I would mention, this is Jeff, that Dr. Feldstein had an emergency and had to leave the deliberation. So, if folks were looking at the numbers, Grace, there will be one less person voting at this point. Thank you.

VICE CHAIR TERRELL: Okay. Thank you. Now, I have now been able to enter for the voting on my technology. Did we confirm?

Is everybody else on? Anybody not on at this point? Okay. I'm assuming we're all on then.

So our first criteria is scope. The aim is to either directly address an issue in payment policy that broadens and expands the CMS APM portfolio and includes APM entities whose opportunities to participate have been limited.

I have not had a chance to vote yet. Apparently it got closed before I got in there. I'm not sure what that means.

MS. MCDOWELL: So, it's unclear, because there are eight votes that are showing. So do we need to revote?

VICE CHAIR TERRELL: I think we do, because I did not vote. If I did, I didn't know I did. Let's do it again. Sorry, folks.

(Pause.)

VICE CHAIR TERRELL: Has it been entered?

CHAIR BAILET: Yeah, it's gone in.

MS. MCDOWELL: So, for some reason, we're seeing nine votes instead of eight.

CHAIR BAILET: It might be possible

that Dr. Feldstein is voting. I'm not clear. But I got a message that he's voting potentially. You have to confirm. Thank you.

MS. MCDOWELL: Okay. Can someone please confirm that?

PARTICIPANT: He is not available. So let's try the vote one more time. Thank you.

(Pause.)

VICE CHAIR TERRELL: There's eight. Okay. So we're ready for the results, Audrey.

MS. MCDOWELL: So, for Criterion 1, one member voted 6, meets and deserves priority consideration. Three members voted 5, meets and deserves priority consideration. Three members voted 4, meets. One member voted 3, meets. Zero members voted 2 or 1, does not meet. And, excuse me, zero members voted not applicable.

The votes roll down until a majority is met, which is five votes. And so the majority has determined that the proposal meets Criterion 1, scope, which is [a] high-priority criterion.

*** Criterion 2**

VICE CHAIR TERRELL: Okay. Let's go to Criterion 2. This one is quality and cost. It's also a high priority. Anticipated to improve health care quality at no additional cost, maintain health care quality while decreasing cost, or both improve health care quality and decrease cost.

(Pause.)

VICE CHAIR TERRELL: Okay, Audrey.

MS. MCDOWELL: Okay. Zero Committee members voted 6, meets and deserves priority consideration. Zero Committee members voted 5, meets and deserves priority consideration. Four Committee members voted 4, meets. Four Committee members voted 3, meets. Zero members voted 2 or 1, does not meet. And zero members voted zero, not applicable.

So the majority has determined that the proposal meets Criterion 2, quality and cost.

*** Criterion 3**

VICE CHAIR TERRELL: Okay. Thank you. Let's go to Criterion 3, payment

methodology, high priority. Pay APM entities with a payment methodology designed to achieve the goals of the PFPM criteria, addresses in detail through this methodology how Medicare and other payers, if applicable, pay Alternative Payment Model entities, how the payment methodology differs from current payment methodologies, and why the physician-focused payment model cannot be tested under current payment methodologies.

(Pause.)

VICE CHAIR TERRELL: Okay, Audrey.

MS. MCDOWELL: So, for Criterion 3, zero Committee members voted 6, meets and deserves priority consideration. Zero Committee members voted 5, meets and deserves priority consideration. Four Committee members voted 4, meets. Three Committee members voted 3, meets. One Committee member voted 2, does not meet. Zero Committee members voted 1, does not meet. And zero members voted zero, not applicable.

So the majority has determined that the proposal meets Criterion 3, payment

methodology.

* **Criterion 4**

VICE CHAIR TERRELL: Okay. Let's go to Criterion 4. It's value over volume. Provide incentives to practitioners to deliver high-quality health care.

(Pause.)

VICE CHAIR TERRELL: Go ahead, Audrey.

MS. MCDOWELL: Zero Committee members voted 6, meets and deserves priority consideration. One Committee member voted 5, meets and deserves priority consideration. Four Committee members voted 4, meets. Three Committee members voted 3, meets. Zero Committee members voted 2 or 1, does not meet. And zero Committee members voted zero, not applicable.

So the majority has determined that the proposal meets Criterion 4, value over volume.

* **Criterion 5**

VICE CHAIR TERRELL: All right. Let's move to Criterion 5, please, flexibility.

Provide the flexibility needed for practitioners to deliver high-quality health care.

(Pause.)

VICE CHAIR TERRELL: Audrey, do the honors.

MS. MCDOWELL: Zero Committee members voted 6, meets and deserves priority consideration. Zero Committee members voted 5, meets and deserves priority consideration. Six Committee members voted 4, meets. Two Committee members voted 3, meets. Zero Committee members voted 2, does not meet, or 1, does not meet. And zero Committee members voted zero, not applicable.

So the majority has determined that the proposal meets Criterion 5.

*** Criterion 6**

VICE CHAIR TERRELL: Criterion 6, please, ability to be evaluated. Have evaluable goals for quality of care, costs, and any other goals of the PFPM.

(Pause.)

VICE CHAIR TERRELL: Okay.

MS. MCDOWELL: All right. Zero Committee members voted 6, meets and deserves priority consideration. One Committee member voted 5, meets and deserves priority consideration. Two Committee members voted 4, meets. Five Committee members voted 3, meets. Zero Committee members voted 2 or 1, does not meet. Zero Committee members voted zero, not applicable.

So the majority has determined that the proposal meets Criterion 6.

*** Criterion 7**

VICE CHAIR TERRELL: Thank you, Audrey. Criterion 7, integration and care coordination. Encourage greater integration and care coordination among practitioners and across settings where multiple practitioners or settings are relevant to delivering the care to the population treated under the PFPM.

(Pause.)

VICE CHAIR TERRELL: That was quick. Audrey.

MS. MCDOWELL: One Committee member voted 6, meets and deserves priority

consideration. Three Committee members voted 5, meets and deserves priority consideration. Two Committee members voted 4, meets. Three, excuse me, two Committee members voted 3, meets. Zero Committee members voted 2 or 1, does not meet. And zero Committee members voted zero, not applicable.

Because the votes roll down until a majority is met, which in this case is five votes, the majority has determined that the proposal meets Criterion 7.

*** Criterion 8**

VICE CHAIR TERRELL: Okay. Let's go to Criterion 8. Encourage greater attention to the health of the population served while also supporting the unique needs and preferences of individual patients.

(Pause.)

MS. MCDOWELL: Are you ready?

VICE CHAIR TERRELL: Yes.

MS. MCDOWELL: Okay. Zero Committee members voted 6, meets and deserves priority consideration. One Committee member voted 5, meets and deserves priority consideration.

Five Committee members voted 4, meets. Two Committee members voted 3, meets. Zero Committee members voted 2 or 1, does not meet. And zero Committee members voted zero, not applicable.

So the majority has determined that the proposal meets Criterion 8.

* **Criterion 9**

VICE CHAIR TERRELL: Wonderful. Thank you. Criterion 9, patient safety. Aimed to maintain or improve standards of patient safety.

(Pause.)

VICE CHAIR TERRELL: Okay, Audrey.

MS. MCDOWELL: Zero members voted 6, meets and deserves priority consideration. One member voted 5, meets and deserves priority consideration. Five members voted 4, meets. Three members voted 2, excuse me, two members voted 3, meets. Zero members voted 2 or 1, does not meet. And zero members voted zero, not applicable.

So the majority has determined that the proposal meets Criterion 9, patient safety.

*** Criterion 10**

VICE CHAIR TERRELL: Thank you. And the final Criterion 10, health information technology. Encourages the use of health information technology to inform care.

(Pause.)

VICE CHAIR TERRELL: Okay.

MS. MCDOWELL: Zero members voted 6, meets and deserves priority consideration. Two members voted 5, meets and deserves priority consideration. Four members voted 4, meets. Two members voted 3, meets. Zero members voted 2 or 1, does not meet. And zero members voted zero, not applicable.

So the majority has determined that the proposal meets Criterion 10.

VICE CHAIR TERRELL: Okay. So we've finished the first part of our voting. Audrey, do you want to summarize the voting on the 10 criteria? And then we'll go to the next phase.

MS. MCDOWELL: Sure. The Committee finds that the proposal meets 10, all 10 of the 10 criteria.

*** Overall Vote**

VICE CHAIR TERRELL: Thank you. Okay. So we are now going to the next part of the voting. Thank you again.

So this, again, is electronic voting. But the three categories that we're going to vote for are: not recommend for implementation as a physician-focused payment model, recommend, and lastly, refer [for) to other attention by HHS.

So we're going to need to achieve a two-thirds majority of votes for one of these three categories. And if a two-thirds majority vote is to recommend the proposal, then we'll vote on a subset of categories to determine the final, overall recommendation to the Secretary.

And the second vote is for the following criteria. I don't know if I was supposed to stop there or not. But let's go ahead and do this part of it and either vote for not recommend, recommend, or refer to the other, attention by HHS.

(Pause.)

VICE CHAIR TERRELL: Wonderful. So, Audrey.

MS. MCDOWELL: So all eight members voted to recommend the proposal.

VICE CHAIR TERRELL: Okay.

MS. MCDOWELL: So that means we move to the second stage of voting to specify which category of recommend.

VICE CHAIR TERRELL: All right. So, in the second stage, the vote is the following four categories.

First, the proposal substantially meets the Secretary's criteria for PFPMs and PTAC recommends implementing the proposal as a payment model. The second category is we recommend further developing and implementing the proposal as a payment model as specified in PTAC comments.

Thirdly, it's to recommend testing the proposal as specified in PTAC comments to inform payment model development. And lastly, PTAC recommends implementing the proposal as part of an existing or planned CMMI model.

So we need a two-thirds vote for these four categories. So let's go ahead and vote on that now.

(Pause.)

VICE CHAIR TERRELL: Okay. Audrey, it's a little harder this time.

MS. MCDOWELL: Yes, it is. So one member voted to implement the proposal as a payment model. Two members voted to further develop and implement the proposal as a payment model as specified in PTAC comments. And four members voted to test the proposal to inform payment model development. And one member voted to implement the proposal as part of an existing or planned CMMI model.

You need a two-thirds majority, which in this case with eight members voting -- excuse me. My phone is going off. With eight members voting, would be six votes.

And you don't have six votes in any bucket. And so I would ask the Vice Chair if the Committee would like to have more discussion.

VICE CHAIR TERRELL: Yeah, so I have gotten two or three chat texts from individuals while we saw these results saying that a couple of members at least were on the fence. I know

I was and would like to revote. So I'm going to ask that it be opened up so that we can revote on this.[15]

(Pause.)

VICE CHAIR TERRELL: Okay. I think we got to a, most of a consensus. Audrey, do you want to -- that's a little easier. You want to summarize that?

MS. MCDOWELL: Okay. So now zero members have voted to implement the proposal as a payment model. One member has voted to recommend the proposal for further development and implementation as a payment model. Seven members have voted to test the proposal to inform payment model development as specified in PTAC comments. And zero members have voted to implement the proposal as part of an existing or a planned CMMI model.

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15 Prior to revoting, Committee members had voted as follows:
* Category 1 - Proposal substantially meets Secretary's criteria for PFPMs. PTAC Recommends implementing proposal as a payment model -1 Committee member, Chair Jeff Bailet.
* Category 2 - PTAC recommends further developing and implementing the proposal as a payment model as specified in PTAC comments -2 Committee members, Kavita Patel and Bruce Steinwald.
* Category 3 - PTAC recommends testing the proposal as specified in PTAC comments to inform payment model development - 4 Committee members, Paul Casale, Lauran Hardin, Angelo Sinopoli, and Jennifer Wiler.
* Category 4 - PTAC recommends implementing the proposal as part of an existing or planned CMMI model -1 Committee member, Vice Chair Grace Terrell.

So the finding of the Committee is that the proposal should be recommended and to, for testing the proposal as specified in PTAC comments to inform further payment model development.

VICE CHAIR TERRELL: Thank you. So the next part of our process is that I'm going to ask specifically each of the members of the Committee to state how they voted.

And then based upon that, with any comments we can begin to guide the discussion on how we would like to construct advice to the Secretary in the letter that we put forward.

So I'll start with myself, that I voted to accept the proposal. And originally, I was the one who was thinking about it within the context of putting it directly into another CMMI model, obviously the CPC+, but moved it with the majority to the category that we all chose.

And I'll turn it over now to Jeff. And I'm just going down the list of people I have here in the order as to, Jeff, if you could state what your vote was.

CHAIR BAILET: Yeah, so I was the outlier. I voted to further develop and recommend implementation. And I was going back and forth.

I know that testing has been a challenge when we have recommended proposals in the past for testing. I thought that I wanted to send a clear signal of support that, while it needs further development, it's clear, and the submitters have said as much, that it is as complete a proposal as any one proposal that has come before this Committee.

And so I felt that voting to recommend its implementation, understanding that further development was necessary, was the appropriate position in my opinion.

But they're acknowledging that there's a lot of overlap between where the Committee ended up, which is testing, and further development. I'll leave it at that.

VICE CHAIR TERRELL: Okay. Jennifer, do you have any -- how did you vote? Do you have any specific comments you want to make sure that, are emphasized?

DR. WILER: Yes. Thank you. I did recommend testing but agree with Jeff's comments around intent and that the category of further development also is one where I had internal debate about where to align.

My comments are, you know, what the PRT surfaced, and that's that there are, one, this is a really important model and appreciate so much the work of the specialty societies over a long period of time to keep refining the proposal.

But the comments around attribution, opportunities around what I'll describe as model harmonization or APM harmonization of different models that have been in play or are currently in play and this idea of incentives to participate, but also balancing accountability are ones that I believe still need to be worked out as many have described.

