PHYSICIAN-FOCUSED PAYMENT MODEL TECHNICAL ADVISORY COMMITTEE (PTAC)

PUBLIC MEETING

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

Tuesday, December 19, 2017
9:00 a.m.

COMMITTEE MEMBERS PRESENT:
JEFFREY W. BAILET, MD, Chair
ROBERT BERENSON, MD
PAUL N. CASALE, MD, MPH
TIM FERRIS, MD, MPH
RHONDA M. MEDOWS, MD
HAROLD D. MILLER
ELIZABETH MITCHELL, Vice Chair (via teleconference)
LEN M. NICHOLS, PhD
KAVITA PATEL, MD, MSHS
BRUCE STEINWALD, MBA
GRACE TERRELL, MD, MMM

STAFF PRESENT:
Ann Page, Designated Federal Officer (DFO), Office of the Assistant Secretary for Planning and Evaluation (ASPE)
Sarah Selenich, ASPE
Mary Ellen Stahlman, ASPE

CONTRACTOR STAFF:
Adele Shartzer, PhD, Urban Institute

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Large Urology Group Practice Association (LUGPA): LUGPA APM for Initial Therapy of Newly Diagnosed Patients with Organ-Confined Prostate Cancer

PRT (Preliminary Review Team):
Len M. Nichols, PhD (Lead);
Paul N. Casale, MD, MPH; Kavita Patel, MD, MSHS
Staff Lead: Adele Shartzer, PhD

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P R O C E E D I N G S

[9:05 a.m.]

* **OPENING REMARKS**

CHAIR BAILET: Good morning. Welcome to the Physician-Focused Payment Technical Advisory Committee's third series of public meetings. We formally go by PTAC. We're pleased to have you all here today in addition to the members that are in the room of the public. We also have some folks on the phone and some folks live-streaming as well.

We'd like to thank all of you for your interest in today's meeting. In particular, we'd like to thank you and the stakeholders for the submissions of the models, especially those who are here today in support of their submissions. Your hard work and dedication to payment reform is truly appreciated.

I'd like to make a few quick acknowledgements. One is to the staff that you see supporting the Committee, some seated at the table, some others in the background. The work that we're doing is very laborious, and they make the work a lot easier for us and help us get through tremendous amounts of material.

I'd also like to acknowledge the folks on the cameras and the microphones. They make it look easy, but

we've been in circumstances where it hasn't always worked, and we really appreciate the talent of the folks who are helping make this meeting come alive for everybody.

We're going to go ahead and start, but before I do, I want to make sure that people remember that what you're going to see today relative to our discussion about these models is the very first time we as a Committee have discussed them in any way.

We have the Proposal Review Teams, comprised of three individuals. They work very closely with the submitters, and they talk amongst themselves about the model, but the full Committee does not deliberate in any way or discuss these models prior to today. So what you see in front of you as it unfolds is really live, our thought process, as we consider and hear and retain the information.

So, with that, I'd like to turn it over. Our first proposal today is the advanced primary care. It's a foundational alternative payment model for delivering patient-centered, longitudinal, and coordinated care. Dr. Kavita Patel is the Proposal Review Team lead, and I'm going to turn it over to her.

American Academy of Family Physicians (AAFP): Advanced Primary Care: A Foundational Alternative

Payment Model (APC-APM) for Delivering Patient-Centered, Longitudinal, and Coordinated Care

*** Committee Member Disclosures**

CHAIR BAILET: Oh, like I said, we need to do introductions and disclosures, and I'll start with myself. Jeff Bailet. There's a process, everyone, as I said. That's why we have good staff here to remind me. So Jeff Bailet, Executive Vice President for Health Care Quality and Affordability with Blue Shield of California.

Tim.

DR. FERRIS: Tim Ferris.

CHAIR BAILET: Oh, no disclosures. Sorry.

DR. FERRIS: Tim Ferris. I practice internal medicine at Mass General Hospital, and I am the CEO of the Mass General Physicians Organization.

CHAIR BAILET: Do you have a disclosure there, Tim?

DR. FERRIS: No disclosures.

CHAIR BAILET: The rest of this group here in a second.

DR. TERRELL: Grace Terrell. I'm a general internist, part of the Wake Forest Baptist Health System, and CEO of Envision Genomics, and I have nothing to disclose.

MR. MILLER: Harold Miller, CEO of the Center for Healthcare Quality and Payment Reform.

I do have a disclosure. Some years ago -- I can't even honestly remember when right now, although I remember it was an icy day in Kansas City that day -- I gave a presentation to the AAFP (board. It was 2009. I guess I do have that down here, and I gave a presentation at the AAFP Annual Leadership Forum in 2012. I received travel reimbursements from AAFP for those two trips to Kansas City, and I received a speaking fee for the presentation in 2012. I have no current or recent financial relationship with AAFP, and I had no involvement with this payment model.

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

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

CHAIR BAILET: We also have the Vice Chair, Elizabeth Mitchell, on the phone, so I'm going to open it up for her to introduce herself and then disclose.

VICE CHAIR MITCHELL: Thanks. Elizabeth

Mitchell, Network for Regional Healthcare Improvement. Nothing to disclose.

CHAIR BAILET: Thank you.

Len?

DR. NICHOLS: Len Nichols. I direct the Center for Health Policy Research and Ethics at George Mason University, and I have nothing to disclose.

DR. PATEL: Hi. Kavita Patel from Johns Hopkins and Brookings Institution, and I have worked informally with the AAFP in the past and attended sessions that they have sponsored, including sessions on payment reform. But I have not participated in the development of this proposal in any way.

I have also had working relationships with some of the D.C. AAFP staff, including working with several individuals prior to their roles in the AAFP.

DR. BERENSON: I'm Bob Berenson. I'm a Fellow at the Urban Institute. My disclosure is that as a Fellow with the Urban Institute, I have been funded by the AAFP to do analysis of payment models. The last such project was about four years ago. I recently was part of a failed bid in a response to an AAFP RFP (request for proposal) on single-payer analysis. I had no involvement with the development of this AAFP payment proposal, and now that I

have read the proposal, I do want to add an additional bit of information to the Committee, which is that they have identified the Goroll, et al., paper as a basis for their proposal. I was the second author on that paper. I come to this meeting with a predisposition to like this kind of a payment model, but I will have a number of questions that I'll be raising about it. So they do cite me as a -- basically as a basis for their proposal, and I just wanted people to know that.

DR. MEDOWS: I'm Rhonda Medows, Executive Vice President, Population Health, Providence St. Joseph Health.

I do have a disclosure. I have not had any involvement in this proposed model. I am, however, a family physician, proud to say it, proud to shout it.

[Laughter.]

DR. MEDOWS: I am also a member of the American Academy of Family Physicians, and I've been so for many years. We will not be counting.

This model would have no special or distinct effect on me, other than as part of a class, and I am not currently practicing medicine.

Thank you.

CHAIR BAILET: Thank you, Rhonda.

We're going to go ahead and let the staff

introduce themselves, starting with Sarah.

MS. SELENICH: Hi. My name is Sarah Selenich. I am an analyst at ASPE, and I help support the PRT that reviewed this proposal.

MS. STAHLMAN: And I'm Mary Ellen Stahlman. I'm the ASPE staff lead for PTAC.

MS. PAGE: And I'm Ann Page. I'm the Designated Federal Officer for this Committee, which is a committee governed by the Federal Advisory Committee Act, FACA.

CHAIR BAILET: All right. Thank you.

Kavita, you're on.

* **PRT Report to the Full PTAC**

DR. PATEL: Take it away. All right.

I'm going to refer to this as APC-APM (just for the sake of brevity, and I'm also going to make, just so that we can get to discussion, assumptions that everybody on the PTAC has read through our PRT reports, so I'll only bring up highlights that are relevant.

And just in general, I'm going through -- sorry. These are basics on the PRT. You can read it at your leisure.

So, in summary, the proposal in front of us has key components around payment, an APM Entity that would be a primary care practice, and a payment methodology. That

I'll just point you to the slide because it actually divides the payment into four parts, and of the four parts, each one of them has different permutations to them, with the first part, a risk-adjusted payment per beneficiary per month, a PBPM, for E&M services, at which point a practice could decide that they could receive that prospective payment for office-based E&M services or include all E&M services, regardless of site of care. That's the first part.

Second, a risk-adjusted PBPM payment for care management services delivered by the practice that are generally not face-to-face, and there are some examples in the actual proposal and in our submitter's responses to our questions.

Then third, a prospectively awarded incentive payment, to kind of think of it as a performance-based payment that might have a clawback aspect or might need to be repaid, depending on the practice's actual performance on selected measures.

And then finally, continued -- Think of it as kind of the fourth element is really kind of a continuation of current state fee-for-service payments under the Medicare physician fee schedule for things other than E&M services that are not included in those first two payments.

So if that -- I'm sure that we will get into further details around that, but I wanted to just offer that as like a basics of the payment.

Quality measures, I mentioned already. The APM Entity, again, potentially a practice, would select six quality measures, including at least one outcome measures. In addition to that, there are actually two utilization-based metrics -- ED and inpatient hospital utilization -- on top of these six kind of selected measures.

And then attribution, risk adjustment, the use of HIT. So given that very brief overview of a proposal, you can see how the PRT evaluated, and I'll break through each one of these so that you can understand some of our thinking.

And in general, the key issues that we grappled with at first were to really try to understand the distinction between this submitter's proposal and the current, frequently cited Comprehensive Primary Care Plus (CPC+) initiative, and for those of you that are not as familiar with CPC+, we actually do have some transcripts with CMMI that kind of go through that.

However, what we did do in our back-and-forth, also included in your packet, are kind of clear distinctions, and we as a PRT felt that these submitters

identified and articulated a clear need for opportunities in primary care that are not currently or would not potentially be currently met by the CPC+ program.

We did note concerns in the model, and we also will go over some of those, including attribution, primarily patient choice, as well as -- I mentioned already the four levels of payment, but the first one has kind of two options within the first level, and then finally kind of this issue of the performance-based payments and the quality.

So let's go to Criterion 1, Scope, which is one of the high priority. The PRT determined that we would meet this criteria, and it was a unanimous decision. And in general, as I already echoed, that this would allow for more opportunities, and in fact, the submitter estimated that there could be potentially an impact of up to 80,000 physicians that could potentially participate in this and a corresponding high number of Medicare beneficiaries.

This is a multi-payer model. So there is also an impact beyond just the Medicare program, and just to kind of highlight some things on this slide, it would completely replace E&M services with a flexible monthly payment, which again is kind of a novel notion, and also enable patients to explicitly choose which practice is accountable for

managing their care, which is not currently in the Medicare system.

The second criterion, Quality and Cost, also a high priority. The majority of the PRT felt that it met this criterion, and I'll talk about kind of where we thought there was some uncertainty, just to highlight. So we found that the focus on -- There was an emphasis in the proposal on delivery transformation, practice transformation, as well as kind of a notion that is embedded in research to show that if there are increased financial resources in primary care that there would be an anticipation in improvement in quality as well as a reduction in total health spending.

However, one of the issues that we contended with was that we couldn't necessarily assure that an increase in payment in primary care would always be balanced by a proportionate amount of savings. So there has been some literature and some models that demonstrated this, but it was certainly not something that we could assume would be part. And in fact, in looking at total metrics, we talked about inpatient and ED utilization. There were no other ways to think about total cost metrics within the submitted model.

And then the other aspects around quality in

particular were that even though the quality measures were reflected to align with the MIPS (program and MACRA, it's possible that an entire primary care practice could select quality measures around one discrete condition, for example, and that might not necessarily reflect improved quality for an entire population.

The third criterion, Payment Methodology, high priority, the majority of the PRT felt that the submitter met this criterion, and I don't want to highlight again kind of what the positive attributes were, but things that were problematic that I just want to point out, that there was this conversation about the complexity of a patient election. And if anybody on the PTAC wants us to walk through what the submitters have proposed, I can point you to that. But basically, a patient election as kind of an initial attribution, but then in addition to that, a claims-based attribution, so mixed methodologies that could be overly complex and/or also lead to potential selection biases.

And then there was also, as I mentioned, this potential for a clawback payment if a practice did not perform as expected on these quarterly incentive payments around quality, there could be some money that needs to be recouped from a practice. And when we're talking about

thin infrastructure or thinly resourced primary care practice, it put participants in a more susceptible area.

And then again the issue of kind of multiple payment methodologies, multiple PBPMs for non-face-to-face and face-to-face, and that could also be complex.

Criterion 4, Value over Volume, unanimous decision by the PRT that the submitter met this criterion and highlighting just some key points for you, risk-adjusted monthly payment. It was a novel aspect to the risk adjustment, which included, without as much detail as we needed, but included some allusion to social determinants being part of that, performance-based incentive payments, as well as, again, this notion that an increase in primary care spending would actually result in better value, both in terms of quality and in terms of cost, and that patient payments are no longer tied to kind of face-to-face or direct patient contacts.

Let me just move on since -- just to get through this. Fifth criterion, Flexibility, we also were unanimous in that the PRT felt that the submitter met this. We talked already previously about the flexibility of the payments as well as the flexibility of the practices to kind of choose which option they were based on whether the practice was in a largely office-based E&M setting or did

things that were not in an office-based setting.

I'll stop there, and then I'll see if anybody else on the PRT later wants to add.

Criterion 6, Ability to Be Evaluated, let me give a little more color because we unanimously felt that they did not meet this criterion. So in looking through the proposal, you'll see key points where the submitter talks about the ability to evaluate potentially against other practices, similar to what the Comprehensive Primary Care Plus model does.

You'll see both in our discussion with the submitter as well as in discussions with CMMI that one of the aspects that let the CPC+ model be evaluated was its pretty strict control about which regions it could be deployed as well as the ability to find kind of comparison groups for those practices.

In the submitter's proposal, we could see that it could be problematic, given how expansive the payment model could be, that it would be hard to potentially establish valid benchmarks, especially if we're using the hypothesis that increased up-front primary care spending would lead to kind of better downstream utilization of resources.

And we also think that just given, again, those multiple payment tracks that someone could follow, one

could imagine that in order to evaluate potentially a practice that's in a particular payment track, creating any sort of control group or comparable group from which to be evaluated could be very complex. So I'll just stop there because I think that might generate more discussion.

Criterion 7, Integration and Care Coordination, we unanimously also felt that it did not meet this criterion. The proposed model does cite in very specific areas the joint principles of the patient-centered medical home, and if you read through those principles, there is very explicit language around care coordination. But there is this assumption most of the practices would be adherent to these joint principles, and therefore, they are coordinating care. But there are no specific called-out requirements around the measures of care coordination for individual payments.

You'll see in our back-and-forth with the submitters that we also addressed about the kind of the issue of care coordination outside of the practice, and we discussed how they responded to our question, talking about how there is not a clear measure for coordination with providers who would be outside this APM Entity. In fairness, the submitters did express that they would be open to that. They just did not have that explicitly

included in their proposal.

Patient Choice, Criterion 8, we also felt unanimously that it did meet the criterion for patient choice. In fact, while we identified this process of patient enrollment as a potential complexity, it obviously offers kind of the most robust option around a patient choosing. But we did want to point out that this just needed to be mitigated, and we just wanted to mention that we wanted to -- and we had a conversation with the submitters about stinting of care or unintended worsening of disparities, especially in key vulnerable populations, and so that was something that we called out. But we did feel unanimously like it met this criterion.

We also felt that it met Criterion 9, unanimously, Patient Safety, in terms of being flexible around resources that could be mobilized by a primary care physician to deal with issues or adverse events for patients, and because payments are going to be risk-adjusted -- and I'll call to the PTAC that they actually talk about kind of five tiers of risk adjustment based on using a risk stratification tool as well as HCC scores that would allow for patients with multiple health problems to be adequately paid for as well as adequately measured.

Final criterion also was met -- Oh, did I just

skip through? We don't care about 10? Okay. Maybe we do.

All right. Criterion 10 is not on here. HIT, how ironic that it's not on the PowerPoint. Okay.

[Laughter.]

DR. PATEL: We were unanimous in that it met the criterion for HIT. The proposed model did require that at least 50 percent of the APM Entity's participants used a certified electronic health record, and in fact, I mentioned a novel -- this kind of notion of novel inclusion of social determinants measures. The submitters went through a little bit of a description of how hopefully electronic health records would help facilitate the collection and categorization of those novel risk -- novel social determinant factors.

So let me just stop there. I was really fortunate to have Harold and Tim as part of this team, and I just have to say I think we started this process as a PRT about four or five months ago? So we've had lots of conversations, as you can see.

So I'll stop there, Mr. Chair, Dr. Chair, Mr. Dr. Chair, and see if Tim and -- I haven't had enough caffeine -- see if Harold and Tim have any additional comments.

DR. FERRIS: I don't have anything to add. Thank you for doing that.

*** Clarifying Questions from PTAC to PRT**

MR. MILLER: I would just add two things, I guess. It has actually -- we worked on this for, I think, actually six months or more because the submitters asked for some more time to be able to respond to some of the questions and had some questions about our questions, and we did burden them with many questions.

I would just observe that we were, I think, pretty clear on the conceptual structure of the model. There were -- though there were a lot of details that are missing from the model. I will say personally I was disappointed that there was not more resolution to some of those details in terms of how much -- how much would the primary care practice be paid and was it enough to support their operations? Exactly how should the risk adjustment be done? And what was the quality measure framework? When you look through the proposal, it's sort of -- in some places it'll mention a measure, and in other places it won't mention the measure. So there was not sort of a really clear, precise thing, and there was in our conversations with them some evolution of thinking, obviously, because some of the things that we heard on the call, on our call, reflected some changes. And that's okay, but it was -- it was a little difficult, I would say,

at least from my perspective -- I won't speak for my colleagues -- difficult to evaluate some of the criteria simply because those details really weren't there in the way one would like. And I would just say I think that given the length of time people have been working on primary care models, I was a little surprised that it wasn't more specific than that at this point.

CHAIR BAILET: Grace?

DR. TERRELL: So, part of a conversation we had yesterday at another evaluation was around the issues of trying to make this fit across a broad spectrum of types of practices and how that may be impacting the way things were coming to the PTAC. Based on what you just said, Harold, that you were disappointed that there were not more details, do you -- we may need to ask this to the presenters, but do you believe that is because of the need to give broad principles for which it can be over a broad type and category of -- in other words, making it generalist enough for different types of practices? Or is there something else underneath it?

MR. MILLER: No, I think it was exactly the opposite. My concern was that without a -- the representation was that a primary care practice should get some percentage of total payer spend, which didn't

necessarily say to me that that was enough for a primary care practice to be able to deliver the desired services. I would have -- I think it would be better to have some analysis of what it would actually cost a small practice, a large practice to do what was necessary to be able to succeed in the model and then base the payment on that. So that was -- it, in fact, seemed to me to be a little bit too generically stated, rather than to reflect potential differences in practice needs. And the risk adjustment of the payment was based on HCC scores with an openness to do something else rather than a reflection that there might be practices who have different patient mixes that really might need something different than that. So that was -- I think the concern was it might have been, to my perspective, a little bit too generic in that regard.

DR. PATEL: They did offer, Grace, just so you could see, they did offer kind of two different -- they accounted for different types of practices in some of their examples and also kind of took into account like you could be in a large integrated organization. So in that respect, they did something that I think we talked about as a PTAC yesterday where they tried to include kind of branch points, depending on, you know, kind of where you -- kind of meet you where you are. However, as I noted, we also

identified that as potentially a problem around evaluation as well as just -- I think what Harold's getting to is that you can see in our transcripts and questions, we were trying to really get a more granular sense of if you firmly believe that you should, let's say, double, which is proposed kind of the percent of Medicare dollars that are spent in primary care because of this downstream, how would this actually work not just in Medicare but, because it's a multi-payer model, in the commercial setting? And that's where there is a lack of that detail in our discussions. But it's probably something we should ask the presenters.

MR. MILLER: And I would just add, I mean, none of that says that we in any fashion thought it was a bad model. I think we thought it was a good model, which is basically why we thought that it met all the criteria that we did. However, it was in that respect as good as many other things, but it was -- I think that there is at least some concern on my part about whether the lack of specificity leaves open some gaps that might make it difficult to implement successfully in some places.

CHAIR BAILET: Len and then Bob.

DR. NICHOLS: So two questions for the PRT. One, when you talk about this lack of detail and how you were somewhat disappointed that you didn't get more detail in

the back-and-forth, do you think that's because they expect these details to be worked out in kind of a testing framework with CMS and they're really looking for technical assistance? Or they know that you can't have one set of parameters that fit every practice in this great big land of ours, and so you're going to have to calibrate -- I mean, I'm just trying to explore why you think the lack of detail is still in the model.

DR. PATEL: I'll start. I mean, there are some aspects that are alluded to that they say are proprietary, so I think that was part of the lack of detail, and then it wasn't -- I'm not sure if it was technical assistance. I'm not going to make assumptions about what the AAFP can do. But I think it was also just kind of trying to understand how to put together a very complex APM in a constrained amount of space. And so it was our back-and-forth you'll notice --

DR. NICHOLS: Surely our 20 pages isn't the problem.

[Laughter.]

DR. PATEL: No, exactly, it's not the -- but it was -- this is a large model.

DR. NICHOLS: Yeah.

DR. PATEL: And I was wrong about -- you know,

with 200,000 physicians who could potentially be in this and 30 million Medicare patients. To be honest, I think it's the largest model in terms of that type of impact or participation that we've seen. And so I think it's a combination. That was my perception.

DR. NICHOLS: Okay. My other --

MR. MILLER: I would say you should ask them, because honestly, I couldn't understand that --

DR. NICHOLS: Okay.

MR. MILLER: I mean, it's in my perception different from other people who are for the first time thinking about payment models. There's been a lot of work done on primary care medical home.

DR. NICHOLS: Okay. Thank you. So the second question, I was I guess not shocked but a little bit surprised at the evaluation judgment that it was not evaluable. And I guess I get totally why it would be complex to find a purer control group, but in those circumstances, I and lots of others long before me used something like step wedge, so you could design -- So did you all consider step wedge as an evaluation strategy to work in a place where you can't get obvious control groups?

