PHYSICIAN-FOCUSED PAYMENT MODEL TECHNICAL ADVISORY COMMITTEE (PTAC)

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PUBLIC MEETING

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The Great Hall
The Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

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MONDAY, DECEMBER 10, 2018
12:30 p.m.

PTAC MEMBERS PRESENT

JEFFREY BAILET, MD, Chair
GRACE TERRELL, MD, MMM, Vice Chair
PAUL N. CASALE, MD, MPH
HAROLD D. MILLER
LEN M. NICHOLS, PhD
ANGELO SINOPOLI, MD*
BRUCE STEINWALD, MBA
JENNIFER WILER, MD, MBA

STAFF PRESENT

SARAH SELENICH, Designated Federal Officer (DFO), Office of the Assistant Secretary for Planning and Evaluation (ASPE)
STEVEN SHEINGOLD, PhD, ASPE
JULIA DRIESSEN, PhD, ASPE

*Present via telephone

A-G-E-N-D-A

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

12:34 p.m.

CHAIR BAILET: All right. We're going to go ahead and start. So good afternoon and welcome to this public meeting of the Physician-Focused Payment Model Technical Advisory Committee, known as PTAC. Welcome to the members of the public who are able to attend in person, and also welcome to those on the phone or over the live stream. Again, thank you all for your interest in this meeting.

This is PTAC's sixth public meeting that includes deliberations and voting on proposed Medicare Physician-Focused Payment Models submitted by members of the public. This meeting also marks two years of the PTAC being open for business and available to receive models from the public.

Over the last two years, including the proposal we will deliberate on today, we have received 28 full proposals. We thank the community of stakeholders who have put in the

time and energy to submit these proposals. Your hard work and dedication to improving our health care system is greatly appreciated.

I have some updates I would like to share with you before our deliberations get underway. First, you may notice some new faces around the table. Well, we have one new face. That's Dr. Jennifer Wiler who comes from the University of Colorado School of Medicine. She's an emergency medicine physician.

So welcome, Jennifer.

We also have on the phone our second new member of the PTAC Committee, and that is Angelo Sinopoli, who's an internist by training and comes to us Prisma Health and the Care Coordination Institute in South Carolina. He unfortunately -- his flight was snowed in, but he is active and fully engaged and participating in today's meeting.

These folks have already hit the ground running. Both are already active on Preliminary Review Teams looking at new models

that we recently had submitted to the Committee.

In addition, I'd like to acknowledge Dr. Grace Terrell, who has recently agreed to serve as the PTAC Vice Chair. Having worked with Grace on the Committee for the past three years, I know the Committee will greatly benefit from her leadership, her expertise and also her creativity in her new role. Emphasize creativity.

So the member of PTAC have been hard at work since our last public meeting in September. In addition, the proposals we'll be reviewing today our Preliminary Review Teams are actively reviewing four proposals. You also may remember that earlier this year we issued a request for public comments on processes and requirements. A summary of the public comments and actions the Committee is asking to take as a result can be found on the ASPE PTAC web site.

Today we will also be debuting new voting categories for our overall recommendations to the Secretary. We believe that these voting

categories which are more descriptive will be able to better reflect our deliberations and recommendations to the Secretary. After we vote on whether the proposal meets each criterion, we will proceed to vote on our overall recommendation to the Secretary.

First, we will vote using the following three categories: Not recommended for implementation as a Physician-Focused Payment Model. The second category is recommend, and the third is referred for other attention by HHS.

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

The second vote uses the following four subcategories: First, the proposal substantially meets the Secretary's criteria for PFPMS. PTAC recommends implementing the proposal as a payment model.

Second, PTAC recommends further developing and implementing the proposal as a payment model as specified by the PTAC comments.

Third, PTAC recommends testing the proposal as specified in PTAC comments to inform payment model development.

And fourth, PTAC recommends implementing the proposal as part of an existing or planned CMMI model. We need a two-thirds majority for one of these four categories.

Today we will deliberate on one proposal before we host a general public comment period. To remind the audience, the order of activities for the proposal is as follows: First, PTAC members will make disclosures of potential conflicts of interest and announce whether they will not deliberate and vote on the proposal.

Second, discussion of the proposal will begin with a presentation by the Preliminary Review Team. Following the PRT's presentation and some initial questions from PTAC members, the

Committee looks forward to hearing comments from the proposal submitter and the public. The Committee will then deliberate on the proposal. As the deliberation concludes, I will ask the Committee whether they are ready to vote on the proposal.

If the Committee is ready, each Committee member will vote electronically on whether the proposal meets each of the Secretary's 10 criteria. This voting has not changed from prior public meetings. The last vote will be on an overall recommendation for the Secretary of Health and Human Services using the new two-part voting system I just described.

And finally, I will ask each PTAC member to provide any specific guidance as ASPE staff -- or to ASPE staff on key comments they would like to include in the report to the Secretary.

A few reminders as we begin discussions today. One, PRT reports are reports from three PTAC members to the full PTAC and do

not represent a consensus or position of the PTAC. These PRT reports are not binding. The full PTAC may reach a different conclusion from those contained in the PRT report. And finally, the PRT report is not a final report to the Secretary of Health and Human Services. After this meeting PTAC will write a new report that reflects the deliberations and decision of the full PTAC which will then be sent to the Secretary.

Our job is to provide the best possible recommendations to the Secretary, and I expect that our discussions this afternoon will accomplish this goal.

I would like to take this opportunity to thank my PTAC colleagues, all of whom have given 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 meeting in person, via live stream or on the phone.

So before we get started I would like to follow up to a discussion that we had at the last public meeting which was providing an update on the status of the Secretary's response to our discussion around the models that we've already approved and what CMMI -- what activities CMMI has been doing to date. We just concluded an administrative call with the Director of CMMI Adam Boehler who we have been speaking to between the last meeting and today.

There are models in flight that are based on the submissions from the proposers that are going through the approval process now. We're not certain of the exact timing on when these models will actually be announced, but we anticipate that it will be sometime in the first quarter of 2019, of next year.

Some of the categories that are under consideration including a primary care model, a kidney care model, an end of life model and there are others under consideration that we'll hear more about hopefully by the next meeting. Adam

plans to -- Adam Boehler plans to come and address the public at the next meeting.

There are also other -- there's a letter that is under construction that will be released soon that will include guidance on the areas of focus that CMMI is interested in driving forward relative to alternative payment models, and that criteria will include the kinds of models that they are looking for, the kinds of elements that will be in those models that will take particular interest from CMMI. And I also welcome my PTAC colleagues who have been in those discussions with Adam.

But we think that this extra guidance will be very helpful as stakeholders figure out who to speak to, whether to come to PTAC, whether to work directly with CMMI. And we think that this letter will include guidance around how to navigate that decision making based on the proposal elements that are under consideration, which will help the submitters prior to actually creating and going into depth and building a

proposal. With this guidance they'll be able to incorporate some of the anticipated attention that CMMI will be taking futuristically which will help us as a committee, but also help the stakeholder community sharpen their focus on what models make sense going forward.

Just before I launch into the review of the model today, do any of my colleagues want to add to my comments summarizing that update? I believe Sandy Marks from the AMA will be making additional comments, who has been speaking with the stakeholders to get their input as well, the proposers who have been working with CMMI. I think we'll hear more about that. But did I miss anything relative to the update we wanted to provide as a committee today?

(No audible response.)

CHAIR BAILET: All right. Hearing none, then let's go ahead and get started.

Deliberation and Voting on the Making Accountable Sustainable Oncology Networks (Mason) Proposal submitted by Innovative

Oncology Business Solutions, Inc, (IOBS)

The proposal we will discuss today is called Making Accountable Sustainable Oncology Networks, or MASON. It was submitted by the Innovative Oncology Business Solutions, Incorporated. And we're going to go ahead and hear from the PRT.

Oh, before we do that we have to have our disclosures, our conflict of interest disclosures. And I'll start with myself and I'll introduce -- we'll introduce each other as well.

Disclosures

So Jeff Bailet, Dr. Bailet. I am the Executive Vice President for Health Care Quality and Affordability with Blue Shield of California. On this particular proposal, I have one disclosure to share. I served on the American Medical Association Large Group Advisory Board advising the AMA Board of Directors for four years ending in 2012. Dr. McAneny was on the AMA Board of Directors at the time, so she attended our quarterly meetings for the last year or so.

I also testified before Congress as one of four physicians including Barbara in April of 2016. I've indicated these items on the form, but I don't feel that they represent a significant conflict, but wanted the Committee and the folks at ASPE to be aware of that.

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

DR. CASALE: Paul Casale, cardiologist, Executive Direct of New York Quality Care, the ACO for New York-Presbyterian, Columbia and Weill Cornell. I have no disclosures.

MR. MILLER: Hello, everybody. I'm Harold Miller. I'm the President and CEO of the Center for Health Care Quality and Payment Reform. I was not involved in this proposal and it would not have any effect on me, but I have worked with Dr. McAneny over several years on oncology payment issues and I realized when I read through the proposal that part of the model

is based on the Patient-Centered Oncology Payment model that I worked with the American Society of Clinical Oncology on several years ago.

I've also visited Dr. McAneny's practice in New Mexico, the Albuquerque version, not the Gallup version of the practice, and I have provided information to her and to Laura Stevens, who's the COO of IOBS on several occasions.

I also do consulting work for the American Medical Association and Dr. McAneny is the current president of the AMA. So while I don't have any financial conflicts, just to avoid any appearance of bias or favoritism, I'm going to recuse myself from voting and from participating in the deliberation on the proposal.

I do know a lot about oncology payment in general, and if there are factual questions about the current payment system, I'd be happy to answer them for my colleagues if that would be helpful, but I'm not going to engage in any

deliberation on the proposal itself.

DR. WILER: I'm Jennifer Wiler, Professor of Emergency Medicine at the University of Colorado. I'm also Executive Medical Director of UCHealth's CARE Innovation Center, and I have nothing to disclose.

DR. NICHOLS: I'm Len Nichols. I run the Center for Health Policy Research and Ethics at George Mason University and I'm a health economist. I don't have anything that rises to the level of a real conflict, but since we're being so phenomenally open and honest, I'll just say I once had a drink with Barbara in a bar. It was with Ian from -- Ian Morrison from Canada, and he paid for the drink because he makes more money than we do.

VICE CHAIR TERRELL: I'm Grace Terrell. I'm the CEO of Envision Genomics, a practicing general internist at Wake Forest Baptist Health System and on the board of CHESS, which is a population health management company, and I have no conflicts to disclose.

CHAIR BAILET: Dr. Sinopoli?

DR. SINOPOLI: Yes, this is Dr. Sinopoli. I am a pulmonary critical care physician and the Chief Clinical Officer for Prisma Health in South Carolina and also CEO of the Care Coordination Institute which is an enablement services company. I have no conflicts and nothing to disclose.

CHAIR BAILET: Thank you.

So we're going to turn it over to the physician -- the Proposal Review Team, and that's led by Dr. Grace Terrell.

Grace?

Preliminary Review Team (PRT) Report to PTAC - Vice Chair Terrell

VICE CHAIR TERRELL: Thank you, Jeff, and thanks everybody.

One of the coolest things I think about PTAC and MACRA legislation, if we take advantage of it, is it's, at least the only example I know of where the Federal Government actually asks the stakeholders who actually

practice medicine and run medical businesses to contribute to the ability to think about health care policy in ways that can make a difference for all of us.

