

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

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

2 12:34 p.m.

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

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

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

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

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

11 So welcome, Jennifer.

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

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

1 that we recently had submitted to the Committee.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

15 I would like to take this opportunity
16 to thank my PTAC colleagues, all of whom have
17 given countless hours to the careful and expert
18 review of the proposals we receive. Thank you
19 again for your work.

20 And thank you to the public for
21 participating in today's meeting in person, via
22 live stream or on the phone.

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

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

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

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

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

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

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

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

17 (No audible response.)

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

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

1 **Oncology Business Solutions, Inc, (IOBS)**

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

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

12 **Disclosures**

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

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

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

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

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

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

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

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

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

1 deliberation on the proposal itself.

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

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

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

1 CHAIR BAILET: Dr. Sinopoli?

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

9 CHAIR BAILET: Thank you.

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

13 Grace?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 we all believe it meets.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 happening at CMS thinking about the drug pricing.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4 Bruce, do you have anything you want
5 to add?

6 **Clarifying Questions from PTAC to PRT**

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

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

1 happy to do so.

2 CHAIR BAILET: Len?

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

7 CHAIR BAILET: All right. Dr. McAneny
8 and team? So just to level set, it would be
9 great if you could introduce your team and then
10 we're going to have opening comments from you for
11 10 minutes and then open it up to exchange
12 between the Committee and your team. Thank you,
13 Barbara.

14 **Submitter's Statement**

15 Barbara McAneny, MD, Kameron Baumgardner,

16 Terrill Jordan, JD

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

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

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

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

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

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

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

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

1 ASCO.

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

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

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

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

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

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

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

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

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

1 a system that penalizes doctors for caring for
2 complex patients.

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

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

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

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

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

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

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

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

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

15 MR. BAUMGARDNER: Thank you.

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

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

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

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

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

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

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

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

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

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

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

13 Bruce?

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

22 DR. McANENY: So the first answer is

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

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

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

22 DR. NICHOLS: So thank you for that.

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

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

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

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

5 And do you want to comment on that?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

19 DR. McANENY: And to add in --

20 DR. SINOPOLI: This is --

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

1 McAneny finish and then we'll --

2 DR. SINOPOLI: Yes.

3 CHAIR BAILET: Okay?

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

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

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

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

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

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

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

12 Does that help?

13 DR. NICHOLS: Yes.

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

19 So go ahead, Dr. Sinopoli.

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

1 this, but I've got one question.

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

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

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

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

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

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

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

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

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

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

22 DR. SINOPOLI: Thank you.

1 CHAIR BAILET: Paul?

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

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

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

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

16 MR. BAUMGARDNER: No.

17 DR. CASALE: Okay. Great.

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

1 just if you had any sort of reactions to that.

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

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

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

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

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

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

1 familiar to CMS.

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

10 CHAIR BAILET: Jennifer?

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

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

22 DR. McANENY: Thank you. So for the

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

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

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

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

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

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

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

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

22 As you go through the NCCN Guidelines

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

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

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

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

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

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

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

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

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

17 DR. WILER: Both.

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

1 relapses, if the patient moves -- completes the
2 planned course of therapy, then they would switch
3 to a maintenance/observation-type of an OPC.

4 So there are real clinical end points that we see
5 in oncology all the time of where we could -- we
6 could demarcate that.

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

1 Do you want to comment on that?

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

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

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

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

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

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

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

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

10 CHAIR BAILET: That was my question.
11 Thank you.

12 Bruce?

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

1 necessary to implement the model?

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

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

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

22 The procedural part of that, of

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

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

12 **Public Comments**

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

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

22 Sandy?

1 MS. MARKS: Okay. Thank you.

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

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

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

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

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

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

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

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

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

20 CHAIR BAILLET: Thank you, Sandy.

21 Stephen Grubbs from the American
22 Society of Clinical Oncology?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 The NCCN Clinical Practice Guidelines

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

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

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

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

1 objectives.

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

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

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

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

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

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

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

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

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

22 As you may know, ASTRO has been with

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

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

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

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

1 outcomes and reduces cost. Thank you.

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

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

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

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

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

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

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

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

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

19 Thank you very much for allowing us to
20 comment.

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

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

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

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

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

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

1 HOME project and the Oncology Care Model.

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

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

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

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

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

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

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

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

22 DR. NICHOLS: I think we should chat

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

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

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

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

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

22 VICE CHAIR TERRELL: So, if you think

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

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

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

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

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

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

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

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

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

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

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

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

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

15 **Voting**

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

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

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

3 **Criterion 1**

4 The first one is scope. A high
5 priority item aimed to either directly address an
6 issue in payment policy that broadens and
7 expands the CMS APM portfolio or include APM
8 entities whose opportunities to participate in
9 APMs have been limited. So let's go ahead and
10 vote.

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

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

15 CHAIR BAILET: So one of the controls
16 is not recording it looks like. But does it give
17 you the number in the -- if it gives you the
18 number in the window then it's probably working.

19 There you go. Okay. It's not you. It's not
20 user error. Okay. Very good. All right. So go
21 ahead, Sarah. Let's get the results.

22 MS. SELENICH: So five members

1 determined that the proposal meets and deserves
2 priority consideration on that basis. Zero
3 members voted five, meets and deserves priority
4 consideration. Two members voted four, meets.
5 And zero members voted three, meets. Zero
6 members voted two, does not meet. And zero
7 members voted one, does not meet. And zero
8 members voted not applicable.