DR. PATEL: Let me start, but I know Tim and Harold will want to chime in. So, in fact, that got --

Len, you're exactly right. We actually got to the point at a PRT where we were considering how they should have put in details about the evaluation and felt like this is a recurrent theme in the PTAC. We had to kind of listen to what they had.

So we started to engage with the submitters in our phone conversations, but still felt -- and, again, you'll see much of this is a reference to the CPC+. So a lot of the methodologies are carried over but then built upon, and we did not feel that they actually went through how we could evaluate this, and to be honest, kind of you can see our transcripts with CMMI, Office of the Actuaries, that same concern was reinforced. So I'll just say that's from my part.

DR. FERRIS: So, as you pointed out, Len, you can evaluate anything. So again like how good is the evaluation, the two questions that I think I was focused on was there is some good evidence, as Kavita said, that greater investment in primary care can bring down costs. But the critical piece of this is can you evaluate in the context of this model whether or not costs are either the same or you bring them down.

So the control group issue was one thing, but the other thing was the attribution model, how you enroll. And

you're really left with a case finding methodology, however you do it, step-wise or prospective controls. But, really, it's got to be a matched process. And how do you match on propensity? How do you match on all of the -- like you can do it. I say, "How do you match?" There are ways you can do it, but it's not perfect. It's not even close to perfect, right? And so it's a -- I would say it's a sub-op -- you're left in a sub-optimal position. It doesn't mean you can't do it, and that's why Kavita said we were imagining ways we might do it. So whether or not it meets criteria is one of these things that is our particular challenge, which is you could -- you might restate it and say it's seriously challenging to do this. It doesn't mean you can't do it. Of course, you can figure out some ways to do it. But I wasn't convinced that given the design of the program, that if someone published on a match control basis cost savings based on this design, I wasn't convinced that I would be able to look at that with great confidence and say, yeah, it's working.

MR. MILLER: I'll just add two nuances to that. First of all, there were -- at least in the proposal as proposed, there were so many different options that people could pick that it was hard to make a judgment about how you might really say so somebody picked to have all E&Ms

and somebody picked not all E&Ms. Well, why did they pick that? And how would you figure out how they picked that, et cetera? That's number one.

Number two is I might look at it and say, "Great model. I'm perfectly happy with it." But there is this little problem called the Actuary, which tends to have a somewhat conservative view of things, right? So, you know, somebody might look at the evaluation and say, "I'm comfortable with that." But when the Actuary's Office is saying, "We have to certify this," I think there is a concern about whether or not all of that would potentially jeopardize the ability to say, yes, it worked from the people who have to make that decision. So...

DR. NICHOLS: Okay. I would just add for the record, I think this is one of those criteria, independent of this particular proposal, that in a way the phraseology of the criteria from the Secretary's -- or from the statutory language, can it be evaluated, ability to be evaluated? It's kind of a lot to expect the applicant to come up with the perfect design. I think it's kind of on the professional realm. I take it that propensity score matching would be --

DR. PATEL: That's fair.

DR. NICHOLS: -- controversial, but it is in a

sense --

DR. PATEL: That's fair.

DR. NICHOLS: -- hard to judge no.

DR. PATEL: And we actually feel like that same statement, by the way, Len, is applicable to many of these criteria.

DR. NICHOLS: Yeah, but more for this one [off microphone].

DR. PATEL: Sure, including value over volume and -- anyway, so we would echo that for some of the other criteria as well.

CHAIR BAILET: Bob.

DR. BERENSON: Yeah, I will start by saying that I practiced under this model 30 years ago, primary care capitation basically. This is improved because we now have better tools on performance measurement and risk adjustment. But I want to emphasize what sort of brought it down to some extent or at least the perceived weaknesses, and sort of I still have some concerns we haven't satisfactorily addressed it, and Item Number 1 is this issue of stinting under capitation with a PMPM to a primary care physician. In fact -- and I want to ask if you had any discussions with the proposers about the fact that the large majority of states prohibit primary care

capitation outside of an HMO because of the concern that the physicians have too strong an incentive to not provide care. So that I think affects the potential of having multi-payer demonstrations. My understanding is it even affected the willingness of private payers to participate in CPC+ to some extent. But here this seems to be a pure global payment, comprehensive payment, capitated payment, and I think that would be an issue.

In reading what they were proposing as performance measures and in the response on what would protect against stinting, I wasn't convinced that that would be satisfactory. I didn't see any measures of patient experience, for example, which strikes me as sort of essential in a primary care -- for any primary care practice. It looked like they could pick six, and they could all be very clinically oriented, and they could be for one condition, so sort of nothing about patient experience, nothing about referral rates, which is the easiest way to get around capitation incentives, is to just refer everybody.

Now, there are some measures around ER use and hospitalization. So for some conditions you probably have some self-protective mechanisms but not for many sort of routine patients for whom the easiest thing to do is to

just refer them out. So I guess my question is: How much attention did this concern about stinting get? The response I read in the Qs and As was basically we won't cherry pick because this is a patient selection problem, and so we don't get to just pick the healthy people. But then the next one was stinting. We don't want to lose our patients, so we're not going to stint. Well, you put the two together, and you stint on high-cost patients.

So I wasn't satisfied that they had addressed that issue, and I wanted to know if the PRT had sort of explored this, because I didn't really see it in your report, the adequacy of the measures, the adequacy of the protections against the stinting concern. State legislatures have prohibited -- I mean they were so concerned about it 20 years ago that they actually banned the practice.

DR. PATEL: So let me take that last part first, Bob, because we actually asked ASPE and our subcontractors to kind of explore, and then we actually did bring this up with the Office of the Actuary, and we couldn't find any current kind of prohibition. So we did actually try to kind of get to the bottom of that issue around state-based regulations and could not find any kind of examples of that. But I know that that --

DR. BERENSON: I can refer you to where you can get that information.

DR. PATEL: Well, you know, since it's the PTAC, we couldn't ask you. But what we did -- we did talk about it and tried to explore and look into it. And then I'll just say I think this issue of stinting, I kind of talked about areas, which we felt like we did -- you know, were significant weaknesses, and you're hitting on kind of the issue of stinting, but it's brought up things that we have specifically called out. They did, as you mention, in this kind of back-and-forth address this issue of stinting in kind of three ways, which I think you've covered. I think we should have the submitters weigh in on this more deeply. But we did bring up a significant amount of concerns around kind of the patient selection piece, the -- we brought up the example around the measures could all be even in one very specific kind of condition and, therefore, not actually get to some of these other issues.

And then I would say the other thing in their response that we discussed as a PRT is that you'll recall that part of this four-pronged stool, so to speak, is that fourth element of kind of retention of the Medicare physician fee schedule, and that is something that they brought up as one of the like fail-safe mechanisms to be

part of this. But I do think that we would benefit from hearing this from the submitter directly on that.

DR. BERENSON: I'll just ask one more now and then wait for the submitters. The proposal that I read said there wouldn't be claims, and for risk adjustment, somebody would have to go into the medical record to get information. I think the experience with Medicare Advantage, which is clearly a different situation, of not requiring encounter data and from commercial insurers who pay providers on capitation are that you have to have encounter data -- you can't not -- to be able to do risk adjustment and to be able to know if there is actual stinting on care.

Did you talk to them about this sort of notion that there would not be either no-pay claims or encounter data? And did you have any views as to whether that was okay?

DR. PATEL: I don't recall that we brought up specifically the lack of encounter data because as we read the proposal, those prospective monthly payments would also be accompanied by some level of measures. Now, whether those measures are adequate or not, that's a question we should bring up. But I don't recall us talking specifically about the encounter data. Do you, Tim or

Harold? I can't --

DR. BERENSON: I mean, I think that's going to be an issue. Even Kaiser has -- which is the fully capitated medical group at Permanente -- is now collecting encounter data and using CPT (current procedural terminology) codes and the whole thing. And as much as it would be nice not to do it, I think that's a real operational issue about it, and, you know, what I saw, they were very vague about how the medical record would be used, I thought.

MR. MILLER: Well, this gets more, I would say, to some of this issue of the details of implementation, because the practice could potentially bill for its monthly payment for the patient, and they could indicate on that monthly bill, "I'm billing for Grace. She's my patient, and Grace has the following set of comorbidities," and that would be how you would do it. It would only be if it was -- and that's -- they didn't make that clear as to whether or not this is all calculated at the plan level and coming down to the practice, whether the practice is billing for it. So there could be multiple ways of doing that, but I think we should ask them what they're thinking and --

DR. BERENSON: No, but I guess my point is that -- and this, I mean, I agreed with you completely that there's a lot of operational moving parts, and that's why I

sort of think that the idea that this becomes where all of the primary care docs who are not in CPC+ because it's limited have an opportunity, I think we should reconsider that. I think there's a lot of detail in getting this right. I think it's worth getting right, but it has to be a fairly well-contained demo, in my view, not open to tens of thousands of primary care docs to work through these issues. It would be great if we didn't have to rely on encounter data and could rely on medical records to provide the information. But just specifically, I don't think it's just about diagnosis. I think it's around services provided to be able, again, to monitor stinting. I don't think at least the measures that were mentioned will get us there. So I'll stop at this point.

CHAIR BAILET: Thank you, Bob, and I've got Elizabeth on the phone. She has a question.

Elizabeth?

VICE CHAIR MITCHELL: Hi. Thank you.

My question was around attribution and your concerns about sort of patient election, and I did want to acknowledge that I was on the LAN work group that had identified patient -- identified attribution as this sort of optimal approach that the submitters cited in their response to the PRT report.

And I had seen this work in commercial settings with employers and private purchasers. Was your concern primarily around implementing this with Medicare, and how does it relate to your concerns about the lack of encounter data?

DR. PATEL: I'll start.

So part of this was our concerns were not just the setting potentially with stinting or some of the issues that Bob even raised in his previous question, but if you actually look at their complete attribution methodology, it starts with patient enrollment. And then there is a plurality-based component that's retrospective. So just even that mixed methodology is complex. Again, we thought that in the spirit of like could even a large practice do this, it could be seen as administratively complex and confusing.

And we know that at least in the Medicare experience, for example, the chronic -- the CCM and things that require that level of patient enrollment and engagement, that that has been complex in the Medicare program.

So we know this is not the CCM, but if you consider that this would be even broader in its mandate, that was something that we thought would be important to

consider.

MR. MILLER: I'll just add I would have been very positive about it if it had simply said this is going to be for patients who have signed up, but it's a really complex four-part structure. It's patients who sign up, and then if they haven't signed up, if they came for a wellness visit -- and if they didn't come for a wellness visit, then it's a plurality of E&Ms. And then if it's not that, then it's if they got a pharmacy -- a couple of pharmacy claims or a DME (durable medical equipment) claim. And you say, "Hmm. So who all might show up in that?" and then when you get to the point, I mean, evaluability aside -- I mean, I've sat with primary care docs complaining about the challenges of simply trying to take their attribution lists from payers and try to make sense out of them every month, and this is describing somebody having to figure that out for these four different criteria. So that was the real concern, was the complexity of that from the practice's perspective and the uncertainty about exactly what kinds of decisions that might lead one to make about which patients went ahead and when didn't, and would one send patients off for excessive numbers of specialty visits in some cases simply to avoid having them attributed to you or whatever.

CHAIR BAILET: Tim.

DR. FERRIS: I just wanted to add to that.

I think what you're hearing from the PRT -- and I'm just speaking for myself here -- is that in multiple areas of this proposal, the submitters actually had thought through in a lot of detail how best to manage the care model that they were trying to support, recognizing the complexity on the ground of all these moving parts.

And what we struggled with was that complexity, recognizing that complexity on the ground, and translating that into something that was -- that you could administer, right? And that's a problem that everyone who thinks about policy is dealing with. The real world is actually really complicated.

They tried to mirror that real world in certain ways. Almost everything they propose has four different ways of doing it, and so as a PRT, we were struggling with all those interacting parts and then how do you project what's likely to happen. And you're really sort of left with "Wow. There's a lot of moving parts here," and it's really hard to say what would happen.

CHAIR BAILET: Bruce?

MR. STEINWALD: When I read the proposal and sort of sat back and thought, I was having trouble appreciating the added value of a second or two per member per month

payments, and I wonder if the PRT discussed that and could help me understand if you appreciated the added -- certainly, there's added complexity. So is there added value that exceeds the cost of the added complexity?

DR. PATEL: I think that's why we pointed it out as a weakness, in fact, kind of the two PBPM payments, and that potentially they are not necessary. And it does make it overly complex.

I do think this is a better question for the submitters because they do describe that that world of -- that second bucket of payments is to account for the kind of non-face-to-face care and a lot of the services that are telephone calls, et cetera, that right now in the kind of existing schedule would not necessarily be captured in an office E&M or another E&M. But we brought that very point up as a weakness in different parts of the proposal.

MR. MILLER: And we're speaking for them again, but they did say that they didn't think that that was a critical element, and they did think that even if it was there, that ultimately it would merge.

CHAIR BAILET: Go ahead, Len.

DR. NICHOLS: I decided I was at risk of speaking for them, so I will wait.

CHAIR BAILET: All right. Very good.

All right. Grace, please.

DR. TERRELL: Getting back to some of the things that Bob was talking about, one of the things that strikes me in this conversation has to do with us as opposed to the proposers, and that is as we've gone through the criteria in all these different models, one after the other, what we've accepted as being okay from the Criteria 10 as it relates to health information technology is if they're on a cert EMR, then they're good. I think that's been across the board.

But the conversation that we're having now implies to me that we as a Committee may need to think about that a little deeper. So, for example, as Bob was talking about stinting, you know, it's not 30 years ago in capitation, and there's a lot that's been learned by organizations such as CareMore that worked on care model design to come up with how you might take care of patients who have a higher risk.

We know that ACG from the Hopkins that's been used for 30 years all over the world is the best in terms of predicting outcome, and that there's never been any encounter data that matches that old-fashioned claims data that's been around forever.

So these types of questions may be getting partly

at what Harold was talking about with respect to granularity on their part, but to Len's point, it's 20 pages. And there may need to be a different level of engagement that we have as a PTAC with respect to models that have complexity, such this one does, and what we need to be expecting out of health information technology as meaningful to new payment models, so just a thought.

CHAIR BAILET: Bob?

DR. BERENSON: Just picking up on that, this is very complex and will be -- I think a lot will be learned and actually operating it, and as Len said once -- I forget in what context -- recently, actually, that what you try to do here is move it forward. Don't get it all exactly right. The PTAC can't get it all exactly right. Does the concept have enough stuff that we should move it forward so it can go -- so I'm thinking that what we need to do is make a decision as to does this model have enough promise that it needs to be tested and then identify a number of the operational issues that have to be explored, but not come up with our suggestion as to how to do it right, because I don't think we know, and I don't think they know. But that there are issues that are easily definable that need attention, and so I'm with your sentiment, Len, that that's what our basic obligation here is, does this have

promise, but not to dot the i's and cross the t's and make decisions on very technical operational issues that will -- The demos themselves will tell us what the right answers are. So I just wanted to say that now.

DR. NICHOLS: If I could, I would just --

CHAIR BAILET: Please, Len.

DR. NICHOLS: I would just very briefly acknowledge that my basic idea was our role is to serve as a filter for the professionals, and the question is, is what is brought to us good enough to engage the professionals at CMS? Because they have to do this; we can't.

CHAIR BAILET: All right. Seeing no additional comments, thanks to the PRT for sorting through all this and teeing it up for us.

I'd like to invite the submitters up to the table now, please. We have no one on the phone. The full team is here in person, so thank you all for coming. If you could just turn your placards over, introduce yourselves, and then you have 10 minutes to address the Committee.

Thank you.

*** Submitter's Statement, Questions and Answers, and Discussion with PTAC**

DR. MUNGER: I'm Michael Munger. I am a

practicing family physician in Overland Park, Kansas, and the current president of the American Academy of Family Physicians.

CHAIR BAILET: Welcome.

DR. MULLINS: Good morning. I'm Amy Mullins, a family physician and medical director of Quality Improvement at the AAFP.

CHAIR BAILET: Welcome.

MR. MOORE: My name is Kent Moore. I'm on staff at the American Academy of Family Physicians as a senior strategist for Physician Payment.

CHAIR BAILET: Great. Thank you.

MR. MARTIN: And good morning. I'm Shawn Martin. I'm a senior vice president of Advocacy Practice, Advancement, and Policy at the Academy.

CHAIR BAILET: Super.

Please.

DR. MUNGER: Well, first, I want to thank you for inviting us to present the APC-APM to the full PTAC. We appreciate the time that the PRT -- Dr. Tim Ferris, Harold Miller, and Dr. Kavita Patel have dedicated to a very productive dialogue with our team, and we believe the model is stronger for it.

The American Academy of Family Physicians is a

national association of family physicians and medical students. It's the largest single-specialty organization in the country, with 129,000 members located in all 50 states, territories, and internationally.

We were founded in 1947 to promote and maintain high-quality standards for family physicians who are providing continuous comprehensive compassionate care to our public.

The shared goals at the heart of MACRA were to enhance the quality and sustainability of our health care system, and it's difficult to achieve these shared goals independent of primary care, which plays a foundational role in the health care system and is often the first and most frequent point of contact for Medicare beneficiaries. Family physicians conduct one in five office visits in this country. That's 192 million visits annually or 48 percent more than the next highest specialty.

Now given the reach of primary care physicians, we believe that the PTAC has an opportunity to both increase physician participation in advanced APMs significantly, but also to increase beneficiary access to care delivered under these models by advancing this APC-APM.

Now, primary care has been on the path for

transformation for decades and has built a strong infrastructure to implement the APC-APM. The Academy and its members are not new to innovation in payment and delivery of care, as reflected in the creation and evolution of the medical home and advanced primary care models over the years.

As a matter of fact, in our most recent member survey, 47 percent of our members are actually now practicing in a recognized PCMH, and 30 percent of our members are in ACOs, with the majority participating in Medicare shared savings programs.

The Academy has been active in supporting further practice transformation in the passage, with the passage and implementation of MACRA, so that our members can be competitive and successful in a value-based payment environment.

Now, we've done this several ways: By providing educational resources and technical assistance to support participation in the quality payment program; supporting participation in innovation center models, including CPC, CPC+, TCPI (to name a few, and by developing this APM, which we believe could be the most broad-based and first primary care-based model that the PTAC recommends to CMS for testing.

Moving forward, we are committed to working with PTAC, CMS, and other stakeholders to advance this model, which we believe is a foundational element to the movement of advanced APMs, as envisioned under MACRA.

Now, the AAFP developed this model based on the need for the physician and patient to work together to improve health outcomes and to help reduce overall cost. Importantly, the model builds on and involves key features of the original CPC and CPC+ programs already under way and incorporates lessons learned from these and other primary care transformational models.

It's important to note that the CPC+ model is closed. It was designed with high barriers for participation and really was not feasible for many small practices. We designed this model to be more widely available and to reduce barriers to participation for all practices.

So, for instance, CPC+ in Round 1, 2,850 practices, primary care practices, and 13,000 clinicians were enrolled across 14 regions. I happen to be practicing in one of these CPC+ practices. Our membership alone consists of 70,000 actively practicing physicians and is located in every state and region in the United States and, thus, really illustrating the gap between the current CPC+

program and what this model would bring.

Now, we have heard and addressed concerns that this model is similar to CPC+, and this model does not reflect innovation in primary care.

We believe that we have made important improvements on existing -- on the existing model in many ways. First, this model expands access to a multi-payer, primary care, advanced APM for beneficiaries and physicians nationwide.

Second, the model supports practice and broader system transformation through greater investments in primary care.

The model simplifies payment for primary care services and reduces administrative burden for physicians and small practices, especially by moving the majority of payments for primary care services away from fee-for-service to prospective payments that give practices a predictable revenue stream in investments and practice transformation, which is extremely critical for our small and solo practices.

Now, while we have proposed multiple E&M levels with the PRT, we do remain open to working with CMS to further refine the approach and address design concerns.

Fourth, the model allows for addressing the

social determinants of health, which affect health outcomes and cost, and facilitates a true longitudinal assessment of patient needs.

And finally, the model uses consensus-based quality measures through the core quality measure collaborative that aims to drive measurement harmonization and reduce administrative burden to incent greater participation in value-based payment programs.

The model includes HIT requirements that can actually support care management through actionable data on patients and their needs, and we designed this model with physician and patient needs at the center. So we are not requiring complex EHRs, but a basic framework and requirements to advance care.

The APC-APM is evidence-based and addresses historic problems in primary care payment necessary to strengthen the health care system. It creates a more advanced primary care model and supports providers in making changes to care delivery not necessarily supported by the traditional fee-for-service PCMH model.

Now, this model strengthens primary care, which Congress and CMS have recognized is essential to building a value-based cost-effective health care system and builds a strong primary care foundation for the health system by

addressing the historic fragmentation and problems in payment.

The undervaluation in primary care services and the fragmentation in care partially driven by our current payment system are well understood. Payment experts, including many on this Committee, have pointed out that building APMs on a flawed physician fee schedule would simply perpetuate current inequities.

Change is needed if we want to improve clinical outcomes, promote prevention in population health, and reduce cost. This model would increase investments in primary care, which MedPAC and other experts have called for. The increased payments would flow through the new payment structure, which promotes continuous, coordinated, comprehensive, and longitudinal primary care.

This model is patient-focused and reflects stakeholder feedback and perspective. It has the ability to expand Medicare beneficiary participation in a primary care-focused advanced APM on a larger scale than any other model.

At the same time, its multi-payer design can help spread the innovation to commercial, Medicaid, and other markets.

Now, while the PRT has raised concerns about how

the model could be evaluated, we believe that there are evaluation methodologies that the Innovation Center is already using that could be applied to evaluating the APC-APM, such as those for CPC+, and we'd welcome the opportunity to work with CMS on designing a strong evaluation, which we believe is critical to any APM.

In addition, the PRT raised issues with the model driving integration and care coordination. The concept of integrating care and coordinating patient care in a longitudinal and comprehensive manner is at the heart of this model and at the heart of primary care.