And so within that context, I very much and my colleagues appreciate the MASON proposal. It comes from the context of an organization that has participated in the Oncology Care Model that's now one of the standard models that's been one of through COME HOME, one of the HCI awards that looked at how to think about models of care that would make a difference with respect to resources and how they might be better used to provide care for patients who have cancer and who from that experience had the ability as well as running a private business in an non-hospital-based oncology practice, understanding what some of the limitations were as well as learnings from the types of things that they thought might make it better.

And so out of that comes the MASON proposal. And within that context, I think the

proposals of it and just grateful that we have the opportunity to be thinking about things from the field that stakeholders are bringing. This is a perfect example of one that comes from that context.

The PRT Review Committee consisted of myself as lead, Bruce Steinwald, as well as Bob Berenson. Bob Berenson, I don't know unless he's on the phone listening, is not with us today because he's rotated off the Committee, but certainly has been very much involved in the analysis and much -- most -- actually all of the work with respect to this was done prior to his rotation off. I think maybe the hour before or something like that we were still working on it, but got it done.

So Making Accountable Sustainable Oncology Networks is the name of the proposal. We've just heard about the team that did it, the PRT and who we are.

The proposal overview, for those of you who are familiar with our process, I won't go

through it in great detail because it's become a real standard, but this one was a little bit different because this one, at least from my point of view, was the first I was involved in since the change in legislation that allowed us to give some preliminary feedback.

And so in many ways it may have prolonged the review process, which is why was not done in September like we originally thought it was, but is here in December. And Bob had actually already rotated off by that point. But on the other hand we've learned from that process and I believe that as a result of that several of the changes that occurred made this, at least from the PRT's perspective, a stronger proposal.

So typically, what happens is that the PTAC Chair or Vice Chair assigned two to three PTAC members to review. Then additional information is requested. In this case we spoke to, we spoke to CMMI in both cases about the Oncology Care Model that was out there as well as the COME HOME award that this same group had been

involved with. We asked in written questions of the proposer. Got those back. Had an interview with them. And then subsequent to that created a sort of early PRT-type report that was allowed to be the initial feedback. So the reason I'm going through this at this time is because that's the new component of it.

From that we've got -- we got more iterations, more interviews, more discussions, more answers, and ultimately some changes from their original proposal. And subsequent to that we wrote up our recommendations, which you all have all now seen and which I'm going to go over as we go forward with it. But that was the process that we went through. It was quite thorough and we had a significant amount of information that we evaluated both from the proposer themselves written and orally, but also from other sources.

So this particular model and proposal is based upon COME HOME. So COME HOME was part of a CMMI grant that was done from a group of

oncologists; they were part of a consortium. And with that they created out of some -- out of that grant some processes in place for which they were able to show that care coordination and other types of processes that they developed saved substantial money off the awards once they were evaluated. I believe it was something like 6.3 percent. Overall, some of that was reduction in high-cost services like emergency departments.

And based upon that, which was not sustainable since it was part of just a grant and the award, they then did a lot of substantial thinking also by participating in the Oncology Care Model on a payment model that might occur that could improve on that work as well as create the opportunity for something that could be sustainable as part of the PTAC proposal that went to CMMI. So that's what this is.

The core elements are that it starts with the first consultation with an oncologist. It's based on the relevant clinical factors that -- and the patient preferences. Many of this is

work that was done related to thinking about the COME HOME care model. They're assigned to a treatment plan at that point that has a target price that is essentially -- reflects all cancer care-related expenses but excludes drugs from the overall OPC, which is a target amount that is established based upon practice pathways as well as some artificial intelligence-related ways of thinking through in great detail the pricing that might be appropriate for that level of care.

The OPC assignment prompts the creation of a virtual account. The usual types of fees are charged in the usual types of way, whether it's a DRG or whether it's a fee-for-service physical payments. And all that is kept in a virtual account and then retrospectively, based upon what the expected cost would be, there's a true-up at the end.

If the patients are managed in a way that reduces their expenditures, below the target amount, then the practices share in those savings provided that the quality benchmarks are

sufficiently met and the quality is measured via pathway compliance patient and family surveys. These pathways are established and developed by this national consortium based on evidence-based guidelines. That is also with contribution from the academic centers as it relates to these guidelines.

Because of the nature of oncology practice, which is changing faster than everything else, not only as it relates to drugs, but as well as genomics and may of the other aspects of care that's changing in real time, the OPCs are a work that changes over time. And that's one of the real issues in this model that we need to think about because it's something that has to basically set established pricing, but at the same time has to go for best evidence in real time in something that's changing very, very rapidly. And so those are the issues that this model tried to resolve and solve and come up with a solution with and one of the most complex areas there is in health care today.

So to basically think about this, there is a target price which is called an OPC, and these are basically established based on disease state, comorbidities, treatment plan that's the expected cost of care for patients in a given OPC. It's really important when you see the PRT's evaluations to understand that these have not been developed yet. And that's really one of the keys to some of the analysis that we had. I don't necessarily personally think that that means that it's a negative or adverse recommendation that we give. It just means they're not developed yet. And this is an ongoing field and a lot has to be thought through with respect to how you get from point A to point B in a system that's evolving in real time.

So there's a one-time $750 payment for a new patient consultation. The E&M visits are also part of that. Infusion center facility fees are part of that as well as the variation -- variable radiation and infusion inputs, hospital charges, facility fees, and any other patient

care charges, physician care that's related to cancer treatment: imaging and laboratory services, but it excludes non-oncology services. So part of the real aspect of this model is that it's related to cancer care and those things that the oncologist can control.

Quality is based upon a four percent withhold from all E&M payments that's used to form a quality pool. The quality is measured by technical quality in terms of looking at its variation from the treatment pathways that have been established and customer service quality in terms of patient and family surveys. And for both criteria, there is an 80 percent threshold established as defining satisfactory performance.

So to summarize the PRT review, we felt that the scope, which is one of our high-priority designations, this absolutely meets criteria and deserves priority consideration. Cancer care is highly complex. The entire business is changing. This particular model is based on some very deep thinking from people in

the field running a business, trying to understand how it might best be modeled in ways from a payment and delivery standpoint that could be sustainable given the changes that are going on.

From a quality and cost perspective, it was unanimous that it did not meet. Again, this was mostly related to the fact that these OPCs have not been fully developed and established and operational yet. Likewise, for the payment methodology our does-not-meet is based upon the same ideology of rationale and reasoning on our part.

From a value over volume, we felt it meets. Flexibility. Clearly, this is flexible relative to some of the other options that are out there. Ability to be evaluated. We believe it meets. The integration and care coordination we believe it meets, particularly as it relates to the COME HOME things that have already been developed and established. Patient choice, patient safety and health information technology

we all believe it meets.

So we identify some key issues. The first one I've already mentioned, which is the OPCs are not currently operational and developing them is going to be a time-intense process that will require frequent and similarly time-intensive updating to reflect the ever-evolving developments in both pharmacology, therapeutics, and diagnostic testing, actually, too, with respect to genetics, the ongoing reality of the current situation in oncology.

There is a granularity of care that the OPCs are evaluating that is much more granular than what we currently see in the Oncology Care Model that's one of the CMMI models or other things that are out there right now, but they are based on utilization patterns that would be from a select group of practices that make up this consortium. And so one of the issues out there was: can this be generalized for the entire population that does oncology in the U.S. or not? So this isn't anything that we necessarily think

can't work or won't be done, but it has to be evaluated further since this is just a small group of oncologists, and there are a group of oncologists that are already pretty evolved if you will with respect to looking at alternative payment models and working with some of the changes that are going on out there.

We were also concerned about compliance within the pathways and how they were assigned, and whether the deviations that are voluntary can be distinguished from unexpected events that trigger clinically necessary protocol changes. So this again is part of the issue of if you don't have this thing entirely baked yet because you have to bake it, we just don't know that we've got that level of detail fixed yet.

And then we have some operational concerns about the adjudication of claims and services based upon some of -- the description of it in the report, in the proposal that we got. When we went back and asked in more detail about that, there was some more information that was

provided to us about looking at cluster codes to help us make those determinations. Again, the issue was that -- as opposed to an appeals process, but the issue was this is new machine learning types of approaches and it has not -- as of yet, it's been untested.

We believe that the clinicians had the opportunity to go and justify being off pathway, but we don't know how they will be really factored into the quality scoring. So you get the sense from what I'm telling you that what we've really found as concerns are the details in many respects that have not yet been developed.

The model's effort to delineate cancer and non-cancer care may dis-incentivize care coordination between core team members of cancer care providers. This is just something that needs to be thought through.

The PRT would like to see more a robust and detailed plan for shared decision-making. A lot of the -- of this starts at the treatment plan. That's when the payment starts

for the initial consultation that we believe all the way through more development of language around shared decision-making could make this a stronger process. And the process for and implications of patients exiting the model probably need to be more fully described and understood.

So I am going to go quickly through the criterion so that we can have adequate time to go in greater detail with the proposers themselves and so the Committee members can ask more detailed questions.

So again, we thought that the -- it met the scope. We think it's really important for there to be alternative payment models in oncology that can -- that are above and beyond what's currently out there with the current model.

This proposal acknowledges the granularity, and it is not based on pre-defined time frame, which we like as opposed to the current model out there which starts specifically

with the initiation of chemo and only goes for six months.

And the proposal has made perfectly clear to us, that's not necessarily the way that cancer works for a patient in the real world. And the type of thoughtfulness they put into alternative payment models around there just really looking at the time of treatment is not time-based we felt was a real positive.

There is direct incentivization for the care -- to provide care coordination which we thought was a real positive. And the payment model attempts to hold oncologists accountable for cancer-related expenditures, which are the things that they have control over as opposed to the total cost of care which the assert that they do not.

With respect to Criteria 2, the quality and the cost, as I mentioned before, a lot of this has not been completely baked or developed yet. Nonetheless, using evidence-based treatment pathways and measuring and rewarding

based on clinical quality is a clear strength of the proposal conceptually and one that we believe if it goes forward ought to be developed and developed in great detail.

We were concerned about how these things that would be done, how these target prices would be established since it's not currently operational. They provided us some detail with respect to that, but the biggest hang-up we had is it just wasn't operational yet. So it was -- a lot of it was them thinking through a process they would like to put in place.

There were also concerns about the generalizability of this based again on the patterns of current group, and then the compliance with the pathways. Maybe you shouldn't be compliant. This is -- in anything that you measure there's always the potential that measurement can lead to adverse outcomes as people's behavior is changed by that. This will be true in anything that is established, so the

real issue is not that this means it shouldn't be done, but it needs to be acknowledged and managed.

From the payment methodology, again the clear strength of the proposal is its attention to care coordination based upon the COME HOME work that was done that had cost of care and high quality associated with it from the previous work at CMMI and the fact that it was based on cancer care rather than the total cost of care.

We were supportive of the inclusion of administrative fees related to drug purchasing and administration. Obviously, there's been some stuff that's come out from CMS since this proposal came on that may make that less of a factor. Initially there was a 2 percent-plus invoice pricing. That was one of the criticisms that -- with initial feedback. When they came back with their proposal, this is what was proposed. We like it, but that actually may be moot now given some of the other things that's

happening at CMS thinking about the drug pricing.

There was a thought process on their part that HCC coding could be used to think about predictors of cancer-related expenditures. It did not -- but because that has not really been developed or -- for cancer as a way of determining -- although it may identify patients at higher risk for not only cancer-related, but non-cancer-related severity index. It's never actually been used in this way, so it's something that would have to be thought about differently.