VICE CHAIR TERRELL: Thank you. Kavita, how did you vote? And what comments do you want to emphasize?

DR. PATEL: Yes. Thanks, Grace. I also voted the third category for testing for

implementation and develop further. And I was also someone who switched categories. Honestly, I stand by what we said in the PRT.

So my comments to the Secretary would be to not confuse the recommendation for testing to mean that we think that this is, or that we think that this does not have merits to be a full proposed Alternative Payment Model.

But it requires some of the further deliberation that we outlined in our PRT report, particularly around attribution, payment methodology, and potentially the quality measurement issues.

So that's it. Thanks, Grace.

VICE CHAIR TERRELL: Thank you. Paul.

DR. CASALE: Oh, thanks, Grace. Yeah, I also, I voted to recommend the proposal and also voted to test the proposal to inform payment model development.

I also was back and forth between further development testing. And as others have already articulated, I struggled around the word test as has already been pointed out.

Really this, as was emphasized by the PRT, is a pilot. I mean, that's what the submitters have said. And that's clearly in the thinking around the PRT and I think the Committee that it's a pilot because there are issues that need to be worked out.

It's a, the model is far enough along that it does warrant implementation. But there are significant issues.

In addition to the attribution issue, which has already been brought up, and the APM overlap, the other concerns I continue to have is around the proprietary nature of the certification recognition program.

I think, as this potentially is implemented, there needs to be an alternative to requiring that certification and I think as part of the further development around the care coordination fee and flushing that out further on the payment side.

And then finally, I'm not convinced that cardiology, ID, and neurology are the three best to start with necessarily, you know, for a variety of reasons, but, you know,

consider other specialties such as endocrinology and nephrology where there [are], again, I think lots of opportunities for better care coordination.

So those are my comments.

VICE CHAIR TERRELL: Thank you, Paul. Angelo.

DR. SINOPOLI: Yeah, I like everybody else waffled between testing and further development but landed on testing and for the same reasons everybody else has already mentioned I think, and I know somebody else said, don't want that to be perceived as a lack of support for this APM but just feel like the issues like attribution, et cetera, that have already been discussed needs a little further due diligence before it's actually implemented as an APM. Thank you.

VICE CHAIR TERRELL: Bruce. Not hearing you, Bruce. Are you on mute?

MR. STEINWALD: I tried to --

(Simultaneous speaking.)

MR. STEINWALD: Can you hear me now?

VICE CHAIR TERRELL: Yeah.

MR. STEINWALD: Okay. I changed my vote from two, further development, to three, but still have some concerns of the kind that others have mentioned, attribution, risk adjustment, benchmarking for payment purposes.

If you'll recall some of our prior conversations with the actuaries, these are the things that make them as nervous as a long-tailed cat in a room full of rocking chairs. That's for you, Jeff.

And so their concerns are always well founded. And so I think that those elements, the kind that give the actuaries concern, really need some attention as this model goes forward.

VICE CHAIR TERRELL: Okay. Thank you. Lauran.

MS. HARDIN: I chose testing primarily in interpretation of this proposal being a pilot, as well as in addition to the comments that have already been made, differentiating attribution of the outcomes related to care coordination, and also teasing out the difference between specialty

intersection with the patient around acute episodic events versus longitudinal engagement and differentiation of the care coordination aspect related to that.

*** Instructions on the Report to the Secretary**

VICE CHAIR TERRELL: Thank you. And I'm now just going to open it up one more time for any other comments any of us would like to make as we've heard each other speak and communicate.

Then after that, we'll hear from Karen Swietek about, you know, sort of some of the things that she can summarize for us about what we were saying.

So any other comments having heard from each other now? And speak up. Don't feel like you have to raise your hand per se.

DR. WILER: This is Jennifer. Sorry. I was just raising my hand.

I believe this is the first time we will be sending materials to the Secretary that includes an expanded environmental scan. And so it might be worth making a comment about,

you know, the optimized process we have with regards to evaluation of many components, not only from a scan of practice but also an expanded financial analysis. So I thought we might want to call that out explicitly.

VICE CHAIR TERRELL: Excellent. Any other comments like that or different or any disagreements with anything anybody said?

One thing I would like to make sure, I suspect it will be emphasized. But I just think that this was, one of the reasons this was so favorable is, at least from my point of view, is that it was addressing two things at once: the need for coordination of care between primary care and specialty, as well as the fact that it is [an] Alternative Payment Model that particularly addresses the dearth of such models within the context of, you know, of the current options that are out there.

So I'm hoping that both of those things will be emphasized in the report, as well as from my point of view the fact that this is proposed to be integrated into another payment model already out there and being

developed and beyond the testing site is in, and of itself something that could be valuable in a way of actually accelerating in the future others who are thinking about getting their own payment models adopted as to whether they could be part of a payment arrangement that's already underway either through CMMI or through something else.

So the former head of CMMI when he was, when Adam Boehler was talking to us about things, he spoke about many of the things that had gone through PTAC quite possibly could be part of another Alternative Payment Model that was already being tested. And there were various opinions about that among the Commission at the time.

But this is actually from the field, someone actually proposing just that. So I think this is a unique opportunity to see if that approach of thinking about things that are already underway and adding them to a broader sort of development process that could be something that's unique.

So that's (audio interference) not

nearly as wordy as I just said but maybe could be focused on a little bit within the report.

Other comments. Okay. Then I'm going to turn it over to Karen Swietek to share an overall, overview of the members' comments. And if you're ready, Karen.

DR. SWIETEK: Thank you. Can you hear me?

VICE CHAIR TERRELL: Yes.

DR. SWIETEK: Okay. So, to briefly summarize, overall the Committee feels that the model addresses the important challenge of compensating specialists for engaging in care coordination with primary care providers, which could have a significant implication for cost and quality.

The Committee notes that the model has a number of strengths, including addressing the dearth of available APMs for specialists. And the report will note that the model will provide a framework for specialists to participate in Alternative Payment Models and has the potential to eventually scale to additional specialties after the initial pilot.

And I will also note that there is some discussion about testing the model in the context of the pilot, which may include an expanded financial analysis.

The Committee also noted a number of areas where the proposal can be further refined during the model pilot.

Some of those nuances to be addressed during the pilot phase include issues related to payment methodology, including further development with the care coordination fee, also the concern that further refinement is needed to the attribution methodology to address model harmonization and the potential for model overlap with the CPC+ and PCF models, and the potential for duplicate shared savings payments, and finally the proprietary nature of the PCSP recognition process merits some further consideration.

So the report to the Secretary will also include some specific comments from the discussion on those issues but will note that the pilot will provide for the opportunity to address those nuances in coordination with CMS.

VICE CHAIR TERRELL: Thank you. Good job summarizing all that in real time.

And so let me once again offer my, on behalf of PTAC, our sincere appreciation to all the submitters from NCQA and ACP for the excellent work you did and the thoughtfulness, as well as your perseverance in bringing this back to PTAC. And we look forward to getting the letter out to the Secretary so that we can have your efforts continue to bear fruit.

So that I believe is the end of the public meeting until this afternoon when we will come back for a second proposal to evaluate.

So this is a break time for the public until I think 1:45 Eastern Daylight Time. So we look forward to all of you this afternoon when we come back from that.

CHAIR BAILET: Thanks, everyone.

(Whereupon, the above-entitled matter went off the record at 12:10 p.m. and resumed at 1:45 p.m.)

CHAIR BAILET: Good afternoon. Thank you all for coming back after our lunch

break.

*** Deliberation and Voting on the Patient-Centered Oncology Payment Model (PCOP) submitted by the American Society of Clinical Oncology (ASCO)**

We now turn to the second proposal scheduled for today, the Patient-Centered Oncology Payment Model. This proposal was submitted by the American Society of Clinical Oncology, known as ASCO.

*** PTAC Member Disclosures**

PTAC members, we'll go around the room, introduce ourselves, in case anyone is just coming onto the afternoon session. As you do so, please read your disclosure statements on this proposal.

Because this meeting is virtual, I will prompt you individually. So I'll go ahead and I'll start. I'm Dr. Jeff Bailet, the CEO of Altais. I have nothing to disclose.

Next is Grace.

VICE CHAIR TERRELL: I'm Grace Terrell. I am the CEO of Eventus WholeHealth,

and I have nothing to disclose.

CHAIR BAILET: Next is Paul.

DR. CASALE: Paul Casale, cardiologist at New York-Presbyterian, Weill Cornell, and Columbia. Nothing to disclose.

CHAIR BAILET: And Jay?

DR. FELDSTEIN: I'm Jay Feldstein, President and CEO of Philadelphia College of Osteopathic Medicine, and I have nothing to disclose.

CHAIR BAILET: Lauran?

MS. HARDIN: Lauran Hardin, Senior Advisor for the National Center for Complex Health and Social Needs, and I have nothing to disclose.

CHAIR BAILET: Josh.

DR. LIAO: Josh Liao. I'm an internist, Medical Director at the University of Washington, and I have nothing to disclose.

CHAIR BAILET: Kavita? Kavita may not be on. I'll go ahead and read her disclosure. She -- actually, let's see, I don't have her disclosure. Ah. But let's see, because of her involvement in ASCO, she is

recusing herself from review, deliberation, and voting on this proposal. So I think that should be sufficient for the purposes of today.

Angelo?

DR. SINOPOLI: Yeah. Angelo Sinopoli. I'm a pulmonary critical care physician and Chief Clinical Officer at Prisma Health. I have nothing to disclose.

CHAIR BAILET: Bruce.

MR. STEINWALD: Bruce Steinwald. I'm a health economist here in Washington, D.C. I have nothing to disclose.

CHAIR BAILET: And Jennifer.

DR. WILER: Jennifer Wiler. I am Chief Quality Officer at UCHealth Denver Metro and a professor of medicine at the University of Colorado School of Medicine.[16]

CHAIR BAILET: Great. Thank you all.

I am now going to turn things over to the lead of the Preliminary Review Team for this proposal, who is Dr. Jennifer Wiler, to present the PRT's findings to the full PTAC.

16 Jennifer Wiler's disclosure statement indicated that she had nothing to disclose.

Welcome, Jen.

*** Preliminary Review Team (PRT) Report to PTAC**

DR. WILER: Thank you very much, and good afternoon to all of our participants. I would like to start with a big thank you to my fellow PRT members, Dr. Paul Casale. I would also like to thank Dr. Charles DeShazer, who was a member of our PRT during the entirety of the review, and his work is represented in our report that's presented to you.

Because of personal reasons, Dr. DeShazer recently resigned from the PTAC. But as I have mentioned, we included all of his work in our report and would like to thank him for that.

We would also like to start off by thanking staff and our contractors, specifically staffs from ASPE and NORC. There was a tremendous amount of work that went into review of this proposal. Given that it is in the domain of cancer care, and as we all know, there have been a number of payment models, and specifically Alternative Payment Models in

advance, Alternative Payment Models which have been considered over the last five years, some have even been developed -- in development for a decade, and this Committee has actually reviewed a number of different proposals.

So thanks to the work of the groups to help us better understand this proposal in that context.

We would also like to thank the Medicare Office of the Actuary also for their help in us understanding the impact of the proposed model, specifically with regards to the Medicare spending.

And finally, and most importantly, we'd like to thank the Society for their what must be countless hours dedicated to this project; also, the conference call and correspondence to our questions. We appreciate their engagement with us, helping us to make sure that we fully understood this model and its recommendations.

Next slide.

As with all PRT reports, we will go through the standard process of presentation.

Next slide. And as a reminder for those of you who weren't able to join us in the morning session, this is a summary of what our PRT composition is, roles, responsibilities, and process. This is available on the PTAC website, so I will not read through it at this time.

Next slide.

So by way of background, the American Society of Clinical Oncology developed the model in front of us, the ASCO Patient-Centered Oncology Payment, which is a community-based oncology medical home model, and from here on out, we are going to refer to this as PCOP.

This is noted to have taken more than five years of input from stakeholders, from oncologists, administrators, and payers.

The stated goal of the PCOP proposal is designed to support community-based oncology medical homes featuring team-based care led by hematologists and/or oncologists. The objectives of the five-year multi-payer model are to transform cancer care delivery and

reimbursement while promoting high-quality, well-coordinated, and high-value cancer care.

The PCOP seeks to provide a comprehensive approach to delivering and paying for this high-quality cancer care. And I think it's probably worth noting that there is 2.3 million Medicare fee-for-service beneficiaries that are diagnosed with some form of cancer and seen by a hematologist or oncologist.

And the most recent data, which is from calendar year '17, and all of this is listed in your reference materials, which are available to the public.

The Medicare total cost of care for these beneficiaries was $68 billion. It's noted that 82 percent of beneficiaries are treated by a single oncology practice, and there are 2,800 hematology/oncology practices in the United States. It is estimated -- and three-quarters of those practices are considered I think what we all would agree is small, and that's less than six providers.

This proposed PCOP model seeks to be a life cycle-based cancer model that focuses on ensuring patient care, comprehensive oncology care, through the application of specific care delivery requirements, safety standards, clinical care pathways, and the calculation of performance-based clinical oncology and cost measures, with the structures designed to support a patient's cancer care with time zero being at diagnosis and through treatment up to a year -- one year active monitoring is the episode.

The model's payment methodology seeks to support an acquired clinical practice transformation and provide incentives for value-based care, but also providing flexibility. This model, as written, has the potential to reach across borders, specifically small to large practices, urban, rural, and across state lines.

The Alternative Payment Model is described as practices providing the services, cancer care, specifically hematology and oncology-led, and specifically those who

prescribe and manage chemotherapy and immunotherapies, which will become important as we go on.

Multi-specialty practices with hematology/oncology providers may also participate. The practices would serve as the Alternative Payment Model entity for purposes of provider assignment, patient episode attribution, and performance measurement.