The Academy would welcome the opportunity with CMS to ensure that quality measures or patient survey data are incorporated to achieve these core principles.

And last, our patient attribution methodology, which uses patient attestation as the primary method, reflects a gold standard in patient engagement and was broadly supported by stakeholders.

Now, since its original submission, the AAFP has solicited feedback and considered issues raised by stakeholders, including other providers, health systems, payers, consumer groups, and payment and policy experts. We've received letters of support from a broad range of stakeholders, underscoring support for the model in its

feasibility for testing and implementation, including several of our chapters such as North Carolina and Colorado, that have significant rural and small-practice members; health systems such as Ascension, which has experience implementing a similar model within its system; and other physician societies, including the American Medical Association, the American College of Physicians, and the American Geriatric Society.

AAFP appreciates the opportunity to present our model for consideration by PTAC. We look forward to answering your questions and having a good discussion. Thank you.

CHAIR BAILET: Thank you very much, Dr. Munger.

I'll turn it over to the Committee, starting with Tim and then Grace. Tim?

DR. FERRIS: Great. Well, thank you. You know, it occurred to me, listening to your comments, which I think 100 percent of which I agreed with, that, you know, we quickly as a group were focused on the details, and I want to just make a comment that looks at the big picture, which to highlight the end of your comments, is about a better way of delivering primary care for all of our patients. And as a primary care physician who works in an integrated system where we have actually -- I work in a

patient-centered medical home. We got our certification just recently. But I've been on the journey for at least half a decade.

We also moved to basically capitating our employed physicians, but with a lot of infrastructure in place to make sure that we are quite comprehensively measuring quality and variation in the utilization of services. And so I have personal experience of how what you're proposing in general is better care and a more sustainable work environment for primary care physicians.

So with all that said, you touched on this but I'd like you to come a little bit more specifically. If CPC+ were available to all family practitioners in the United States, would you be proposing this model? And why?

DR. MUNGER: And why? The answer is yes. We view this as the next generation of innovation in primary care delivery and payment model, driven by our experiences from capitation through micro practices through the medical home through CPCI, ACOs, et cetera. There's a couple of key things that I think we have witnessed, learned since the CPC+ design, which is a good program, but a couple things we did in this model that are different is we reduced the documentation guidelines tremendously. We went away from some of the data criteria that many of our

participating practices in CPC+ feel are overly burdensome and not productive to their overall care delivery or design of their models.

We are probably going to talk about this, but we also emphasized the expansion of scope at primary care by leaving some of the fee-for-service component there to incentivize a broader array of services at the primary care level to cut down on or reduce referral for services that could and should be provided at the primary care level as a means of both comprehensiveness at primary care but a reduction in duplication of services across the health care spectrum.

I don't know the right time to add this comment, but I was struck by the questions in your discussion earlier. We are, in our opinion, both blessed and cursed by a long history of innovation in primary care. We have studied this for a long time. We are also blessed and cursed by diversity of pathology at the practice setting. We are not a single-episode, we are not a single-disease state. You know, the patients of primary care are diverse in every aspect. Our members are diverse in every aspect of medicine -- geography, practice type, age, et cetera.

But I think what we have attempted to do in this model is -- is simply capture our best learnings, including

those from CPC+, and continue to accelerate but also simplify what we think is an appropriate primary care delivery and payment model -- not the final best primary care payment and delivery model, but the best that we can do today to continue to drive learning and innovation.

CHAIR BAILET: Grace?

DR. TERRELL: I have a couple of questions, and thank you for your proposal. I've been the first of patient-centered medical home in North Carolina, which was in 2006, so I'm glad that Massachusetts is catching up with us.

[Laughter.]

DR. TERRELL: One of the things that Dr. Patel mentioned was that there was information that was proprietary. I think you used the word "proprietary." And if this is -- I don't know what that was, but if this is something that needs to be a model that's broadly across different models at a policy level, could somebody explain to me what was meant by that as it relates to this? Is that -- yeah.

MR. MOORE: So I will attempt to answer that question. I don't know exactly what Dr. Patel meant when she used the word --

DR. PATEL: It was the proprietary chart, when we

asked about distribution of payments.

MR. MOORE: Right. So as Dr. Miller alluded, we were asked several times -- maybe "several" is a little -- anyway, we were asked a couple times exactly how much would physicians get paid under this model, and, quite honestly, we were uncomfortable attributing specific dollar amounts to specific pieces of the payment methodology. We acknowledge, as Mr. Miller pointed out, that in terms of dealing with Medicare, there's a certain amount of protection in terms of public advocacy. But we were concerned that if we started throwing dollar amounts out attached to certain pieces of the payment methodology, that that could be, I'll say, misconstrued --

DR. TERRELL: Okay.

MR. MOORE: -- as, you know, an attempt to price fix. And so with some reticence, we hedged our comments in that regard. So I believe that's what Dr. Patel was referring to.

DR. TERRELL: Okay. All right. That's helpful. Thank you.

There was another statement that I wanted -- that you had in your proposal that was something along the lines of that you were very emphatic that primary care physicians should take on no more risk than what they essentially had

control over. I don't exactly remember the exact phrases of it, but I've heard that before from primary care physicians and that nobody wants to be responsible for something way downstream that they have no ability to control.

I'm wondering if you could give some granularity around that with respect to the cost and what you can say you would be -- have control over in this particular model, because it seems to me that that's important as it relates to how much you could actually control from a cost point of view with the payment model that you're talking about here.

MR. MOORE: So, again, I'll take a crack at that. I think that question gets to the extent to which we think primary care physicians can be held accountable for total cost of care. The reality is that, you know, while family physicians, general interns, primary care physicians exert a tremendous amount of influence over the total cost of care in terms of the referrals that they make, the decisions to admit or not admit, et cetera, there remain elements of total cost of care for which they have literally no control. So if I have a heart attack, you know, my family physician has no control over which ambulance company I call, which hospital they take me to, et cetera, and we don't feel it's appropriate to hold them

accountable for things that they have literally no influence over. So that's where we come out in terms of not holding primary care physicians accountable for total cost of care. We certainly think the model as a model should be evaluated on the basis of how it impacts total cost of care.

DR. TERRELL: Okay.

MR. MOORE: But in terms of holding the individual physician accountable in terms of his payment stream, you know, the performance incentives, et cetera, we just acknowledge that in the current state that's, quite honestly, unfair because they don't control every aspect of total cost of care, plus even amongst the things that they do have influence over in terms of hospital admissions, referrals, they don't always have a complete picture in terms of what those other entities in the system are costing the payer or the people that are paying the bills. And so to the extent that there is a lack of transparency in the current environment about the downstream effects of decisions made at the practice level, that's another reason for us to hedge against holding primary care physicians accountable for total cost of care.

DR. TERRELL: So right now, I believe the number is that in the U.S., primary care accounts for about seven

percent of the overall total cost of care, about what brokers cost and -- in the total cost of care. So in terms of what you're talking about with respect to performance risk, are you talking about performance risk just with respect to that seven percent in terms of the performance risk for the things that primary care does? Or are you talking about something beyond that in terms of how the model would work?

MR. MARTIN: Let me -- I'll attempt. I don't have the expertise of Kent Moore, but I think what we were suggesting, both through this model and in a broader policy context, is that primary care should be held accountable or responsible for items within their sphere of influence, and we've pointed out a couple. Some of them, you know, are utilization of emergency rooms.

DR. TERRELL: Okay.

MR. MARTIN: Admission for, you know, primary care intensive health conditions, you know, readmissions. I think in the very near future you could -- you know, we would suggest that they could control, you know, some referral patterns within their community, not patient migration but within, you know, a defined community you could see some accountability for referrals patterns in the future based -- but we need better data feeds, quite

honestly.

But I would put it inside a sphere of influence of primary care versus the total cost of care similar to what Kent just said.

DR. TERRELL: Okay. And you think there's going to be adequate granularity around that that it could be defined within the care model as to what that is specifically? You said you put a couple examples in it, do you think that it could be flushed out in more detail?

MR. MARTIN: I think there's -- I think we believe there is great commonality across primary care, advanced primary care models in the country, whether they be medical home or otherwise, that there are two to five pretty standard total cost measures that have primary care influence.

DR. TERRELL: Okay. And then my final question is really one to just ask your thoughts on in a broader way, not -- and, that is, a lot of the measurements that we have are related to past performance when it comes to quality, and where I believe and many people believe we need to go is predictive modeling going forward so that we can not only measure how we've done but figure out how we can do better in the future by identifying patients that may require higher levels of care.

Is there anything specific in this model with respect to the way you're thinking about information that is looking at predictive modeling? Or is most of it or all of it still about performance measurement?

DR. MULLINS: I'll take that. So we do have the performance measurement, but we do ask the practices to risk-stratify their patients. So that's probably the closest --

DR. TERRELL: The closest you get --

DR. MULLINS: -- thing to that is to risk-stratify your patients to try to predict who is going to be those that are going to be the sickest patients.

DR. TERRELL: Okay. Thank you.

CHAIR BAILET: So Len, Bob, and then Rhonda.

DR. NICHOLS: So let me just start by saying I love the idea of increasing spending on primary care. Some of my best friends work in primary care. It's a good plan. But as you know, there's no guarantee that savings will take place without serious process and care delivery redesign.

Now, global payments for -- global payments for E&M and PMPM for non-face-to-face and the prepayment for the performance-based things certainly create the potential, no question about that, but not the guarantee.

And you take and just took a pretty strong stand against putting primary care docs at risk for stuff they don't control. I understand why. I get all that. But I guess my question is: What gives you the confidence that total cost will fall just because we increase the spending without that very explicit pathway to specific redesign? I mean, as I understand it -- I could be wrong, but it would seem that the reason CMMI imposed such specific structural changes inside CPC and now CPC+ was precisely to try to sort of engineer from above what changes needed to happen. I think all of us think they went overboard a tad, but I'm trying to figure out, okay, there's overboard a tad and then there's tabula rasa. So help me out here.

MR. MARTIN: Well, I think it's a, you know, Len, a very fair question. I think there are a couple of evolutionary data points that we can start to point to. I mean, we have learned, you know, really over the last 15 years that there are some areas of commonality that lead to higher-performing primary care, maybe not high-performing, but they continue to improve their processes. And many of those are based in the principles of the medical home, but certainly the kind of core aspects of the CPC+ program. You know, team-based accessible primary care lends itself to higher touch, higher intensity of care at the primary

care level, which, if you subscribe to our opinion, reduces upstream utilization of health care services in many instances. And I think that patient home -- patient-centered medical home evaluations across the country all point to some common things around reduction in emergency room visits, particularly for primary care-related disease states or illnesses. I think they, you know, contribute to a reduction in readmission if the hand-offs are appropriate. And there's lots of reasons why hand-offs aren't always appropriate. But if the systems are in place, it leads to better adherence, you know, so patients tend, because of the emphasis in our model on the population-based payment and the emphasis on the non-direct patient care aspect, you get better adherence of pharmaceutical regimen, you get better adherence of making sure they're seeing, you know, mental or behavioral health services. And these are, you know, aspects that reduce upstream spending in many instances across the country, and, you know, they're not similar in each market, but they all point in the same direction of the capabilities of these models.

"Confidence" is a big word. You know, I think we have a high degree of confidence that this model and emphasis and investment in primary care result in a better

health care system for individuals and payers and the country as a whole. But, you know, we need it to be more broadly spread. I mean, I think there's these pockets of innovation, and I think one of the challenges we faced in developing this model was making sure that we could go to central Nebraska with a one- or two-person practice and give them the same opportunity to have the impact as, you know, Dr. Munger's group in suburban Kansas City. And I think, you know, we're pretty confident that this model provides that opportunity.

DR. NICHOLS: Okay. Thank you.

DR. MUNGER: And I'll jump in to say -- I'm sorry.

DR. NICHOLS: Sure.

DR. MUNGER: But at the risk of now sounding like a practicing physician, but also in my role as both president-elect -- And this year I visited over half our chapters, so now you get a little anecdotal information. But having a chance to talk to our members all over this country -- and, again, half are participating in and have checked the boxes to be a PCMH. But what do I hear from them? I don't have the ability to build the infrastructure to practice the way I want. And so far we've been in this game of, "You show me results and we'll increase payment."

And I say, "But I don't have the margin to be able to build the infrastructure to show the results I need. I need some capital to be able to do that."

And so it's -- quite honestly, for most of our members, it's been this stand-off up to now, and so I think that's part of it.

DR. NICHOLS: I appreciate that. I appreciate that, and I -- you know, I totally support the notion that a lot of people were drawing global conclusions about the failure of PCMH, and you may know I wrote a little blog post trying to calm everybody down about that. But the truth is there are these success stories, but CPCI, evaluated just before CPC+ came out, did find no net savings, even after all the excitement, even if you don't take into account the prepayment; but if you do, then clearly there were no savings on net.

Now, they gave roughly $50,000 per physician. They required all this stuff, and on balance, they saved enough in Medicare not to lose money, but they didn't really save money either. So I guess my question is: How do you interpret those CPCI evaluation results? And where should we go from there?

DR. MULLINS: I think part of it -- and when I was practicing, I was in -- I was in the national

demonstration project, and it was a patient-centered medical home doing that work back in 2006, yeah, and --

DR. NICHOLS: The good old days, yes, yes.

DR. MULLINS: Yeah, the good old days. And so when you started doing this work and you started, you know, reaching out to patients and bringing them into your office that you hadn't seen in a long time, those diabetics that got lost to follow-up, when you brought them in, they hadn't been seen in a long time, and they had been lost to follow-up, and they cost you a lot of money.

DR. NICHOLS: Yeah.

DR. MULLINS: They hadn't had a colonoscopy or a mammogram or Pneumovax -- anything. So initially they are going to cost a lot of money. It's going to take a while to see those savings down the road. Two years is not enough time or three years is not enough time to see that net savings. You have to wait to see the return on investment, to see that, you know, doing that mammogram's going to pay off, doing the colonoscopy's going to pay off; getting the A1C under control is going to save an amputation. That's not something that's going to happen in a year or two. It's going to happen in five or 10 years. So it's going to take a little while to see that savings. I think the CPC results were just a little too fast. This

came out -- they did increase costs right at the front because you got all those sick people back in, which is good.

DR. NICHOLS: Yeah.

DR. MULLINS: You need to do that.

DR. NICHOLS: I was going to say that's actually a good thing, yeah.

DR. MULLINS: Yeah.

DR. NICHOLS: Okay. So here's my problem. So CMMI conducted CPCI. CMMI had the evaluation results before the rest of us did, and they designed CPC+. You may have noticed I was stunned. The evaluation from Mathematica came out, and the next week CPC+ was announced. Okay? So, clearly, they had read the report ahead of time. And I noticed they didn't choose to do your model. They chose, in my view to sort of double down on PMPM structure, with more subtlety than CPCI. They took total cost of care out of the objective function and redirected some of the specific structural changes. But they didn't go as far as you.

So here’s my concern. We push you over the transom and say, "Go forth and test this." They've already chosen CPC+. So I know we had a question before, but I need to hear more how do we articulate the value add of

this model vis-a-vis CPC+ so that they will be, if not enthusiastic, at least willing to try to push this down the road?

MR. MARTIN: So they being?

DR. NICHOLS: CMMI.

MR. MARTIN: CMMI.

DR. NICHOLS: Given the CPCI results and the CPC+ design choices, because that's where their thinking is, and they're going to have to be persuaded to take another slice at this.

MR. MARTIN: Run at this?

DR. NICHOLS: Yeah.

MR. MARTIN: Well, I think there's -- I think there's a couple things. I think the point of entry into this model is far less complicated than the point of entry into CPC+. From a technical standpoint, we don't require contracts with the EHR vendors. You know, we don't have a mandatory beneficiary or patient population level on this. I mean, it is attempting to meet physicians where they are and put them into a model that provides an economic and emotional motivation for them to provide better care and take greater responsibility for the overall health of the individual and also of the health care dollars.

This model -- you know, CPC+ has some tentacle

outreach in our opinion to rural communities, but I think this actually is a plug-and-play model that you could go to Capitol Hill to a practice, you could go to the middle of Nebraska to a practice, you could go to Southern California in one of the biggest health systems and draw out practices and put this model in place and test and evaluate it.

We are most excited because we think it applies to small practices. We think this gives -- in a world -- not at anybody's fault or intentions, but in a world where it is becoming increasingly difficult for small practices to even participate in MIPS, you know, this gives a model to give them a fighting chance to create an economic model that may allow them to continue to move forward on some type of transformation progression.

If they were here, I would argue that the simple reach into small and particularly rural or, you know, urban underserved communities, the fact that you can plug-and-play this in those practices is the motivation for why they should test it.

DR. NICHOLS: Thank you.

CHAIR BAILET: Bob.

DR. BERENSON: So I'll have just a couple of concrete operational issues, but I want to pick up on what Tim and Len just mentioned about the interest of family

physicians in this model. I believe I have this right. A couple years ago, Bruce Landon published some information based on surveys of the payment models that were supporting 120 or so PCMHs around the country, and I think he had one or two -- one being Albany, New York, that was using something called a "comprehensive" -- something like this. So I guess the question is: Other than the five percent bonus opportunity, do practicing physicians want this model? Or would they rather that CPC+ be broadened so that they could participate? Do physicians really want to be in what's essentially a capitated model? And the second part of that question is: What do you know about the interests of private insurers to want to participate in a multi-payer demo of this model?

DR. MUNGER: I'll take the first swing at that. For your first question, yes, members, family physicians would be interested in having this global payment because, again, I'm in CPC+, and at the end of the day, I am continually -- I'm continuing to play in the fee-for-service game which doesn't reflect what I do. It doesn't allow me to be now in this day and age of the fact that we do have EHRs, we have the opportunity for e-visits. If you try to bill for an e-visit, good luck. Trying to get together and do things different around group visits,

trying to bill for a group visit, you jump through a lot of hoops, and you may not get it. And yet these are ways that we know that we can deliver care in a meaningful way. This global payment gives me the flexibility to be able to do that. And I'm hearing the same thing from physicians all over the country, is that, you know, even those participating in upstate New York in CPC+, I'm hearing complaints of, "This still doesn't really address how I can be managing my population."

So I do believe that, yes, there would be interest, and I think this model really gives the flexibility to be innovative and deliver care differently.

MR. MARTIN: May I add? May I add?

CHAIR BAILET: Please, go ahead.

MR. MARTIN: Thank you. I think the other thing is, you know, I want to come back to the simplification we attempted to put in here, you know, not elimination but reduction of documentation. You know, our members are enthusiastic about programs like CCM and the transition care management, but they loathe the documentation guidelines that are associated with those programs. So we attempted to combine all of that through our population-based payment and just saying, look, you know, we understand that there are two aspects to really highly

functioning primary care today. One is direct care, and the other one is all the team-based non-face-to-face services that are essential to providing high-quality, longitudinal care to a population of patients. And you need to document, you know, for the purposes of a medical record and continuity of care, what you're doing. But all the, you know, labor-some documentation guidelines that exist in these programs today are actually incentivizing physicians not to do those things. And we tried to simplify things down to allow them to do it and be emotionally motivated to do those things.

DR. BERENSON: So let me just follow one or two quick ones. That was going to be my next question. For no-pay encounters, it gets a lot simpler. Are you committed to not having encounter data and using medical records as the basis for getting information to do risk? -- I mean, you are adopting the HCC model for risk adjustment, and you need diagnoses, so why not have encounter data without -- for not-pay, you don't have documentation requirements. You submit encounter data. So what is your view about that?

MR. MOORE: So I think in the proposal, we sort of laid out where we'd like to be ultimately, but I think we're realistic enough to know that we can't start there.

So to your question, I think we would be open to the idea of practices submitting encounter data, whether that be a monthly claim, as Mr. Miller was alluding to earlier, or just, you know, a claim when you see the patient. The fact that you're -- you know, that you're being capitated and then, therefore, don't have to worry about the level of service, per se, and all the documentation guidelines that go along with that would be an incredible step of administrative simplification for our members, even if they still had to file, as you said, a no-pay claim for that encounter. So I think we would be open to that.

DR. BERENSON: All right. And my last one would be to pick up my concern about this -- the inherent incentive in a PMPM or per person per month payment is to take the money and send the patients elsewhere.

Now, to the extent that they're sick and wind up in the hospital, you've got protection because you're measuring that, but there's all the routine stuff that could be done by the primary care physician or it could be sent to the orthopedist or to the dermatologist or whatever it would be.

Are you satisfied that your performance measure package really will be good enough to -- why not have

patient experience, for example, and why not have referral rates where you're discouraging referrals, actually, rather than encouraging referrals? Are those things you've thought about?

DR. MUNGER: So, yes, in terms of patient experience, I think we would agree that including that would make absolute sense. I mean, that's something that I think we would agree with.

I also think that, you know, we have -- one of the quality measures that are in CPC+ is closing the referral loop, and so there is even an existing quality measure that could be implemented as part of this.

But to your point, I think also in terms of stinting, one of the -- so I think it gets mitigated in two different ways with this model. One is if I have someone who is really sick, you know, when we risk-adjust that, I'm going to get a higher payment in, so now I see your next point. But in terms of referral to dermatologist, referral to orthopedist, most of that's going to be covered in that small per -- or that small fee-for-service. So I have incentive to continue to do skin lesions and continue to take care of non-displaced fractures and continue to do that.

DR. BERENSON: Back pain.

DR. MUNGER: Well, I have trouble finding anybody that would see somebody with back pain, anyway, so they still are in my office, so --

DR. BERENSON: The final one, since you brought it up, the experience in Medicare Advantage using HCC is severe up-coding of diagnoses. The estimate by MedPAC is about 10 percent extra payment because of up-coding, and the MA plans are one step removed from the actual coding.

So for many physicians, they will -- I mean, I'm a big believer in this model. They'll do it right. They'll code accurately. There is the potential for gaming the coding. Have you thought about that at all? I mean, if their payment actually is based on how they're coding patients, is that something you've thought about?

I think it needs to be thought about, and that's one reason I think that there needs to be a good demonstration of this before it goes very broad to sort of -- you get the kinks out.