And the process of adjudicating with it related to cancer care or not obviously could be the new fight, right, because since it's just going to be for cancer only, then what becomes cancer care-related as it relates to expenditures? So these are just things that have to be thought through.

With respect to value over volume, the review of the counts and the process of identifying providers delivering low-value care as related to pathway is compelling and would

likely improve cancer care. The payment model addresses the previous criterion such as practical issues related to isolating cancer care expenditures, but this also will create some complexity in the model relative to just looking at total cost of care like the current model out there does. And again, how you actually handle those deviations from pathway at the practice level as well as at the federal policy level has to be really thought through to create a situation that's flexible, simple and not overly complex, which gets us to flexibility.

We like the ability of these evidence-based pathways to change in real time, to basically look at the fact that not everything is going to be on a pathway and be able to focus on that. There may be some benefit that could happen from a more nuanced process of accommodating deviations from the quality measurement process in terms of understanding why somebody went off pathway. It's not really clear how this would be put into the current model.

We believe this has the ability to be evaluated. The submitter was very articulate with respect to the types of metrics that could be evaluated with respect to quality of care cost and patient satisfaction. Again the as-of-yet undeveloped nature of the OPCs and any lingering concerns we have is really related to that. And then there's concerns about how we would use the OCM patient cohort as a comparator because one of the things that was proposed is, well, let's compare this to the ones that are currently in the OCM model, but perhaps that's not the best comparator group. Maybe it needs to be oncology care at large.

We think that there is significant integration and care coordination strength with respect to cancer care. We do believe this is more inclusive of independent practice physicians than perhaps the current models that are out there are. We are somewhat concerned about the model's effort to delineate cancer and non-cancer care as it relates to the payments and some of

the complexity related to that and believe that the emphasis on spending and granular detail on spending is going to be a real plus as clinicians are able to see the data, as the public is able to see the data and come up with ways of actually improving on the efforts that they have.

But one of the potential concerns is because they'll have the ability to exclude high-cost clinicians that may not necessarily generate a highest quality team or even overall cost savings if sometimes -- sometimes high-cost physicians are high cost because most complex patients go to them. So that just has to be thought through.

With respect to patient choice, it's explicitly stated that the patient preferences for providers and hospitals will be solicited and accommodated. There were some other descriptions of other aspects into it including applications. And there may be again some benefit from a more explicit or detailed shared decision-making plan as part of the model. Again, there was some

concern about the cumbersome process of switching OPCs as cancer changed or diagnosis or pathways changed and any type of impact that might have on patients if that occurred.

And then the processes for exiting the model were not fully described. But then again, we only give them 20 pages. And we've got plenty of other types of information out there that they were thinking through these things.

We think that the evidence-based pathways is clearly a win for patient safety and will likely yield improvements particularly because it's groups of clinicians working together across the country in consortiums to come up with evidence-based pathways. The data capture will also improve this as learning occurs in real time and the transparency will as well.

Health information technology was all over this proposal, everything from machine learning to looking at clusters as it relates to thinking about deviations from the pathways. So I don't even have to go into 10. It's just sort

of a given. We thought that it certainly met all those criteria.

That's it. I'm sticking to it.

Bruce, do you have anything you want to add?

Clarifying Questions from PTAC to PRT

MR. STEINWALD: Just one. You've made it clear that our principal reservations had to do with the development of the OPCs, but I note that in their recent response to the PRT report they state, and I quote, "The oncology payment categories are not only possible, but have been produced and can be modified in a timely manner to accommodate changes in care." I'm looking forward to hearing more about that when Dr. McAneny and her team approach the table.

VICE CHAIR TERRELL: Yes. So I'm hoping that most of the deliberations this day will be questions that are directed at the applicant rather than me or Bruce or the spirit of Bob, but if we have any direct questions that you all need us to answer right now, we'd be

happy to do so.

CHAIR BAILET: Len?

DR. NICHOLS: I was just going to move we bring up the presenters, because I think you've done a fantastic job. It's all about the OPCs, so let's play the game.

CHAIR BAILET: All right. Dr. McAneny and team? So just to level set, it would be great if you could introduce your team and them we're going to have opening comments from you for 10 minutes and then open it up to exchange between the Committee and your team. Thank you, Barbara.

Submitter's Statement

Barbara McAneny, MD, Kameron Baumgardner, Terrill Jordan, JD

DR. McANENY: Thank you very much, members of the Committee. I'm Barbara McAneny. I'm a practicing oncologist in New Mexico. I am AMA president, and I did have the COME HOME Innovation Center Grant. And I'll have Kameron introduce himself and Terrill as well.

MR. BAUMGARDNER: Good morning. My name is Kameron Baumgardner. I am the Chief Technology Officer of a data science and analysis consultancy known as RS21.

MR. JORDAN: Good morning. My name is Terrill Jordan. I'm the President and CEO of Regional Cancer Care Associates out of Hackensack, New Jersey.

DR. McANENY: Making Accountable Sustainable Oncology Networks, MASON, is the next step in the transformation of oncology services from fee-for-service to an alternative payment model. In November of 2017, CMS requested pilot projects to develop APMs that could be scaled across multiple sites and service. MASON is a pilot using a group of practices willing to open their EMRs to combine with claims data using advanced data science to prove to CMS and to oncologists across the country that we can create an advanced APM for oncology.

The transformation began with IOBS' CMMI award COME HOME, which showed that

independent practices transformed them to oncology medical homes, could intervene early in the toxicities of cancer and its treatment and avoid hospitalization. COME HOME provided patients with services delivered by their doctor's practice, kept patients healthier and able to spend more time at home, resulting in healthy, very satisfied patients. COME HOME also saved a significant amount of money per patient.

However, COME HOME lacked a payment system to support the patient services that constitute an oncology medical home. The savings, which were considerable, came from the avoidance of hospitalization, but the expenses fell to the practices without the reimbursement process.

A team of physicians and health economists for the American Society of Clinical Oncology developed a more accurate payment system to pay the medical home costs, known as the Patient-Centered Oncology Payment System, and is incorporated into MASON with permission from

ASCO.

CMMI's Oncology Care Model, OCM, implemented the first attempt at a payment system adding MEOS payments, Medical Extended Oncology Service, and a shared savings model. To become an advanced APM, practices were to take two-sided risk where their total costs of care were compared to a target price. Only a third of practices have shown savings, and so far no practices have accepted two-sided risk.

MASON is a model built on the foundation laid by the OCM to solve the problems encountered by practices. One, the lack of accuracy of the target price. Two, the inability of practices to manage the entire cost of care. Three, the inability of the OCM model to keep up with the rapid technical advances of care including new drugs and four, the lack of real-time data that allows practices to make mid-course corrections in care.

As shown in slides 3 through 5 in your deck, cost of care varies significantly for

factors not put into the OCM model and the R-squared correlation between the actual costs of care of COME HOME patients with the Oncology Care Model targets is 0.33. Practices would be irresponsible to accept risk based on these targets because the possible required repayments could exceed the ability of the practice to repay resulting in practices leaving the model, depleting the infrastructure of cancer care by going out of business, or doubling the amount CMS pays for care by selling to a hospital.

We address excess risk by having NCCA, National Cancer Care Alliance Practices, jointly purchase a captive insurance product as stop-loss insurance. The practices remain at risk for the quality withhold, the cost of practice transformation, the cost of the re-insurance, and for patients whose cost overrun is small enough to handle without a claim, but are protected from practice-ending risk.

The entire cost of care was included in OCM because of the inability of the OCM model

to segregate oncology-related costs from other costs of care, and we will demonstrate a methodology that will leave the oncologists at risk for only those costs related to cancer.

MASON removes all drug prices from the model and reimburses the oncology practice for the invoice prices of the drugs. This not only removes the major reason that oncology practices were unable to hit the OCM target, but reassures both patients and CMS that drugs are not selected for a better margin or avoided because the new better biologics would cause the target to be missed.

We want a transparent selection of drugs and we never want to put a physician in the position where doing the right thing for a patient causes an adverse outcome for the practice. It also eliminates the concern of the practice that a patient with a pre-existing condition requiring a biologic agent or with serious expense comorbidities would adversely impact the financial performance. We never want

a system that penalizes doctors for caring for complex patients.

Quality of care consists of customer service, delivering the care the patient wants when and where they want it and by whom. And technical quality, delivering the treatment plan that optimizes the goals of a patient. The medical home processes have been shown in COME HOME to generate excellent customer service resulting in patient satisfaction scores in the high 90s. Technical quality of care consists of the patient being offered all of the options for care that are appropriate while avoiding inappropriate care.

The gold standard for quality is the NCCN Guidelines. With the assistance of NCCN, MASON will help transform those guidelines into pathways imbedded into the practice EMRs. Electronically proven compliance with the pathways will include failure to deliver appropriate care as well as the delivery of inappropriate care, and actual causes for

deviations can be built into that so that the physician is not penalized when a patient for example elects to refuse recommended care.

For example, if a patient with a rectal cancer is not offered pre-operative radiation therapy with chemotherapy or is not referred for resection, the oncologist would be off pathway, unless the patient had refused, and would sacrifice their quality withhold. Similarly, if excess imaging or inappropriate chemotherapy were delivered, the oncologist would be off pathway and the quality withhold would again be returned to CMS.

Part of the technical quality of care is the patient safety components of having an infusion facility certified by the ASCO QOPI processes that meets regulatory standards, a radiation facility that is ACR-accredited and appropriate accreditation of surgical suites and hospitals.

As the drug margin has been used to pay for the infusion fee, we are removing the

drug margin. A facility fee will pay for the fixed cost of having the appropriate QOPI-certified infusion facility. And the cost should be the same regardless of site of service.

The Oncology Payment Category is created via data science techniques. The target OPC amount is visible to the practice and to CMS as a virtual account. Every non-drug claim that is submitted related to cancer care is subtracted from the virtual account allowing the practices to monitor patients with increased needs or physicians using excess resource use.

I'm now going to turn this over to Kameron who will demonstrate the OPC.

MR. BAUMGARDNER: Thank you.

We have created a proof of concept to demonstrate the feasibility of quickly creating and updating the MASON OPCs. We have used the clinical and demographic data of 2,500 episodes, which were then fed into a density-based clustering algorithm that allowed us to identify individual clusters. We then expanded each

cluster to a more statistically valid sample set of 5,000 episodes through a Monte Carlo simulation and analyzed those claims of those simulated episodes to produce the OPC cost curves.

For this demonstration, we selected three breast cancer clusters for further analysis. These three clusters we chose grouped episodes that were prevalent with ductal T1, ductal T2, and lobular T1 tumors. You can see some of the analysis on these OPCs in slides 8 through 13.

The analysis revealed some unexpected results such as a lobular histology of the tumor having a greater impact on cost of care than the size of the tumor itself demonstrating why the MASON model is a more accurate way to set targets for costs of care.

We also used this proof of concept to demonstrate the computational feasibility of quickly creating and updating these OPCs. We were able to cluster these episodes and produce

cost curves in under an hour and have determined methods to scale this performance to millions of episodes.

First, indexing the data fed into the clustering algorithm reduces the computational complexity of the clustering process, meaning that instead of adding 25 additional computations for reach additional 5 episodes we are only creating an additional 11 computations. The more computationally-complex process is actually the creation of the cost curves from episode claims. Frankly though, this is a common problem in the field of big data analysis with numerous well-supported solutions such as Hadoop, Spark and BigQuery that create parallel processes which divide up the work. RS21 has experienced using these kinds of technologies to process many terabytes of data in hundredths of a second.