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So core elements of the program -- I am going to go through these in detail, because, again, we reviewed a number of models in the past, and some of these details may become important for us to deliberate. So I'd like to go through them now.

First, the proposal calls for the creation of something called a PCOP community, and that is comprised of multiple providers, payers, and other stakeholders to facilitate implementation of the model in each geographic area. Participating practices would be required to comply with the 22 PCOP care delivery requirements that are based on the

oncology medical home standards, and have an emphasis on the use of evidence-based treatment pathways.

For those who may be interested in the reference material, there's a nice -- a couple of articles in the peer-reviewed literature about pathway tools that currently are available and how they compare for your reference.

The payment model includes a care management payment, a CMP; there's a performance incentive payment, a PIP; and the ability to receive bundle -- what is being called a CPOC, not to be confused with PCOP, but the CPOC or consolidated payments for oncology care.

The performance methodology is based on meeting quality metrics, adhering to pathways, and ultimately reducing care. The model includes three phases of cancer care: new patient, cancer treatments, and active monitoring.

Models for delivery requirements and the level of financial risk would differ

between two tracks, a Track 1 and a Track 2. Track 1 practices would be encouraged to advance as a Track 2 within two years, and we'll talk a little bit about that going forward.

Each PCOP community would need to be able to meet the requirements related to sharing electronic health record data from participating vendors via certified electronic health records, and there are some other data-sharing requirements.

Importantly, the PCOP model is designed with two tracks. Track 1 has no downside risk, but it's designed to encourage the participation of providers that may have less experience with Alternative Payment Models and small practices who may lack the resources to engage in Track 2.

I would note that there is a year zero in this model that allows for that infrastructure building.

Both tracks require adherence to many of the same care delivery, safety, and clinical care pathways. And in our PRT report

there is a table available for you to see the differences between Track 1 and Track 2. But the main difference is that there are slightly different care delivery requirements, and then the bundle that I described previously of the consolidated payment is available because of the increased risk that is required in Track 2.

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This just is a visualization that shows the main components of the model.

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So an overview of the proposal. The first is the role of the PCOP community, the expectation, or in the proposal it is described as multi-payer, employer, hematology/oncology practices, and other stakeholders in a geographic region. It could represent a single metropolitan area, a state, or multiple states. And this would be led by an Oncology Steering Committee.

The Oncology Steering Committee is important because it makes many decisions about this model. It would select the high-quality care pathways and a subset of six quality

measures from ASCO's QOPI[17] program that are most relevant to the patient population for which it is managing. It identifies partners to facilitate successful implementation of the model, which include funding and project management.

It potentially sets targets for pathway adherence rates -- and we'll talk about that in a little bit going forward -- and distributes performance metrics. It is also responsible for establishing the value of the CMP and PIP payments based on the PCOP guidelines.

Although the proposal does not specifically define a minimum criteria for what a PCOP community participation is, the submitter has indicated that the 18 regions in the CPC+ model, as well as some states that have the ability to leverage search technology, including existing health information exchanges or oncology-specific alternate forms databases, would be most appropriate for this initial

17 Quality Oncology Payment Initiative (QOPI)

implementation due to the proposed model's data management requirements.

The submitters also, during our discussions with them, indicated that while the model is designed to be multi-payer, it could be implemented as a single-payer program with Medicare.

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With regards to the care delivery aspects, the proposed PCOP model built on the oncology medical home model concept and features team-based care as previously described. Participating practices would be required to comply with the 22 care delivery requirements that are in seven categories, including adherence to safety standards, and specifically in Track 2, it would be subject to additional requirements that include patient and family advisory councils, triage, and urgent care processes, in addition to utilization of pathways, patient navigation, risk stratification, and advanced care planning.

And, again, I am referring you back to our report where it specifies all of those aspects or to the submitter's proposal.

Next slide.

With regards to performance measurements, the proposed model focuses on providing incentives for value-based care that is further demonstrated in this performance methodology which includes quality and cost performance metrics. It includes quality metrics and adherence to care pathways and also test of care metrics that are related to avoidable hospitalizations, emergency department use, and observation stays, and supportive and maintenance drugs costs, which do include chemotherapeutic and biologic agents as previously described.

This aggregated performance score, which is based on one third, one third, one third of what I have just described, quality metrics pathways and costs, but would be weighted to a practice's performance.

However, the submitter has indicated the PCOP communities have flexibility to adjust

weighting for other payers should the Steering Committee choose to do so.

So with regards to these quality metrics I have already previously described, then, adherence to pathways and cost of care we will dive into here in just a few minutes.

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With regards to highlights of the payment model, the payment model includes a two-track design. Both tracks require data reporting on quality metrics to gain adherence to the pathways and care delivery requirements, but the main difference between Track 1 and Track 2 is it employs a bundled payment that includes downside risk. Track 1 does not include that.

Both tracks include a care management payment, a CMP, and a PIP, which is the performance incentive payments. And they will be calculated as a percentage of total cost of care, and they are adjusted based on where the patient is in our cancer care continuum, specifically the three categories of

a new patient, cancer treatment, or active monitoring.

Providers in Track 1 practices would receive monthly care management payments that are worth two percent of the total cost of care, which includes all medical care fee-for-service payments, whereas providers in Track 2 practices would receive three percent of total cost of care.

We would note that the care management payments are not case mix or risk-adjusted. Participating practices will also receive monthly performance incentive payments based on the performance and quality and cost measures and adherence to the pathways. For Track 1 practices, they would earn up to two percent of the total cost of care, and performance incentives for Track 2 are up to three percent.

The clinical pathway adherence rates are included in the PIP calculation, and those are weighted by the proportion of treatments by cancer type. The cost measurements that are

included in the PIP calculation are -- those are risk-adjusted for cancer type.

We describe this in the report, but include things like secondary malignancy, bone marrow or stem cell transplant, clinical trial participation, et cetera.

In Track 1, practices will continue to receive fee-for-service reimbursements in addition to the case management payment and the potential performance incentive payment. In Track 2, providers are required to participate in consolidated payment for oncology care, or, again, the CPOC for short. And they may elect to bundle either 50 percent or 100 percent of the value of specified services and earn between a maximum of 90 percent and 104 percent of the previous fee-for-service amounts, depending on this aggregated performance score, which is made up of the three performance quality metrics, adherence to critical pathways and total cost of care.

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So with regards to the payment model, the CPOC is the feature of the PCOP

payment methodology that distinguishes it from the current Oncology Care Model, or OCM, and has the potential for the greatest Medicare cost reductions.

There is a lot of analysis, and this is actually where the Medicare Office of the Actuary was very helpful to us in trying to understand what that opportunity was for savings. And I will refer you to our appendix for that financial assessment.

But, briefly, the CPOC seeks to introduce financial risk for Track 2 using this bundle that would be adjusted on a prospective basis based on performance, which would allow participating practices to know their expected revenue for the next period. The same performance methodology will be used to determine the CPOC that is also used to determine the incentive or the PIP.

Track 2 practices could face up to 10 percent downside risk and four percent upside, depending on what their aggregated performance score is. And the proposal states that practices of Track 1 are expected to

advance into Track 2 within two years or be subject to discontinuation of the care management and incentive payments.

However, the submitter indicated that participating payers would have discretion regarding whether to discontinue the CMP or PIP payments, or to extend the deadline for transitioning based on business interests.

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These are the 10 criteria that we were asked to provide as the PRT. These are our preliminary recommendations for us to review at this time.

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These are the key issues identified by the PRT. There are several aspects of the model that warrant consideration as other care models are developed, such as the need for more local, multi-payer efforts;, greater payer participation; and a more balanced payment methodology that allows more practices, in particular small practices, to participate.

A cancer model and the related care management payments that address the entire

continuum of care rather than just the chemotherapy component, we thought was valuable while holding participant practices accountable for only quality and cost, which we thought was appealing.

However, the model does not appear to meaningfully expand the portfolio of Alternative Payment Models in our opinion that are available to hematologists and oncologists. The four aspects of the model are similar to the OCM model, which it is our understanding it is public that CMMI has an intention to extend that program through June of 2022.

And that is currently going under potential revisions, and that there are several other oncology-related CMMI models it is our understanding that are in development, including the Oncology Care First Program.

We noted that the proposal raised awareness from our local multi-payer efforts as we described. However, there were concerns that requirements of this proposed model, including the performance and reporting complexities and a governance model of standing

up one of these Steering Committees and all of the requirements that were -- or decision-making that was held within this governing body was challenging. And it may limit the potential number of communities, payers, and practices that are actually able to participate.

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While the PCOP model has the potential to improve quality and reduce cost, there may not be sufficient reductions in total cost of care to achieve cost neutrality or net savings.

I mentioned this before, but although the proposed model includes several features that encourage high-value care, the PRT is concerned that the recent evaluation of the CMMI OCM model indicated that care management payments are not resulting in statistically significant effects on Medicare expenditures or total cost of care.[18] And these

18 Abt Associates. Evaluation of the Oncology Care Model: Performance Period One. https://innovation.cms.gov/Files/reports/ocm-secondannualevalpp1.pdf. Published December 2018.

programs are older and more mature and have not yet netted a significant savings to Medicare.

I will note -- and, again, these are all in the appendices -- by way of background, a third evaluation of CMMI's OCM model found no statistically significant declines in total episode payments. In fact, the combined monthly enhanced oncology services and the performance-based payment for the two performance periods were greater than the small overall reduction that was -- that was noted.

The proposed model also gives participating payers discretion related to applying the incentives that are designed to encourage practices to transition to Track 2. As we mentioned, Track 2 is where there is risk, and that's where there is an opportunity for savings.

In the original proposal, it states that practices that elect Track 1 are expected to advance into Track 2 within two years or be subjected to the discontinuation of the CMPs and PIPs as I previously described.

However, the submitter has indicated that practices do not advance to Track 2 within two years. Participating payers in the PCOP model would have flexibility to decide to discontinue these payments or continue to expand the deadline. And so we've had some concerns that ultimately without this selection of Track 2 or transition from Track 1 to Track 2, as a mandatory process, there is a potential that cost savings would not occur, and actually accrue costs.

Next slide.

Criterion 1, scope, which is high-priority. Our conclusion was that this did not meet this criteria, and this was a unanimous conclusion. Briefly, the proposal seeks to provide a comprehensive approach to delivery in paying for cancer care as I have described.

The proposed model's use geographically-based, multi-payer stakeholders led by the Steering Committees and community-specific flexibility in selecting clinical pathways and metrics, could facilitate greater

participation by private payers and smaller practices.

The proposed model could provide an opportunity to test some alternative approaches related to value-based oncology care, including a life-cycle continuum or episode that I previously described.

But with regards to the proposal's potential to expand participation by medical hematologists and oncologists, including small practices, we thought it was important to note that currently approximately five percent of the nation's hematology and oncology practices participate in the CMMI OCM model, and those participating practices are noted to be relatively large.

However, PCOP's two-track model, Track 1 is the model that would be most attractive to these practices who have limited experience as opposed to Track 2, which would require much more infrastructure if we assumed maturity.

So, that said, while the model could encourage the engagement of smaller practices,

there may still be obstacles that could inhibit their adoption, such as the startup costs that are associated with establishing these PCOP communities, again, employers, payers, providers, all working together, and also private payer adoption.

What I've noted before with regards to the Steering Committee being responsible for, lack of a better description, adjudicating performance, so the data analytics, governance, and ability to do assessments is quite rigorous, and may be a barrier to entry for practices.

And, lastly, I will mention that the model's data management requires also could be a barrier because there is -- either they have to be established or there is a commitment to developing, for instance, participation on a regional health information exchange or all-payer claims databases.

And thank you especially to the Society, who helped clarify to us that leveraging the 18 regions that are currently participating in CPC+ may be the right target,

although we were a little confused because, you know, a large portion of the justification of the model was around practices who had no experience. And so we'll be interested to hear a little bit more about that.

Criterion -- sorry, next slide. For Criterion 2, cost and quality, this is a high-priority criteria. Our conclusion unanimously was that it did not meet this criterion.

As mentioned before, the proposed PCOP model emphasizes quality improvement through practice transformation and allows some flexibility within the PCOP community as governed by the Steering Committee to address these issues.

The oncology -- the OMH[19] concept and the model's care delivery requirements, adherence to CMP pathways, CMP standards, and high-quality care pathways, have been shown to improve quality and safety and have the potential to reduce cost. And, again, references to that are in the materials. However, there may be variation in the model's

19 oncology medical home (OMH)

impact on quality across these various communities due to discretion in selection of these pathways, and ultimately performance metrics. Again, because those are picked within these community models or through the Steering Committees.

There is a risk that any quality metrics that are achieved under the model may not correspond with significant reductions in the total cost of care. And, again, we have other models that currently exist, too, who have potentially informed that, in order to achieve net savings for cost neutrality.

And then I think it's also important to note that although the proposed PCOP model may not result in reductions in total cost of care or net savings, it would be helpful to address existing issues related to the quality of oncology care by improving adherence to pathways, improving an increasing consistency of care coordination and reducing variabilities and treatments. We absolutely agree that that's important.

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With regards to Criterion 3, which is payment methodology -- and it's a high priority -- our PRT concluded that the proposal did not meet this criterion. This was unanimous.

Again, the proposed model provides financial support for clinical practices through the CMPs. It includes financial incentive related to quality and cost. Track 2 seeks to increase the potential for cost savings by introducing financial risk and notable downside risk through the CPOCs using a bundle that will be addressed prospectively.

However, several of the proposed model's payment methodology features have -- that have the greatest potential to reduce costs are either optional or flexible and could be delayed, as I mentioned before, and that drug costs, which are included in Tracks 1 and 2, may be difficult to predict, which may make the proposed model challenging to implement and manage.