MR. MARTIN: So, yes, we've thought about it.

I think we -- We did a series of interviews with Medicare Advantage plans, Medicaid managed care plans, I mean, people that are really evaluating both risk adjustment and risk stratification of populations of payment to kind of better understand what's out there.

I don't think there's a perfect model, but I think there's some really good models that would lend itself to testing. Nothing is perfect, but certainly data feeds and experience are starting to point in a better direction of being able to do that on a consistent population basis.

CHAIR BAILET: Rhonda?

DR. MEDOWS: So I have to say that we've come a very long way from the future of family medicine work from two decades ago. You need to be commended on the transition that you are trying to foster and to go forward with.

The move of -- how many thousand family physicians in the effort? Hundred thousand? Going forward into value-based care, transforming how they are approaching this, it is tremendous, and there's not "but." There's not "gotcha" to this comment. That is very sincere.

I have to tell you that I understand the value of a prospective payment. I understand the value and the need to invest in primary care up front. You are talking about a mixture of physicians that are in a variety of practices, the majority of still onesies, twosies, but some are employed, and some are in larger practices. But the

majority are not, and so they need that investment to be able to do this right.

I really appreciate the effort being made to help these physician practices prepare not only for MACRA but for the broader newer world.

I also understand the importance of actually doing just not only for Medicare but for Medicaid, which quite a bit of our patient population is taken care of, as well as commercial.

The quality and performance metrics you've proposed, I know there's -- have had some questions about should they be more robust, and I think you've taken to heart some of the conversations and suggestions that are being made.

When you talk about going out, Doctor, and meeting other physicians who are in practice, particularly these smaller group practices, they understand the prospective payment. They understand the capitated or global payment arrangement, and they need to talk to them about the potential for clawback, if performance is not poor.

I'm not asking for a scientific paper. I'm asking for what is their initial response about the potential for a clawback. Is that something they can live

with, work with, and survive?

DR. MUNGER: And I would say yes, and I think that members look at this, and many are already looking at some of these quality measures in the response that we have gotten when talking is more, "You mean I can actually have something tied to this? I can actually be recognized for the care and what I'm trying to do?" and understanding that there may be a clawback, it still I think is -- also provides an amazing incentive for that practice to keep the foot to the pedal and make sure that they are really focusing on these measures moving forward.

DR. MEDOWS: That's great.

And can I do a part two, please?

CHAIR BAILET: Please.

DR. MEDOWS: So I want to respond a little bit about coding, up-coding, under-coding-type thing. From what I understand -- and I don't think it's changed much. I'm an old doc, but I don't think it's changed much. Family physicians typically under-code. I know that I have done Medicaid waste, fraud, and abuse work for many years. Again, we will not be dating me. We will just leave it at that.

And I also did some of the assessments with Medicare during my time with CMS. Family physicians

typically under-code. I'm not just saying that because of the concerns or questions about whether or not the payment is appropriate, but it also impacts how you do your risk adjustment. So that's something that needs to also be part of the work of getting these practices ready. They need to appropriately code and reflect the risk of the patients that they are managing.

Thank you for coming in today.

CHAIR BAILET: Thank you, Rhonda.

Paul.

DR. CASALE: Yeah. Thank you for bringing this model forward.

I just want to, I guess, add on to Bob's questions, particularly around specialists, because we know the three big buckets of hospitalization, ER, and specialists, right, in terms of cost, and I'm still trying to understand in terms of what prevents referring out.

In the response letter to your PRT, you mentioned the compensation for specialists is beyond the scope, and you referenced the Ascension health model where you say it promotes coordination of care. Specialists see when they provide value, they get more referrals in the Ascension model.

So two questions. One is, will you understand

who is sort of a high-value specialist in this model? Because it's sort of outside -- Would you get a view into it?

And then, secondly, I'm still trying to understand -- maybe I'm missing it -- around the referral. So, okay, I'm a cardiologist. So what would prevent the primary care physician for just sort of referring all the chest pain patients to the cardiologist and not necessarily managing them?

And I apologize if I've missed that in the model.

MR. MARTIN: Not being a physician, although I'll take that on -- I think there's a couple. The model lends itself to a generation-next data feed that could, you know, put in place an evaluation of referral patterns, and there are particularly private payers in certain markets in the country that have instituted or implemented a referral evaluation on primary care physicians and primary care teams. That is possible. There is nothing that would prohibit that from being added to a model like the APC at some point in the future.

Today, particularly with Medicare and Medicaid, I would suggest that there is just not a suitable data feed that would really allow that to happen in real time at the point of care for it to influence referrals based upon cost

and quality.

I mean, most of it, most referrals now are system-based, attitudinal, relationship-based, and quite honestly, for many of our members, referrals are who's available. You know they live and operate in communities, exurban and rural, and a lot of times, as you know, the cardiologist is the cardiologist. That's your choice. So I think we would be open to a next-generation idea of a referral evaluation.

I'll stop there. Amy may have --

DR. MULLINS: I just wanted to just tack on -- one other perspective to that is if you are a continuous referrer of your patients and your patients don't like that, your patients are no longer going to attribute themselves to you. And your patients are going to vote with their feet, and then you're not going to be getting that revenue stream of their PMPM into your practice.

So if you just see your patient and send them away continuously, they're no longer going to be your patient, and your patients are not going to like that. So that is one way that that could mitigate it, so --

DR. CASALE: Although it could be the other way too, right? I mean, a lot of patients -- again, sort of -- and again, I'm -- you know, the cardiology hat, sort of

want to see the cardiologist, even if they don't necessarily need to. So part of where primary care could manage it doesn't necessarily need to, and then you have the patient sort of pushing, "Well, I want to see the cardio" -- I'm just trying to understand how this model, either sort of -- can affect that.

MR. MARTIN: So I think there's one point that I should have made earlier. I think also as most of the patients in a primary care practice, particularly of the Medicare population, have multiple health conditions, they're not simply -- some of them may just have cardiovascular disease or the need for cardiology, but the comprehensiveness of primary care that we attempt to incentivize through this model, you know, would in theory prevent some of this segmentation around episodes of care. They would be caring for a patient, and while they may go out to the cardiologist and come back to the primary care practice, we incentivize that longitudinal care.

CHAIR BAILET: Thank you.

Harold.

MR. MILLER: So under the model that you're proposing, if a patient signs up for the practice or if a patient is attributed to the practice, the practice would be paid a monthly payment rather than individual visit

payments, right? But if the patient didn't sign up or if the patient wasn't attributed, but came to the practice for a visit, they would simply pay for a visit fee, right? That's the way the model is structured.

MR. MOORE: That's correct. Un-attributed patients would be billed on a fee-for-service basis.

MR. MILLER: Right. So if I'm an attributed patient or a signed-up patient, what's my cost share? Is it -- under this default Medicare model, it would be 20 percent of the monthly payment, right? And so if it's a risk-adjusted payment, if I am the sicker patient, I would be paying 20 percent of a higher monthly payment, right?

MR. MOORE: So I'll look to my colleagues to correct me if I'm wrong, but I quite honestly don't believe we would attribute cost sharing to the per-beneficiary per-month payments.

MR. MILLER: So how would the beneficiary pay cost sharing?

MR. MARTIN: So I honestly would defer to CMMI on this, that the cost sharing in my mind today would be based upon the per-beneficiary per-month payment at the statutory required 20 percent rate. So they would pay 20 percent of the prospective amount.

MR. MILLER: Because I think that needs some

thought --

MR. MARTIN: Yeah.

MR. MILLER: -- because the beneficiary says, "I'm fine. Thank you very much. I don't need to see you. Why am I paying 20 percent per month for no visits?" And I ask that because a few years ago, I did some work up in Michigan with a group of family docs, internists, and self-insured employers and unions. I think I shared some of that stuff with Kent at one point -- or with Shawn. I'm not sure. But we developed a payment model there, but there was deep concern by everyone, including the docs as well as the unions and the employers, about a pure capitation payment because they didn't think it was fair. That somebody, a patient who didn't use the primary care physician as often, was paying the same amount as somebody who was abusing the primary care practice. And everybody, of course, you can imagine, had their stories about the people who abused the primary care physician and were, you know, calling constantly and showing up and particularly if there was essentially no cost-shared deterrent to that, you know, that you could come in every day.

What the group came up with that they liked was the idea of a -- it has some operational difficulties to it, but was basically saying that there's a monthly payment

essentially to support preventive care and chronic disease management, which essentially shouldn't be office-based, but that there was still some payment for office visits if they were made. That's different than the CPC+ model, which basically says you get a payment for, you know, half of a payment for everything and half of a monthly payment, but that you got essentially some visits free for your monthly payment. And then if you were somebody who used it more heavily, that there was some additional payment for that, which in a sense was sort of a secondary risk adjustment.

So if somebody was using the practice more, then there would be a higher payment based on that, not just their diagnosis codes.

I'm curious as to what you would think about that compared to the model that you have as to why you would think the pure -- the pure risk-adjusted capitated payment would be better, both from the practice's perspective and the patient's perspective than something that had at least some differential based on the patient's actual utilization of the practice.

No, I'm not going to let Shawn answer that. I'd like Michael to answer that. I want to hear from the doc's perspective. Your patients, your perspective as a

physician, you know. You're taking this payment. You're getting the same payment, and you've got -- one patient has got the exact same HCC score who is showing up every day, and another patient who is doing everything exactly right and, you know, doesn't manage to cut themselves in the kitchen every night at dinner and doesn't manage to fall off the motorcycle and doesn't manage to do all that stuff. How do you feel about that model? Why is this better than something that has at least some differentiation based on visits?

DR. MUNGER: So your descriptions are welcomed in my practice, and again, I would say that this now will give me the ability just for that HCC patient who is, quote, "Doing everything right," and those aren't in my practice, by the way. But if there is one out there, then that would give me the ability to be innovative, be able to reach out, be able to link up to them and still provide care.

Maybe they're not getting in as often as they should. Now I have the chance to be able to use other methods. Maybe I can do video visits or e-visits with that individual, reach out in a prospective manner to them to make sure that we're getting gaps closed to make sure they're being compliant with their medications.

I understand we're going to have over-utilizers

as part of primary care. That's a part of primary care, but I think that this overall payment is much more stable because, again, I have individuals that will show up once a year and they have an HCC score that's 2.7. Well, they ought to be seeing me quarterly, you know, so that I now have the incentive to be able to reach out and really try to meet them where they are.

MR. MILLER: No question about that. That's why I think it's a good model.

What I'm asking about, though, is that the margin, sort of all else being equal, you've got a patient who has lots of minor acute issues and is coming in frequently for that versus one who is not. And I'm just saying that at least what I heard from a group of physicians and from patients was that they thought it was unfair on both sides that everybody would -- those people would be paying the same amount, essentially. That the doc would be being paid the same amount for those two different kinds of patients and the patient would be paying the same amount, even though they weren't abusing the system. And I just wondered that sort of multiple minor acute patients, minor acute visit patients versus ones who aren't, and whether you think this model works well for that.

DR.MUNGER: And actually, I do because that also

allows me for those minor acute patients to be able to be seen and managed by all members of the team, be it a physician assistant, be it an APRN, be it being able to get their care through a video visit or an e-visit. Again, there are ways that you can work with patients and educate patients and get them to the appropriate level of care that's necessary.

CHAIR BAILET: Thank you.

DR. MULLINS: I was just going to add on to that that I completely agree as a physician as well, and it's kind of like the concept around medical home. And you say, "Well, which patients are in your medical home?" Well, they're all in their medical home, and you treat them all the same, regardless of their insurance or not or are they a part of this plan that's doing this pilot or not. Everyone that walks in the door is treated the same, and you can't start segmenting patients -- well, they're the over-utilizer or the under -- I mean, if you were part of my practice and were doing this, everyone is carte blanche treated the same.

CHAIR BAILET: Thank you for that.

So I like the model in the sense that it broadens the ability for clinicians, the primary care side of the business, to participate in alternative payment models. I

think that's -- and if it's fully implemented, really opens up the opportunities. There's lots of degrees of freedom, and specifically, I appreciate the challenge of -- I need the infrastructure to be able to be successful in moving from volume to value. I need someone to invest in my practice, particularly systems folks who are either in single practices, couple-doc practices. They don't have the infrastructure, and they're not part of a system that can make that investment.

So sitting on the other side of that, someone who’s going to have to provide that investment, whether it be Medicare or commercial payer, clearly the return on investment is top of mind, and you have lots of degrees of freedom in your quality framework.

I think one of the comments that the PRT made was that the freedom exists so much that people could focus on one particular condition, perhaps, and I guess what I would like to know is -- again, I see the value of the investment up front, but I also am curious if you could talk a little bit more about potentially things that are in the framework that could guarantee with more up-front certainty, how to actually create the value that that up-front investment is trying to purchase.

DR. MULLINS: I'm going to start with the

measures, and I'll point out that we are using the core quality measure collaborative, primary care, ACO measure set that we developed with public and private payers all around the table, and it's a set of measures that some of you are familiar with. But it's a fluid set. It's not a set of measures that is meant to be static and never changed and updated. In fact, it's something that we are in the process of beginning and updating the process here in the near future.

So that being said, the measures you can select are from that set. In CPC+, there are 19 measures, and you can choose nine. Ten of those measures are actually in the core set as well.

In MIPS, there are 257 measures, and you only need to choose six. Again, you have the freedom to choose whichever six you want, and you could choose six diabetes measures if you so choose. You could choose six sports medicine measures. You can chose six pediatric measures. I mean, you have the flexibility and freedom to choose any six measures you want in MIPS. You can choose any of nine measures of the 19 in CPC+, so this is not a new phenomenon that we are saying here's a list of 21 measures and you can choose six of them. So this isn't something that is a new concept to choose from.

You could choose -- I did the math. You could choose up to five measures that are of the same disease, that it would be diabetes. I don't know that that would be a bad thing. Diabetes is a very expensive, very complicated diseases that costs a lot of money, and if someone were to choose five diabetic measures, I don't know that that would be a bad thing to do. So that would be the one way you could almost choose all six measures from the same disease category.

Otherwise, you would have to choose -- and pick and choose around and choose other preventative measures, and again, this core measure set was something that would be fluidly updated with the Core Measure Collaborative.

CHAIR BAILET: Go ahead, Tim.

DR. FERRIS: I'll follow up with that. So there's a little bit of -- it seems to me that while there is certainly precedent for that, the question actually was about accountability in a capitated environment, and the stinting issue, which doesn't apply in MIPS at all, doesn't actually apply to those other situations, so the quality framework that you're applying is not a capitated -- it's not in the context of a capitated arrangement. And I think the concern, certainly the concern for me and I think this is what I heard from Jeff was when you're in a capitated

arrangement, the accountability issues for prevention of stinting are actually quite different than sort of a pay-for-performance-type arrangement where you've got a list of metrics and you pick six, and it's great that you're improving.

So I want to drive that home because I didn't hear in your answer, yes, other people are doing it this way and there is precedent. I get that. But the question is really about accountability in a capitated model where people could make a lot of money, and I'm not saying people would. I'm just saying the financial incentives for physicians, when they get a payment, how do you measure the fact that they're not stinting on care? And that's I think at the -- that's at the core of my issue.

DR. MULLINS: Yeah. And --

CHAIR BAILET: Before you answer, could I just flesh that out just a little bit more, so we can get a comprehensive answer? And the stinting is a piece of it, but then the patients sign up. I would want to direct the areas of focus where there is the biggest opportunity to return, meaning if I -- I'd like to know what my panel looks like and where their areas of illness are, so I can as a physician, even if I'm in a small practice, where I can focus my efforts to provide the biggest value. So

that's sort of -- The other question is: Given the fact that people are going to -- patients are going to sign up for this, what optically -- and you've got this pool of measures. And I think this challenge applies to other models as well, but you've got this pool of measures. How do you get line of sight on which measures you want to focus on that are going to drive that value, given the up-front payment?

So I think there's two parts to it. Thank you.

DR. MULLINS: So I'm going to answer the first part first. So CAHPS is actually in the core measure set. So I think we would be open to maybe making CAHPS one of the required measures along with the hospitalization and ED utilization. CAHPS is actually a part of the core measures.

So I think that if you are stinting care on your patients, you are not going to do well on CAHPS. So I think that's something that we are open to, and I think maybe that would help address some of that issue.

And I think that picking measures in the practice is something that people struggle with all the time, and I think in primary care, it is probably a little more complicated than in other specialties because everyone's practice -- you've seen one practice, you've seen one

practice. So what measures I might want to focus on in my practice may not be the same measures that Dr. Medows would want to focus on or Dr. Munger because they may have a different patient mix.

So for us to say you need to pick three diabetic measures and three preventative care measures may make no sense at all if your focus is sports medicine in your primary care practice, and it very well could be.

So I don't think that we can be prescriptive in saying that these are the measures you need to focus on.

MR. MARTIN: Yeah. I want to add one thing. We do have a core competency of the eligibility criteria that they have to risk-stratify their patient. So there's going to be some risk stratification of the population, and, you know, if you have one diabetic, you're probably not going to report on a diabetes measure. If you have 500 diabetics, I mean, most likely that's going to be an area of focus within your panel.

CHAIR BAILET: Thank you. Rhonda?

DR. MEDOWS: I think you've already answered my question. I was going to ask about the risk assessment, but I think I heard you say that you already include in the high utilizers -- you identify them not just by their diagnosis code but by their access rates to ER,

hospitalizations, readmits, et cetera, and then you didn't focus your interventions on trying to prevent that from occurring. Thanks.

CHAIR BAILET: So Bob and then Grace.

DR. BERENSON: We've made, I think, very good progress in the last few minutes. Tim sort of teed up the issue around accountability and capitation as different, and I would not be citing MIPS as a model that we want to be trying to replicate in any way, shape, or form.

I just wanted to also comment on Harold's comment, which I think is real important. In my experience with primary care capitation, the patient's cost-sharing obligations were converted into visit co-pays, and I don't know the ability to do that in Medicare, but it directly takes on your issue, and I think it is a very important issue that will need attention. The reason, a primary reason for all the burden of the CCM codes is because patients are paying 20 percent by law, and they aren't going to pay 20 percent when they're not seeing somebody for care coordination. And so a lot of the burden comes from that. I think we have the flexibility here to do it the right way, and that would be to probably not -- we did not receive a percentage of capitation from the patient. We had a visit co-pay. And I think that is the rational

way to do it.

CHAIR BAILET: Thank you, Bob. Grace?

DR. TERRELL: Just a very quick couple of things. One is I've heard for a good long time, Bob, about your concerns about the upcoding that may be inherent with respect to risk. It's also true that if you can't do that, you can't identify the patients that are your sickest ones and actually develop models of care around it. So I think it's going to be a dilemma that's important, and we'll get to the heart of what we need to get to, which is, you got to find your sick patients and focus on those.

I'm also, though, concerned about another existential threat to primary care that's related to access, and if we look at the recent announcement, for example, with CVS and Aetna, I think that's a response in many ways to patients needing convenience or different other types of things than the concept of patient-centered medical home. We see all the time people go into a convenience care clinic and urgent care clinic because they don't have access to their primary care, and we are a small breed for which many of the concepts around telemedicine or team-based care are part of the solution, but maybe not the entire solution.

So I wonder if you could talk a little bit with

respect to this model as it relates to alternatives to the medical home and how you would -- how you interact with other sources of, I would say, episodic, acute, low-acuity care, not ER, not specialist, not hospitals, not SNFs, but Urgent Cares, Convenience Cares, Minute Clinics, that sort of thing. How does that

-- How does this model impact that if you're getting a managed care -- you know, a monthly fee?

DR. MUNGER: So right now our members, we have three-quarters that are currently offering extended hours. We have 50 percent that offer weekend hours, so that we do have, you know -- so first off, our members are recognizing that they need as part of being in a medical home to have expanded access. I think that if, you know, the patient is going to be paying out of their pocket, they're going to be really looking to the practice to make sure that they do have some sort of advanced access to provide the care, and at the end of the day, you know, one of my two utilization measures is going to be ED utilization, and I certainly want to keep them out of the ED, and that means I'm going to have to be available, I'm going to have to have extended hours. That's probably, I think --

DR. TERRELL: So is that going to be a requirement in this? I mean, right now, the reason

convenience care and urgent care exist is because patients don't have access. My practice is open from 7:00 in the morning to 7 or 9 o'clock at night, seven days a week, and has been since 2007. But patients still periodically will go elsewhere for what could be construed as primary care. So I'm really talking about the interaction with other sources of primary care as it relates to a PMPM, not only how that might be adjusted, how that might impact it. Is it just because we're going to do a better job with access so we don't worry about it, or is that going to be something taken out of the -- you know, if they're going elsewhere and they're getting a fee-for-service, is that going to be something that's, you know, subtracted from the care we're providing? How has this been thought about?

MR. MARTIN: Without, you know, really getting into the whole attribution model, I mean, if there was a patient, even if the patient selected the primary care practice, but they sought a large number of their primary care-related visits at an urgent care or minute clinic or an environment like that, and that was captured through a claims process, then when there was the evaluation of the attributed panel or attributed life, there would be a true-up. I mean, there would -- you know, you would identify that the patient -- you know, a plurality of their primary

care-related services for any evaluation period took place at a site other than the primary care physician or practice where they were attributed. So there is a mechanism to do that.

I think what we're suggesting from, you know, a concept standpoint is the economic model incentivizes practices to take on a level of comprehensiveness similar to your practice that starts to reduce migration of patients to other care sites because they have a connectivity with their primary care team, whether that be through e-visits or telemedicine or they can walk -- you know, same-day visits or after-hours visits, et cetera. But, yes, we did account for the fact that there could be patients that say, "Dr. Munger is my doctor, and then I never see him," and there's a way to measure that.

DR. BERENSON: But, quickly, it means you still have to be collecting claims, right?

MR. MARTIN: Well, I mean, I think to Kent's earlier point, we acknowledge that there would have to be some type of accountability for the encounter.

CHAIR BAILET: Great. I want to thank the submitters for their attention and incredible, you know, detailed answers to our Committee and also working with our Committee and the PRT prior to today. As you guys take

your seats, we have a few people on the phone and one person, I believe, here to make a comment. So, again, thank you for coming. Appreciate it.