Finally, we have implemented several techniques to determine what are cancer-related costs and what are non-cancer-related costs. The ways in which the Monte Carlo episode simulation

selects claims ensures that non-cancer-related costs will not be common in the simulated data sets. Furthermore, setting baselines of costs with HTC data and other statistical models such as isolation forests can further filter out costs that practices have no control over.

We appreciate PTAC's time and attention and look forward to answering questions.

CHAIR BAILET: Thank you. So we're going to now open it up to the Committee to ask specific questions of the submitters.

Bruce?

MR. STEINWALD: So let me get this straight. You have developed the Oncology Payment Categories. Have you developed them for all of the cancers that you propose to include in the model? And if so, or even if not, is the methodology and/or the categories themselves proprietary or are they available for use by others outside of your organization?

DR. McANENY: So the first answer is

no we haven't gone through the process of doing it for all of the several hundred tumor types that are out there, but I think what our goal was for today was to demonstrate that this is indeed possible. We use the claims data from the COME HOME practices that we had plus their clinical data to generate this and just selected this one as a demonstration to show that we could do it. Equivalently we could take the claims data for colon cancer patients or for prostate cancer patients and create the same process.

And as for the proprietary nature, I'll refer that to Kameron.

MR. BAUMGARDNER: The analytical methodologies themselves are not proprietary. They're open source and freely available. They're very well documented. The expertise that we've provided is in combining those with big data application and processing services to make the generation of these in a timely manner feasible.

DR. NICHOLS: So thank you for that.

You mentioned that you had 2,500 I think patients from the COME HOME and you had the clinical data to go with the claims with them. How many patients would it take to do -- not all of the cancers, but some 25 percent of all cancers or something -- to create a critical mass for OPCs for a larger range of cancers? How many -- because my concern would be Medicaid and Medicare has lots of claims. They don't have EHR data. Where can we get enough EHR data to replicate what you've done for COME HOME?

DR. McANENY: So I have Terrill Jordan here to represent the National Cancer Care Alliance.

This is an organization of 16 practices, independent practices coast to coast who are all on the same EMR essentially; I think there's one or two who are not, who have all agreed that they're willing to participate. So we see about 75,000 new patients per year, have about 500,000 patients on treatment for various tumor types. So we -- with access to claims

data, which would have to be supplied by CMS, that we think that that would be sufficient numbers to generate especially for the more common cancers.

And do you want to comment on that?

MR. JORDAN: Given RCCA's involvement in value-based arrangements we wrestle daily with an avalanche of data necessary to manage cancer care patients and we are intimately acquainted with the need for robust analytics. A deeper integration of analytics into clinical practice is a primary goal of modern health care. Data-driven decisions are fundamental to practicing medicine in an increasingly complex environment and data analytics are essential to modern physician's delivery of high-value patient-centered care.

Physicians face the challenge of a landscape exploding with clinical therapies and diagnostic tests. Physicians are finding it challenging to make the appropriate diagnosis and decide the most favorable treatment plans. In

fact, the pace of growth and medical information makes it difficult for physicians to keep up with the latest clinical research. Evidence-based medicine driven by data analytics is the key to physicians making sense of all this medical information.

Additionally, physicians and their clinical staff must receive relevant information at the point of care to impact clinical decision-making most directly. The right information received at the right time is critical to patient-centered care. Physicians desire intelligent decision support with detail that is tailored to address specific patient needs. As such, private practices must integrate clinical data into the entire work flow to reduce the added burden of value-based arrangements on their physicians.

Physicians able to execute evidence-based guidelines using algorithms driven by data analytics will deliver meaningful quality improvements. In addition, the larger pool of

patients analyzed, the more stable the conclusions regarding the guidelines. This will enable physicians to provide more efficient and effective medical decisions, yet private practices are facing extraordinary administrative burdens as both governmental and commercial payers begin shifting financial risk to physicians.

To reduce unnecessary tests and procedures while ensuring the quality of overall patient care practices will require technology to meet minimum quality metrics for value-based care. Hence, to adequately participate in risk-based arrangements private practices require a full suite of data aggregation, analytic capabilities, and actionable reporting on behalf of physicians.

Participation in a project like MASON will allow physicians to work towards centralized analytic -- toward a centralized analytic database and will enhance performance reporting of all the participating practices. This will

significantly further the evidence-based decision support necessary for physicians to successfully navigate MASON or similar value-based programs.

DR. NICHOLS: So clearly they anticipated the question. But what I really want to get at here -- and that was great. You figured this out. But what I want to know is if I heard the PRT correctly, they're worried about a time frame of updating the OPCs, of reclassifying a patient because of a particular pathway of their own disease, and you get the point. And you just told me you got to keep sending the equations out to the hinterlands so the doctors can use the right one. So what's your idea of time frame of adjustments?

MR. BAUMGARDNER: Thank you for the clarification. So we developed the proof of concept explicitly to kind of address some of the initial questions about the feasibility of quickly updating this data given the changing and cost structures and adding new patients into the clusters.

Our initial results, as I mentioned, were able to be produced and computed in under an hour. We believe that that's feasible to scale up to larger number of claims.

DR. NICHOLS: That was on a patient base of 5,000. So in a patient base of 500,000 it can't be that quick.

MR. BAUMGARDNER: So this is -- so there are a few emerging technologies in the big data analysis space. That parallelization process that I mentioned allows us to have hundreds of computers working on this at the same time in parallel rather than having one big machine deal with it. That's the optimization process that we have suggested based on our initial discovery and we believe that we can hold that performance level up to hundreds of thousands or millions of episodes.

DR. McANENY: And to add in --

DR. SINOPOLI: This is --

CHAIR BAILET: Angelo, we hear you trying to break in. We're going to let Dr.

McAneny finish and then we'll --

DR. SINOPOLI: Yes.

CHAIR BAILET: Okay?

DR. McANENY: One of the other concerns from the PRT report was the concern about switching an OPC. So if the patient were to select, for example, a high-cost provider which is generally in oncology an academic surgeon with specific expertise in doing something or proton therapy or something that is not provided within a practice, then that patient would be referred and that would be the end point of that OPC because that patient would then not be being managed by that physician.

Similarly, if a patient completes their block of adjuvant therapy, they would end that OPC at the end of that time and go onto to like a maintenance OPC which would be much lower cost because they're basically getting a few office visits and maybe a few basis tests. If that patient were to relapse, at the time of relapse the restaging process would then assign

them to a different OPC that would be there for metastatic cancer.

To create these various OPCs need to be an iterative process because any time you fix something in time and space and then medical science continues to advance, pretty soon you have a set of targets that don't reflect the reality of cancer care. And so by working with this group of practices who have agreed to open their EMRs to submit accurate data to us so that we -- when we discover things like lobular breast cancer is different from ductal breast cancer, which was a surprise to me as an oncologist of 30 years. I didn't think the cost would be different. That means that we can then retool and have that data submitted and then send it to the data feeds in the computer to be able to update that on a continuous basis.

So part of the time frame of creating the OPCs for the really common cancers, the ones where it's really important to have an exact target: lung, colon, breast, prostate, for

example, there are sufficient numbers of those in the database of the group of practices that those could be generated as the initial part out of the chute and then modified as science changes.

If you're looking at something that's very rare, a Merkel cell tumor for example, that I've seen three in my career, we may never need an OPC for that. They may not be something that it's worth the time and effort to compute an average price for something that is exceedingly rare.

Does that help?

DR. NICHOLS: Yes.

CHAIR BAILET: So Dr. Sinopoli is on the phone and he can't see the queue, so we're going to go ahead and turn to him. And then I've got Paul, Jen and then I've got a question as well.

So go ahead, Dr. Sinopoli.

DR. SINOPOLI: So thank you. First of all, let me say I'm impressed with the comprehensiveness of your thought process around

this, but I've got one question.

So are you suggesting that this be a single national database that's driven by a machine learning at that level or are you envisioning this to be multiple databases that pop up across the country driven by multiple cognitive computer partners across the country? Or how are you seeing this scale out to more and more oncology practices?

DR. McANENY: So I'll start with -- this is Barbara. I'll start with the answer to your question and turn it to Kameron.

So we would start with this with the idea of a model that before oncologists across the country will be trusting enough of this that they're willing to accept the two-sided risk that is built into this process we would need to be able to demonstrate its accuracy. And therefore, we would start as a pilot project using the NCCA practices and demonstrate that. So in that sense it's the one data set that we would have in one common database that would get used.

The concerns that the PRT suggested about are we using this one group and therefore the treatments are somehow idiosyncratic to that one group I think is allayed by the question of using the NCCN Guidelines, because that is a national standard of care.

Then to scale this it could be scaled with -- like Kameron talked to how the multiple computers and databases work with that. But to scale this, then once we've identified the processes that are there and identified the OPCs that are there, it will be a little bit like telling all the hospitals in the country that they have to use DRGs. They figure it out pretty quickly.

And so we can help then as well with here's what the COME HOME processes are. This is how you use triage. We've seen that happen through the oncology care model. Multiple oncology practices have really switched over to embracing all of these processes that have shown to improve care.

So I think once we prove it, then we will be able to encourage oncologists around the country and possibly other entities, other specialties that are managing chronic disease with acute exacerbations into using this kind of a process.

So for the computing question, I'll give that to Kameron.

MR. BAUMGARDNER: Yes, so we would need to evaluate the population as an entire set. The important thing to note there though is the geospatial location is taken in as an aspect when we're talking about what are the variables that we're looking at when we're determining similarity between clusters.

As far as the computational feasibility of sorting data that large, as I mentioned we are experienced in the use of these decentralized storage and computing solutions that prevent us from having a single source of failure either geospatially or technologically.

DR. SINOPOLI: Thank you.

CHAIR BAILET: Paul?

DR. CASALE: Thank you and thanks for bringing this forward.

So the first question; I apologize, I might be a little slow, but when Bruce asked about is any of this proprietary, I wasn't sure I heard a yes or a no. So could you just clear -- I mean, I heard follow some of NCCN, but so is it yes or no? Is some of this proprietary or not, if someone were to participate?

MR. BAUMGARDNER: I can't speak to the data, but the analytical models are not proprietary.

DR. CASALE: Okay. So no is the answer?

MR. BAUMGARDNER: No.

DR. CASALE: Okay. Great.

And then some of the discussion makes me think back to Hackensack, which came forward with Cota. I don't know who would like to answer this, but I'm just curious how you comport their model or what they brought forward with yours,

just if you had any sort of reactions to that.

MR. JORDAN: Well, Regional Cancer Care Associates is a separate organization, so we're not actually part of Hackensack and weren't part of that presentation.

DR. CASALE: So you're not familiar with the Cota?

MR. JORDAN: I am familiar with it, but I'm not --

DR. CASALE: So I'm not asking you to represent Cota necessarily, but just your -- thinking again they were sort of using algorithms just sort of being more specific around therapy.

MR. JORDAN: I wouldn't want to comment on someone else's model because I might say something out of turn.

DR. McANENY: One of the things that I can say with this one -- I've read the Cota but I don't really know that model, so we did not incorporate that into this. One of the things we tried really hard to do with this model was to build on constructs that are already in place and

familiar to CMS.