The PCOP CMP amounts for new patients and cancer treatment are two or three

times higher than payments for current E&M[20] services and are also higher than the OCM's MEOS[21] payments, and they would not be case-adjusted.

The submitter did provide data for us regarding the State of Maine's model, which is estimated monthly CMP amounts for Medicare beneficiaries for new patients, which is currently $450 for Track 1 and $675 for Track 2.

For cancer treatment, it is $225 for Track 1 and $348 for Track 2. And in their active monitoring phase, they provided us data describing the program as $75 for Track 1 and $113 for Track 2. The proposed PCOP CMP amounts for new patients in cancer treatment as mentioned are two or three times higher than the OCM's MEOS payment, which is actually $160 per month and is typically guaranteed for the entire six months.

Finally, while part of the proposed model's success is dependent upon multi-payer provider and stakeholder engagement, the PCOP's

20 evaluation and management (E&M)
21 monthly enhanced oncology services (MEOS)

proposed community-led multi-payer practice and stakeholder model, including employers, we thought may be difficult to implement in practice.

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Criterion 4, volume over value. We -- it does meet this criterion. I won't go through the details, but the quality metrics and adherence to pathways is one that is an improvement in the literature to decrease care variability and we believe improve value with regards to outcomes with use of pathways as a process measure.

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Criterion 5, flexibility. The PRT concluded that this proposal met the criterion, and this was unanimous. If anything, you've heard us describe that we actually had concerns that there was too much flexibility and that that amount of flexibility can actually be problematic from an implementation perspective.

Criterion 6, ability to evaluate. The PRT concluded here that the proposal did

not meet this criterion, and this was a unanimous consideration.

Again, the decentralization of this process into one that could be community-based, it was unclear how many of these communities exist. Again, the suggestion was during our inquiry phase that leveraging CPC+ practices may be a viable option. But, as written, it -- there is no limit to the number of these communities that could be created, and, therefore, we thought the analytics of such a program would be very difficult to evaluate the model, in addition to the data requirements and multi-payer aspects.

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Criterion 7, integration and care coordination. The PRT conclusion was that the proposal met this criterion, and this was unanimous. I have already described a number of features relating to this.

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Patient choice, Criterion 8. The PRT -- our conclusion was that the proposal had met this criterion, and it was a unanimous

conclusion. Given that patients were allowed to select providers within multiple of these communities, we felt that it met this metric.

Criterion 9, patient safety. The PRT conclusion was that the proposal met this criterion, and it was a unanimous conclusion.

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Criterion 10, health information technology. The PRT conclusion was that the criterion was met. Just our assumption was that all of the access to each of these all-payer claims databases or registries or information exchanges, if we assume that those are available, given what was described, and so that is a concern that we expressed through some of these other criterion.

But with regards to the health information technology factors that we were asked to evaluate on, our PRT unanimously determined that that criterion was met.

And with that, I conclude my presentation.

CHAIR BAILET: Thank you, Jen. That was a nice, detailed summary of a fairly

complicated -- not complicated in a negative way, but a fairly extensive proposal. So we appreciate that.

And, Paul, I wondered -- you're on the PRT. Did you have any additional comments that you wanted to make before we open it up to the Committee?

DR. CASALE: No. I just want to thank Jen for a very comprehensive overview, as you said, of a somewhat complex not to be -- not in a negative way, but just complex model. And I also want to also add my recognition to ASPE staff and NORC for their help in understanding the context of this model within other models in oncology.

So thank you, Jeff.

CHAIR BAILET: Thanks, Paul. And I think before we open it up to the Committee, I just want to acknowledge Dr. Charles DeShazer, who was an excellent contributor to the PTAC and, unfortunately, had something come up that created his inability to continue on the PTAC despite that would be what he wanted.

So we just want to thank him and acknowledge him for his contribution while he did serve on the Committee. So if you're out there listening, Charles, thank you.

*** Clarifying Questions from PTAC to PRT**

I'd like to just turn it over to the Committee to ask clarifying questions of the PRT, Paul and Jen. Any questions for them?

MR. STEINWALD: This is Bruce. I have one.

CHAIR BAILET: Bruce.

MR. STEINWALD: Jen, at the beginning of your presentation, you thanked -- I believe you thanked the actuaries for their help in evaluating the proposal. And I didn't find that in the materials, and I apologize if it's there and I just missed it.

But could you summarize for us in what way the actuaries helped to evaluate the proposal?

DR. WILER: Happy to. I'll defer to staff to identify the location of their report. But their summary -- and, Paul, please chime in

here -- was that the description of the potential cost savings in the proposal was overstated. They cited previous models that were similar but obviously not the same and that's why we're here today.

I would refer folks to a nice summary where there is a side-by-side of the PCOP model, the CMMI, CPC+ model, and the OCM model. That is also available.

But specifically with regards to cost reductions for Emergency Department observation in patient care, they thought that the opportunity for savings in that space, based on their assessment of participation, was limited, and thought, as we have described here, ultimately that there would be -- it would be cost-neutral, and actually their findings were that it would probably -- there would not be a cost reduction and actually add costs.

MR. STEINWALD: Thank you.

MS. MCDOWELL: This is ASPE staff just clarifying that in the ASCO PRT report on page 15, it indicates that the PRT sought

additional information by communicating with staff in the CMS Office of the Actuary to gain a fuller understanding of the implications of the proposed model for Medicare program spending.

In addition to that, as part of the overall environmental scan, our contractor, NORC, did some additional analyses, and there are also some data analyses that were done, which also helped to support the findings of the PRT.

CHAIR BAILET: Thank you, Audrey.

Any other questions for -- from our Committee to the PRT folks? I don't see any, but just wanted to make sure. We're going to go ahead, then, and invite the submitters to participate and --

MS. MCDOWELL: Josh has a question. Josh has a question.

CHAIR BAILET: Oh, sorry. Go ahead.

DR. LIAO: Sorry about that, Jeff. I may have been on mute. Can you hear me now, everybody?

CHAIR BAILET: We can. Thanks, Josh.

DR. LIAO: Okay. Great. Jen and Paul, thanks for the thoughtful, thorough review of the reports. You know, I -- my question is related to how PCOP thinks about quality. It may just be a clarification for me, but when I look at what is contained in Section 6.1.3 in the proposal, and 6.2.2, where they talk about the pathways and the quality metric, it wasn't quite clear to me how the quality would be measured, whether it would be, for lack of a better word, fit to a distribution where there would be clear high and low performers.

Certain parts of it seem to suggest that's related to quartile and percentile cutoffs. And then others note where everybody is performing well, so we may go back and redefine that.

And so it relates I guess to Criterion 2 about this notion of being potentially able to increase quality. To what extent would that issue, a kind of clumping of

performance and quality, versus a true distribution forced that way by the model, did the PRT consider?

DR. WILER: It's a good question. I'm going to answer it, and then I think this is one that we let the presenters and especially the Society and authors of the proposal also opine on.

But from the PRT perspective -- and this is a nice summary of our report, of our findings on page seven of our report, there are these three buckets -- quality, pathways, and cost. You know, one could argue that adherence to clinical pathways is quality, just to say it, so right there is -- there is two domains with regards to that.

For quality metrics, they describe an opportunity for these communities, governed again by the steering Committees, to select six quality measures. And then, you're right, the methodology of adherence to benchmarks in performance-setting is, as we understood it, to be a distributed governance model or where

these local communities get to decide how they want to evaluate that performance.

And so there was not a standardized methodology approach with regards to that, at least to a specificity that we thought that we could -- we could understand that would be standard and, again, that there was, you know, discussion around flexibility to be reactive to the five years. Actually, it's six years for -- the first year is zero year of performance.

So the short answer is that methodology is not well described from our understanding, that we'll defer to the presenters coming up to get additional information on that.

Thank you.

DR. LIAO: Great. Thanks.

*** Submitter's Statement**

CHAIR BAILET: Seeing no other questions, I think it would be good to go ahead and introduce the submitters. So while they're coming on, just a little housekeeping. I'd like -- Brian Bourbeau is the -- will be the monitor -- moderator for the team, so any

questions that we have will be directed to him, and then he can direct them to his teammates.

But I would ask the folks, as they come on, to please introduce themselves, and then Dr. Jeffery Ward will be actually presenting the material.

Thank you.

DR. WARD: Hi. Can you hear me? My camera -- the video feed from my camera seems to be having a little hard time loading. My picture may show up soon.

Good afternoon. My name is Jeff Ward. I'm a practicing medical oncologist at the Swedish Cancer Institute. My site of practice is a community hospital in a clinic north of Seattle. I have had the pleasure of 14 years of service on ASCO's Clinical Practice and Government Relations Committee. And with a lot of help, I founded and chaired ASCO's Reimbursement Workgroup for a number of years.

Allow me to start today by thanking the Preliminary Review Team and this Committee for taking time to discuss the Patient-Centered

Oncology Payment model and to convey the importance of your work today.

Medicare's Oncology Care Model, as you know, is nearing its end. It's expected to accrue its final episode in December of next year. And while CMS has laid out some conceptual design elements in the Oncology Care First RFI[22], they have yet to publish a finalized model.

So we have an opportunity to shape what comes next. And unlike prior discussions this Committee has had regarding oncology models, today we have the additional benefit from the Abt Associates' evaluation of OCM's first three performance periods.

So we have a clear picture of what is working and what is hindering the goal of improving quality and reducing the costs of cancer care. We can consider those lessons learned as we discussed ASCO's Patient-Centered Oncology Payment Model, or PCOP, as we refer to it. I am joined today by Dr. Blase Polite, a professor of medicine at the University of

22 request for information (RFI)

Chicago. Dr. Polite and his colleagues were early adopters of clinical pathways and Alternative Payment Models. His work has helped to shape ASCO's platform on the development and use of clinical pathways and their inclusion in the PCOP model.

I am also joined by Stephen Grubbs. Dr. Grubbs, in his role as Vice President of Clinical Affairs at ASCO, oversees the distinguished quality oncology project initiative. It's a quality measurement and practice certification program, which has contributed many of the measures, including in the current quality payment program.

And, lastly, I am joined by Brian Bourbeau, Division Director of Practice Health Initiatives at ASCO. Prior to joining ASCO staff, Mr. Bourbeau had firsthand experience in nearly a dozen Alternative Payment Models and pathways programs. Together we are available to answer any questions that this Committee may have regarding PCOP.

The nidus of this work was actually in 2012 at the request of the supercommittee

tasked with finding a way out of sequestration. PCOP was first published in 2015 in the Vanguard, a physician-focused payment model.

Since that time, we have benefited from shared experiences in multiple Medicare and private payer models. Recently, we submitted a multi-disciplinary or assembled a multi-disciplinary team from clinical practice payer and purchaser communities to update PCOP and prepare for submission to this community.

In the few minutes that we have, I wanted to highlight a few features of the model.

PCOP is, first and foremost, a care transformation model. It includes specific delivery -- care delivery requirements for participating practices. These requirements are rooted in evidence and expert consensus to improve the quality and cost effectiveness of cancer care delivery.

PCOP's performance and payment methodologies are designed to measure and incentivize the successful deployment of this new oncology medical home model of care.

In designing the model, we were guided by two core principles. First, no provider should be financially penalized for providing the appropriate care to the appropriate patient at the appropriate time. And, second, providers should be held accountable for aspects of care under their control but not for aspects that are outside of their control.

For all of its strengths, the Oncology Care Model violates these principles. It essentially focuses on only one aspect of oncology care -- the price of cancer drugs. The PCOP model, in contrast, focuses on the appropriate utilization of drugs rather than their price and equally weights that with an adherence to well-established and well-validated quality metrics and the costs of cancer care most directly under the control of an oncology practice, unplanned hospitalizations, ER visits and observation stays, and the supportive care drug costs.

Paramount to these care delivery requirements is the inclusion of adherence to

clinical pathways. For years, Medicare and Medicaid have struggled with the question of how to include oncologists in the effort to bend the cost curve of cancer care, when neither oncologists nor CMS actually set the price of those cancer care drugs.

Clinical pathways offer us a solution by promoting use of treatment regimens that have been methodologically weighed by their efficacy, potential side effects, and the total cost of care. Adherence to these value-based pathways has been shown to reduce the overall costs of drug treatments while mitigating the risk of stinting on care.

Further, if broadly applied, the incorporation of value into clinical pathways has the potential to exert downward pressure on some drug prices as competing therapeutics seek pathway inclusion.

Finally, PCOP introduces a payment methodology which enables its goal of improving quality and reducing the costs of cancer care. It is easiest to describe PCOP's methodology in contrast with the current OCM. For example, if

we recall, OCM establishes its monthly enhanced oncology services payments based on a four percent of calculated total cost of care. These payments of $160 per beneficiary per month were necessary for practices to put in place the enhanced services required under OCM.

But this largest category of model payments failed to reflect the performance of practices who received them. Practices who wisely invested in MEOS payments in the newest systems of care waited nearly two years for additional performance-based payments, whereas practices who struggled in the model experienced no change in their reimbursement.

PCOP's care management payments are similar to OCM's, but their base payment is calculated at two percent of the total cost or three percent of practice -- for practices in Track 2. The remainder is critically included in monthly performance incentive payments, variably based on the practice's ongoing performance with the model.

This methodology rewards practices for achievement of improved quality, cost, and

pathway adherence. Further, PCOP disrupts fee-for-service with consolidated payments for oncology care, taking a portion of current fee-for-service and moving it to monthly, partially capitated payments, that are also variable based upon performance.

PCOP enables the shift from a fee-for-service system that encourages increased utilization through a payment methodology that provides oncologists with the resources necessary for implementing innovative methods of care delivery, something that OCM has failed to do because of its myopic focus on drug prices.