*** Comments from the Public**

CHAIR BAILET: Sandra Berkowitz from the Advanced -- it's Sandy, right? Oh, hi, Sandra. If you could come up to the microphone and introduce yourself, and you've got three minutes to address the Committee. Thank you.

MS. BERKOWITZ: Thank you. Ladies and gentlemen of the Physician-Focused Payment Model Technical Advisory Committee, my name is Sandra Berkowitz, and I'm the CEO of NNPEN, a network of nurse practitioners who aspire to be owners of and employees within nurse-led clinical practices, frequently the small practices that we've been talking about today. These NPs are included within MACRA's QPP definition of eligible clinician and CPC+'s definition of practitioner.

My comments relate to the AAFP's payment proposal specifically, but more generally to PTAC itself. In fact, to the Committee's very name, which currently reads the "Physician-Focused" -- not "practitioner-focused" -- "Payment Model Technical Advisory Committee." Almost as an afterthought, PTAC's FAQ addresses the discrepancy this way: "PTAC welcomes the input of non-physician providers

on all processes and invites the submission of payment models from all eligible professionals as defined by MACRA."

This answer, buried as it is halfway through the FAQs, does not execute MACRA's intent. As currently titled, PTAC in practice narrows the solicitation to physician proposals. PTAC's narrowed solicitation of payment proposals eliminates responses from nearly 200,000 nurse practitioners, that is, the 80 percent of nurse practitioners that have gone into primary care and who are prepared to independently deliver primary care services in a way that boosts access and convenience.

If 10 percent of the 20,000 NP -- 200,000 NPs in primary care, roughly 20,000 NPs, choose to own their own practices, they, too, need innovative payment models that sustain their operations year after year. Closing off these NPs means closing off access to primary care services to patient panels of those 20,000 NPs, roughly 30 million or more underserved or even unserved consumers of care.

In Scripture, Jacob wrestles with an angel and at dawn receives a new name and sets out on a new path. Renaming or even clarifying in big font PTAC's title corrects an HHS error committed at Committee inception. Unaddressed, PTAC cleaves to the past rather than welcoming

the new eligible clinicians and practitioners envisioned by MACRA.

Renaming PTAC is a procedural step. With respect to substance change, NNPEN urges PTAC to require that proposals like AAFP's, which explicitly builds on CPC+, be read to insert the more broadly inclusive term "practitioner" where "physician" now appears. For example, we've been talking about the attribution modeling. As currently read, the AAFP's patient choice attribution modeling would preclude access to these nurse practitioners, similarly as they are precluded access and attribution to ACOs under Medicare.

So on behalf of 30 million consumers and 20,000 nurse practitioners who are interested in ownership, NNPEN thanks you for the opportunity for commenting today. It's been a wonderful conversation, and it applies to us and hopefully to deliver the goods for all of our consumers.

Thank you.

CHAIR BAILET: Sandra, thank you for coming and addressing the Committee. We sincerely appreciate that input.

We're now going to move to the phone lines. We've got at least one individual, potentially two, who want to make comments. I'm going to start with Jean

Antonucci. She is with the American Academy of Family Practice. Are you on line, Jean?

DR. ANTONUCCI: Yes, I am. Can you hear me?

CHAIR BAILET: Yes.

DR. ANTONUCCI: Should I go ahead?

CHAIR BAILET: Please.

DR. ANTONUCCI: Thank you. I'm afraid I am not with the American Academy of Family Practice. I am a solo practitioner. I'm a family doctor in rural Maine. I'm not a dinosaur. I run a very innovative, high-functioning practice with really good quality measures, and I am very involved with many small practices across the country. I'm currently the Chair of the Primary Care Department at my hospital. I'm not a great speaker. I will do my best to be organized and not go over my three minutes.

I am capitated by one provider, and, Dr. Berenson, I do submit encounter forms for that. I get that point. And it's not hard. I also do e-visits, and the patients pay for them. I've done group visits and gave up on that.

I thank the AAFP for an enormous amount of good work, but I have a few comments. One is as a physician who runs her practice, if I look at this -- you know, a lot of people, if this goes forward, sure, physicians will sign on

to this. But there are a lot of faults. This was a wonderful discussion. I'd love to talk to you all more. But the things I notice are, yeah, it's not at all transparent what a physician would be signing up for, how you'd get paid. No one takes a job without being paid, and there are -- Most of us in small practices know how much it costs us to take care of patients. We can take of low-risk patients for $60 or $80 a month and higher-risk patients for about $90 a month. We know this, and physicians do want to know how much they're going to earn.

Part of the context here is that there's been so much change in the last several years, and I think it was Grace - I'm so uncomfortable calling you all by your first names, but that's how you're going -- for thanking people for all the work they've done. But I think we have to honor the fact that primary care is incredibly exhausted and discouraged. And so while we need to support it, the way I saw this project -- and I'm absolutely in favor of capitation -- was that this is awfully complicated. There is this specter of repayment for some incentives. This is really chilling in the current political environment. You may want to earn an incentive, but we should not have to give back. We take risk as physicians in so many ways every minute of every day. The current environment seems

to be pushing us toward risk as insurance companies, and I would warn against that.

Finally, I think that, if I can express this well, this would be, as Mr. Harold Miller says, operationally difficult. But the big, huge, gray elephant that is not included here anywhere is that if you're going to give money to primary care and you're going to support us, we have to have, somehow, changes that allow for us to spend all that money and time on the patients. Now, that's not the same thing as the stinting that Dr. Berenson rightly talks about. We currently spend a great deal of our day getting other people paid. And somehow or other, although I know the P in PTAC is for "payment," we need to have a talk with payers about the fact that when Bob Berenson breaks his arm, I'm the one that has to fill out a form that keeps him from paying and gets the orthopod paid. This escapes notice. If I am paid well, I may be paid to do that. But we have made primary care file clerks and librarians, and we need to somehow build that into any project, because I don't think that even with much more money we will get people into primary care. And that is the only way you're going to get better outcomes and cost savings. We need to support primary care. We need to make simple payment projects and not call them "crude," and we

need to support primary care but not just by giving us money.

I will tell you one very brief story. I have very good friends in Rhode Island who run small, innovative practices. They're incredibly frustrated. Yes, Rhode Island has legislated that more money go to primary care. They've been forced to do vendor-supported things like -- I'm no fan of CAHPS, and I am no fan of NCQA. And I sat on NCQA's 2017, whatever it was called, the committee to make it do better. I was not impressed. And yet there's a really big practice in Rhode Island that I'm not going to name that gets all kinds of good press. If you live there locally, you can't get access and you don't get good care.

So we seem to miss things somehow. Money isn't everything. We've got to support primary care by changing our work flow, and I have to bring that to your attention, although it may be difficult to do.

Thank you. Thank you much.

CHAIR BAILET: Thank you, Jean.

Our last person on the phone is Rebecca Love. Is Rebecca on the line?

DR. LOVE: Yes, I am. Can you hear me?

CHAIR BAILET: We can. Please proceed. Thank you.

DR. LOVE: Okay. Thank you.

I am a family physician in North Carolina with 20 years of experience in private practice and in leading a home-based palliative care program for a nonprofit hospice in a mostly rural area. I have this year gone back into primary care as a solo practitioner to develop a collaborative practice using care communicators and specialty partners to help me provide comprehensive primary, palliative, and collaborative care. CPC+ is not available in North Carolina.

For my needs to serve the patients that I see, CMS needs to provide an acceptable alternative payment model that reflects the value of what I do, removes the excessive burdens that limit the number of people I can reach, and restores the respect and priority to the healing power of the doctor-patient relationships.

The APC-APM comes the closest to this of any model I have seen. I have researched the collaborative care models for a number of years and used methods from those models in developing my new practice.

I recognize the need to examine for ways that any model can be distorted and for assuring accountability, and I've enjoyed the conversations today. I think that the APC-APM provides the articulated structure able to

coordinate a multitude of small units that the economist E.F. Schumacher observed that was unbelievably urgent in 1968 for the conscious utilization of our enormous technological and scientific potential for the fight against misery and human degradation.

I also see the APC-APM as the foundation that could be built upon to simultaneously solve tax, insurance, and health care crises by combining features of collaborative care models and a plan for shared reimbursement specialty partners. We face cuts to the CMS programs that will endanger health and lead to suffering and death. No one is invulnerable. More shifting of dollars to pay for managing care only diverts funds to abstractions which cannot provide healing or promote desirable growth. The APC-APM attempts to assign fair payment based on risk-stratified past and current experience data to those providing quality care to people.

CMS has access to historical data and the means to do the economic modeling to predict the effect of offering a choice on Medicare, Medicaid, and on the established health care marketplace to pay directly for primary care provided by physician-led teams using a refined version of the APC-APM with wrap-around insurance coverage for medications, tests, specialty care,

hospitalizations, or catastrophic health events. This should be far less costly for all payers, especially taxpayers, than the current options and would guarantee access to high-quality, satisfying care that could be estimated in the same way that the CBO (estimates effects of legislation.

It's ironic that this highly developed plan supported by evidence-based medicine and years of research is passing through this deliberate process at the same time the complex tax cuts are being whisked through the legislative process. Conscious utilization of our enormous potential to fighting its misery and human degradation was urgent in 1968. It's medically emergent now. Solutions to our problems require the finest focus of our best minds from many fields, deliberating with the honest transparency that science demands and that we expect from our best agencies.

I thank you for your devotion of time and expertise to the search for valid solutions, and I ask you to engage our enormous potential and move the APC-APM forward in the process. Thank you.

CHAIR BAILET: Thank you for your comments.

* **Committee Deliberation**

CHAIR BAILET: I now would like to turn to my

Committee members and see if there's any further discussion that we'd like to have or are we ready to proceed with our vote?

I'm hearing proceed, so we're going to go ahead. Matt has got to tee it up electronically. I want to remind folks that the Vice Chair, Elizabeth Mitchell, is present on the phone and watching on the live stream, so she is going to vote with us, and we have that coordinated through our staff. So it takes a minute to set this up.

* **Voting**

CHAIR BAILET: All right. So we're going to go through the ten criteria, starting with Criterion Number 1, which is Scope. It's a high-priority item considered by the Committee. The aim is to either directly address an issue in payment policy that broadens and expands the CMS APM portfolio or include APM Entities whose opportunities to participate in APMs have been limited. So we have 1 and 2, does not meet; 3-4, meets; 5-6, meets and deserves priority consideration. The asterisk represents a new judgment that the Committee has attributed to certain elements and certain proposals, and that is that the particular model is not applicable to a particular criterion. So if that is the case on any of these, that will show up there.

So we're ready to go ahead and vote, please.

[Electronic voting.]

MS. PAGE: Okay?

CHAIR BAILET: Yep, okay. Go ahead, Ann. Sorry.

* **Criterion 1**

MS. PAGE: One member has voted 6, meets and deserves priority consideration; six members voted 5, meets and deserves priority consideration; three members voted 4, meets; one member voted 3, meets; and zero members voted 1 or 2, does not meet; zero members voted not applicable. The majority finds that this proposal meets Criterion 1 and deserves priority consideration.

CHAIR BAILET: Thank you, Ann.

We're going to move to Criterion 2, which is Quality and Cost, also a high-priority item. Anticipated to improve health care quality at no additional cost, maintain quality while decreasing cost, or both improve quality and decrease cost. Please proceed and vote, please.

[Electronic voting.]

* **Criterion 2**

MS. PAGE: Zero members voted 6, meets and deserves priority consideration; one member voted 5, meets and deserves priority consideration; four members voted 4,

meets; six members voted 3, meets; and zero members voted 1 or 2, does not meet; zero members voted not applicable. The majority finds that this proposal meets Criterion 2.

CHAIR BAILET: Thank you, Ann.

We're going to move to Criterion 3, which is the Payment Methodology high priority. Pay the APM Entities with a payment methodology designed to achieve the goals of the PFPM. Criteria addresses in detail through this methodology how Medicare and other payers, if applicable, pay APM Entities, how the payment methodology differs from current payment methodologies, and why physician-focused payment model cannot be tested under current payment methodologies. A high-priority item. Please vote.

[Electronic voting.]

* **Criterion 3**

MS. PAGE: Zero members voted 6, meets and deserves priority consideration; one member voted 5, meets and deserves priority consideration; four members voted 4, meets; six members voted 3, meets; and zero members voted 1 or 2, does not meet; zero members voted not applicable. The majority finds that this proposal meets Criterion 3.

CHAIR BAILET: Thank you, Ann.

Criterion 4 is Value over Volume, provide incentives to practitioners to deliver high-quality health

care. Please vote.

[Electronic voting.]

* **Criterion 4**

MS. PAGE: Zero members voted 6, meets and deserves priority consideration; two members voted 5, meets and deserves priority consideration; seven members voted 4, meets; two members voted 3, meets; and zero members voted 1 or 2, does not meet; zero members voted not applicable. The majority finds that this proposal meets Criterion 4.

CHAIR BAILET: Thank you, Ann.

Criterion Number 5 is Flexibility. Provide the flexibility needed for practitioners to deliver high-quality health care. Please vote.

[Electronic voting.]

* **Criterion 5**

MS. PAGE: Zero members voted 6, meets and deserves priority consideration; five members voted meets and deserves priority consideration; six members voted 4, meets; zero members voted 3, meets; zero members voted 1 or 2, does not meet; and zero members voted not applicable. The majority finds that this proposal meets Criterion 5.

CHAIR BAILET: Thank you, Ann.

Criterion 6, Ability to Be Evaluated, have the evaluable goals for quality of care, cost, and other goals

of the PFPM. Please vote.

[Electronic voting.]

* **Criterion 6**

MS. PAGE: Zero members voted 5 or 6, meets and deserves priority consideration; one member voted 4, meets; eight members voted 3, meets; two members voted 2, does not meet; zero members voted 1, does not meet; and zero members voted not applicable. The majority finds that this proposal meets Criterion 6.

CHAIR BAILET: Thank you, Ann.

Criterion 7 is Integration and Care Coordination. Encourage greater integration and care coordination among practitioners and across settings where multiple practitioners or settings are relevant to delivering care to the population treated under the PFPM. Please vote.

[Electronic voting.]

* **Criterion 7**

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

The majority finds that this proposal meets

Criterion 7.

CHAIR BAILET: Thank you, Ann.

Criterion 8 is Patient Choice, encourage greater attention to the health of the population served while also supporting the unique needs and preferences of individual patients.

Please vote.

[Electronic voting.]

* **Criterion 8**

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

The majority finds that this proposal meets Criterion 8.

CHAIR BAILET: Thank you, Ann.

And Criterion 9, Patient Safety, to maintain or improve standards of patient safety, please vote.

[Electronic voting.]

* **Criterion 9**

MS. PAGE: Zero members voted 5 or 6, meets and deserves priority consideration. Three members voted 4,

meets. Seven members voted 3, meets. One member votes 2, does not meet. Zero members voted 1, does not meet; and zero members voted not applicable.

The majority finds that this proposal meets Criterion 9.

CHAIR BAILET: Thank you, Ann.

And finally, Criterion 10, which is Health Information Technology, encourage the use of health information technology to inform care.

Please vote.

[Electronic voting.]

* **Criterion 10**

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

The majority finds that this proposal meets Criterion 10.

CHAIR BAILET: Thank you, Ann.

Can you please just summarize our voting on the 10 criteria while Matthew sets up the next phase?

Thank you.

MS. PAGE: Okay. On the first criterion scope, the Committee voted that it meets this criterion and

deserves priority consideration, and there are other nine criteria of the Secretary, the Committee found that it meets the criterion -- criteria.

CHAIR BAILET: Thank you, Ann.

Are we ready to move to the final phase, which is making a recommendation to the Secretary? Yes?

So this process again is actually two steps. First, it's an electronic vote. There are four potential options: not recommending to the Secretary, recommending for limited-scale testing, recommended for implementation, and then recommending to the Secretary implementation with high priority. There's also the asterisk category of not applicable.

So what we're going to do is we're going to vote electronically first, and then we'll go around the room and share with each other how we voted specifically. So if we could go ahead and vote, please.

[Electronic voting.]

CHAIR BAILET: Ann?

* **Final Vote**

MS. PAGE: Yes. Four members voted to recommend the proposed payment model to the Secretary for implementation as a high priority. One member voted to recommend the proposed payment model to the Secretary for

implementation, and six members voted to recommend the proposed payment to the Secretary for limited-scale testing. No Committee member voted to not recommend, and no Committee member said it's not applicable.

According to the decision rules of the Committee, with this spread, the votes aggregate down until we have a majority of eight, so the recommendation is to recommend the proposed payment model to the Secretary for limited-scale testing, if we're two-thirds.

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

CHAIR BAILET: Thank you, Ann.

Could I start with you, Tim? We'll just go around. Thank you.

DR. FERRIS: Sure.

So I voted for limited-scale testing, and I think maybe the summary of my summary thinking here is that the concept is clearly the right direction to move in. But I found, as my questions indicated, there's a lot of lack of detail, and with so much lack of detail, it's very difficult for me to say go do it. And so I came back to limited-scale testing.

I think the submitters have a careful balancing act here. They were trying to improve on the burden associated with CPC+. That was the answer to my question,

but there's also another burden. It's a societal burden to have accountability for the taxpayer dollars, and where to put that balancing point, I found the proposal was a little bit like help out the practitioners and maybe at the expense of a lack of accountability, particularly around the opportunities in the setting of a capitation for stinting on care and, as Jeff was saying, the value creation.

I fundamentally believe that this model will create those things, but I think we're in a world where you don't just pay and think it's going to happen. You pay and you then verify that you're getting that model, and how you do that without burdening the clinician, which I am all for, is a trick, but I believe it can be done, especially in this world of electronic health records where the data is all electronic and available.

So that's why I came down where I did. Thanks.

CHAIR BAILET: Thank you, Tim.

As we go around, also if you have a specific comment or position that you'd like to make sure it gets included in the Secretary's letter, I think we should call that out as well, so, Tim?

DR. FERRIS: Just to be clear, that was the -- those were my comments that I would like to have called

out.

CHAIR BAILET: Great. Thank you.

DR. TERRELL: So I was the sole one in the middle that said to proceed, but not with highest priority. And I agree with a lot, if not all, of the comments that Tim is making, but I came down to go ahead and proceed with the implementation based on several things.

One of them is that there is already a vast amount of study that's been done with respect to CPC, CPC+, patient-centered medical home, and data. And the speakers themselves alluded to the long history that has been in primary care in terms of data out there with respect to transformation.

My concern with limited-only is it would go into the quagmire of CMMI, yet another pilot project that would come out five years from now and nothing had changed in the world.

And the second component of my thoughts is that primary care is in real trouble right now in this country, and we need to move forward with a model that will be something that will help us as we move forward in health care that's going to support primary care, not, Tim, for the sake of supporting it, because our patients need to have other ways of getting access to primary care if we're

going to have a system that is going to stand up.

And I fundamentally believe that to do that, there is going to have to be a monthly payment. The details are not fleshed out in this in a way that will allow the creativity of nurse practitioners, internists, family physicians, and pediatricians, and OB/GYNs (obstetrician-gynecologists) who practice primary care to be creative with the work that they do.

So that's where I am on this.

CHAIR BAILET: Thank you, Grace.

Harold?

MR. MILLER: I voted to recommend to proceed with high priority. I think the country has been screwing around for entirely too long, talking about trying to improve primary care.

We know that it's paid badly. We know that it needs to be paid more. It is, I think, a national embarrassment that CMS does not have a medical home model for primary care across the board.

What exactly that primary care medical home model should be, it probably is in some degree of a discussion, but I don't think that that means that we should do limited-scale testing here and there for 5 and 10 and 20 more years to be able to get there because I agree with

Grace. I think we know that patients need better primary care. We know that primary care is at risk, and so I think that we need to start doing something broadly pretty darn fast.

I think that this model has the basic correct structural elements to it in terms of being able to pay on a monthly basis, a risk-adjusted monthly basis. This is not a capitated model in terms of traditional capitation. It's a risk-adjusted model, which I think makes a huge difference in terms of protecting against some of the issues associated with stinting, not all, but some.

What I would put into the report, my recommendation would be that I think there is unnecessary complexity in what was proposed. I don't think that there needs to be two separate PMPMs. I don't think that there need to be two different versions of E&M. I think that is unnecessary complexity, which as far as we can tell achieves nothing in terms of value in terms of result.

I do think, though, that in terms of resolving some of the other things, the risk adjustment needs to be fixed. There needs to be, I think, a risk stratification.

I think one of the arguments against the problems of HCCs is that it is a continuous linear in a non-linear-world thing that rewards people for getting one more

diagnosis code shoved in there, and if it was a risk-stratified model, you would reduce significantly some of that. And I think that we all know that HCCs is not the right way to be able to risk-adjust patients in a primary care practice, and so, therefore, I don't think it should be HCCs. It could be ACGs. It could be a modification that we know the patient functional status needs to be in there.

So I think to me, it would be a priority for AAFP, not just wait for CMS to do it, but AAFP to try to figure out what they think that risk stratification structure would be, and maybe there are a couple of different choices, and those maybe should be tested separately through this process.

So I think something should be done broadly, but that to me doesn't mean that it has to be the exact same thing done broadly. It might be that we test two different risk stratification models with the notion that in both cases, we are improving primary care, and we are helping things. But we're not exactly sure what the right way is to do that, and I think the same issue may hold with some of the quality and performance measures, is that there may be two different versions of that.

The second point I would make is I think that the

quality and accountability for cost is completely and totally inadequate in this model and needs to be fixed. I don't think that means to vote against it because I think that the basic concept is there, but I think it needs to be dramatically improved, along the lines we were talking about earlier, as Tim mentioned, that it needs to be focused on trying to make sure that all the patients in the practice are getting the right care.

So I think, again, I would urge AAFP to take the lead in figuring out what the right way is to do that, not say they're relying on MIPs or anything else. I think all of the current quality measurement systems are broken, and I think it would be incumbent on AAFP to figure out what the right one is.