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

13 **Criterion 2**

14 CHAIR BAILET: Thank you, Sarah.
15 Criteria Number 2 is quality and cost, which is a
16 high priority criterion. Anticipated to improve
17 health care quality at no additional cost,
18 maintain health care quality while
19 decreasing cost or both improve health care
20 quality and decrease cost. Please vote.

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

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

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

9 **Criterion 3**

10 CHAIR BAILET: Thank you, Sarah.
11 Criterion Number 3 is payment methodology, a high
12 priority criterion. To pay the alternative
13 payment entities with a payment methodology
14 designed to achieve the goals of the PFPM
15 criteria. Addresses in detail through this
16 methodology how Medicare and other payers, if
17 applicable, pay APM entities, how the payment
18 methodology differs from current payment
19 methodologies and why the Physician-Focused
20 Payment Model cannot be tested under current
21 payment methodologies. Please vote.

22 MS. SELENICH: Zero members voted five

1 or six, meets and deserves priority
2 consideration. One member voted four, meets.
3 Four three, meets. Two members voted two, does
4 not meet. Zero members voted one, does not meet.

5 And zero members voted not applicable.

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

8 **Criterion 4**

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

13 MS. SELENICH: One member voted six,
14 meets and deserves priority consideration. Zero
15 members voted five, meets and deserves priority
16 consideration. Three members voted four, meets.

17 Three members voted three, meets. Zero members
18 voted one or two, does not meet. And zero
19 members voted not applicable.

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

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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

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

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

7 **Criterion 7**

8 CHAIR BAILET: Thank you. Criterion
9 7 is integration and care coordination.
10 Encourage greater integration and care
11 coordination among practitioners and across
12 settings where multiple practitioners or settings
13 are relevant to delivering care to the population
14 treated under the PFPM. Please vote.

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

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

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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,

1 meets and deserves priority consideration. One
2 member voted five, meets and deserves priority
3 consideration. Four members voted four, meets.
4 One member voted three, meets. Zero members
5 voted one or two, does not meet. Zero members
6 voted not applicable.

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

9 **Criterion 10**

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

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

22 The finding of the Committee is that

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

4 **Overall Vote**

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

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

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

22 MS. SELENICH: Zero members vote to

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

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

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

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

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

21 So we're going to go ahead and vote.

22 MS. SELENICH: So a two-thirds

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

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

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

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

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

5 MS. SELENICH: Okay. So zero members
6 vote to implement the proposal as part of the
7 CMMI model. One member votes to test the
8 proposal per PTAC comments. Six members vote to
9 develop and implement the proposal for PTAC
10 comments. And zero members vote to implement the
11 proposal as a payment model. So the finding of
12 the Committee is to develop and implement the
13 proposal for PTAC comments.

14 **Instructions on Report to the Secretary**

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

1 forward now in public.

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

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

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

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

22 DR. SINOPOLI: Okay. So I just wanted

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

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

14 CHAIR BAILET: Thank you, Angelo.
15 Len?

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

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

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

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

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

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

17 CHAIR BAILET: Grace?

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

1 transformative model.

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

10 And there are people out there that
11 are not evangelicals. Within the context of
12 change management, the top 5 percent or the top
13 20 percent of those that embrace change have to
14 get above and beyond that to the tipping point.
15 And to get to that tipping point, it needs to be
16 a bit broader and needs to involve those that are
17 not evangelicals.

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

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

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

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

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

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

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

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

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

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

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

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

1 So that's all I had. Thank you.

2 Bruce?

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

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

16 CHAIR BAILET: Thank you, Bruce.
17 Paul?

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

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

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

12 And then to Grace's point around
13 getting the physicians on board and being sure
14 that this model has, you know, the flexibility,
15 which, you know, part of the quality measures was
16 80 percent compliance with the pathway.

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

1 development process that needs to happen.

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

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

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

22 The sort of primary places I'd like to

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

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

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

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

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

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

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

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

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

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

15 (Whereupon, the above-entitled matter
16 went off the record at 2:46 p.m. and resumed at
17 2:54 p.m.)

18 **General Public Comments**

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

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

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

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

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

16 CHAIR BAILET: We'll let you know.

17 MS. MARKS: Okay. You let me know.

18 CHAIR BAILET: Okay. All right.

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

22 So the AMA strongly supported the

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

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

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

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

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

3 We contacted people at 14
4 organizations whose models PTAC has recommended
5 to HHS and heard back from 10 of them. We told
6 them we would keep their responses confidential,
7 so I'm summarizing them for you but will not
8 identify the organizations. Also, we did not get
9 10 answers to every question we asked so the
10 numbers don't always add up to 10.

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

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

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

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

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

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

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

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

1 covers the same patients.

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

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

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

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

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

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

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

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

1 disappointed in the lack of progress so far.

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

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

13 CHAIR BAILET: Thank you, Sandy.
14 Harold?

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

22 I did want to comment, though, based

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

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

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

1 providers.

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

7 CHAIR BAILET: Thank you, Harold.
8 Len?

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

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

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

1 zero.

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

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

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

20 **Adjourn**

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

1 MR. STEINWALD: So moved.

2 DR. CASALE: Second.

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

5 (Chorus of ayes.)

6 CHAIR BAILET: Thank you. Thank you,
7 everybody.

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

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C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: Public Meeting

Before: PTAC

Date: 12-10-18

Place: Washington, DC

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