PCOP's balance of specificity and flexibility actually provides communities a model that allows for a true multi-payer participation and achievement of a common goal of a high-quality, cost-effective cancer program. We hope that our proposal and the answers given today will assist this Committee in its review and recommendations of PCOP to the Secretary.

We expect that you have many questions, perhaps clarifications we can answer. There were three specific issues broached by the PRT review that we would invite questions about specifically.

First, the review expresses concern that the Abt Associates find that the OCM failed to generate overall savings from ED and hospital utilization during periods 1 to 3, and that this dooms any model that purports savings from utilization.

Second, it questions why we believe that PCOP will attract and retain practices and payers where OCM or the model suggested by OCF RFI cannot.

And, finally, we fear that we were not able to convey adequately to the PRT review team why eliminating the cost of drugs in a bundle and utilizing value-based pathways compliance to bend the cost curve is a radical departure from OCM, distinguished PCOP as a truly unique payment model. We would hope in particular to have a robust discussion on this latter topic.

Thank you for listening. Please, any questions?

CHAIR BAILET: Great. Thank you, Dr. Ward. And I'm now going to turn it over to the Committee to ask questions for the proposal submitters, and please direct those questions to Brian Bourbeau, and then he will allocate them out to his colleagues.

Thank you.

So I don't see someone queuing up. So maybe I'll -- maybe I'll ask the first question while we get -- while we get seated here. HIE or health information exchange is clearly one of the backbones of this model to accelerated success.

My question -- my experience with starting HIEs or existing HIEs, they are -- they are not ubiquitous. They are hard to get going. In California, we have been trying to stand up an HIE for the last three years, and so far have been unsuccessful in garnering the support to participate in freer data.

All payer claims databases are great when they exist, but those too are also

difficult to stand up. And so I would very much like to hear your input on sort of how you view that process unfolding, and from a timeline standpoint how long you think that will take. It would be great to hear your approach.

Thank you.

MR. BOURBEAU: Thank you. And this is Brian Bourbeau, and I'll take that particular question. So as part of CPC and CPC+, and now Primary Care First, the idea of multiple-payer, multi-practice data exchange is core to being able to evaluate costs across multiple payers, and to be able to do so in a common format.

We benefited in recent years from -- there is actually an all-payer claims database council, which has a common data layout that they have provided states on the claims side. And so we feel, you know, getting to a multi-payer model really requires that data interchange. We're now up to, in Oncology Care First, 26 regions that have dedicated to supporting multi-payer data and quality

measurement for primary care, and we feel those regions are kind of primed to add oncology using the PCOP model.

And so, yes, understand that there will be certain regions of the country who may not be as mature in being able to adopt a multi-payer model, but we hope that they will get there.

CHAIR BAILET: Thank you, Brian. I'm going to go ahead and turn it over to Grace for her question, please, and then Josh.

VICE CHAIR TERRELL: I've got several. So what I might do is just ask one or two, and then if there is more people that want to do it, I'll come back to the others, as opposed to dominating things.

But one of the things, first of all, thank you all for your -- for presenting this and for proposing this. I think that oncology in general is one of the real miracles out there that we don't realize very much that we have actually achieved a whole lot, at least over the course of my training.

And when you actually look at survival rates and all that we've done, even within all of the dysfunctions of our current health care system, the work that has been done in oncology is impressive. So from that point of view, I think one of the things that we need to be very careful with is that we don't break things with new payment models, even if we need them, as a result of somehow suppressing innovation.

So I've got some background in genetics and genomics and a professional certification in that. And as precision medicine is completely potentially upending a lot of oncology in so many ways, my concern as it relates to this, or at least my question is, can the evidence-based medicine, the care guides, all of the pathways that you all very consciously put in place -- I noticed a lot of it was not related to, for example, DNA fingerprint, but, you know, still some organ or tissue sort of approaches to things, can that keep up with the pace of innovation in the oncology field such that we're going to

continue to have all of the success we've had, even as we're trying to measure things by evidence-based pathways? That's my first question.

MR. BOURBEAU: Yes. Thank you for that question. Dr. Polite, would you like to discuss pathways and inclusion of emerging evidence?

DR. POLITE: Yeah. And thank you for that. And, to me, that's why it is absolutely critical that you actually have pathways in the system.

So if you look at the Oncology Care Model right now, about 60 to 65 percent of episode costs are drugs. And if you look at the Abt report, you know, essentially the reason why there wasn't savings, you know, was Part B drug expenses.

So if you're going to deal with oncology with drugs, the problem of course becomes our choice of what to give is so dependent on individual characteristics. The beauty of pathways -- and there are several, you know, successful commercial pathway

companies out there, we have implemented one here, B Oncology that came out of University of Pittsburgh, and several of our academic colleagues across the country, all names you would very well recognize, are also on this.

And these are Committees that we frequently -- and the way the pathways are designed is actually you embed molecular component into it. So when I see a colon cancer patient, I check whether or not they have RAS mutations, whether they have microsatellite instability, and this then leads to pathway choices.

So by having the pathways in there, you, number one, ensure that how you actually -- I am actually practicing the most up-to-date evidence-based care based on molecular subtype, and then driving that quality change. So I think you actually improve quality.

But the second thing is it allows us as an oncology community to adjudicate areas where we may have two or three competing drugs or there may be a new drug that has, you know,

perhaps small improvements that we don't feel is justified by the cost.

So I think the pathway that I think is the one place that really allows you to, one, make sure that care is not stinted; that, two, drive quality improvement by, you know, requiring that people look at these molecular subtypes; and, three, allow us to deal with the major cost drivers, which are drugs, in a way that does not result in any way hampering the innovation and care.

You know, I would suggest that if you design value-based pathways correctly, you actually encourage pharma and companies to look for higher value, meaning treatments that actually improve survival, improve quality of life to a greater degree, that will allow them to achieve, you know, higher places, you know, in a -- in a pathway that requires sort of forced choice.

VICE CHAIR TERRELL: Thank you. I'll let Josh do the next question. That was -- that was excellent. Thank you.

MR. BOURBEAU: Thank you for the question.

DR. LIAO: All right. Well, thank you, Mr. Bourbeau, and Drs. Ward, Grubbs, and Polite, for the presentation.

I think, you know, as is mentioned in the CARES[23] report, and as mentioned in your presentation, there are questions about kind of potential for improving quality and containing costs.

And I'm curious if we take a big step back. I was struck by one of the responses to the PRT letter regarding OCM being, I believe, in the words of the letter, a cost source model and how PCOP is kind of a balanced model that focuses on cost and quality.

Just so I'm not misunderstanding it, is it right to say that as PCOP is written now, it is a model that in your estimation will improve quality while simultaneously reducing cost? Does it kind of keep the cost or

23 CARES Act: Coronavirus Aid, Relief, and Economic Security Act of 2020

spending neutral while improving quality? Or the last permutation perhaps, which is kind of maintaining quality and reducing cost. I don't think that's the one, but I'm curious how you guys are describing it.

MR. BOURBEAU: Sure. Thank you. I'll take that particular question. And so as the PRT shared, we have three categories in the performance methodology. We have cost of care, we have quality, and then we have adherence to pathways, which, as Dr. Polite mentioned, straddles and addresses both cost and ensuring high quality of care.

And so a practice can succeed in the model and be above average if they hold costs equal but improve quality of care, or they hold quality equal and reduce cost of care. And so these categories are weighted equally for that reason, to encourage, you know, striving on both those ends.

Also, there was a question -- and I don't know if the Committee wants me to follow up on the question to the PRT, which was

mentioned as a potential question for us regarding the scoring methodology?

CHAIR BAILET: Yeah. Well, go ahead, Josh. Sorry, go ahead.

DR. LIAO: Go ahead.

CHAIR BAILET: Well, I also want to -- I know Grace has a couple more questions as well, but, yeah, I -- why don't we go ahead, Brian, and answer that question, and then we'll get back to Grace.

Thank you.

MR. BOURBEAU: Sure. And so, yeah -- yeah. So in the scoring methodology, both for clinical pathway adherence, as well as quality metrics, we have designed quartile scores. And so in pathway adherence, if you're above the 75th percentile, that's 100 percent scoring on pathway adherence, and then in each quartile that score goes down.

In the quality measurements, we have -- if you're above the 75th percentile, that's a 100 percent score. On quality metrics, if you're between 25th and 75th percentiles, then you're within a spectrum there of scores. And

if you're below the 25th percentile, you're at zero percent.

Now, what we absolutely hope is that every practice is then well performing in each one of these areas, and some of the side effects of that is topped out measures. And so then we leave it to the multi-payer stakeholders to address on how to handle topped out measures, whether or not to continue with them and score everyone at 100 percent, or whether to drop that measure and select a new one. And that's just something, you know, you have to anticipate that as practices are striving for good performance topped out measures could happen.

DR. LIAO: If I could just follow up on that, because I think I raised the question in my question to the PRT. I think that's helpful clarification, and it goes back to this question of -- my first one about quality versus cost, and the idea that you can imagine a situation where outside of the extreme of being topped out, that the status quo may be

quality as measured by a pathway or a set of metrics.

It may be high, low, in the middle. There may be lots of spread, very little spread, and so we could see situations where certain PCOP communities had quality performance that right at the gate was very high, which may be excellent, but kind of begs the question of, what is the quality improvement there versus the other side of it where there may be a distribution performance that is beginning.

And so the question is really to understand kind of the flexibility and the design around that. So thank you.

MR. BOURBEAU: Okay. Thank you. Yeah. I think that's a great question, and so perhaps, Dr. Ward, can you talk maybe to the different tracks and how the tracks are put in place and options within PCOP to address where a practice is entering the model? Dr. Ward?

CHAIR BAILET: He may have fallen off, Brian, for bandwidth issues.

DR. WARD: No. I'm here. I just -- it had remuted me.

There have -- we have kind of followed and tracked I think why practices have struggled with agreeing or staying in OCM. One of the struggles OCM is having right now is that there are very few practices that are willing to move to a two-sided risk model.

And we believe that the primary purpose -- reason for that is actually the issue of including drug costs, something they can't control in a bundle, that's way too easy for your bundle to be broken by patient mix. We have actually demonstrated that in some studies that we've done at ASCO, that your patient mix determines whether you're successful in OCM, not your choices.

But what -- the other I think factor certainly is just getting your toes in the water. And so we really believe that once a practice gets the infrastructure in place and is able to do so, that there are significant advantages and savings to both the practice and to payers in Track 2, but that we need to be

able to bring them into the fold, and in some degree teach them how to do it.

But the real key to the difference in the model and bringing people into it I think, and what will attract people, is the idea that they are not going to be responsible for something that they can't control.

I would refer you to a viewpoint, an opinion article that was in last week's JAMA Oncology, authored by some authors from Tennessee Oncology, a very large group that is in OCM and actually is one of the few groups that have decided to go ahead and take two-sided risk, and yet the whole opinion is that they shouldn't be in a position where they have to do that and that the substitute should be pathway compliance as a way to control drug prices instead of putting a patient's financial viability completely at the risk of the flip of a coin based on who walks in their door.

I hope that answers the question.

CHAIR BAILET: Thank you, Jeff.

Grace, do you want to ask your next question?

VICE CHAIR TERRELL: Sure. And I'm going to call it the two I's for integration and innovation. And, first of all, with respect to integration, not only with this oncology proposal but with one that we had received earlier, there had been some not altogether positive comments from the public, from other oncology types of organizations, such as radiation oncologists, who were basically saying that they felt that it was really important to have something that was not just restricted to medical oncologists as we were thinking about models of care.

So that's the integration piece that seems to have been something that a lot of folks have objected to, although the specific problem you're solving for here is very specific to all of the issues around chemotherapy. So I understand that piece of it.

But having been the CEO of a multi-specialty medical group that had an oncology practice before OCM, trying to do some innovative stuff, there were some other types

of innovations that were -- that we did, such as embedding psychology in the middle of the practice, using pharmacy in a different way, having an oncology-only urgent care, where people with medical emergencies who are oncology patients could deal with things.

So one of the things I'm asking in all of this is, does this model adequately address the two I's, the ability to integrate with the larger -- to use the theme of this morning -- medical neighborhood of other oncologists or surgical oncologists for that matter that need to be involved with the care; and, number two, is it going to allow other types of innovation besides just that related to therapy in a way that would be rewarded in the payment system here?

MR. BOURBEAU: Yeah. Dr. Grubbs, would you like to mention some of your work with, you know, other oncology specialties and how they relate to this model? And then maybe I can address how fee-for-service helps innovation.

DR. GRUBBS: Yeah. Thanks, Dr. Terrell. Those are both important aspects of this model and a good question.

The first one I'll tackle. If you read through the PCOP proposal, you're right, it is concentrating on getting medical oncology's house in order to be able to provide better quality care and also bend the cost curve. But it is set up where other specialties in the oncology space can join in.

So I think our long-term vision is, yes, this would be attached to other types of Alternative Payment Models that might work very well for radiation oncology, and surgery and others. So I think the potential down the road is to bring together different specialties under one big tent and one Alternative Payment Model.

Having said that, I think there are issues that have to be worked out with our other specialists along the way that I know are working on right now certainly in radiation oncology. So I think the potential there is to come together, and over the years we have

discussed these Alternative Payment Models with our colleagues in other parts of the care team, because this is a multi-specialty treatment program.

So, yes, I do believe this is set up to be able to expand beyond our medical oncology part of it, but we'd certainly like to be able to feel that we have that worked out properly, so that's why this program really concentrates on that.

And then the other question you asked, and which I think is really an excellent one is, we're talking about drugs all the time, and we're talking about, did we pick the right treatment, did the patient get the correct treatment, but that's not the entire care delivery system. It's just one piece of it, and this program is set up and we build on the concepts of an oncology medical home that will need to incorporate all of those things you have just said to be sure that the care delivery for a patient and their family is optimal. And that includes having access to the care team around the clock, having access

when you're ill immediately, so you don't end up in the emergency room.