So I think risk adjustment needs to be fixed. I think that there needs to be a much better method of quality measurement and utilization measurement built into the model, but I think something needs to move forward quickly.

And I would just note, not necessarily for the report, but I would put on the record that I think that given the need to improve primary care, I think that doing this under the framework of CMMI and alternative payment models is potentially problematic and potentially the wrong

way to go.

Congress, for whatever reason, decided that ACOs should be a program open to everyone, but somehow primary medical home models are not a program open to everyone. And it would seem much more logical for me to say let's make that a program rather than doing it under the testing and evaluation model.

And I would say that because I think that the evidence so far on primary care medical homes, they may not have saved money, although it's a diverse thing, but they haven't exactly cost money either. And there have been significant quality improvements.

So my interpretation of the CPCs, the CPCI results was better quality, cost-neutral, therefore, why don't we do that more broadly because that would be a good thing to do.

So I just would not, not necessarily for the report, unless other people think it should be in there, that this kind of thing really, I think, needs to be done in a broader way and not -- it's not necessarily appropriate as the CMMI model of things.

Thanks.

CHAIR BAILET: Thank you, Harold.

Paul.

DR. CASALE: Yeah. I voted for approval with limited-scale testing, and a lot of the comments have already been made. I guess I would just -- in terms of my comments, I would emphasize that Tim's comment about balancing the reduction and burden -- and there's no question that that should be a major priority. I think clinician well-being these days is a high priority in general, and I think certainly reducing the burden around regulation is really critical. And this starts to move in that way. However, balancing that with assuring accountability, I think that is really critical.

It's interesting when we have specialty models coming forward, the other concern, we're always -- or I'm always thinking how are they going to coordinate with primary care, how are they going to integrate with primary care.

It's interesting that I'm thinking in this model, "How are they going to coordinate with specialty?" So I do think that is a concern that needs -- and to Harold's point, I would like to see AAFP come up with thoughts about doing it, rather than saying, well, we'll have CMMI kind of figure it out when they go forward because I'm sure they have some very good ideas on how to do that. But that will get at the ensuring of accountability, both quality and

financial as well, because certainly the specialty care is going to be critical.

CHAIR BAILET: Thank you, Paul.

Bruce?

MR. STEINWALD: I also voted for approval for limited-scale testing.

I support what others have said about the need to support and improve primary care, and I think that ought to be a focal point of the report.

The problem I see, though, the reason I voted for limited-scale testing is because of all of the unknowns, all the important details that can't be fleshed out until we have some actual experience.

The problem is the complexity of the model suggests that the scale can't be so limited. In order to uncover the unknowns, it would probably have to be of some substantial scale, more than, let's say, a single demonstration site.

So I would suggest two things about that. One is potentially some simplifications of the kind that Harold mentioned and maybe some others for a model to be tested on limited scale, and that it's clear in our report that when we say limited scale, we're talking about not full implementation, but implementation on a scale that's large

enough to acquire the information that we need to go forward in a larger scale.

CHAIR BAILET: Thank you, Bruce.

I, too, voted limited-scale testing, and a couple of thoughts about that.

I think the power of this model is the inclusiveness and the expansiveness and the ability for people who are currently not in the field of alternative payment models, the clinicians to get on the field and participate.

I think the challenge with this model is that there are -- even Harold has called out several soft spots, if you will, with the model that needs to get worked out and before exposing this to patients in a broad scale and clinicians in a broad scale because we want this to work. We want this to be successful. We don't want unintended consequences to create barriers to actually having this model be successful, and I think having the opportunity to have a limited scale analysis in testing set it up for success with a broad implementation.

If there was a category for limited-scale testing with high priority, I would have checked the box. That wasn't an option, but that was what I was thinking because -- and I would be remiss, my colleagues would be very

disappointed in me if I did not provide what I have a habit of doing, is the visual on this.

And so I want to be clear for the people who are listening, and I've shared this with Congress. We do not as the PTAC -- we do not want our recommendations to go into the vast chasm, and the "Raiders of the Lost Ark" visual comes to mind with that person pushing that trolley down into that incredible warehouse with that wonderful idea. That's not what limited-scale testing means in my mind, particularly in this model. We want and we will work with CMMI and Congress and CMS to make sure that this gets sharpened, so that we can go ahead and push it out in a broader scale because I totally -- I'm deeply committed to the comments that have been made around the challenges with primary care and the pipeline, creating the aura of desirability and getting future medical, medical students, nurses, to participate in these alternative payment models, particularly around primary care.

And right now, it is burdensome. I think it's a huge amount of toil, and the opportunity for us to make a significant change on that course and get people interested, because we know the pipeline for training is measured in many, many years to get someone through the process.

So, again, I think this model has tremendous promise, and I'm hopeful that CMMI and CMS will work with us to push this forward as quickly as possible.

Thank you.

Elizabeth?

VICE CHAIR MITCHELL: Thank you.

I also voted for limited-scale testing, but like Jeff, I think it is absolutely a high priority. I know of many physicians who wanted to participate in CPC, CPC+, but couldn't get plan support to do that. I think there is a real demand and a need for this.

I do have concerns about the quality metrics and the cost metrics, and to Tim's point, the accountability, but I think those can all be addressed and refined through regional testing. And I hope that it is entirely clear to CMMI, Congress, and others that we -- that I at least fully support this and hope that it moves forward. I think there is an urgent need and want to thank the submitters.

CHAIR BAILET: Thank you, Elizabeth.

Len.

DR. NICHOLS: So I voted for limited-scale testing, but I want to be clear. I share the sense of urgency of pushing this forward as far as possible, and I love your new category there of limited scale, but do it

now, damn it. So what I would propose we put in the letter is a note. As far as I can tell, this is the first time we voted in this bipolar way, right? Four were for high priority, and six were for limited scale, and one was for just do it.

So, fundamentally, I think we should reflect that very clearly in the report, and I would ask that we say this should be tested in a limited way so we can work out the details. We can't turn this loose tomorrow, but what we could do is test it on a scale of CPC+ and hold that up as a model. It's got to be at least that big a test, so that we can do these different forms of it in different places and get some knowledge about how to move forward fast.

So I think that kind of statement might convey the commitment we have to moving with a sense of urgency because I would just like the report to also say I at least -- and I think a number of us -- are extremely worried about the survival of primary care out there, at least independent primary care, and I see this as a lifeline brought to us by actual doctors who do that stuff. I'm totally in favor of economists being involved, but when doctors come up with models this creative, I think we need to reward them.

CHAIR BAILET: Thank you, Len.

Kavita.

DR. PATEL: So I actually voted -- I was one of the four that voted this as a high priority, and it's not because it -- I don't like the new category idea, even though I respect it. I actually decided to vote high priority to send a signal, and I want my comments to reflect a very strong signal that CMMI or somebody at CMS has to do something better in primary care.

And I'll just put three things that I think are critical. Number one, I would highlight that this aligns with the recent RFI that came out from CMMI. They cited, quote, "direct primary care," but in general, they put forward this notion kind of that primary care is an important area of concentration.

Number two, I think MACRA and MIPS with respect to the submitters is deeply flawed, and I am one of those practicing primary care physicians. And even though I'm in kind of an integrated system, it's much more of a community-based internal medicine practice than anything. And it is extremely difficult to even know how to pick the appropriate measures because we have no information on what we're doing.

So I think that for the submitters to make this

proposal work with HHS that we would actually think about not using the same refrain of the core quality measures set and things that got like unanimous agreement between the blues and the this and the that, but that we actually think about using a practice's own data to, as Jeff put it, better understand the population you're treating and then actually have flexible measures that put those kind of quality milestones in place, so that if you happen to be treating more diabetics or hypertensives, then you'll have those measures, but that we probably aren't doing a good enough job in a lot of preventive care, and we need to have some of those measures in place too.

And then the third thing I'll say has to do with kind of this notion of not including total cost, and there was a letter from the AMA, and there were a couple of other letters that kind of described why it would not be fair to include total cost.

But I would also put forward to the Secretary in the letter that I think that this is exactly the kind of model where at least illustrating what total cost is and demonstrating the potential impact will only strengthen the argument that the submitters made, that we should actually be paying 12 percent of spending to primary care versus the current six to seven percent. So while I understand

there's reticence with that, I think it's critical.

And then I guess the final point, this is more personal. I think it's incredibly complex. It's incredibly hard and incredibly discouraging to practice great primary care. I'm actually not worried about -- I know that a lot of people have brought up stinting. I think the stinting that's going on is because we're seeing a great degree of burnout. We're seeing many doctors go into concierge models to do their own version of cherry-picking, and I do think that we're unintentionally worsening kind of disparities in vulnerable populations because we're telling doctors -- I was told many times that I was too smart to do primary care; I should have gone into cardiology or I had good hands and I should have been a surgeon. And there are days when I was in my 20s and 30s, I thought, "No, those people don't know what they're talking about."

Now that I'm in a different decade in my life, I actually don't know if they're wrong, given the alignment of current incentives. So I'll just state from a personal standpoint that I think it's incredibly important that HHS do this, they get it right, and that we find a way like as a community of medicine to actually come together and do what's in the best interest of our patients.

CHAIR BAILET: Thank you, Kavita.

Bob.

DR. BERENSON: So I voted 4 for high priority, and I was tempted to say what you beat me to, which is high priority for limited testing, but I think a couple of comments, Bruce and others. This isn't really limited-scale testing. It's testing on the order of CPC+, so I thoughts that's more like a regular demo.

I do think that we have to disabuse AAFP of the notion that this becomes the opportunity for all physicians who can't get into CPC+ to get into an alternative payment model because for the reasons everybody said. This needs work to get it right. We need to test it on a broad enough scale. I think there will be some barriers to participation by private payers, and I think this would work a lot better if we have some private payers. So I don't think even if we said we want all primary care docs to come into this that that would be practical.

So I think it's high priority largely because I think if it works, this is the right way to practice. This is more compatible with transforming primary care than any other payment model around, and that's why you should have high priority.

I actually think my own personal view is that

total cost of care performance with attention to Winsorization or whatever the terminology is to minimize the impact of patients outside the control of primary care is doable, but if you're going to go the other way, which is to pick very good utilization measures, which are surrogates for total cost, which that's reasonable, I think then the measurement set needs to be expanded.

And as Paul and I were probing, I think, the most, I think there's a real potential -- a real attention to referrals and what some have called the medical neighborhood. I think that needs a lot more attention here.

I do think there is a real concern about just shipping people off, not when they have a minor procedure, but for the bread and butter stuff of back pain and headaches and everything else that primary care physicians and practitioners see, and that needs more attention.

So we've made progress already today with the notion of having some patient experience, perhaps using CAHPS. I think we want to look at referral, potential referral measures to identify over-referring as a potential problem.

And did I have anything else to say? And I agree with Harold. If we could come up with an alternative to

HCC, which seems to me not really relevant for primary care even, that would sort of satisfy my concerns about gaming. So I think that would be a high priority.

The bottom line here is that there's just a whole series of operational issues that need to be worked through, so that's broader scale than limited, but it is not huge scale. So it is comparable, I think, to CPC+ in terms of its scope, but I would put it on a high priority.

CHAIR BAILET: Thank you, Bob.

Rhonda?

DR. MEDOWS: So, ditto.

[Laughter.]

DR. MEDOWS: I recommended that it be -- I recommended that it be recommended to the Secretary as a high priority for all the reasons already said.

My chief concern -- I will be honest with you -- was about the opportunity and the scale that this brings to actually transform how care was delivered by the bedrock community of primary care, family physicians, practitioners, and care teams. This would be a tremendous change.

I do understand, and I do agree, that there is some fine tuning that needs to be done in terms of measures, performance tracking, risk adjustment, et cetera,

but the magnitude of the opportunity is tremendous. It is also extremely timely.

When the presenters talked about one in five Medicare recipients being treated and cared for by family physicians, we're talking about not only the physicians, the care teams, but also an immense, a large population base that needs this help.

So, thank you.

CHAIR BAILET: Thank you, Rhonda.

And now we have additional comments. Harold and then Tim.

MR. MILLER: Two things. First of all, I wanted to add to my list. I mentioned risk stratification. I mentioned the quality measures, and I also meant to mention attribution, which I think is a key thing here. Again, I think that's something that could be tried in a couple of different ways, but I personally think that at least there should be some trial of a pure patient sign-up model rather than this sort of complex hybrid.

The second point, though, is I guess I am troubled by us having this in the limited-scale testing category because everybody who said that they voted limited-scale testing was not talking about limited-scale testing of the type of limited-scale testing we have talked

about before when we said limited scale.

CPC+, I believe, is the largest-scale test that CMMI has done of anything. So for us to say limited scale, we mean CPC+ side, to me, I think is an inconsistent thing. I personally would recommend that we revote, to be honest with you. I know that may send shudders up Mary Ellen's spine, but I really don't think that -- I think we need to be thinking about the consistency of what our recommendations say.

I think we put some other things into the notion of limited-scale testing, meaning do this in a few practices, literally in a half a dozen or 10 practices, because there's so much in terms of numbers that no one even knows that you need to get that data to even be able to go out more broadly.

I don't think that is the case here. I think that there is stuff that needs to be refined, but all these other things can be refined -- I mean, if we're talking about CPC+. So if those who voted limited-scale testing really meant consistent with the other things, okay, but if they meant testing on CPC+ scale, that to me is what we would call a "recommend to the Secretary," because it would be done. It would be done as a test, and it would be done with some large number of practices. So I am troubled

about having that recommendation come out the way it is right now.

CHAIR BAILET: So, Tim and then Elizabeth.

Go ahead, Tim.

DR. FERRIS: So, first of all, I want to say that I agree with all the comments about the people who were voting for high priority for the reasons that they were voting for high priority.

But like you, Harold, I was troubled, but troubled by a different inconsistency, which is you listed all the ways that you would change this model in order to do this high priority. So you weren't actually voting high priority on the model that was in front of us. You were voting for a model that you have a whole series of amendments, too.

So I chose to vote on the model that I had in front of me, thinking that conceptually I was all in favor of this, got to fix primary care, got to do all the things that all the people were saying, but I felt torn between the categories, as I heard actually almost everyone was torn between these categories.

DR. TERRELL: Not me.

DR. FERRIS: No, actually -- that's true.

[Laughter.]

DR. FERRIS: So I guess I would say that, personally, I don't think we need to revote. I think this conversation has -- and the documentation of this conversation will very accurately reflect the situation that PTAC has found itself in, which is incredible enthusiasm for fixing primary care, believing that this is conceptually correct and it's the way to do it. But it is not in its form on the paper that we received, a model that we think should be implemented just this way. So that would be my caveat.

And since we're making recommendations, specific recommendations about how we would fix it, although not providing assistance, the other potential way, besides Winsorization, to mitigate the potential stinting issue is to just cap the penalties that would be in place on your performance. And there's a lot of literature that suggests that doing that would be -- you could have a total cost-of-care model, but just limit the downside on the performance, on the total cost of care. That way, you sort of get the best of both worlds.

CHAIR BAILET: Thank you, Tim.

Elizabeth.

VICE CHAIR MITCHELL: Thanks, Jeff.

I was going to say almost exactly what Tim said,

and so I won't say too much more.

I would not change my vote if we were to revote. I do think this was urgent and high priority, but I think that regional testing is going to be really important for all the reasons stated.

I also think there's going to be regional differences in terms of interoperability in the infrastructure and relationship with specialists, and I think that there's a lot to be learned. But I don't think that in any way diminishes the urgency of moving forward.

So I would just stay with the votes we have.

CHAIR BAILET: Thank you.

So it would be Bob, Len, Bruce, and then Harold.

DR. BERENSON: Yeah. I think I'm with Harold on this one because I do think we had a different notion for limited-scale testing, which is largely a figment of our imagination at this point in terms of its reality, and so that's my concern about saying we're recommending it for limited-scale testing, but we really like it as opposed to we recommend it for a standard demonstration, which is what I think we really mean.

I don't think we've ever had a model which we said, "Oh, we'd love it in this exact form. Just go demonstrate it." We've always assumed -- and this is

consistent with the discussion we had earlier -- that we want to move it forward, and then as we remember from Mai Pham's presentation two years ago, CMS, CMMI goes through 24 steps before they actually take on a demo. We would work through those operational issues. I want to get it on a track where that happens as opposed to, oh, we got another one of these limited-scale testing proposals from PTAC; we don't have to really act on that.

So that's why I'm sympathetic to Harold's suggestion that we finish this conversation about what we really mean by limited-scale testing and then consider re-voting.

CHAIR BAILET: Len.

DR. NICHOLS: So I'm not opposed to re-voting. I'm not going to change my vote.

What I would say is that we're all prisoners of our interpretations of all these little categories, and let me just, while we're at it, tell you what the hell I think this stuff means.

Limited-scale testing means it ain't ready for prime time. I love this model. I love this idea. I totally agree it's directionally correct, and I do believe we can work it out. But, Harold, it is not ready, and for us to say it is, in my view, harms our credibility in a

consistent way going forward.

I don't think it's ready. I do think it should be tested. I do think it should be tested on a scale large enough. I would say on a scale large enough to reflect the potential value of the project, and that's what I meant by CPC+. I just think it's a better model than CPC+ for our country, and I would rather have it be the dominant one. But it's not ready for prime time, and that's why I think we've got to do this scale.

I'm totally in favor of -- I think of it like what if Congress had taken the shared savings program and instead of putting out a draft reg, put out a test, and you said, "We're going to do this, date certain, four years down the road, but we're going to learn some stuff in the meantime," instead of saying, "Here are the parameters. This is what we're doing." And that's why I would submit it needs to be tested. It's different.

CHAIR BAILET: Thank you, Len.

Bruce.

MR. STEINWALD: I'm with Len on this one. I don't see the need for a re-vote.

I think, as we have said from time to time in different contexts, the important thing is that the report -- in the discussion section of the report, it says exactly

what we think and what we meant.

I agree with Len also that the limited scale part of it is, as he put it, a recognition that it's not ready for prime time. I think it's different from other proposals that we've seen in two respects. One is there are more things to uncover to make this work right than I think the typical proposal where we think it has one or two things that need to be adjusted.

And second, when we were talking about limited scale here, we are talking about scale that's large enough. I don't know if it's CPC+ or something, you know. Who knows? But it's limited in the sense that it's not full implementation making it available to primary care physicians. It's scaled large enough for us to work out the kinks and figure out how to make it scale up effectively with information that we don't have at hand.

CHAIR BAILET: Thank you, Bruce.

So we've got Harold, Grace, and then Paul.

MR. MILLER: So just to clarify my opinion, I think that in the absence of all other alternatives, I would say implement this model as it was proposed. I do not think that the model as proposed -- it has some details to be worked out. Everything has details to be worked out, but I would say if we can't change it, then it should go

forward. That's different than saying, boy, I think this thing really needs work, and if they were to do it the way they proposed it, it would be a problem. I don't think that's true.

I think, to go back to my earlier point, I think primary care needs something now. It needs something like this right now, and yes, I think it could be made better. But I think it's above the threshold for saying it should go forward.

The second point is just I still am troubled. I think that, yes, people can read the report, but you know they won't. They're going to see the vote, and the vote says limited-scale testing. And the other things all said limited-scale testing and meant something different. They meant do it in a very small number of practices because we don't have cost data, et cetera. Those were not because the methodology needs to be fixed up, but that's evolving. So I just am troubled by that, but that's okay. If people want to leave it the way it is, okay, but I just am concerned that we will end up explaining why one limited-scale testing vote is different than the other limited-scale testing vote, and why one limited-scale testing vote meant six practices and one meant several thousand.

CHAIR BAILET: Grace.

DR. TERRELL: It strikes me as we're having this conversation that the thing we're concerned about is that we're sending a signal to the CMMI to not prioritize this, and so many of us went on the side of priority because we think that that's incredibly important for primary care. And the others went on the side of -- but it's not quite ready yet, so let's get the kinks out.

And the real issue that we have is to make sure that the categories that we created ourselves do not give the signal that we're all afraid of that has to do with prioritization, and so what needs to be said in the report -- maybe it's in boldface on the first page in red -- is that this is -- limited-scale testing does not mean low prioritization.

CHAIR BAILET: Yeah. Right.

DR. TERRELL: And go ahead and put that in the very first sentences as it relates to what clearly was a consensus among all of us that we have a need for urgency with respect to doing something for primary care. This seems to have most of the principles around, which we agree is the general direction, and almost everybody else have said, but it's not quite ready for prime time yet.

So there was a consensus about that. The consensus -- the lack of consensus was, “How do you

actually categorize that in the categories that we invented ourselves?" It's not in the statute or anything else. So the way to get around that, I believe, is to make sure that our report uses -- up front with CMS, the world "prioritization" and this is not a signal that we say limited scale and just to make that the very first and most urgent thing we need to do, or to just get rid of the things that we made up for this, this one, and just come up with a consensus statement.

CHAIR BAILET: Okay. Thank you, Grace.

Paul and then Harold -- actually, Len and then Harold.

DR. CASALE: Yeah. No, I wouldn't change my vote, but I was going to -- my comments would be similar to what Grace just said. I mean, the beginning would be this needs to be a priority, and then to Len's comment, limited testing is what's in my mind and what I'm thinking, to signal that it's not ready, but it's a priority.

And I think we did that with the other ones where we did limited. We sort of defined why we thought limited testing should be for the one model was, well, you should try some surgical and some medical conditions or we felt that it was important that they try more than one, not just a proprietary software. So we really did define a lot of

that.

So if a few more people put their cards up, we'd actually have a re-vote, probably, but I think we sort of hit the right balance, to be honest with you, and to Grace's comments and Len's as well, I think we would send the right signal.

CHAIR BAILET: Thanks, Paul.

Len?

DR. NICHOLS: I was just going to say to Harold's point, I don't feel as constrained by limited-scale testing in the past because I think we have to define it uniquely to each case.

Think about all those conversations we've had with Amy and others at CMMI. They never thought of anything going forward that would be one site only. They always thought multiple sites for the very purpose of getting a proper evaluation out of it, and I think what we're saying here is our sense of urgency is unanimous. And our sense of urgency is strong enough that we say test for the purpose of implementing as soon as you can. I have no problem with that being in the language.