CMS would have to continue to pay claims in the usual fashion. They're very good at doing that. They can pay facility fees. The OPC we figured would look akin to a DRG or an APC, so we're trying to use constructs that would be more within the computing normal business work of CMS. And so the Cota project seemed a little different to me from that.

CHAIR BAILET: Jennifer?

DR. WILER: Thank you very much for your presentation and specifically thank you for creating a model based on digital health innovation, making an improved care delivery systems. I have two questions germane to Criterion 2 around quality and cost.

The first question is around who will be paying for access to these pathways? And then also who will be paying for the cost associated with the OPC algorithm updates? And then I'll ask my second question.

DR. McANENY: Thank you. So for the

access to the pathways, one of the concerns that I had had at the beginning is that most of the pathway vendors are proprietary and they do charge significant amounts more than I can afford in my practice to have those.

So I reached out to NCCN, who is the source of all of these guidelines and who are here today to comment during the public process. NCCN is open source. I think that having the medical literature become proprietary is unfortunate and I think that having an open source process for the best care is the best way to spread that care across the country. So we're very much looking forward to having NCCN work with us on this.

For the costs of developing it, all the costs of developing any sort of a payment system have to be filed into the process of the payment system. If we look at for example the quality withhold here or we're looking at the cost now that an ACO uses to create its models, the savings from the models have mostly gone back

into creating the IT infrastructure for those particular models, and frankly some of the payments that we would be getting would be able to be funneled into doing this. There would -- we have to pay all these data geniuses to do their work and to be able to come up with this. So there is some infrastructure costs to any payment model.

However, having it be electronic and having it be visible through the CMS processes is very appealing because that's significantly less than the amount that we pay to submit a claim to any of the commercial payers, etcetera. So I think that it's one of the costs of doing business.

DR. WILER: Thank you. And my second question is a piggyback onto a question that Bruce had asked before, and that's when describing this episode of active cancer treatment and then remission, when does that episode end? And a corollary to that is why were outcomes not described in the model? And then

thirdly, this OPC algorithm readjustment -- obviously that -- it sounds like in your previous description there would have to be an adjustment based on active treatment versus remission. So if you could address that. All obviously related to this question and cost question.

DR. McANENY: Okay. So one of the frustrations that we had with the -- as we participate and we still are in the oncology payment -- the oncology care model is that all patients get chemo. We have patients, prostate cancer patients, who are most appropriately watchfully waited on and observed to make sure that they don't progress, but they require a fair amount of effort, but they're not in the model. If a patient only requires radiation therapy, an early Hodgkin's patient, for example, the radiation oncologist is not in the model. And in this model, any oncologist could be the initiating consultation that would start that.

As you go through the NCCN Guidelines

they're very specific in terms of the options of therapy and the optimal therapy, and we would put into the models -- and we have imbedded into our electronic medical record the pathway, the process of you need to have an echo at every three months for -- if you're giving someone Herceptin, you have to have all of these various testing at various opportunities.

But we know for example in the adjuvant setting that it starts with the first payment, the first visit to the oncologist and there is a point where adjuvant therapy is completed. And so at that point, that person would be switched to the different oncology payment category. So these episodes, in these episodes that we create, time is just one of the variables and not the defining variable, which I think strengthens it.

For outcomes, I think producing real outcomes data for the first time will be an interesting byproduct of this in that if we have the ability to take a patient who starts out with

a given chemotherapy regimen or a given radiation regimen or any initiating event, we will then be able to look over time and see whether or not they activate the triage pathways more frequently than a different regimen would have them activated. So we'll be able to have the initial event, measure the toxicity in a very objective manner and at the end of that episode then we would be able to say what the outcome was.

Outcomes in oncology can take years. So we would have the short-term outcomes of have you successfully completed all of the adjuvant therapy and how toxic was it, and therefore what do we have for the total cost of care? And then be able to do outcomes of regimen A versus regimen B, which I think will be incredibly valuable in helping oncologists understand when we're selecting regimens, when we're sitting down with a patient to say if you pick this one, you can expect these toxicities; if you pick this one, you can expect these other toxicities. I think that will be incredibly useful to

oncologists moving forward to be able to better help patients select what they wish to have.

And your third question was the -- so we will eventually get to outcomes, but outcomes on oncology can take years to really demonstrate.

But as we develop these episodes, they can turn into bundles. And the eventual long-term goal would be to say I have a breast cancer patient who fits in this OPC. Let me have the bundle and go at risk for that. That's past where we are here. That would be the next phase, but I think that would be a valuable way to look at that.

As for the OPC algorithms changing, were you talking about the updates or switching from one to the other?

DR. WILER: Both.

DR. McANENY: Both? Well, the switching from one to the other is a clinical decision so that when a patient say elects -- I'm going to leave your practice and go somewhere else, that episode would end. If the patient

relapses, if the patient moves -- completes the planned course of therapy, then they would switch to a maintenance/observation-type of an OPC. So there are real clinical end points that we see in oncology all the time of where we could -- we could demarcate that.

As for the constant updating of things, oncology is very fluid and any payment scheme that does not reflect the ongoing changes that are occurring would give us targets we can't hit or would give the adverse incentives of better avoid that patient with psoriasis who has this expensive drug or this patient who has other comorbidities that are going to make them more expensive because I won't hit my target. We need to be able to have this process to say, okay, now we have the OPC and we've learned that diabetics who have this particular problem or people with food insecurity who have this particular problem are going to cost at a different level and we'd be able to get increasingly granular using the data science processes.

Do you want to comment on that?

MR. BAUMGARDNER: Yeah, on the frequency of the updating specifically that process would need to be triggered any time there's a significant change in the data that's being introduced, so any shifts in payment structure or costs. It would also need to change when we get a statistically significant number of additional cases, right? And that number will change as our population size gets larger. So adding 10 episodes into our set that we are evaluating is less impactful at 500,000 cases than it is at 500, right? We would be able to evaluate that and trigger it dynamically based on the size of the sets and the data that we're seeing.

CHAIR BAILET: Thank you. Thank you for your proposal and all of the work that you've done with the Committee to answer all of our questions.

I have one question that could be clarified. In the proposal, you call out under

the quality section that the evaluation process will be done by the Innovative Oncology Business Solutions and select contractors. And so my question is, is the model reliant on the Innovative Oncology Business Solutions or could there be another entity that provides that backstop? I'm just curious. And I don't want to say proprietary, but what's the reliance on that intellect in this model itself?

DR. McANENY: Actually I would prefer to have that be evaluated by others. We worked -- when we had the COME HOME grant we worked very hard to make sure that we supplied all of the data to that. So I look at the role of IOBS, which would have to be reconfigured because it does not currently have all of the people necessary to help manage all these 16 practices produce the data.

So what I would prefer would be to have an external process that evaluates much as happened with COME HOME, and we would be the data suppliers to the external process.

CHAIR BAILET: Okay. So what you're suggesting is ideally you'd prefer that there be a different infrastructure set up to provide that input and takes IOBS out of it to a large degree? Is that --

DR. McANENY: Yes, I would think so. It's not ideal I think to have the person who's managing the model also evaluate it. I think it's better to have an external evaluation.

CHAIR BAILET: That was my question. Thank you.

Bruce?

MR. STEINWALD: Yes, thank for all this hard work. I've been sitting here looking at these very satisfying slightly skewed to the right normal curves. If, and it's still an if -- if we accepted that you have indeed demonstrated proof of concept; and I think that's something that is for discussion among the Committee members -- but if we accepted for the sake of argument, what next steps would need to be accomplished in order to actually have what's

necessary to implement the model?

DR. McANENY: So in order to implement the model one of the things that would be incredibly useful would be to have access to more claims data from CMS because the more data we have to start the faster we can generate these, and some time to -- you know, not excessive amount of time, as Kameron has said, but to be able to pull the data sets that look at the tumor types and generate this immediate process. Then we have these practices that are willing to work with that so that we will have an internal validation kind of process.

MR. STEINWALD: That doesn't sound like a whole lot and it doesn't sound like -- well, how much time do you think is involved in that?

MR. BAUMGARDNER: From an analytical perspective, as I mentioned, we can do this very, very quickly, on orders of magnitude that probably aren't relevant for this discussion.

The procedural part of that, of

integrating that into the practices and into the model is I think where we would need to spend the time.

CHAIR BAILET: All right. So we're going to open it up. First of all, again, thank you. And you guys are not going away. You're just moving away from the table. You'll be here for the full deliberation and discussion. But we've got a number of people queued up to provide public comments and we want to make sure we hear from those folks.

Public Comments

And I'm going to go ahead as you guys have a seat and just remind folks that in the interest of time we want to make sure everyone's heard, but we also need and ask for people to comply with the three-minute guidelines around the time required.

So we're going to go ahead and start with Sandy Marks from the American Medical Association.

Sandy?

MS. MARKS: Okay. Thank you.

The AMA disagrees with the PRT's conclusion that MASON does not meet two priority criteria because of concerns about developing the Oncology Payment Categories or OPCs.

OPCs are the same basic concept as hospital DRGs based on the diagnosis being treated, comorbidities and whether surgery is needed. OPCs would classify patients based on their type of cancer, the services that are needed and patient characteristics that affect treatment costs. New technology costs are excluded from DRGs to avoid discouraging the use of desirable but expensive treatments and OPCs would similarly exclude drug costs for those reasons.

At one time people questioned the feasibility of DRGs. In his history of this system, Brandeis professor Jon Chilingerian said, quote, "The idea of setting 518 diagnostic payment rates for 4,800 hospitals seemed unimaginably complicated, an ambitious endeavor

unlikely to succeed. But not only did it succeed; CMS is now using Version 36, so updating should also not be considered too complicated."

The detailed structure of OPCs was viewed as a strength by the PRT under Criterion 1. Here the PRT says MASON, quote, acknowledges the very granular and individualized nature of treatment plans for different types of cancer and the payment model reflects this precision by using evidence-based pathways as the basis for establishing payment amounts. This is in contrast with the relatively one-size-fits-all approach of OCM, end quote. The AMA believes that this should also be viewed as a strength for the other criteria.

We also do not think that generalizability of the OPCs should be a concern because the most important quality factor, as has been described again today, is the NCCN Guidelines which apply to all oncology practices, not just those that are participating in this APM. Data from participating practices will

determine the costs that practices incur to implement services, but the guidelines will determine what services should be delivered.

Other episode groupers use a combination of clinical judgment and data to decide what's in or out of an episode and that is how MASON would decide what is cancer-related or not. We agree with the PRT that this is preferred over a total cost of care approach.

The AMA thinks PTAC can be confident that MASON will save money, improve quality and be sustainable for practices because it's based on the actual experiences of the COME HOME practices. Those practices demonstrated that significant savings can be achieved by delivering better care, not withholding necessary services. MASON is also designed to solve the problems in OCM that have made it difficult for the COME HOME practices to sustain their success.

CHAIR BAILET: Thank you, Sandy.

Stephen Grubbs from the American Society of Clinical Oncology?

DR. GRUBBS: Yes, I want to thank the PTAC for allowing ASCO to make some comments on this wonderful proposal. ASCO has a special interest in this since as you heard ASCO has published in May of 2015 the Patient-Centered Oncology Payment model that's been some of the backbone for the MASON.

We're supportive of the MASON which has been proposed by Dr. McAneny and her colleagues and we believe that deploying and testing multiple oncology-based alternative payment model pilots will allow more oncology providers to participate in the APM process and will lead to an optimal oncology APM to serve all practices and patients as we learn the positives and negatives of these different pilots.