And you have to build those systems within your practice. You need to have nurse navigation. You need to have support in areas other than just treating the cancer. So, yeah, this system is built on that type of model of an oncology medical home.

There already is information out there on what the standards of that should be, and I have to tell you right now that we are in the process at ASCO, working with the colleagues in the Community Oncology Alliance, to actually update those standards, which I think you'll see published by the end of the year. So, yes, that's part of that.

And can I circle back, because I think you asked a really good question about pathways and you're concerned that it may actually slow down innovation of cancer care patients as new things come out. I think Dr. Polite gave you the example of how quickly genomics are put into it.

ASCO has actually looked at and defined what a high-quality cancer treatment pathway program system should look like and the types of things that need to be put into it, and one of them is rapid change in the pathway when new technology becomes available that is superior to the existing treatment.

So, in that regard, pathway compliance gets the physician and the practice on track as new technology comes out in a short amount of time.

And I have to, unfortunately, tell you that's one of the problems we have across the entire country in oncology. When new technology comes out, the adaption of that sometimes is too slow. So compliance on a well-designed, rapidly-changing pathway program solves that problem.

And on the other side of it, by being compliant with the latest newest treatment, it prevents stinting of care to patients, too. So I think you get the best of both worlds. You get rapid change with new technology, and you also protect patients from

stinting on care, because the physicians in this program will be measured on giving the right treatment at the right time, not having to pick between the cost of the drugs.

DR. WARD: Grace, I want to circle back to the question you had about innovation. I love the fact that you had psycho-oncology in your practice. We have it in ours. It's a great addition to what we do.

I remember, though, a number of years ago when we were pulling palliative care into our practice in the outpatient setting, I sat across from a CFO who said, "I will not pay for palliative care when it's a program that's going to decrease my ER utilization without making any money."

And in a fee-for-service world, it inhibits the ability to make that kind of innovation for that very reason. The things that you want to do that will decrease ER utilization and bring value to it are often things that are not paid for well in a fee-for-service world. That's why practices will move

to a Track 2, because when you're in Track 2, you have the ability to innovate.

I can now say, okay, if I can actually help my practice by decreasing ER utilization, that gives me the opportunity to say a psycho-oncology program or a palliative care program or an urgent care after-hours are all things that can help me achieve that, that I could not afford to do before that I can do now because I can take that money out of a very expensive ER and put into a lower cost program that will help change the cost curve.

VICE CHAIR TERRELL: I think I sat behind that same CFO, so --

DR. WARD: He is retired now. We have moved on.

MS. HARDIN: And I was the palliative care provider with you.

VICE CHAIR TERRELL: Thank you so much.

CHAIR BAILET: Are you done with your questions? I've got one.

VICE CHAIR TERRELL: I'm done. Thank you.

CHAIR BAILET: Great. So the Oncology Steering Committee clearly is -- as Jen mentioned, is an instrumental component of the proposal. They make a lot of decisions. They represent the stakeholders, and they are interwoven in pathway selection, quality outcomes, et cetera, and really are driving the success of this proposal.

Could you share a little bit more about how -- these steering Committees and your approach to forming them, how they are governed, you know, what's the composition? I know you touched on it a little bit in your proposal, but, you know, the big tent, which I think Brian mentioned, I'd like to get a little greater insight into how you see that coming together.

Thank you.

DR. WARD: Sure. Brian, do you want me to take that? I can talk a little bit about Washington State.

MR. BOURBEAU: Yeah. You can talk about Washington State. I'll talk about Cincinnati. We've done it in --

DR. WARD: Okay.

MR. BOURBEAU: I think we can do it in oncology. So, go ahead, Dr. Ward. Thank you.

DR. WARD: So in Washington State, you may be familiar with the work of HICOR[24], the Hutchinson Institute for quality outcomes, cancer outcomes research. They have actually been kind of the go-between that has allowed us to develop a collaborative between a large number of practices in our state and the payers to begin to share both payer data and cancer program data, to begin to look at things that bring value to our practice.

Vance developed a layer of trust and collaboration that we really think can be parlayed into being able to develop this kind of a network that could evolve into what we are describing. Certainly, it's going to require a collaboration and a degree of trust that we haven't had with payers before and that they haven't had with us. But I do think that the payers recognize that that is going to be

24 Hutchinson Institute for Cancer Outcomes Research

necessary and that building an infrastructure to develop their own sets of pathways to be able to shepherd us or herd us is something that will be a lot more difficult than working with us.

So I think that they are ready to come along and begin that collaboration. That is certainly what we've seen in our state, and we think that as providers I think we are beginning to realize that we actually have a lot more in common with the payers and what our goals are for our patients than pharma has sometimes, and that we can work together to bend the cost curve in ways that we could never do apart.

MR. BOURBEAU: Thank you, Mr. Ward.

Yeah. So I would, you know, mention that today the Acting Deputy Administrator and Director of Medicaid and the Deputy Administrator and Director of CMI, CMMI, release an informational letter to state Medicaid directors on how they can more get in the game of shift to value-based care.

And they mentioned a couple of strategies that states should apply. One is multi-payer participation, that we need alignment of multiple payers in order to, you know, achieve true value-based care and motivate providers to transform the care delivery systems.

And we need to adapt payment incentives and financial risk to the relative readiness of providers, especially for small practices and safety net providers. We need to promote advance HIT, including the ability of providers to exchange data with their state, and, importantly, stakeholder engagement. And that's multiple providers, that's multiple payers.

The letter mentions patients and -- as PCOP. One party I didn't see in that letter but is definitely in PCOP are employers. You know, as a provider, when activist employers say, "We want you to move on quality initiatives" or "We want to shift our network to value-based care," hospital systems definitely listen to that.

And so, you know, this is -- these PCOP communities are modeled after experience, for example, in Washington or experience in my own town here in Cincinnati where in primary care we brought together multiple payers, multiple providers, the activist employers, patient advocates, our health board, and so on, to set priorities for our community to discuss data, you know, exchange and benchmarking local to the community.

And, you know, I think that's where you really get -- drive high achievement of goals rather than a fractured, you know, system that we have today where I may have one set of quality metrics with Medicare and OCM but another with Aetna UHC, and so on.

CHAIR BAILET: Thank you. Thank you for that great answer.

I don't see any other questions from the Committee, but I'm giving our -- giving one more last call, if you will. If there is someone with a question, this would be a great time to speak up.

Hearing none, I, too, want to thank the presenters for attending today, but more importantly for putting this proposal forward and working closely with the PRT and the ASPE staff to get us to this place. We appreciate, Brian, you and your team, Drs. Ward, Grubbs, and Polite, and at this point we're going to transition over to the public commenters. But, again, thank you for your presentation and participating today.

MR. BOURBEAU: Thank you.

*** Public Comments**

CHAIR BAILET: As we transition now, we have two folks who have signed on for public comments, the first of which is Harold Miller, former PTAC Committee member. He is with the Center for Healthcare Quality and Payment Reform. Harold?

MR. MILLER: Hi, Jeff. Thank you. Can you hear me okay? I appreciate the opportunity to comment. I wanted to point out what I think are two unique and important aspects of this proposal that I don't think the Committee has adequately recognized so far.

One is that this model includes explicit protections against both undertreatment and disparities in care. All of the current CMS APMs include incentives to discourage overuse of treatment, but none of them have good methods of protecting patients against being undertreated.

The CMS Oncology Care Model gives physicians bonuses if they spend less on cancer treatment, but it has no mechanism for assuring that patients are receiving the most appropriate treatment. I want to emphasize that. The CMS model has no measures of appropriateness at all. None.

In contrast, the ASCO model would be the first APM of any kind to tie payment to clinical pathways that specify what treatments are appropriate based on both effectiveness and cost. This, by definition, avoids both overtreatment and undertreatment.

We should be particularly concerned about payment models that encourage undertreatment, given the substantial evidence

about the racial and ethnic disparities that exist in cancer treatment.

The ASCO model would actually help to reduce these disparities, since it requires that all patients receive appropriate care. And the reasons for any deviations from the recommended clinical pathways have to be documented, not hidden.

The second unique aspect of this model is how it would reduce spending on drugs, which is an issue that is getting a lot of attention these days. Some of the differences -- it differs in some substantial ways from OCM, and it's better than the Oncology Care Model. Some of those ways have been discussed. I wanted to highlight two that really haven't been discussed.

First, one of the problems with the oncology care model is it only counts Part B drugs in its measure of total cost, not Part D drugs. That creates a perverse incentive to use a more expensive Part D drug in place of a less expensive Part B drug. The use of the clinical pathways in the ASCO model actually

ensures the most appropriate drug is used, whether it is oral or infused.

Second, the ASCO model focuses separately and specifically on supportive drugs. If you don't work in oncology, you may have no idea how expensive some supportive drugs are. Neulasta, which is a white cell stimulating factor, is the number six drug on the Medicare Part B spending list. Medicare spent $1.4 billion on Neulasta in 2018, more than it spends on most types of chemotherapy.

There are studies showing that 30 percent or more of the patients who get Neulasta don't need it, and that represents hundreds of millions of dollars in potential savings. And that's not the only highly expensive supportive drug that is overused. That is a major opportunity for savings, and it exists in both Track 1 and Track 2 of this model.

The ASCO model not only focuses specifically on reducing unnecessary spending on supportive drugs, it also measures ED visit

rates in order to ensure that patients aren't being undertreated in the process.

I think the ASCO model is very different and superior to the CMS oncology model in many ways, but I think these unique components that I just highlighted are particularly important because they address some important national priorities right now, and they could also be used for APMs for patients with other kinds of conditions.

So I would strongly urge that you recommend the ASCO model, so that both oncology patients can benefit from this, and these kinds of techniques can be used in other areas, too.

Thank you.

CHAIR BAILET: Thank you, Harold.

Sandy Marks from the AMA.

MS. MARKS: Thank you. And, again, I'm Sandy Marks, and I'm making comments, again, on behalf of the American Medical Association.

Congress created PTAC in 2015 in MACRA because of widespread concern about the lack of physician-focused Alternative Payment

Models in Medicare, particularly for specialists. Unfortunately, five years later, there has been little progress in filling that gap, as we also discussed this morning.

Oncology, though, is the prime example. Every year, approximately one million senior citizens are diagnosed with cancer, and Medicare is spending about $70 billion a year for cancer treatment. But only five percent of oncology practices are participating in the Oncology Care Model, and the evaluation results to date have been disappointing.

The more than 2,700 other medical oncology practices across the country have no opportunity to participate in an APM that is designed for cancer care, and they would be unlikely to enroll or succeed in something like OCM.

The Patient-Centered Oncology Payment Model developed by ASCO would fill this critical gap. Unlike the OCM, PCOP was designed by oncologists to enable them to improve the quality of care for patients, as well as control Medicare spending. Because it

specifically addresses the problems with both current payment systems and OCM, we expect oncology practices will participate in PCOP not just willingly but enthusiastically.

PCOP has many of the same strengths that led PTAC to unanimously recommend testing of the MASON oncology payment model last year. Moreover, the two models are complementary, not duplicative. PCOP could be implemented by many oncology practices across the country, and it could also help practices successfully transition to a model like the MASON model.

Although it was appropriate for the PRT to identify the areas of uncertainty regarding PCOP's impacts on quality and cost and participation by other payers, these uncertainties exist in every payment model. And as with other proposals, the only way to definitively resolve them is to actually implement and evaluate PCOP.

The AMA believes that the many strengths of PCOP far outweigh the concerns that the PRT identified, and that PCOP has

significant potential benefits for both the Medicare program and for patients with cancer.

We strongly urge PTAC to recommend its implementation. Thank you.

CHAIR BAILET: Thank you, Sandy.

I am going to ask the operator, those are the two folks who signed up, is there anyone on the line that has also raised their hand to provide a public comment?

PARTICIPANT: No other comments.

CHAIR BAILET: All right. Thank you.

So that concludes the public comment section. I would turn to my colleagues on the Committee. Are we ready to vote on the 10 criterion? I'm getting some telepathic yeses here.

DR. SINOPOLI: Yes.

*** Voting**

CHAIR BAILET: So we're going to go ahead and open up our electronic application here and start the voting process.

All right. Let's go ahead and start, and we have -- with Jay back, we're

going to have nine folks voting on the proposals on the criteria. So we're going to go ahead and start with number 1, which is scope.

* **Criterion 1**

The aim is to either directly address an issue in payment policy that broadens and expands the CMS APM portfolio or include APM entities whose opportunities to participate in APMs have been limited. Please vote.

Audrey, please?

MS. MCDOWELL: Zero members voted 6, meets and deserves priority consideration; one member voted 5, meets and deserves priority consideration; zero members voted 4, meets; three members voted 3, meets; five members voted 2, does not meet; zero members voted 1, does not meet; and zero members voted zero, not applicable.

The votes roll down until a majority is met, which in this case is five votes, and so the majority has determined that the proposal does not meet Criterion 1, scope.

* **Criterion 2**

CHAIR BAILET: Thank you, Audrey.

Moving on to Criterion 2, quality and cost, which is also high priority. Anticipated to improve health care quality at no additional cost, maintain health care quality while decreasing cost, or both improve health care quality and decrease cost. Please vote.

Audrey, please.

MS. MCDOWELL: Zero members voted 6, meets and deserves priority consideration; one member voted 5, meets and deserves priority consideration; zero members voted 4, meets; two members voted 3, meets; six members voted 2, does not meet; zero members voted 1, does not meet; and zero members voted zero, not applicable. So the majority has determined that the proposal does not meet Criterion 2.

* **Criterion 3**

CHAIR BAILET: Thank you, Audrey.

Let's go to payment methodology, Criterion 3, which is high priority as well. Alternative Payment Model entities with a

payment methodology designed to achieve the goals of the PFPM criteria.