CHAIR BAILET: Harold, you may have the last word here.

MR. MILLER: Well, maybe not.

Jeff proposed another category. I thought Grace just suggested labeling it. I'm wondering why we don't today create a new category called "limited-scale testing with priority," and put this into there, if that's what everybody feels, rather than say it's the same old limited-scale testing and then, oh, by the way, please read the red words in the report, because you know what, this is going to get reported. It's going to get reported as to what the vote was, what the category of recommendation was. And if we really believe -- I'm still on the regular testing with priority, but if the people who voted limited-scale testing really agree that there's priority, which Grace was suggesting there was a consensus around, then why don't we say that that's the category that we want. It may be the -- we'll do it only today, but why don't we say that's our recommendation? That's my proposition.

CHAIR BAILET: Paul?

DR. CASALE: So I guess my reaction is I feel like I'd give the Secretary or whoever more credit that they'll actually read beyond the first, and yes, maybe some headline will be limited testing. My expectation is that he would actually at least read the first paragraph where it says high priority.

So I'm really not in favor of a new category.

CHAIR BAILET: All right. So I think before we -- no, no. Harold, we're going to hear back from Sarah, summarize the discussion. I think we have already summarized it, but just stay with the process, now putting Sarah in the hot seat. That gives us -- and then I think we can put the question on the table, but before we do that, Sarah, please.

MS. SELENICH: Sure. I'm going to summarize, and then I'm also going to just ask a few clarifying questions.

So I have that the Committee finds that there's an urgent need to preserve and improve primary care, and that this proposal is a move in the right direction and has the right elements. However, there are areas where more specifics need to be worked out, such as the PBPM amounts, risk adjustment, cost sharing, and performance measurement, including quality, cost, and utilization.

The Committee also noted concerns about the complexity, including balancing against physician burden, accountability, and potential for stinting, encounter data and coding intensity in both directions and also attribution.

The overall finding is that the Committee is recommending to prioritize the limited-scale testing of the model on a large enough scale to obtain the feedback

necessary to move this model forward.

DR. BERENSON: So that means moderate scale.

CHAIR BAILET: All right. So --

MR. MILLER: I do think --

CHAIR BAILET: Go ahead.

MR. MILLER: Did you say in there what you thought, what the scale, the limited scale was? I don't think I heard that, but maybe I missed it.

MS. SELENICH: I said that it is -- that we're prioritizing it, and that it needs to be large enough to acquire needed feedback. But if you would like me to say on the scale of CPC+, I'm happy to do that.

MR. MILLER: I think if that's what people meant, we should say something along those lines.

DR. NICHOLS: I would say -- I would suggest -- and Lord knows I'm open to suggestion here I would suggest that we say at a scale that would enable it to be implemented within five years, something like that, implemented program-wide, country-wide.

MS. SELENICH: How do folks feel?

CHAIR BAILET: Bruce, please.

MR. STEINWALD: Well, I agree with the sentiment there. I don't know about the five years, but maybe we should express it in terms of on a scale that's large

enough to obtain the information necessary to go to full implementation without delay. The sense of it is --

DR. NICHOLS: [Speaking off microphone.]

MR. STEINWALD: I like that. Is there one of the forbidden words that we can put in there?

DR. NICHOLS: I just thought time, getting a time certain out there is actually not a terrible way to convey the essence of Harold's proposal, which is this is different than what we have had before.

CHAIR BAILET: So, as I sit here and take it all in, I guess my position is this Committee functions beyond a check in the box. We have provided tremendous insight in our recommendations to the Secretary. We have structured our recommendations to include those insights and allowed the Committee to provide qualifying comments, sharpening up where we landed.

I'm concerned that checking a box for high-priority implementation, full throttle, is inconsistent at least on how we have progressed on decisions prior to this one.

I think we have injected enough of the urgency into the letter to the Secretary to prompt a response to our recommendation, which is testing, to be able to full-throttle implement this, but to do it in a way that's

prudent, but do it in a way that is effective and efficient because of the dire need to support primary care and more importantly get more of the primary care clinicians on the field in alternative payment models.

So I am not hearing re-vote. I'm hearing potentially we as a Committee could come up with another category. I'm not sure that that's necessary. I guess I have confidence in the Secretary's ability to read our proposal recommendation, with clarity. I don't think we're ambiguous about this. I think we're going to put it right on the front headline that we urge the Secretary and CMMI to strongly consider putting this on the field in a big enough way that sharpens the ability to implement it without unintended negative consequences.

So I guess I would put that motion out there that our letter with our recommendations that we've talked about is sufficient and see if the Committee will support that motion.

DR. NICHOLS: Second.

CHAIR BAILET: Discussion?

[No response.]

CHAIR BAILET: I'd like to take a vote, then. All in favor?

[Chorus of ayes.]

CHAIR BAILET: Any opposed?

[No response.]

CHAIR BAILET: Elizabeth? Stay with the doctor here.

MS. STAHLMAN: She is not on the line.

CHAIR BAILET: She's lost? We lost her? We lost her.

Well, if you're out there, Elizabeth, watching, send me a text.

But that even if we didn't count her vote, the motion carries.

MS. STAHLMAN: Sarah has a quick question.

CHAIR BAILET: Sarah?

MS. SELENICH: So just a quick question. There was discussion both by the PRT and some members of the Committee about concerns regarding ability to be evaluated as well as integration and care coordination, but the full Committee voted that those criterion were met.

I'm just wondering if you could provide additional feedback to support the overall finding.

DR. NICHOLS: I would say we agreed that it could be evaluated, but it would not -- it would be difficult, and it would be more challenging than the typical evaluation. That's the way I would put it, but we were

persuaded it was evaluable by the criterion.

MR. MILLER: Also, part of the concern about evaluability was the multiple options and to the extent that they have already indicated that those might be collapsed and that we were suggesting that that would make it easier to evaluate.

DR. TERRELL: Another aspect of that, Sarah, that I mentioned in my discussion and also some others was that part of the evaluability may be because there's already been so much testing that's happened with other programs at CMMI, so that was one of the things that I looked at with respect to why I thought so relative to what's in the actual language of this is that it's evaluable because of other data that's already out there, so that may be -- that was one reason I voted the way I did, that it was evaluable.

DR. CASALE: And I think on the integration coordination, again, I think the expectation is we would see that, but we've already mentioned the need to work out the details around that to make it better.

MR. MILLER: And I think also the discussion that we had with them and the greater clarity about the measures in terms of utilization, referral, et cetera, and what they're managing would help to address that. The more

things that one is responsible for managing, the more one is going to be worried about that, and whether it goes to total cost of care or some hybrid in the middle, that would get to that, whereas the way it was proposed was not quite as clear about that.

CHAIR BAILET: Okay. I thank you. I want to extend our gratitude to the American Academy of Family Practice for the good work here and all the work that was done to get us to this point where we could evaluate this proposal, and I know Michael and Amy had to catch a plane, but please, Shawn, convey our appreciation to them.

I appreciate everyone, the stakeholders who are on the phone, the ones here in the room, the Committee for their diligence and engagement.

We're going to adjourn until 1:15 to pick up the next proposal. Appreciate it. Thank you.

[Whereupon, at 12:34 p.m., the meeting was recessed, to reconvene at 1:15 p.m., this same day.]

AFTERNOON SESSION

[1:19 p.m.]

CHAIR BAILET: So, we are going to start in one minute.

[Pause.]

CHAIR BAILET: All right. Cue the music. I've always wanted to say that.

[Laughter.]

CHAIR BAILET: So welcome back. This is the second day of our third public hearings for the Physician-Focused Payment Model Technical Advisory Committee, PTAC. We have two proposals to review this afternoon.

I'm Jeff Bailet, the Executive Vice President of Health Care and Affordability with Blue Shield of California. The proposal in front of us is the Large Urology Group Practice Association Advanced Payment Model for Initial Therapy of Newly Diagnosed Patients with Organ-Confined Prostate Cancer.

Large Urology Group Practice Association (LUGPA): LUGPA APM for Initial Therapy of Newly Diagnosed Patients with Organ-Confined Prostate Cancer

*** Committee Member Disclosures**

CHAIR BAILET: As we begin our review, we're going to declare any conflicts of interest, so I'll start

with myself. I have no conflicts of interest, and I guess I'd start with Rhonda, if you want to go around the room and introduce each other and declare.

DR. MEDOWS: I'm Rhonda Medows. I'm Executive Vice President, Population Health, at Providence St. Joseph Health. I have no conflicts to disclose.

DR. BERENSON: I'm Bob Berenson. I'm an Institute Fellow at the Urban Institute, and I have no conflicts.

DR. PATEL: Kavita Patel from Johns Hopkins and Brookings, and I have -- I'm just reading my disclosure. I have not had any involvement with LUGPA or the LUGPA proposal. I do have -- I have a prior professional relationship with individuals I understand may have been involved in assisting drafting the proposal. However, I have had no interaction with them on this proposal.

DR. NICHOLS: I'm Len Nichols. I direct the Center for Health Policy Research and Ethics at George Mason University, and I have no conflicts.

CHAIR BAILET: Thank you. We're going to go to you, Bruce.

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

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

MR. MILLER: I'm Harold Miller, President of the Center for Healthcare Quality and Payment Reform, and I have nothing to disclose.

DR. TERRELL: I'm Grace Terrell, practicing internist at Wake Forest Baptist Health and CEO of Envision Genomics. I have nothing to disclose.

DR. FERRIS: Tim Ferris, practicing internist at Mass. General Hospital. I'm also the CEO of the Mass. General Physicians Organization. I have nothing to disclose.

CHAIR BAILET: And Elizabeth Mitchell, who is not quite yet on the phone but will be joining us, she's the Vice Chair of the Committee. She has nothing to declare, and, Harold, check me on this if I get it wrong. She -- is that Elizabeth?

[No response.]

CHAIR BAILET: Not quite. So she is the CEO of the National --

MR. MILLER: The Network for Regional Healthcare Improvement.

CHAIR BAILET: Network for Regional Health Improvement. I knew I was going to -- I got it wrong intentionally just to test you, Harold.

All right. So I'm going to turn it over to Professor Nichols, who is the lead proposal review team member, please.

*** PRT Report to the Full PTAC**

DR. NICHOLS: Thank you, Mr. Chair. So we will go through all this. I'll very briefly go over the Preliminary Review Team proposal overview, although, of course, we, like we have in the past, expect you all to have read the proposal, the PRT review, and the response from the submitters, and some of the tables and information brought to us by our contractors and ASPE. And then we'll talk about our evaluation using the Secretary's criteria and the key issues we think we all should consider.

As has been made clear before, the PRT report is a Preliminary Review Team report. It comes from, in this case, myself, Kavita Patel, and Paul Casale, who -- they both are physicians. I'm just a simple country health economist. And the idea that we need to convey is that the PRT meets among themselves, reviews the material, asks questions of the submitter, asks questions of our contractors and ASPE staff. And in this case, we sought

counsel from a specialist at Penn, and I believe we got some data from various places. And we come up with our suggested ways of judging the proposal by the criteria. Then it goes to the full PRT, and -- I mean the full PTAC committee, and we are not allowed to discuss that among ourselves as a group until this moment. So we have not had the benefit of our colleagues' counsel and, therefore, this outcome could be quite different than the one we recommended.

The model overview, essentially think about it like this, and these things I think are the most important. Obviously, it's for Medicare patients, but it's for those specifically who are diagnosed with localized prostate cancer, and localized really matters because it means that they're eligible for active surveillance, which has become or is in the process of becoming very common recommended standard of care.

The proposal has a 12-month episode idea around this active surveillance with subsequent episodes possible. There would be a $75 a month management fee or PMPM during the months of the episode, and then there would be a performance-based shared savings or shared losses payment based upon sort of how it all came out.

I would say that the -- I'm not going to go

through all of this. I'll just say it's complicated. It's complicated in lots of appropriate ways. There are many different modalities and treatment. There are obviously different degrees of severity of the illness. At the same time, there are very different treatment patterns in our country across sites of care and across regions of care, and I would characterize this proposal as one that tried to reflect that full range of variation as it constructed benchmarks as opposed to constructing benchmarks that might be more standardized. And, therefore, there's a heavy component of the individual practice historical performance as well as the practice's region performance as opposed to something that might be on a broader scale.

When we got to the criterion -- and I do think it's -- we'll go through these specifically briefly, but I do think it's fair to say that when you look at the totality of judgment here, we were often unanimous; and when not, obviously there was a majority. Most of the criteria were judged to have been met, and indeed two of the three high-priority items were met. But you will see at the end we ended up recommending something less than full approval. So let's go through these one at a time.

Scope actually is among the more important, in my view, because it highlights what I think is the fundamental

issue here. It is certainly true that patients with this low -- with this localized form of prostate cancer don't qualify for the Oncology Care Model. It is also true that urologists are not participating in APMs at the moment, so in that sense and those senses alone, scope is obviously met by certain criteria.

However, the majority of the PRT thought that, in fact, urology practices are changing their behaviors, and active surveillance is becoming a more standard care recommendation, and because of that the potential impact was much smaller than what could be imagined when you think about the variation in practice at present in the moment. And that's why the Committee voted to say it does not meet the criterion for scope.

For quality and high cost, I don't think there's any question in the minds -- this is unanimous -- the structure of the proposal would indeed incentivize more physicians to pursue active surveillance, and the model would definitely encourage greater effort toward and focus on patient education and shared decision making, all of which everybody we know is in favor of.

The concern was that the quality of -- the measure of time on active surveillance seemed to a number of us as a low bar for performance, and it's also true that

proposing the auditing actions to ensure quality would possibly be a large burden for CMS and for providers. But, nevertheless, unanimously we thought it met this criterion.

The payment methodology, like I said, it's kind of complicated in the sense that the benchmark is, I would say, almost practice-specific because the historical performance of the practice is such a high weight at the beginning; over time it does evolve. And I would say it would be difficult to construct control groups to match these sorts of benchmark activities, and in a way I think it's fair to say that this approach to constructing benchmarks led to a bar that we thought was pretty easy to hit and, therefore, would not drive a powerful incentive to improve the performance as much as we would like, and so that was the concern. Nevertheless, unanimously we voted -- or a majority voted to say it did indeed meet this criterion.

Value over volume, no question. It meets the criterion. Flexibility, absolutely. The whole point is to give folks resources to do more patient education and active surveillance. We certainly thought it could be evaluated.

Care coordination, I think the primary concern here, it is interesting how often our proposals to PTAC

fail this criterion. The main concern here was that there was not a lot, in fact, not very much at all discussion of how to coordinate care among primary care, among other practicing physicians who might be relevant. And the response we got from the viewers was -- from the applicants was, well, yes, but that's because we're focused on the change in behavior on the part of urologists and sort of everybody else just does their job, it'll be fine. And I think that's certainly a reasonable conclusion, but it's not the goal of this criterion.

Patient choice, no question. The idea would be to precisely facilitate shared decision making. We thought the protections for safety were adequate.

HIT, basically there was not much attention to using health information technology other than tracking labs, and so we didn't think that met criteria.

Now, the bottom line, I would just observe and assert that the fundamental difference of opinion here has to do with an appraisal of how quickly the standard of care is evolving, could evolve, should evolve. We basically concluded go back to that big chart. By most criteria, this proposal met them. In that sense I would say it met the letter of the law. But there's a question about the spirit of the law, and the fundamental reality is that the

standard of care is evolving. The major relevant specialty societies have recommended active surveillance for localized prostate care. And what this proposal would end up doing would be paying doctors more for doing what is the right thing. That's good. But do you have to pay them more to do the right thing as opposed to what they're doing now? That's kind of the question. And I think it's fair to say that we came down on the side of while technically this met the specific wording of the criteria of the payment model that would be suggestive of recommendation, we thought that would be the wrong signal to send because of this evolving standard of care.

We also said if it's going to go forward, we definitely think the benchmark should be set more on a regional basis and less on a historical practice basis and, therefore, be a higher bar.

So, Mr. Chairman, I can stop now and ask --

CHAIR BAILET: Thank you, Len.

Other PRT members want to make a comment at this point? Clarification? Ask questions? Yeah, Kavita.

*** Clarifying Questions from PTAC to PRT**

DR. PATEL: I'll start first. We also had just some additional points of information for the PTAC. I think what's clear, you can tell, like our struggle was how

important the topic is, kind of watchful waiting, active intervention, active surveillance, and the desire to really have the field move towards what's considered kind of best evidence and best practice. And we certainly -- buried in the transcript with our clinical expert, we tried to get at this tension of, you know, lower rates of adoption of active surveillance in the community and the need to increase that.

We did also engage in a very direct conversation with CMMI because we wanted to compare and contrast the current OCM model, which, as we understand it, has some urology practices. But we understood very clearly that the current OCM model is not appropriate and does not really offer an opportunity specifically not just for urologists but really also specifically to look at some of these issues in prostate cancer.

I would say philosophically kind of we struggled with each of these criterion, and this is a recurrent theme, where the individual criterion we felt like, okay, yes, the 20 pages met this criterion. But then we kept coming back to, I'll call it, the "Bob Berenson problem," but it's probably a larger issue of could we actually make necessary changes, you know, in an RVU or a physician fee schedule and in existing codes that would do exactly what

we want to do?

So just as some context for the rest of the PTAC, we actually asked ASPE to kind of explore boundaries and limits of whether current G Codes and other opportunities could potentially do what the submitters had asked, and if PTAC members are interested, we can get into that. So I wanted to just offer that.

And, also, another point of information that I don't think I see anywhere in our packet, Len, but we did have a conversation -- make sure I'm not crazy -- with CMMI where they did just express concern because this is such a moving field that the inclusion of a total cost of care metric might actually do the submitters more harm than good because the trend factor put forward would actually be decreased in terms of utilization costs. So I think there was some -- am I remembering that correctly? The idea was that as more people are in active surveillance, their benchmark kind of -- obviously, the trend would fall over time, and so the inclusion of the total cost of care metric might not be the best one. So I'm just trying to --

DR. NICHOLS: I believe it was raised. I think you might have been more worried about it than I was, but yes.

DR. PATEL: That's probably -- yes, that's

generally the case. Many things. I worry about everything. I'll stop there.

DR. CASALE: I don't have much more to add. I agree with what has already been said, and we did struggle with the proposal sort of technically meeting many of the criteria, but on the sort of bigger picture issue -- and I think we did have a lot of discussion around -- because a lot of this is around -- there's a significant focus on the care management piece, and so, you know, can they -- can there be changes? You know, if it doesn't quite fit the chronic care management, specifically, you know, can that be tweaked in a way -- which would be much simpler than what's been proposed.

CHAIR BAILET: So I have a question for you guys. Under “Scope,” the first criterion, the recommendation was it didn't meet. And then when I looked at the context of some of the weaknesses that were included, it helped sharpen that decision, 6,000 urologists -- and I did a little research, maybe Google. I googled the number of practicing urologists, and I got a number slightly over 12,000 in the country. Maybe I have that wrong, or maybe I looked at the wrong website, but 6,000, you know, that's roughly, back of a napkin, about 50 percent of the practicing urologists. So I said, well, you know, that's a

pretty -- if we're looking at trying to get specialty alternative payment models on the field, that's a pretty good cohort, pretty good slice. And then I looked at, okay, for this cohort of disease, how many patients have this, you know, newly diagnosed limited cancer to the prostate gland, and I think the number's a little over 60,000. And I'm thinking, okay, these guys are putting 20,000 potential members in the mix here. And these are statistics that were included in your PRT, so I'm just trying to understand and clarify. And that's a third, I guess, of the eligible people with this disease state actually would be in this model.

So I was just struck by that, and I guess I'd like your perspective.

DR. NICHOLS: I appreciate that, Mr. Chairman. You're very observant. I would also point out this vote was split. A majority did not think it met, but some member did. So there was a difference of opinion. I would submit it's a difference in judgment about the direction of this diagnosis becoming standard of care. So the potential patients that could be improved by this proposal, I believe some members thought, would go down over time because they would be put under active surveillance anyway.

CHAIR BAILET: Without the need for the model.

DR. NICHOLS: So while the numbers are not in dispute -- and totally I agree with the general inference that it would be logical to say this met the scope criterion as we've typically applied it, but a majority of our PRT thought that other factor was important.

CHAIR BAILET: Okay. Thank you.

DR. CASALE: Yeah, I guess I would just highlight again, you know, the second concern we had about, you know, can they use care management fees that are already in place, so does it really need to be broadened? And then I know we focus on Oncology Care Model as the APM that you're -- but, you know, there are ACOs as well. I mean, I'm sure there's quite a few urologists that are in an ACO. And couldn't you -- the goals of the ACO are to, you know, improve quality, lower costs. And if your urologists are a part of that, couldn't they be doing this work? Which, again, is, by their guidelines and standards, the way to go, do that activity within that APM.

CHAIR BAILET: Thanks, Paul. Harold and then Grace.

MR. MILLER: Grace.

CHAIR BAILET: Oh, Grace. Sorry.

DR. TERRELL: I've got a bunch of questions. So, first of all, with respect to what is being called active

surveillance in this, you're talking about organ-confined with a low Gleason score or acceptable Gleason score prostate cancer. And the active surveillance would be a digital rectal exam and a prostate-specific antigen on a regular basis per whatever guidelines are out there. Correct?

DR. PATEL: Yes, that's correct.

DR. TERRELL: Okay.

DR. PATEL: And we addressed that with our clinical expert who said that it in his practice would probably be done every six months.

DR. TERRELL: Right, and --

DR. CASALE: And then repeat biopsy depending on the results of --

DR. PATEL: Correct.

DR. TERRELL: Okay. So that was the issue was -- was respect to the biopsy, which is where I wanted to go with this. So if you're looking at what it requires for a blood test and a digital rectal exam, it requires a glove and a finger, but biopsy requires a certain amount of proceduralist skills that typically is confined to the urology specialty. So was there conversation -- you said that they didn't talk a lot about other types of providers, but was there conversation about the aspects of this care

that are often not provided by urologists? Or is there evidence out there that in the non-urology people that are specialists or primary care that are providing this service that active surveillance is not occurring at all? Was any of that evaluated?