ASCO supports many of the MASON features consistent with much of the PCOP design that also now incorporates new features from what we've learned in the last three years from all the different alternative payment model activities. Specifically, ASCO supports the

flexible payment system. This provides reimbursement for services critical to an oncology medical home functioning. It leads to better care and lower cost. The flexible payments that are based on the PCOP analysis were designed by utilizing data from the COME HOME projects, the oncology medical homes, CMS claims, the main All-Payer Claims Database, as well as experience surveys from ASCO volunteer practices.

ASCO supports the cost accountability for services and expenses under the control of the oncology team and elimination of the drug costs from the cost calculation. The drug utilization addressed by the pathway utilization will take care of the drug cost. This also, as Barbara mentioned earlier, appears to be a program that potentially serves as an on-ramp to bundled payments, which we all believe we need to get to.

Finally, I'd like to go back to the pathway. The pathway utilization here is very important and ASCO fully supports it. I want to

make sure it's clear a pathway is an evidence-based treatment protocol based on type, stage and molecular subtype of cancer. It's designed to eliminate unnecessary variation in care and the use of sub-optimal treatments. In the end, it promotes quality, value and cost savings. And one could argue the way that it's being employed here pathways are leading us to precision medicine oncology that can lead to precision cost coverage.

Features of pathway utilization include standardization of care, flexibility for patients and patient autonomy at the time of informed decision-making, rapid dissemination of new therapies into the practice field, and it simplifies clinical data collection decreasing administrative burden. Also, pathway utilization can be easily evaluated through electronic capturable compliance.

So in summary, ASCO supports the MASON alternative payment proposal as an advancement for oncology-centric APM pilots and encourages

the PTAC to promote the model. Thank you very much.

CHAIR BAILET: Thank you. Robert Carlson from the National Comprehensive Cancer Network. Thank you.

DR. CARLSON: Good afternoon. My name is Robert Carlson, and I am the Chief Executive Officer of the National Comprehensive Cancer Network and a practicing medical oncologist.

I'd like to thank the Committee and DR. Bailet for the opportunity to speak in support of the MASON proposal before you today.

NCCN's mission is to improve and facilitate quality, efficient, effective and accessible cancer care so that patients can live better lives. As such, NCCN is committed to addressing the rising costs of cancer care while advancing and improving the quality of care. The MASON model demonstrates strong potential to achieve these goals.

The NCCN Clinical Practice Guidelines

in Oncology are a comprehensive set of guidelines detailing sequential multi-modality management decisions and interventions across the continuum of care and apply to over 97 percent of patients with cancer.

NCCN Guidelines and their derivatives help assure access to appropriate care, assist in clinical decision-making across the continuum of care and facilitate quality improvement initiatives.

Our guidelines are widely used by health care professionals, patients and payers, including CMS. Recommendations in our guidelines are updated continuously to ensure patient access to the highest standard of care is never disrupted.

NCCN supports the movement toward a health care system that rewards quality over volume. New physician payment models have the potential to be particularly impactful in oncology, and we believe the MASON proposal poses great promise and is aligned with PTAC's

objectives.

The 2016 study, Transforming Prior Authorization to Decision Support, conducted by UnitedHealthcare, eviCore and NCCN demonstrated that mandatory adherence to NCCN guidelines significantly reduced total and episodic costs of care.

Drug costs were reduced by 20 percent in the pilot state of Florida as compared to national and regional comparisons. And by adding decision support, retrospective denials of care were reduced from approximately 10 percent to 1 percent. The MASON model demonstrates strong potential to achieve these savings as well.

If the MASON model is approved, NCCN is committed to supporting its implementation. The MASON Model proposes to include a technical quality metric, requiring at least 80 percent compliance to pathways based upon the NCCN guidelines to ensure quality of care.

NCCN is pleased to serve as the guideline resource for this project. We are

committed to working with the MASON team to ensure patients have access to guideline concordant care. Thank you.

CHAIR BAILET: Thank you. Anne Hubbard from the American Society for Radiation Oncology. Hi, Anne.

MS. HUBBARD: Good afternoon. Thank you for this opportunity to comment on the MASON model. Again, I'm Anne Hubbard, Director of Health Policy for the American Society for Radiation Oncology.

We represent nearly all radiation oncologists as well as the physicists, dosimetrists, radiation therapists and others who provide cancer care as part of their radiation oncology care team.

We appreciate that the MASON model seeks to address shortcomings found in the oncology care model. However, we believe that those efforts should be taken one step further by excluding radiation therapy services.

As you may know, ASTRO has been with

CMMI on a separate and distinct radiation oncology APM that is designed to standalone for those patients who require radiation therapy services but can also nest within a larger model such as OCM or even MASON for those patients who require multidisciplinary care.

This allows radiation oncologists the opportunity to actively participate in value-based care that will ultimately improve patient outcomes and reduce costs.

Recently, HHS Secretary Alex Azar announced that CMS will be introducing new APMs in the near future, including a radiation oncology APM. ASTRO is pleased that a radiation oncology APM is getting closer to reality. We have worked for many years to craft a viable model that would stabilize payments, drive adherence to nationally recognized clinical guidelines and improve patient care.

ASTRO believes its proposal will allow rad oncs to participate fully in the transition to value-based care that both improves cancer

outcomes and reduces cost. Thank you.

CHAIR BAILET: Thank you. Steve D'Amato, New England Cancer Specialist. Is Steve here?

DR. D'AMATO: Yes. Good afternoon. My name is Steve D'Amato. I am a CEO of New England Cancer Specialists and a pharmacist by trade.

We were one of the seven practices that participated in DR. McAneny's COME HOME project, and we are an oncology care model participant.

Drug costs have represented a significantly higher proportion of total costs in OCM performance periods compared to the historical periods. This is a function of many new and more expensive drugs that have come to market that has increased the total cost of care across many cancer types.

As a prudent user of novel therapies, our practice is below the national median in utilization and yet we do not get a novel

therapies adjustment in OCM. A practice that's cancer mixed can also affect the ability to hit target prices as many novel therapies can impact a particular disease's target price.

We at New England Cancer Specialists have not been able to hit target prices or show savings in OCM due to the high cost of drugs in the types of patients we see based on the DTO of data analytics that we have.

We excel in all other components of OCM. Currently, we are unable to accept two-sided risks, but we do wish to be on an advanced alternative payment model. And if MASON is approved, we would very much want to participate.

We believe the drugs need to be comp'd out in a fashion that will allow practices to show the quality and value they are providing. And we believe MASON can also accomplish this.

Thank you very much for allowing us to comment.

CHAIR BAILET: Thank you. Greg Rasp from the Dayton Physicians.

DR. RASP: Gregory Rasp, Dayton Physicians. I'm a radiation oncologist, medical director of a large group in Southwest Ohio.

We participated in the COME HOME program as well as OCM as part of a multispecialty group. And we found both to be excellent at helping us integrate in a multispecialty fashion.

While there were flaws in both systems, having radiation be part of this system rather than a separate carve out seems to be optimal from my perspective. And we would be excited to participate. Thank you very much.

CHAIR BAILET: Thank you. Indranil Dey from the Private Health Advisory Group. They're not on. Charles Bane from Dayton Physician Network.

DR. BANE: Yes. My name is Charles Bane, and I'm a medical oncologist with Dayton Physicians Network in Ohio. We have been active participants in a variety of different alternative payment models, including the COME

HOME project and the Oncology Care Model.

We strongly support the move toward patient-centered value-based care. We do understand that two-sided risk is a potentially valuable tool that could emphasize and encourage value-based decision-making.

However, unfortunately, the current two-sided risk models that are available are potentially devastating to practices by making oncologists responsible for things outside of their control, including the high cost of drugs, particularly with the rapid development of new agents at a very high cost and also responsible for total cost of care, including the treatment of co-morbid conditions outside of our control. It places a two-sided risk model as an unacceptable or flawed thing that would be potentially devastating to the practices.

So we are very eager to test models that build on the lessons that have been learned from prior initiatives, models that promote quality in evidence-based care that help to

reduce variability and enhance care coordination and to promote meaningful communication with patients and their families and align financial incentives in a rational and sustainable way.

So in summary, we strongly support the MASON proposal and express our willingness to participate.

CHAIR BAILET: Thank you. Is Indranil Dey on the line? No? So is there anyone else present who I didn't call on who wanted to speak? Is there anyone else on the line who wants to speak? Yes? No?

OPERATOR: We have no further public commenters at this time.

CHAIR BAILET: Thank you. So we are now at a point where we're ready to begin those deliberations. And I believe we can go ahead by criteria and start to vote unless there are additional comments that the Committee members have based on the public comments or the interactions that we've heard. Len?

DR. NICHOLS: I think we should chat

a little bit first. I would find it useful. I have a question. So, you know, I like to simplify things.

I sort of feel like there's two questions here. One is, is there value-add vis-a-vis the existing OCM? That's obviously EAS, I think.

And the second question is, is this thing close enough to being meritorious of CMS' attention to develop it? It clearly cannot be done without combining the various data resources we talked about.

It clearly cannot be done without substantial investment and perhaps teaching people some of these new techniques. But more importantly, it cannot be done without CMS' true engagement. And that to me is the question before us.

So, I guess, I just wanted to ask are you in a different place than you were when you made your recommendation how you see these?

VICE CHAIR TERRELL: So, if you think

about where we were before we came up with our new criteria, we had this sort of limited scale testing. Okay?

And within that context, this to my mind looked pretty darn perfect because that's where it came from, right? COME HOME was a grant. And they got money and they demonstrated, you know, improvement in costs and quality.

And then they've created and thought about an alternative payment model. And then they say, I mean, like almost in the very first portion of their application or their proposal, these things haven't been developed yet. Okay?

You know, what we've heard since then is it's going to be okay. We can do it quickly. There's lots and lots of stuff that we can do this. We know it's feasible. We've thought about it. And I believe every word of that. Okay?

There's not one thing they've said about clusters or anything else that I don't believe is true. They didn't say winterization

today, but it would have sounded so cool if they had said that in the middle of Monte Carlo and blue bottled that. Okay.

So within that context, okay, we had criteria, which is where is it right now? Okay. And so in my head where we were was where we were as we were creating the thought process, which is, it's ready to go, right?

Now where we are right now in conversations we've had with CMMI, with the experience we've had with others with their disdain of the word limited scale testing is this new nether land with these new criteria for which I think personally this fits in one of those categories quite well.

Okay. So I personally believe that, as you go through the criteria, those things are still true in real time with respect to they aren't there yet, but they've got a methodology for getting there.

And we've got a process in place that is new for this meeting, which would allow what I

believe is the intention, which is here's the payment model that may fix some things as you've said. It's been well thought out. It's looking at a problem that is in the current situation that needs to be improved upon.

And there's a group of people willing to do it. And if it were successful, it could change the world at a much larger scale. But it needs to be developed in a partnership with CMMI willing to do it. So, I mean, that's where I think it is if that makes any sense to you.

CHAIR BAILET: Any other comments from the Committee? Then are we ready to go ahead and vote on the criteria? I'm seeing affirmative.

Voting

So we're going to go ahead and start -- while they queue up the mechanics, if we could just get the first slide up here for Criteria Number 1.

And just to remind folks that we have a not applicable category. We have a does not meet, meets and meets and deserves priority

consideration. And we're going to go through the process of all ten.