Address in detail through this methodology how Medicare and other payers, if applicable, pay APM entities, how the payment methodology differs from the current payment methodologies, and why the physician-focused payment model cannot be tested under current payment methodologies. Please vote.

Audrey?

MS. MCDOWELL: Zero members voted 6, meets and deserves priority consideration; one member voted 5, meets and deserves priority consideration; zero members voted 4, meets; one member voted 3, meets; seven members voted 2, does not meet; zero members voted 1, does not meet; and zero members voted zero, not applicable. So the majority has determined that the proposal does not meet Criterion 3, payment methodology.

*** Criterion 4**

CHAIR BAILET: Thank you, Audrey. Moving on to Criterion 4, value over volume.

Provide incentives to practitioners to deliver high-quality health care. Please vote.

Go ahead, Audrey.

MS. MCDOWELL: Okay. Zero members voted 6, meets and deserves priority consideration; one member voted 5, meets and deserves priority consideration; three members voted 4, meets; five members voted 3, meets; zero members voted 2 or 1, does not meet; and zero members voted zero, not applicable. So the majority has determined that the proposal meets Criterion 4.

*** Criterion 5**

CHAIR BAILET: Thank you, Audrey.

We're going to move to flexibility, Criterion 5. Provide the flexibility needed for practitioners to deliver high-quality health care.

Audrey?

MS. MCDOWELL: Zero members voted 6, meets and deserves priority consideration; zero members voted 5, meets and deserves priority consideration; six members voted 4, meets; three members voted 3, meets; zero members

voted 2 or 1, does not meet; zero members voted zero, not applicable. So the majority has determined that the proposal meets Criterion 5.

* **Criterion 6**

CHAIR BAILET: Thank you, Audrey.

And Criterion 6, ability to be evaluated. Have valuable goals for quality of care costs and other goals of the PFPM. Please vote.

Audrey?

MS. MCDOWELL: Zero Committee members voted 6 or 5, meets and deserves priority consideration; one member voted 4, meets; one member voted 3, meets; six members voted 2, does not meet; one member voted 1, does not meet; zero members voted zero, not -- zero, not applicable. So the majority has determined that the proposal does not meet Criterion 6.

* **Criterion 7**

CHAIR BAILET: Thank you, Audrey.

Criterion 7, integration and care coordination. Encourage greater integration

and care coordination among practitioners and across settings where multiple practitioners or settings are relevant to delivering care to the population treated under the PFPM. Please vote.

Audrey?

MS. MCDOWELL: Zero members voted 6 or 5, meets and deserves priority consideration; two members voted 4, meets; seven members voted 3, meets; zero members voted 2 or 1, does not meet; and zero members voted zero, not applicable. So the majority has determined that the proposal meets Criterion 7.

* **Criterion 8**

CHAIR BAILET: Thank you, Audrey.

We are going to move to patient choice, Criterion 8. Encourage greater attention to the health of population served while also supporting the unique needs and preferences of individual patients. Please vote.

Audrey?

MS. MCDOWELL: Zero members voted 6 or 5, meets and deserves priority consideration; six members voted 4, meets; three members voted 3, meets; zero members voted 2 or 1, does not meet; and zero members voted zero, not applicable. So the majority has determined that the proposal meets Criterion 8.

* **Criterion 9**

CHAIR BAILET: Thank you, Audrey.

And Criterion 9, patient safety. Needing to maintain or improve standards of patient safety. Please vote.

Audrey?

MS. MCDOWELL: Zero members voted 6, meets and deserves priority consideration; three members voted 5, meets and deserves priority consideration; five members voted 4, meets; one member voted 3, meets; zero members voted 2 or 1, does not meet; and zero members voted zero, not applicable. So the majority has determined that the proposal meets Criterion 9.

* **Criterion 10**

CHAIR BAILET: Thank you, Audrey.

And the last criterion, Criterion 10, health information technology. Encourage use of health information technology to inform care. Please vote.

Audrey?

MS. MCDOWELL: Zero members voted 6 or 5, meets and deserves priority consideration; six members voted 4, meets; three members voted 3, meets; zero members voted 2 or 1, does not meet; zero members voted zero, not applicable. So the majority has determined that the proposal meets Criterion 10.

CHAIR BAILET: Thank you, Audrey. Do you want to just provide a summary of our voting for the 10 criteria, please?

MS. MCDOWELL: The Committee finds that the proposal meets six of the 10 criteria relating to Criterion 4, value over volume; Criterion 5, flexibility; Criterion 7, integration and care coordination; Criterion 8, patient choice; Criterion 9, patient safety;

and Criterion 10, health information technology.

The Committee voted that the proposal does not meet the remaining four criteria: Criterion 1, scope; Criterion 2, quality and cost; Criterion 3, payment methodology; and Criterion 6, ability to be evaluated.

* **Overall Vote**

CHAIR BAILET: Thank you, Audrey.

We are now -- if there are any comments the Committee wants to make before we move on to actually voting on the first cut of the recommendation to the Secretary, which is not recommend implementation, recommend with subcategories, which will be the follow-on vote, and then referred for other attention by HHS.

So are we ready to move forward? Looks like we are. So we're going to go ahead and vote.

Audrey?

MS. MCDOWELL: So three members voted to recommend -- excuse me, to not

recommend the proposal, two members voted to recommend the proposal, and four members voted to refer the proposal. At this point, we need to have a supermajority, which would be a two-thirds majority, which would be six votes.

Right now, you don't have six votes in any bucket, and so I would ask the Chair if the Committee would like to talk some more.

CHAIR BAILET: Well, I think -- I think we do. And what I'd ask is I'll call on individuals, and we can share how we voted individually and the reasons why, and potentially that information will help bring us to the point where we can revote.

So I'm going to go ahead and call on Angelo first, and then I'll just work through the Committee members, starting with you, Angelo. Thank you.

DR. SINOPOLI: So thank you. Can you hear me?

CHAIR BAILET: Yes.

DR. SINOPOLI: So I voted to not recommend, and I voted on that on the basis of that the three highest priority criteria, we

all voted -- or the vote was majority does not meet criteria.

As we discussed, it doesn't add to the portfolio, that CMS CMMI has today. And there were certainly cost issues and questions around the ability to evaluate this model. And so certainly did not meet the criteria to meet or recommend. And I wasn't sure that referring it to attention by Health and Human Services was going to add any value or anything else that we might be considering. So --

CHAIR BAILET: Thank you, Angelo.

Paul?

DR. CASALE: Yeah. Thanks, Jeff. So I went with refer for their attention, but my reasoning was similar to Angelo's. I was going back and forth between one and three, meaning should I do not recommend but then highlight that I think there are some pieces of the model that I think CCMI and HHS should consider as they are thinking about oncology care models in general?

So whether I put it in the not recommend or the -- when I put in refer, it was

really with the same message that I think there are some issues. Angelo brought up several of them, which I agree with, and also the Oncology Steering Committee challenges as well.

So that was my thinking. I could have either gone with -- I would have had the same message either going with not recommend or refer.

CHAIR BAILET: Paul, thank you.

Bruce?

MR. STEINWALD: I voted to not recommend, but I really am feeling pretty much along the same lines as Paul. I'm very -- I'm not comfortable with the not recommend choice, even though I think it's dictated by the results of the voting. But I'm very interested to hear more about what others think could be in a referral.

And I agree that there are elements of the proposal -- it's a serious proposal, it's got a lot in it. There may be elements that we would want CMS to pay attention to as they further develop their own portfolio of cancer models.

So I'm interested to hear what others have to say.

CHAIR BAILET: Thank you, Bruce.

Let's go ahead, Grace, please.

VICE CHAIR TERRELL: So I've been the outlier on all of these votes that has been pressing the fives and fours, and I did vote to recommend. And, really, it has to do with our new process where if you vote to recommend, within the context of that, there are options out there that basically say to look at it within the context of another planned CMMI model, or, you know, to do it within the context of testing.

So I believe many of the same things you all do with respect to there is complexity to it, hard to understand whether various aspects might work. But I actually think this is one of the most crucial issues that need to be solved for, which is, how do you make sure that chemotherapy, which is so important as we take care of patients in this country, is neither stinted on nor a source of excessive

profit, and, therefore, overused in a population that is vulnerable.

And both are potentially things that can happen in our current fee-for-service payment system. So I thought that the focus on, you know, evidence-based medicine that was rapidly able to be sort of fixed in real time solved for a lot of those, and is something that CMS really, really ought to think about within the context of how it will continue to evolve its Oncology Care Model after it I guess, you know, sunsets the current program in the end of 2022.

I thought that Harold Miller's comments were true, that the current system does not necessarily focus on what to do about stinting. But the fee-for-service system, quite frankly, doesn't focus on what to do about excessive chemotherapy. So this was really focused on something that really crucially needs to be dealt with within our current health care system, and I thought they had some -- I thought they were very thoughtful

with their answers to my questions, as well as the rest of yours.

So if we go down the path, as it looks like we are going to, of refer, I want to be very clear from my point of view what that referral needs to be focused on, or the things in this model that I do think address and solve for some of the problems in the current oncology model.

We heard in the MASON proposal previously similar things, that there were things that just weren't working, and we know that from some of the results coming out that we do see that there are things that CCMI is wanting to solve for.

So if we're going down the referral route, I'm okay with that. But we need to make sure that it's very clear from the report that comes out that they are thoughtfully addressing one of the crucial issues in the payment system.

CHAIR BAILET: Okay. Thank you for those comments, Grace.

Jennifer?

DR. WILER: I think's interesting because many of us, you know, have voted differently, yet have similar reasons for our excitement about the proposal.

My vote was aligned actually to Paul's, in thinking that because our high -- and then also Angelo -- if we are not able to support high-priority areas, I felt that I could not vote for one, but I agree with Grace's comments completely that there are a number of features in this model that are interesting and attractive and also agree that there is a concern that the current model or models that exist are not fulfilling the desire by the provider to the community to participate in a meaningful way. And they are identifying opportunities to do so. That's why my suggestion or my vote was for refer for attention.

With regards to the points that I will make now, there's three areas. One is what Harold described around the benefits of pathways. We had a similar discussion within a protocol, and I'm excited to see that there is

now peer-reviewed literature that are showing the value of adherence to care pathways, and also the thoughtful discussion that presenters and submitters made with regards to flexibility, because, as we know, pathways are based on best evidence, then on consensus, and then on local resources. And so there has to be flexibility to continue to reevaluate them.

The other point made around community that this proposal makes is around the value of community engagement in care delivery models, which I think is -- has its own unique features in its submission, which I think it's important to us to note.

And then, finally, the comments about cost of drugs and why, you know, this model -- I would not call it radically different, but when you look at the total spend, one might use the word "radical."

But the idea that there is an expansion of inclusion of drug costs, which obviously then because providers don't -- may not control some of that cost, there is still room to take on the risk because no other

decisions around prescribing are within their purview.

And so the recognition of expansion of the definition of drug costs is one that is valuable and comprehensive.

Thank you.

CHAIR BAILET: Thanks, Jen.

Lauran?

MS. HARDIN: I voted not recommend, primarily rooted in not understanding fully what "refer" means. What I would ideally like to see is the elements that they identified around the flexibility in payment, the community-based collaboration, and the patient-centered approach, and staging around how they've staged the risk, that they are actually partnering with CMS as they are redesigning that OCM model, integrate some of those unique elements.

I thought Harold Miller's comments were really compelling, and ideally that's what I would like to see happen. But as a new member, I wasn't sure what "refer" actually means.

CHAIR BAILET: Thank you. Thank you, Lauran. We're going to have a discussion about that at the end of this.

I go with Josh, and then Jay.

DR. LIAO: Great. So I won't, Jeff, belabor the point. I think I share a number of the views that other Committee members have expressed. I voted three, refer, for many of the same reasons. Just stepping through them, I thought -- I did not vote one, not recommend, because I thought that the issues that this model, as I perceive it, tried to address for importance.

I think Grace said it well as well, that cancer care and chemotherapy are key, as evidenced by models that are being considered and focused on. So I thought there were issues to raise to HHS as that focus continues.

As others have said, whether that's through kind of option three here or another means, I'm open to that.

The reason I couldn't vote to -- I think others have echoed also -- is that I thought around the high-priority areas, these

were the fundamental ways in which this model is created that it wasn't, you know, using another number, tweaking something here on a second or third order. There were fundamental ways that limited this model as proposed.

And I would say the connection here is that I think the key parts of the model actually don't necessarily address. They could, but they don't, so they -- that's actually the issue that others have mentioned, which I think should be referred as points for attention.

So those are from your three -- one, kind of engaging more oncologists across the spectrum and the patients they care for; two, disparities; three, stinting. I think these are key. I think we should signpost them. But I think that this model, as I understand it, doesn't fundamentally address those. So I voted three.

CHAIR BAILET: Jay, you're up.

DR. FELDSTEIN: Well, I guess the beauty of going last is that everybody else

voices your viewpoint at some point in time. So I'm a combination between Lauran and Grace.

I didn't want to not recommend it, but not fully understanding "refer," I went with recommend. I think there are some, you know, really valid points to this model that are unique. I like the fact that it, you know, really discounts costs, because they don't control it, and try to get -- you know, we've been -- in my past life trying to get oncologists engaged in this area for 25 years.

So, you know, anything that we can do to increase oncology engagement around, you know, pathways I'm in favor of, and that we need to push.

CHAIR BAILET: All right. Well, thanks, Jay. You're not the last. I'm in a -- I'm going to take up the rear here, but I voted to refer. And just for the newer Committee members, I'll share with you my perspective on refer.

Refer is not -- and you've heard me say this at the Committee before -- where you sort of -- the Raiders of the Lost Ark, the

last scene where they are pushing, you know, the ark into that great mass warehouse. Refer is not sending it into a tarpit or a sinkhole. I would say, you know, my feeling about this is this needs to be referred with high priority, as Grace has said.