Criterion 1

The first one is scope. A high priority item aimed 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. So let's go ahead and vote.

Somebody has got to push it one more time with feeling here. Angelo, are you voting?

DR. SINOPOLI: Yes. I am. I'm on though.

CHAIR BAILET: So one of the controls is not recording it looks like. But does it give you the number in the -- if it gives you the number in the window then it's probably working. There you go. Okay. It's not you. It's not user error. Okay. Very good. All right. So go ahead, Sarah. Let's get the results.

MS. SELENICH: So five members

determined that the proposal meets and deserves priority consideration on that basis. Zero members voted five, meets and deserves priority consideration. Two members voted four, meets. And zero members voted three, meets. Zero members voted two, does not meet. And zero members voted one, does not meet. And zero members voted not applicable.

A simple majority is needed, which is four votes for the seven voting members. And the majority finding is that the proposal meets and deserves priority consideration.

Criterion 2

CHAIR BAILET: Thank you, Sarah. Criteria Number 2 is quality and cost, which is a high priority criterion. 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.

MS. SELENICH: Zero members voted six, meets and deserves priority consideration. One

member voted five, meets and deserves priority consideration. Two members voted four, meets. Four members voted three, meets. Zero members voted one or two, does not meet. And zero members voted not applicable.

We roll down until we reach the necessary simple majority. So the finding of the Committee is the proposal meets Criterion 2.

Criterion 3

CHAIR BAILET: Thank you, Sarah. Criterion Number 3 is payment methodology, a high priority criterion. To pay the alternative payment 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 APM entities, how the payment methodology differs from current payment methodologies and why the Physician-Focused Payment Model cannot be tested under current payment methodologies. Please vote.

MS. SELENICH: Zero members voted five

or six, meets and deserves priority consideration. One member voted four, meets. Four three, meets. Two members voted two, does not meet. Zero members voted one, does not meet. And zero members voted not applicable.

The finding of the Committee is the proposal meets this criterion.

Criterion 4

CHAIR BAILET: Thanks, Sarah. Criterion Number 4 is value over volume, provide incentives to practitioners to deliver high quality health care. Please vote.

MS. SELENICH: One member voted six, meets and deserves priority consideration. Zero members voted five, meets and deserves priority consideration. Three members voted four, meets. Three members voted three, meets. Zero members voted one or two, does not meet. And zero members voted not applicable.

Therefore, the finding of the Committee is that the proposal meets this criterion.

Criterion 5

CHAIR BAILET: Thanks, Sarah. Criterion Number 5, flexibility. Provide the flexibility needed for practitioners to deliver high quality health care. Please vote.

MS. SELENICH: Zero members voted six, meets and deserves priority consideration. One member voted five, meets and deserves priority consideration. Four members voted four, meets. Two members voted three, meets. Zero members voted one or two, does not meet. And zero members voted not applicable.

The finding of the Committee is that the proposal meets this criterion.

Criterion 6

CHAIR BAILET: Thanks, Sarah. Criterion Number 6, ability to be evaluated. Have evaluable goals for quality of care, cost and other goals of the PFPM. Please vote.

MS. SELENICH: One member voted six, meets and deserves priority consideration. One member voted five, meets and deserves priority

consideration. Two members voted four, meets. Three members voted three, meets. Zero members voted one or two, does not meet. And zero members voted not applicable.

The finding of the Committee is the proposal meets this criterion.

Criterion 7

CHAIR BAILET: Thank you. Criterion 7 is 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.

MS. SELENICH: Zero members voted five or six, meets and deserves priority consideration. Three members voted four, meets. Four members voted three, meets. Zero members voted one or two, does not meet. Zero members voted not applicable.

The finding of the Committee is that the proposal meets this criterion.

Criterion 8

CHAIR BAILET: Thank you, Sarah. Criterion Number 8, patient choice. Encourage greater attention to the health of the population served while also supporting the unique needs and preferences of the individual patients. Please vote.

MS. SELENICH: One member voted six, meets and deserves priority consideration. One member voted five, meets and deserves priority consideration. Three members voted four, meets. Two members voted three, meets. Zero members voted one or two, does not meet. And zero members voted not applicable.

The finding of the Committee is that the proposal meets this criterion.

Criterion 9

CHAIR BAILET: Thank you. Criterion Number 9 is patient safety. Aims to maintain or improve standards of patient safety. Please vote.

MS. SELENICH: One member voted six,

meets and deserves priority consideration. One member voted five, meets and deserves priority consideration. Four members voted four, meets. One member voted three, meets. Zero members voted one or two, does not meet. Zero members voted not applicable.

The finding of the Committee is that the proposal meets this criterion.

Criterion 10

CHAIR BAILET: Thank you. And Criterion 10, which is health information technology. Encourage the use of health information technology to inform care. Please vote.

MS. SELENICH: Three members voted six, meets and deserves priority consideration. One member voted five, meets and deserves priority consideration. Three members voted four, meets. Zero members voted three, meets. Zero members voted one or two, does not meet. And zero members voted not applicable.

The finding of the Committee is that

the proposal meets this criterion and that the proposal deserves priority consideration on this basis.

Overall Vote

CHAIR BAILET: Thank you. So we're now going to move into the recommendation stage of our process. I remind folks that we have three categories, not recommended for implementation as a PFPM, recommended, which is a two part voting process, which I shared with you at the opening, and three referred for other attention by HHS.

So we're going to vote electronically at first. And then we're going to go around the room, probably starting with you, Jen, and declare how we voted and then move into the second part.

Or are we going to hold off on the comments? It depends on the distribution. Okay. So we're going to go ahead and vote on the first section at this point. Wow, Sarah.

MS. SELENICH: Zero members vote to

refer the proposal for other attention by HHS. Seven members vote to recommend the proposal. And zero members vote to not recommend the proposal.

CHAIR BAILET: All right. Thank you. So let's get the second part up, which is a little more complicated, but again, there are four subcategories. Substantially meets the Secretary's criteria for PFPMs and we are recommending implementing the payment model as proposed.

PTAC recommends further developing and implementing the proposal as a payment model as specified in the PTAC comments.

Third, PTAC recommends testing the proposal as specified in PTAC comments to inform payment model development.

And the last category is PTAC recommends implementing the proposal as part of an existing or planned CMMI model.

So we're going to go ahead and vote.

MS. SELENICH: So a two-thirds

majority is needed to come to the final recommendation. That's the five in the case of these seven voting members. So currently, zero members recommend to implement the proposal as part of a CMMI model. Two members recommend to test the proposal per PTAC comments. Four members recommend to develop and implement the proposal for PTAC comments. And one member recommends to implement the proposal as a payment model. So we need to vote again.

CHAIR BAILET: Well, but I made a mistake. I'm the one that voted 1 and I meant to push 2. So that's an -- I know. I'm a surgeon, okay? Come on, guys. Come on.

Yes, I know. I just cut the wrong leg off on that. Hey, come on. After three years, you've got to give me one. Give me one. Okay. I've got to look at the size of that thumb. My goodness. I come from a family of butchers. Oh my God.

So I think just for completeness and Sarah's going to look over my shoulder. I'm

going to actually try and push it. Let's re-vote, please. Can we do that? God, you guys are ruthless. I know, right? There we go. Okay. Goodness. I'll never live that down. All right.

MS. SELENICH: Okay. So zero members vote to implement the proposal as part of the CMMI model. One member votes to test the proposal per PTAC comments. Six members vote to develop and implement the proposal for PTAC comments. And zero members vote to implement the proposal as a payment model. So the finding of the Committee is to develop and implement the proposal for PTAC comments.

Instructions on Report to the Secretary

CHAIR BAILET: Okay. So as part of our process, and thank you, Sarah, for your guidance there. Part of our process now is to make sure because we're recommending based on our comments is to make sure that our comments, beside the deliberative comments that we've already made, make sure that if there's specific comments we want included, we need to bring those

forward now in public.

So why don't we start with you, Jen, and just you can declare how you voted and then any specific comments you want to be recorded and make sure they get into the Secretary's letter.

DR. WILER: I voted Number 2 in support. The comments I'd like to make are testing has shown successful implementation of a pilot funded by CMMI that does show improved quality and decreased cost.

The use of digital health solutions are novel, innovative. And it is my personal hope that the partnerships that have been previously described by the other specialty societies allow competitiveness in the marketplace so that these are not proprietary and are accessible to improve precision care to cancer patients.

CHAIR BAILET: Thank you. Len? Oh, Angelo, you're on the line. Why don't we let you go ahead?

DR. SINOPOLI: Okay. So I just wanted

to comment that I think this is a tremendously aspirational task and very much congratulate the people that worked so hard to put this together.

And my view is it is the most comprehensive program I've seen around oncology and really support moving forward. I would echo some of the previous comments in terms of making sure that given all the support for it that this would not be proprietary and that the methodology and ability for others to generate similar models across the country be supported and that CMMI supports the efforts around looking at the data and modeling for this.

CHAIR BAILET: Thank you, Angelo. Len?

DR. NICHOLS: So I voted to recommend for further development. And I would say ever since we started discussing oncology in general we've been hearing about the problems with the OCM.

It was a good first step. I love the idea of thinking of this as sort of OCM 2.0. And

what I really like is the continuous learning that's baked into this.

I think the potential for updating over time which allows both reclassification of patients and a resetting of the targeting is exactly what we need in a field this dynamic.

I'm reasonably certain this is a very unfamiliar methodology to certain people inside CMS. They're just not used to this. So it's going to be a, shall we say, collaborative process.

But I think it's one that has potential to give great value. And therefore, we should be encouraging CMS to devote their resources to develop and test this on a large scale as soon as possible.

CHAIR BAILET: Grace?

VICE CHAIR TERRELL: I was the one that didn't switch her vote and kept it at testing. And I say that within the context of how important this is to get it right because I do think that this is potentially a

transformative model.

And I hope that within the context of the way that we, the PRT, presented our report, both written and verbally, got that across, which is that this is -- people that have thought a lot about this have thought about details that are not present in the current models and if it's done right could be a real game changer, but they are evangelicals.

And there are people out there that are not evangelicals. Within the context of change management, the top 5 percent or the top 20 percent of those that embrace change have to get above and beyond that to the tipping point. And to get to that tipping point, it needs to be a bit broader and needs to involve those that are not evangelicals.

And so within my thought process, that's what testing, I believe, is about in this context. So some of you have talked about non-proprietary. I'm thinking of it as being how do we make this more broadly applicable among those

that are just so bought into the world that is with all its misery, that they can't see to do this and are going to need some much more hand-holding to do so.

So it's probably splitting hairs. I do think that the timing of our new categories was perfect for this because a lot of the PRT thought process was in the context of the old categories of limited scale testing.

And what we've done with this, I believe, is a proof in process that our new way that we're thinking through things may be more effective.

So that may be good for public comment later on, not today. But as others who have been through the process both pre and now this and then post if they can reflect upon this experience. But we just got to get this one right.

CHAIR BAILET: Thank you, Grace. And I voted in the second category. I really did. And so, look, a couple of additional comments.

First of all, this is a very elegant model that is in a field that, I think, probably everyone either knows someone or has a family member that's experienced cancer care. And despite a lot of efforts to date, it still remains highly variable. Shared decision-making, which is part of this model, is critically important. And I think that that's a huge gap that I believe this model will help fill.

It was interesting to see the level of support from the societies that actually are in the trenches to support the clinicians that are actually taking care of the lion's share of these patients. I'm not surprised by that. But the outpouring of support was noted and certainly helped me in my decision-making process.