There are very -- there are several elegant and important components within this -- within this proposal, not the least of which is evidence-based pathways and adhering to them and having to explain in writing when you deviate from agreed-upon care pathways that have been demonstrated to be successful.

The clinical community -- creating that clinical community of stakeholders, but also other critically important stakeholders, employers being one, who are often writing the checks and funding a lot of the oncology payments in this country, I think what intrigues me is those kinds of infrastructure accomplishments that would be necessary to drive this model, like the HIE data-sharing, the all-payer claims database, establishing those communities, that infrastructure can then

be used to power other proposals, other Alternative Payment Models, that will be introduced.

It has been a conundrum for CMS and CMMI, and for this Committee, frankly, as we think about how to implement these models. But having that infrastructure actually built out and those tracks laid will be very, very helpful, and I think there is enough -- enough of a compelling argument that this model drives forward that would create the impetus to build those -- that infrastructure. And I would hope that the Secretary and CMS and CMMI would pay particular attention to those elements.

I appreciated Harold and Sandy's comments. Undertreatment is key, and often I won't say invisible, but it's very hard, it's very oblique, it's hard to discern when that's occurring. And I think that this model addresses that.

So I firmly believe -- I have high hopes for this model, and I think that referring it is not -- is anything but pushing it into, you know, obscurity, but actually

putting it in a position where and making a recommendation where CMS, CMMI, and the Secretary can actually take this -- take these components and build them out in an appropriate way to get a model in the field as the Oncology Care Model sunsets here in the next year.

So I hope that helps. If there is other comments now, you know, having heard everybody share their perspectives, before we revote, because we do need to revote, are there any other comments from the Committee members before we take on revoting?

VICE CHAIR TERRELL: I've got one, and I see other hands up. I don't know if they just put their hands down and -- or forgot to or whether I'm jumping the gun, but I'll go ahead and jump the gun. And that is, based on what I just heard in this conversation was we got stuck in the original way that this high-priority language was, you know, constructed from, you know, the original stuff that came out of the Secretary's office, HHS, back in 2015, and that we have all said there are

elements of this that really must be considered and, you know, part of what goes forward.

But yet we would get stuck on the word "recommend." Recommend seems to be something close to implement in our heads now. And if you don't have these high priorities, you can't recommend. I think some of that is semantics, which is why we were all over the place with this.

And after this conversation -- I'll just let everybody know, I'll go ahead and move it to refer, because I don't think I'm going to get a whole bunch of you to move it to recommend, but at some point we need to think, maybe deliberate, in public about what "recommend" means with respect to if it flunks a high priority and whether that entire criteria needs to be broadened, so that it's either not recommend or recommend where something that includes referral is part of that.

At one point, we -- for the newer members, we were talking about referral, something that came forward, and it was like it

really wasn't part of an Alternative Payment Model. It was somebody had a clever idea for something in fee-for-service or, you know, something like that.

You know, there was the not applicable category, which was this isn't even in our, you know, purview of what, you know, we were responsible for under the statute. And then there was the refer because it was something interesting, but not really what we were doing.

So this a broader conversation for later on, but I do think that what happened today with this particular one is an example that we need to think a little deeper about it going forward.

CHAIR BAILET: Thank you, Grace.

I don't see hands up, but I just welcome Committee members to please speak up if you have additional comments. Josh? Bruce?

DR. LIAO: Yeah. Josh, I'll go next maybe.

I think echoing, again, the sentiments around kind of the pieces are

important. The way I put it together was that, you know, the key colors of a model are important, and then the -- kind of the glue that holds it together, how it is pieced together really matters as well.

I can look at pathways and say that is a clear -- maybe for lack of a better word -- innovation. So the question is: if we deploy in a way where every Committee can pick different ones, right, then that's a part of how is it implemented that I think makes a big difference.

We want to disrupt fee-for-service. I've heard that phrase mentioned a few times. But if there is no clear one way to Track 2, what does fee-for-service disruption look like in that way? So I think it's the way that these come together for me that is really important.

And on the issue of disparities, since it was mentioned in public comment, I think many of us have mentioned it, I'll just highlight that in a model like this that oncologists in practice would sign up for,

there are layers to this thing, right? As Jeff mentioned, it's oblique, it's hard to capture. Think about kind of the geographic representation. Not every place have High Core, like Washington State, and so where practices adopt this model, whatever benefits are there, if there are those benefits, people may be excluded from getting them in the first place. And then once you step through that level, the question is, do you get treatment? And that, then, is on pathway.

So there is only two, three, four layers here that I think speak to this issue of, can we highlight the issue but that how it's fashioned together really makes a difference. And I just want to share that.

CHAIR BAILET: Thanks, Josh.

Bruce, did you have a comment?

MR. STEINWALD: My comment is I think the people who have rationales for wanting to refer make very good points, and I'm ready to revote.

CHAIR BAILET: Okay. Thank you, Bruce. Thank you, Committee members.

Adil, let's go ahead and open it back up for revoting. Thank you.

I don't think -- I think we are actually past this point, aren't we? My screen glitched out. I'm sorry. Didn't mean to confuse you guys. Sorry.

Has everybody voted? Because I only see eight. Thank you. Audrey?

MS. MCDOWELL: So on the revote, all nine members voted to refer the proposal for other attention by HHS.

CHAIR BAILET: Thank you, Audrey.

*** Instructions on the Report to the Secretary**

CHAIR BAILET: I think this is -- this has been really helpful, and I think the next part of our meeting is critically important. A lot of us have already made comments, so I'm not asking for people to repeat them. But if there are areas of emphasis that we want the ASPE folks to hear and the public to hear that will be incorporated in the Secretary's letter, this

would be a good time to share your point of view.

If it's -- I'll just go around and maybe start with myself. I think I was -- I think I was pretty clear that refer -- that I would like to see this referred on with a high priority because of the comments that I made earlier, everything from infrastructure establishment to care pathways and holding people accountable, and the fact that this is much more expansive for oncology care beyond the cost of drugs.

Those are my points, and maybe I'll turn it over to you, Grace, and then I'll just run through the Committee. Thanks.

VICE CHAIR TERRELL: I think I've made my opinions pretty clear in the previous discussion. But I really like this new category that you've made of referral with high priority, Jeff, because it's not anything that we've used before, but I think that we should basically make sure that in our sentences that that is bold-faced when we write to the Secretary and say, "We refer this with high

priority" for all the reasons that I and you and everybody else has already articulated.

CHAIR BAILET: Thank you, Grace.

Jen, do you want to go next?

DR. WILER: The only other additional comment I would make, because we had so much conversation around pathways, is in innovation. This was surfaced by the submitters, and it didn't come up here, so I want to acknowledge it. And that's the idea that choosing to go off pathway should not be the path of least resistance.

So documenting pathway not appropriate is something that would create some unintended consequences. The submitters described an intent to have a majority of patients on pathways, and that there are products in the marketplace where that is feasible, and then we have some data in the materials Stephen referred to, you know, around rates, their expectation where rates of adherence would be 80 to 90 percent. And so I just want to acknowledge that.

Thank you.

CHAIR BAILET: Thanks, Jen.

Jay, do you want to go next?

DR. FELDSTEIN: I don't have anything else to add, Jeff, than what I said earlier and the other comments.

CHAIR BAILET: Jay, do you want to go next?

DR. FELDSTEIN: No. What I said was I don't have anything else to add.

CHAIR BAILET: Thank you, Jay.

Bruce, anything?

MR. STEINWALD: Nothing to add.

CHAIR BAILET: Yeah, I got that. And thank you.

Bruce, go ahead. Nothing to add? All right.

Lauran? Lauran?

MS. HARDIN: The only thing I would add is when they called out the five percent participation rate in OCM, I think this model seems like it comes deeply from the medical oncologists themselves, which may increase participation if their ideas are incorporated.

CHAIR BAILET: Thanks, Lauran.

Josh?

DR. LIAO: Yeah. I'll just be very brief to make one other point I think we've talked about, but from my perspective clear, which is that I think -- I would hope the referral with high priority identifies the issues that this proposal seeks to address.

I think it's important to recognize kind of balancing what's the best way to get there, and it's not clear to me that the key coming together, the components of this put together, is a way to get around some of these issues.

So I think as HHS has considered these issues, maybe starting from a broader level to think about all of the options would be wise.

CHAIR BAILET: Thank you. Thank you, Josh.

Paul?

DR. CASALE: Yeah. Only one thing to I guess be sure to emphasize or at least acknowledge. The concept of the Oncology Steering Committee, although I think somewhat

problematic in the proposal, I think is something -- the sentiment of a multi-stakeholder group I think is important for further exploration by CMMI, HHS, as I think identifying a role within a model would be of interest.

CHAIR BAILET: Thank you, Paul.

Folks, can you hear me okay?

PARTICIPANT: You're breaking up a little bit.

VICE CHAIR TERRELL: You're just breaking up, but you're -- you're still there.

CHAIR BAILET: Hmm. Okay. I'm going to have -- just take a minute and just close this out.

PARTICIPANT: What?

MS. MCDOWELL: Actually, Jeff --

VICE CHAIR TERRELL: If Jeff can't do it, I see the --

CHAIR BAILET: You guys keep unmuting.

VICE CHAIR TERRELL: If he can't do it, I can -- I see the script in front of me, Audrey, and I can read it.

*** Administrative Matters**

MS. MCDOWELL: Right. Well, I actually also have one piece of unfinished business from the morning that I wanted to address. So whenever you're ready for that.

CHAIR BAILET: Right. Well, go ahead, Audrey, and then we'll try and wrap this up. Thank you.

MS. MCDOWELL: Sure. So in our -- in our --

CHAIR BAILET: Go ahead, Audrey.

MS. MCDOWELL: Sure. Relating to our deliberation on the --

CHAIR BAILET: Go ahead.

MS. MCDOWELL: Sorry. Can you hear me? Relating to our deliberation on the ACP NCQA proposal in the morning, when we did the revote, we did not confirm the previous votes of a few of the Committee members who had changed their votes. And so I wanted to just, for purposes of the completeness of the transcript, to confirm which of the Committee members had changed their votes when we did the

vote on the overall recommendation in the morning.

And so in the morning we had -- the final vote was that we had one Committee member who recommended further developing the proposal and seven who recommended testing the proposal as specified in PTAC comments. And so to the extent that you remember, if you changed your recommendation, could you provide that information?

For example, there was one person who had originally recommended implementing the proposal as a payment model, and then they changed their vote. Do you recall who that person was?

CHAIR BAILET: Audrey, can you hear me?

MS. MCDOWELL: Yes.

CHAIR BAILET: I believe I was the one outlier there in both instances.

MS. MCDOWELL: Okay. So Jeff was the one who voted to recommend implementing as a payment model.

Okay. There was one person who -- one additional person during the first round who had voted to recommend further development -- developing and implementing the proposal as a payment model.

As specified in PTAC comments originally, we had two in that category. And when we revoted, we only had one in that category. Is there anyone who --

MR. STEINWALD: That was me, Audrey. It's Bruce. I changed my vote from two to three.[25]

MS. MCDOWELL: Okay. Thank you.

All right. And then we had one person that had originally voted in Category 4, PTAC recommends implementing the proposal as part of an existing or planned CMMI model.

VICE CHAIR TERRELL: Grace. That was me.

MS. MCDOWELL: Okay. All right. Thank you very much. That's very helpful, just for the sake of having a complete record for

25 Kavita Patel also changed her vote from two to three.

the transcript and for purposes of our voting documentation. So thank you very much.

VICE CHAIR TERRELL: Jeff, are you back up and running now? If you're not, I'm just going to take it from you here.

CHAIR BAILET: Well, if you -- can you see me? And can you hear me?

VICE CHAIR TERRELL: No. I can see you sometimes, and your voice is still lagging a little.

CHAIR BAILET: Can you hear me?

VICE CHAIR TERRELL: I can hear you now. But then I didn't.

All right. Angelo did not get a chance to actually add final comments. I'm getting --

CHAIR BAILET: Go ahead.

VICE CHAIR TERRELL: -- a message.

CHAIR BAILET: Go ahead, Grace.

VICE CHAIR TERRELL: I already have, Jeff.

DR. SINOPOLI: Thank you. So I don't really have anything to add. I think capturing all the comments on the discussion

that resulted in the changes in votes was very thorough and hopefully somebody captured all of those comments. So thank you.

*** Closing Remarks**

VICE CHAIR TERRELL: Okay. Jeff, there's still a lag, so I'm going to finish it out here.

Just want to thank everyone for your attention at today's public meeting. It's not easy to do an all-day-long virtual meeting, particularly if you're Jeff in San Francisco and having all sorts of issues out there right now.

But anyway, we do want to encourage all of you here tomorrow for our first-ever theme-based discussion. It's going to be centered around telehealth. If you're registered for the second day of the public meeting, you will receive the meeting Webex link, password, and log-in information to join via email tomorrow morning, along with an overview presentation and a list of panelists for tomorrow's panel discussions.

Registration for tomorrow will remain open through the meeting tomorrow, so please join us if you find you have time during the meeting. We look forward to welcoming previous PTAC proposal submitters and subject matter experts to learn more from the field about how telemedicine may impact Alternative Payment Models.

So tomorrow's half-day public meeting will begin at 7:00 a.m. Pacific Time, 10:00 a.m. Eastern Time, and the meeting is available by a livestream at www.hhs.gov/live.

And thank you very much, and take care. The meeting is adjourned.

(Whereupon, at 4:10 p.m., the above-entitled matter went off the record.)

C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: Advisory Committee Virtual Meeting

Before: PTAC

Date: 09-15-20

Place: teleconference

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

Neal R Gross

Court Reporter