The pricing for drugs, the way drugs are addressed in this model, it sort of tackles, I believe, maybe not completely, but it certainly makes a significant move in factoring out that question of how are you making decisions about the actual therapeutics that are in queue and,

you know, is there a pricing component that is going to benefit the practice. And this model neutralizes that to a large degree, which I think is incredibly important.

So I look forward to seeing this in effect. The rapid cycle of continuous learning, leveraging machine learning in that process, I think, is incredibly valuable. And this model offers that opportunity to explore that and see that in action.

I don't want to underestimate the complexity of implementing this model. You've got budgets and people who are at risk and things are in flight. And then with expensive therapies that may come to light, just CAR T therapy is just a small example of that. It's going to require some diligence and some flexibility in how the model is built and implemented and an understanding, as Grace has said, from the provider community on how to go ahead and actually incorporate this into their practice style.

So that's all I had. Thank you. Bruce?

MR. STEINWALD: I'm like Grace. I did move from three to two based on the presentation today and the materials that we got to look at because I think the development that we are concerned about has already begun.

However, I wouldn't mind if someone with a little bit more methodological expertise took a peek at these tables, either the CMS actuaries or our own consultant just to validate what I think we all believe, that the proof of concept has been demonstrated. But it would give me some comfort if someone with the appropriate expertise could weigh in on that as well.

CHAIR BAILET: Thank you, Bruce. Paul?

DR. CASALE: Yes. I also voted two. And a lot of great comments. So not much more to add. Just adding on to Bruce's, and I know this part of the process is we do get this information late. And I'm not criticizing the submitters,

you know, this PowerPoint. But, you know, we realistically didn't have a chance to understand it. So I certainly support Bruce's comment if we could get some further feedback either from our own -- or others, I think that would be helpful.

And I think that's part of why I voted towards the development because I'm still a bit uncomfortable. I'm thinking -- I certainly think that they are able to develop these, but I have more confidence with a little bit more time and evaluation.

And then to Grace's point around getting the physicians on board and being sure that this model has, you know, the flexibility, which, you know, part of the quality measures was 80 percent compliance with the pathway.

And, you know, physicians often bristle around all of that, you know, cookbook medicine and all of that. So ensuring that there's a flexibility for the appropriate patient that, you know, they would go off of that pathway. And, again, I think that's part of the

development process that needs to happen.

CHAIR BAILET: Thank you, Paul. I appreciate the Committee's engagement and helping provide that input which will be incorporated in -- I think, Julia, if you could take a second maybe and just reflect back. I know I maybe caught you by surprise. But that's part of our process.

It would be great if you could just reflect back what you heard and make sure that there is nothing else that we don't need to include.

DR. DRIESSEN: Sure. So the general sort of tone of the response will indicate pretty unequivocal support for the premise of the model and conceptually how to build on OCM. And despite some acknowledgment of the complexity, that there was sufficient sort of assurance in the feasibility of implementing and updating it based on the new information that was presented today from the submitters.

The sort of primary places I'd like to

clarify are the departures in voting on the two criteria that are high priority from the PRT report. So primarily thinking about the notion of quality and cost and payment methodology.

So at this point, sort of the primary update is that while there were concerns that were identified in the PRT about the feasibility of the OPCs that really what I mentioned before that the demonstration and additional information is sort of sufficient at this point to satisfy those criteria for the Committee.

CHAIR BAILET: Thank you, Julia. Were there any other elements that we wanted to add to her summary?

MR. STEINWALD: Let me just respond to -- because I switched my vote to meet on quality and cost, in large part because of the emphasis on the use of nationally tested guidelines embedded into the OPCs.

Also, there's a little bit of a tactical thing there on because I stayed at a two on payment because of the need for further

development and therefore didn't feel the need to stay on a two on quality of cost.

CHAIR BAILET: Angelo, you're on the phone. I just wanted to make sure if there was anything you wanted to add.

DR. SINOPOLI: I think all of that was well covered.

CHAIR BAILET: Thank you. So that concludes our consideration of your proposal. Barbara, again, my compliments to you and your team for bearing with our process.

What I'd like to do is take literally a five minute break real quick and then come back at five minutes to the hour. Thank you.

(Whereupon, the above-entitled matter went off the record at 2:46 p.m. and resumed at 2:54 p.m.)

General Public Comments

CHAIR BAILET: So this is the part of the public meeting where general comments are made. We, as a Committee, sent out some information about providing feedback. We also

wanted to get input on how CMMI is working with the stakeholder community, particularly those that have submitted proposals that we recommended.

We have four people teed up to speak. I want to make sure we have time to hear them. So if you could refrain or keep your remarks within three minutes that would be great.

Sandy Marks from the American Medical Association is going to lead it off for us. Thanks, Sandy.

MS. MARKS: Thank you. I have actually more than three minutes but I'll try to quit when I think I've reached three minutes. How about that?

CHAIR BAILET: We'll let you know.

MS. MARKS: Okay. You let me know.

CHAIR BAILET: Okay. All right.

MS. MARKS: And I'm also, I'm not a doctor. My father was a doctor. But I'm not one so. I like doctors though.

So the AMA strongly supported the

PTAC's creation and has worked with a number of medical societies to help them design APMS. We are among several organizations that regularly attend the PTAC meetings, often comment on proposals and respond to requests for input on the process.

A generally different set of organizations has submitted most of the proposals to PTAC and gone through the PTAC review process.

The report that PTAC issued last month on the September public comment session indicated that PTAC received some feedback from the AMA and others in the former group but did not hear from most of the stakeholders whose models PTAC had recommended to HHS.

After discussion with some PTAC members, the AMA decided to contact the submitting organizations ourselves to find out how the PTAC process has worked from their perspective, what follow-up has occurred with CMS since PTAC recommended their models, what kinds of data or technical assistance would have been

helpful and whether there were or are ways the AMA could help.

We contacted people at 14 organizations whose models PTAC has recommended to HHS and heard back from 10 of them. We told them we would keep their responses confidential, so I'm summarizing them for you but will not identify the organizations. Also, we did not get 10 answers to every question we asked so the numbers don't always add up to 10.

Four submitters had discussions with CMMI about their model before they developed the proposal to PTAC and three of the four proceeded with their PTAC proposal because they were encouraged to do so in those discussions.

Five submitters were contacted by CMMI after PTAC had recommended their proposal to HHS, including one of the four who had met with CMMI ahead of time.

Several submitters have had multiple meetings with CMS. Two submitters described their post-PTAC interaction with CMMI as involving some

limited collaboration. Another two characterized the discussions as CMMI asking them for information.

Three of the five submitters who met with CMMI after their proposals were recommended by PTAC had meetings recently or had meetings planned. The other two last met with CMMI over the summer.

It is our impression that there has been significantly more outreach by CMMI to the submitters since Adam Boehler became the CMMI director.

Based on these interactions, one submitter thinks that CMMI is almost certain to implement the model that it proposed or something close to it within the next year but said that CMMI has suggested a different payment model for the changing care delivery that was proposed in the APM.

Two submitters think it is possible that CMMI will either implement a model close to what they proposed or a different model that

covers the same patients.

Three said CMMI is not likely to implement their model. And two said they do not know CMMI's plans. One said they believe CMMI wants to do something.

All but three submitters felt they had been able to obtain the data they needed to develop their proposal and go through the PTAC review process although some noted that the data analyses had been expensive to obtain.

The others said they would have been better able to respond to questions from the PTAC if they had been able to access CMS claims data with utilization spending and risk score data on their patient population.

The technical assistance that some submitters said would have been helpful is expertise in modeling the impacts of the proposed APM and having a better understanding of what the barriers are to the PTAC recommended proposals being pilot tested or implemented for Medicare patients and how to get over them.

Barriers include the approaches proposed for financial risk, proposed quality measures and operational and legal challenges to implementation.

Several submitters have already implemented their models with health care innovation awards or private payers and achieved cost savings and quality improvements and do not understand why CMMI has not supported the proposals recommended by PTAC so that Medicare patients can benefit from them.

Most submitters want the AMA's help to overcome these barriers so the models can move forward. And several indicated our outreach to seek their feedback was itself a great start. So we're glad we started that dialogue.

Over the years, the physician community has worked collaboratively with CMS on many aspects of its payment systems. Many proposal developers believe that the creation of the PTAC would foster this type of collaboration on APMs for Medicare patients and are

disappointed in the lack of progress so far.

We know that Adam Boehler is working to get some of the PTAC recommended models implemented and the AMA strongly supports these efforts.

Going forward, we hope that a more interactive and collaborative process can be developed with a clear roadmap for submitters that can further advance our shared goals of having more physician focused APMs that will improve outcomes and lower costs for Medicare patients. Thanks.

CHAIR BAILET: Thank you, Sandy. Harold?

MR. MILLER: Thanks, Jeff. I just wanted to say -- and thank you, Sandy, for the report. I think we've all been concerned about the lack of progress on the recommendations that we had made. And it sounds like there is now at least some progress being made with some models in process.

I did want to comment, though, based

on Sandy's report, that I think that the process that is used to get to those models is also very important and that if simply a model comes out that is the CMS version of something rather than having been developed in conjunction with the physician community and the physicians that developed it I think it is inconsistent with what really the vision for PTAC was.

And I think that the success of these models is going to be not just the payment model themselves, but the active engagement of the physicians who are involved in implementing it. And I don't see that that is going to be nearly as enthusiastic and committed if it is not the model that they developed but something that CMMI might think is better.

And I think up until now in general both in Medicare and in the private market, we have seen mostly payer developed models that have not worked very well. And I do think that it's time that we see some more focus on models developed by physicians and other health care

providers.

So I hope that CMMI will, as it does take action on PTAC recommendations that it does it in collaboration with the applicants. And I just wanted to communicate how strongly I feel that that's going to be important to success.

CHAIR BAILET: Thank you, Harold. Len?

DR. NICHOLS: So I'd like to see Harold's point and raise him one more and that is I want to thank Sandy for the presentation. That was very helpful. And thank you for doing the survey. I know that's not easy to do.

But what to me was the most compelling line out of Sandy's presentation was submitters need a clear roadmap of what the criteria are or what the barriers are, all that stuff. And I hope we can work to a place.

I certainly share Sandy's judgment that I think we're making progress. I think what Adam has been doing lately is an improvement over where we were before, but we still are batting

zero.

And we hope to do better than that between now and March. But if we don't get a roadmap out of this, we will have failed. And that's really what we need to continue to strive for.

CHAIR BAILET: Thank you, Len. We have Robert Carlson from the National Comprehensive Cancer Network signed up. No? Like I said, we don't.

So that actually concludes the additional folks who signed up for generalized comments. And, again, Sandy, I want to thank you and the AMA for working with the stakeholder community specifically to provide that important feedback because, as a committee, it's not always possible for us to know the conversations that are happening behind the scenes. So thank you for those insights.

Adjourn

I need a motion from the Committee to adjourn. Is there such a motion?

MR. STEINWALD: So moved.

DR. CASALE: Second.

CHAIR BAILET: I'm hearing that. I'm feeling it. All in favor?

(Chorus of ayes.)

CHAIR BAILET: Thank you. Thank you, everybody.

(Whereupon, the above-entitled matter went off the record at 3:04 p.m.)

C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: Public Meeting

Before: PTAC

Date: 12-10-18

Place: Washington, DC

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

Neal R Gross

Court Reporter