DR. PATEL: I mean, I'm not sure -- I'll just say that my recollection is that we did talk about the fact that even amongst -- you know, if non-urologists did this, that there's variation in kind of PSA lab values. They did talk about the need to have kind of infrastructure and kind of robust training that is largely done in a urologist's practice.

DR. TERRELL: Okay, so that would be -- in certain areas of the country, there may be a shortage of urologists, and there may be others that are performing part of this or not. But it might be important to the question or concern that you all raised about primary care and other aspects. We can ask them about that.

Secondly, there's a fair amount of new types of potential that will go into what will allow some more granularity with respect to active surveillance, such as Oncotype DX, which is a particular genomic marker out there now that's providing prognosis difference. It may or may not be standard of care right now, but in terms of your

concerns about the cost of care relative to this or others, was there any discussion about not just this changing standard of care but the changing technology that may or may not become part of this?

DR. CASALE: I don't -- I don't think we -- we were really more focused on, you know, this model and --

DR. TERRELL: Just what it is right now.

DR. CASALE: Yeah, rather than sort of -- I don't recall that we asked about that.

DR. TERRELL: Right. Did you get anything from our SSS (or whatever with respect to the cost of the alternatives right now overall in the U.S. versus particularly as it relates to frequency of re-biopsy versus radical prostatectomy? Do we have those numbers in terms of so we could understand the scope of that?

DR. NICHOLS: I think both the applicant and SSS gave us total spend for people with different diagnoses for a year. So, Grace, it would all be wrapped up into that, and the distance is quite large between active surveillance and active intervention. But I don't think we did this biopsy-related --

DR. TERRELL: Was there any evaluation or was data provided on the cost of -- you mentioned a registry. You mentioned education. You mentioned -- well, we just

talked about re-biopsy when that was appropriate. You mentioned, you know, there's an exam and a blood test. Was anything done to actually -- what I'm getting at with this is there's certain types of distinct services that could be costed out, but what we're ask -- what's being asked for here is a monthly payment. But my experience is some of these services are only provided once every six months or once every year, depending on the particular practice and all that. So I'm trying to understand the cost, the $75 per month, relative to the overall cost of the services that are provided. It sort of gets to the Bob Berenson concepts related to current fee schedules. In other words, if they just get a single E&M code once every six months and it's not covering these other services, but it's once every six months, as opposed to the concept that they need something every month, was any of that looked at from a quantitative point of view?

DR. CASALE: I think it was more qualitative, Grace, to be honest with you. I think they had -- there's a list in there what they felt the cost relate to, whether hiring, you know, the coordinator to call people and make sure they get their biopsy. And then part of it also, when we talked about the care coordination, there was this discussion, well, maybe some of that care coordination fee

could go to other members of the team.

DR. TERRELL: Okay.

DR. CASALE: Although that was vague and not well prescribed.

DR. NICHOLS: I think it's fair to say that the 75 was an average over what they thought the combination of services would -- and as you say, different services are going to be tailored to different patients, and they fully expect that, and 75 is just a reasonable number they came up with.

DR. TERRELL: So it was sort of a monthly fee for the --

DR. NICHOLS: It's PMPM to cover --

DR. TERRELL: -- bundle of the services, okay. But there wasn't any particular deep dive into the actual cost of that relative to what that number is.

DR. NICHOLS: Other than their experience in providing these services now.

DR. TERRELL: Their experience. And, finally, my experience as an internist is when people hear the word "cancer," quite often, irrespective of whether this is the most rational choice, an active surveillance for somebody with low-grade early prostate cancer or not, they want to see a urologist, irrespective of what me, as a primary care

physician, sees. And their choice is often at the patient level related to their feelings about the diagnosis of cancer. So I get the education that needs to occur with respect to this because there's a significant amount of patient choice that goes into it related to whatever somebody's personal thoughts are about the various side effects of prostatectomy versus the fear of living with a low-grade cancer. Was there any discussion either in this proposal or with the team with respect to how patient choice ought to be thought about with respect to incentives to do this to the urologist if a patient particularly doesn't want this as it might relate to -- you know, patients don't always choose what's the cheapest or most -- you know, most rational from an economical point of view because they have personal opinions about what they want. Was any of that part of the discussion?

DR. NICHOLS: So what I remember -- and certainly I would ask Kavita and Paul to chime in -- precisely because of the way the average human being responds when they hear the word "cancer," that's kind of why they want to do this, because they would like the resources to enable them to sort of reach and get around them and have this patient education discussion so people don't panic and insist on intervention. So, yes, Grace, I think that's one

of the motivations of the whole thing.

DR. TERRELL: Thank you.

DR. SHARTZER: Grace, to follow -- sorry. I just wanted to clarify. To follow up on one of your questions about how they kind of came up with the care management fee, on the last page of the additional information from the submitter, there's a table where they costed out what they thought, and they came up with about $900 annually, which they then divided into 12. So it includes tracking the beneficiaries to ensure compliance, tracking lab results, education, care coordination, reviewing the care plan. That's in this table right here.

DR. PATEL: I was just going to add that they specifically called out incorporating shared decision making to get to your point about being able to approach individuals, and something they pointed out, which we vehemently agree with, is that doing that takes a lot of time. So -- so just getting back to your question about financial incentives and costs, there's actually quite a bit of data around kind of costs that they've submitted that LUGPA did around, you know, kind of comparing costs. But just the point was made that it is actually far easier to do -- you know, kind of AI is just easier for a lot of reasons, including the fact that it doesn't take as much

time to sit down and talk to someone about active surveillance and have like shared decision making and all that kind of back-and-forth conversation. So I think that's just to keep -- to get back to Jeff's point where we struggled the most was like is this something that needs like a new payment model or is it something that we need to fundamentally fix because --

DR. TERRELL: [off microphone].

DR. PATEL: Correct.

CHAIR BAILET: Harold.

MR. MILLER: I have some questions about the payment model and somewhat similar to what Grace is asking, and I'll defer to the applicant. I guess I just wanted to probe a bit on the issue, what you did on the first criterion, which the way -- it's more nuanced in the report, but the way you described it, Len, was because this is a standard of care, we shouldn't pay for it; it should just be done. And it seems to me that that gets into this -- what aggravates me is this constant mixing up of the words "incentives" versus "payment to fill gaps." And if one argued that -- that this is the standard of care and somehow docs are just unwilling to do it, you know, and they want to be paid as an incentive to do it, you know, I think that's legitimate. But, on the other hand, if

there's a payment gap, then you'd say, I mean, that's why we're doing payment reform overall, is because there's lots of things that people think need to be done but can't be done because -- and so it sounded to me like when I was reading this -- this is sort of just to clarify what you said in the presentation -- reading this that you thought that there was a gap of some kind. You weren't exactly sure what the magnitude of the gap was and whether the gap could be filled adequately with existing payment codes. It didn't sound to me like you addressed whether there were any disincentives. In other words, if the urology practice -- and I want to ask them that question -- is delivering some of these active intervention services and they choose to not deliver them, they will lose revenue that could be potentially problematic, and that would not necessarily be addressed simply by paying a care management fee to cover the costs of the active surveillance, because there's kind of two pieces to this. One is, “Am I not getting paid adequately to do what's involved in good active surveillance, shared decision making, monitoring?” And then, “Am I taking a revenue hit because my practice has been based on getting paid for all these other things, now I'm going to lose it?” And it didn't sound to me like you had addressed the second one at all.

DR. NICHOLS: We probably didn't address it at the level of nuance which your good question raises. What I would say, Harold, is I think I wrote somewhere, you know, hard cases make bad law. This is a hard case. And it's a hard case for precisely the two dimensions you just laid out. I think we all -- certainly the PRT would be unanimous in agreeing that some kind of incentive realignment is called for here because you don't want people to have to suffer for doing something that shouldn't be done, right? You want them to actually adopt the appropriate standard of care that everybody thinks is the right way to go for this particular class of patient. And so, therefore, I think we would totally support -- that's why we researched “How could you do this with a code change?” But I think at the end of the day, Harold, we just felt like there's enough either alternative ways to solve that problem, which is the same thing at the end of the day as making it not costly to do the right thing. You're still going to sacrifice revenue that you could get for doing, if you will, the wrong thing. But at least it's less of a sacrifice than it is now, and that's why I think we would totally support getting the code change. And I don't think we're going to throw our body across the train if you all vote to do it. We just think the benchmark

ought to be set in a way that is more demanding. That's the way I would describe them.

CHAIR BAILET: Bob?

DR. BERENSON: Yeah, the Qs and As I thought were very interesting, and they were quite responsive. I want to pursue one of them and see if the PRT had a reaction to this one. The question was, “Participants in the model are responsible for total cost of care. Describe how urologists would manage the spending.” And the response was, as I had thought was the case by looking at the average episode cost, that for active surveillance, the work related to the management of the prostate cancer was only 10 percent of the total. And the response was that we anticipate that the managing urologist will be able to influence non-urology-related spending by coordinating with primary care physicians and other specialists, which is part of the purpose of the monthly care management fee. We heard this yesterday by the renal physicians, that they were going to be talking to oncologists about end-of-life care and withholding dialysis. Here -- as a primary -- as a former primary care physician, I am highly skeptical that my management of patients with diabetes and congestive heart failure and aches and pains is going to be helped by the urologist who should be doing an expert job as the

principal physician for managing their urologic problems. Did you pursue with them the reality of this? Did you believe it?

DR. CASALE: Yeah, I think that was -- well, we pursued it because we asked that question there and in follow-up discussion, and, yeah, I think that answer's totally inadequate. I think that the expectation that a urologist is going to influence, you know, all of the -- again, we're talking about Medicare patients with multiple comorbidities who have prostate cancer.

DR. BERENSON: So I guess where I would go -- I mean, that's my sort of sense, so I think we are still talking about whether there should be an episode-based payment, but a total cost of care component of it I just think is problematic. And go ahead, Kavita.

DR. PATEL: I mean, this is the only chance we have to kind of talk about it other than our PRT calls. If I had had my druthers, I wish they would have kind of come with a very different version that brought -- they did a nice job kind of delineating like everything from, you know, XRT, drugs, et cetera. There's so many factors that go into that kind of potentially avoidable spending or inappropriate spending, and we kind of -- I felt like -- and this was just me talking now. We did not discuss this

at the PRT level. I felt like there was this desire to kind of take -- like we've seen in other submitters' proposals, take pieces of what CMMI has already done and kind of use that as a basis when I think that's building on a flawed -- for this particular example, might not be the best example because the current oncology model uses a chemo trigger, et cetera. It would have been much more interesting to kind of have this group of very diverse entrepreneurial people kind of think about how can we look at prostate cancer as a whole, how can we think about appropriate -- to Harold's point, kind of appropriate buckets and not necessarily kind of mix in some of these other elements around non-kind of urological care because, as you mentioned, I think it's extremely hard to do that unless you're doing really aggressive ongoing management outside of your specialty. So I think that that's where -- when we were probing, in some ways we were trying -- I know myself, I was trying to think how could we help them think about a way to revise this proposal to come back so that it would be a little bit strong?

Now, unfortunately, the way our PTAC is set up, we can't really do that, so we were trying to do a lot of these questions back and forth, Bob.

DR. NICHOLS: I think it's fair to say, Bob, that

the original proposal did not devote much time and attention to coordinating care for non-urologists. And I think that was because their basic a priori model is everybody else should just do their job, and we're going to manage the urology piece of this. And because there's so much savings to be had by switching people from what would have been, you know, active intervention trajectory versus active surveillance, that'll take care of the total cost of care issue all by itself, regardless of what the primary care guys do, and that's when --

DR. BERENSON: I actually think that could happen.

DR. NICHOLS: I do, too, and that's why --

DR. BERENSON: That's my --

DR. NICHOLS: That's where they came from.

DR. BERENSON: Yeah, all right. So, well, I'll ask them, but I wanted to ask you also, they have sort of five bullets that describes what the fee would be used for, which seems to be very specific to the prostate. Did you go through each one and try to define that there's real work involved with those five bullets? Because I'm skeptical.

DR. PATEL: I know -- just you can read our transcript with our clinical person and then we kind of did

our own research based on tables and things that the submitter had provided. I don't recall us getting into kind of the line-by-line discussion.

DR. CASALE: I don't remember doing a line-by-line, but we did -- with our expert from Penn, we did probe that with them as well.

DR. BERENSON: Okay.

DR. PATEL: And we tried to probe, just in fairness, because I think one of the things you'll hear, which is appropriate, is that, you know, in an integrated academic setting, things are very different. So we tried hard to also understand kind of what really is reflected both with the submitter and with the clinical expert and then just, you know, Paul, Len, and I, you know, doing like searches very wisely, trying to understand what standard of care is, to Grace's point about how frequently digital rectal exam, you know, prostate test, you know, all the things that would be a component --

DR. BERENSON: So, I mean, I guess what I'm -- what I want to probe a little bit more is -- I mean, my instinct is that existing fees could probably cover the surveillance, and that a lot of what is in these bullets are not covered under established fees. So I want to know how real they are, is what I -- and I will -- and I'll

pursue that a little bit. Okay.

CHAIR BAILET: Bruce.

MR. STEINWALD: Yeah, on that same point, I was going to seek a clarification on your statement that existing chronic care management fees or CPT codes could be utilized to achieve the objective of the proposal. Yesterday we had a proposal that wanted a payment change that we determined could be accomplished through an existing rulemaking process. And so my question here is: Is your sense that the objectives of the proposal could be accomplished with existing codes and care management fees without seeking any changes in those codes or fees or could be with existing?

DR. PATEL: So we did get -- we did get clarity that -- I think Paul mentioned that even in the existing like CCM structure, you couldn't use parts of that -- you could not give part of that money to like another provider. It would trigger Stark kind of issues to give money to somebody else or to pay people as part of that. But I think you're bringing up a point that we would say especially given the prevalence of other comorbidities with the majority of these patients, that could we not even use the existing codes. So that's, I think, the question.

DR. CASALE: You could argue -- I think the

submitters argued that early on after the diagnosis a lot of their care is urologic, and so they could bill for the time when -- if the preponderance is urologic. The problem becomes when you're trying to potentially give some of that fee to primary care. It becomes much more complicated.

CHAIR BAILET: So I had my card up and down, and I'm just -- I think the reason I -- I'm probably going to answer my own question, but the way I see this, this is -- the word is "active" surveillance. It's not surveillance. And it counterbalances active intervention, and you're talking about talking to patients, beneficiaries, with a diagnosis of cancer, where historically the backbone has been active intervention. And in my former surgical practice, to talk to patients who are coming out of that frame, we're not -- we're not ten years out where we've had really clear demonstration that active surveillance is -- I mean, we're not even debating it. It works. Everybody's on board. This is sort of at that transition, right? Going from active intervention to active surveillance for this particular cohort of patients with this disease.

So my sense is that this is a -- This is a fairly big lift to work with your patients to get them comfortable with riding on the surveillance, knowing that they have cancer, and the backdrop of what historically has been

active intervention. And what I'm not hearing is that while they want to be -- while the physicians want to be recognized for that effort, as they catalogue the activities that have to be required for that active surveillance, that shared decision making, that sort of calming, if you will, come on, come with me, you know, we don't need to operate on this, or we don't need to provide adjuvant therapy, that did not -- how far up the scale of work lift was that? Because it wasn't -- it's not clear to me. Was that like the primary -- primarily amount of focus that this payment was supposed to cover, the time with the patient, kind of walking them through, or was it not, Paul?

DR. CASALE: I was just going to comment on, you know -- you know, I think this has been moving for a while, and we saw this dichotomy that in academic -- you talk to academic medical centers, their percentage on active surveillance is significantly higher than the patients in the community. And why is that? You know, there could be a lot of reasons. One may be certainly related to the way their finances are set up. At least that's what we heard from our expert, you know, whether the patient -- you know, and even in their proposal, they talk about changed practice patterns, you know, you have to take in account practices with integrated ancillary services.

You know, so, anyway, to get to your question part of it is -- I'm not sure we're at the beginning of this movement to -- you know, I think we're well into this, that active surveillance is sort of the standard of care. And the recognition that the care -- there is some care management that needs to go on in order to educate the patients and bring them forward. You know, I think that makes sense.

MR. MILLER: One of my questions, Jeff, which I'm going to ask them, I think is what you're saying, is when I looked at the list of what they said they were paying for, the shared decision making time wasn't there, and --

CHAIR BAILET: Exactly, yeah.

MR. MILLER: And it seemed to me that that's sort of critical to all this, is being --

CHAIR BAILET: Right.

MR. MILLER: And so I maybe don't need to pay for that. But I was kind of surprised. It didn't seem to be -- there seemed to be a disconnect -- and I'll ask them that question -- between what they were asking to be paid and how with what needed to be done.

CHAIR BAILET: Right, and, Harold, you said that a lot more eloquently than I did. That's that -- it's not balanced, and I just can't sort it out, but we --

DR. NICHOLS: So maybe we can ask them up.

*** Submitter's Statement, Questions and Answers, and Discussion with PTAC**

CHAIR BAILET: I think it's perfect timing to bring the submitters up to the table, please. And all of the submitters are here in public. No one is on the phone. So we want to thank everyone for coming today.

As you take your seats, introducing yourselves, and then you have ten minutes to address the Committee, and then we'll open it up for questions. So thank you very much.

DR. KAPOOR: Do we do introductions first and then start our ten minutes?

CHAIR BAILET: Absolutely. Please.

DR. LATINO: My name's Kathleen Latino. I am a urologist who's also a medical director of a large urology group practice.

CHAIR BAILET: Welcome.

DR. SHORE: Yes, good afternoon. I'm Neal Shore. I'm a urologist in South Carolina. I'm the President of the Large Urology Group Practice Association, LUGPA.

CHAIR BAILET: Great. Thank you.

DR. KAPOOR: I am Deepak Kapoor. I am Chairman and CEO of Integrated Medical Professionals, which we have

the distinction at the moment of being the largest urology practice in the United States. I'm also Chairman of Health Policy for LUGPA.

CHAIR BAILET: Thank you.

MR. MULDOON: Hi, I'm Dan Muldoon. I'm a health care consultant with Milliman, and we provided some financial analysis for this proposal.

CHAIR BAILET: Welcome.

MS. PELIZZARI: I'm Pamela Pelizzari. I'm also a health care consultant with Milliman, not with the Large Urology Group Practice Association, and we provided financial and actuarial support for this proposal.

CHAIR BAILET: Great. Thank you.

DR. SHORE: Well, thank you very much, all of you. As I said, I'm Neal Shore, the president of LUGPA, and on behalf of our organization, the thousands of urologists nationwide, as was said, who support the proposal and most importantly the men annually diagnosed with prostate cancer, which represents the highest yearly incidence of newly diagnosed cancer in the United States, I thank you for the opportunity to speak on behalf of the LUGPA APM for initial therapy of newly diagnosed patients with organ-confined prostate cancer.

I am appreciative of the PRT's analysis of our

proposal, yet disagree with their recommendation to the Committee. The PRT recommendation underlies a misinterpretation of the financial potential of the proposal as well as current trends in active surveillance utilization. Today we look forward to presenting a summary of our written response to the PRT review and of the LUGPA APM proposal overall.

We greatly appreciate the demonstrated support of the American Urologic Association and the American Association of Clinical Urologists. Their commitment to this project is testament to the nationwide applicability of this proposal to urologists in all practice settings, both academic and community. We look forward to the AUA's public commentary later this afternoon. We also thank Drs. David Pence and Matthew Cooperberg for their written comments. The detailed analysis from these international authorities on active surveillance for prostate cancer provides expert perspectives supporting the relevance and value of this proposal. We are especially appreciative to the leadership from the Prostate Health Education Network, the Prostate Conditions Education Council, and ZERO-The End of Prostate Cancer for their public comments today. The views of these three leading prostate cancer patient advocacy groups provides critical insight into the

beneficial impact of this proposal on patients and their families while reducing racial, ethnic, and socioeconomic disparities in prostate cancer care.

Our organization embraces the notion of value-based care, clinical best practices, and shared decision making. We identified utilization of active surveillance of prostate cancer as an evolving clinical paradigm whose adoption would be facilitated by aligning provider incentives with clinical best practices. It is for this reason we are committed to implementation of this proposal. I believe that the information previously provided during the PTAC process as well as to be presented today will provide ample justification for the Committee to recommend to the Secretary that this proposal be approved with high priority.

Dr. Kapoor, LUGPA Chairman of Health Policy, will continue with the balance of our statement, and, again, thank you very much for all of your time and effort.

DR. KAPOOR: Thank you, Dr. Shore.

As Chairman of Health Policy for LUGPA, it's been my privilege to have been involved in this project since its inception, and I thank you for the opportunity to discuss its details.

I would like to start by addressing the number of

providers, patients, and costs impacted by this proposal. The PRT report suggests that 19,000 patients would be affected with program savings of $28 million. However, this represents a very limited subset of patients with the initial adoption of the APM. The full potential upside of the proposal is really much greater.

There are 63,000 Medicare beneficiaries newly diagnosed with prostate cancer each year. Best available clinical evidence suggests that 43 percent of these patients might be candidates for active surveillance, yet at present, only 23 percent of those patients are actually on surveillance protocols. At scale, moving this halfway to 33 percent would represent 6,300 lives, and although we understand that 100 percent adoption for a variety of reasons is not possible, would that utopian ideal be created, that would be over 12,500 patients.

At a cost differential of more than $20,000 per patient, the adoption, the maximum upside of this proposal is $252 million annually, nine times greater than the $28 million reported.

Furthermore, the 6,000 patients likely to participate in APM is the sum total of all urologists that perform prostate biopsies in the United States over the three-year analysis period. By comparison, yesterday the

Committee recommended approval of the RPA end-stage renal disease proposal. That proposal included 78 million in program savings with 30 percent adoption by 7,000 nephrologists. Applying the same parameters to the LUGPA proposal would result in virtually identical savings for 6,000 urology practitioners.

This proposal provides an opportunity for the majority of the Nation's urologists who are presently excluded from active -- from participation in alternative payment models to participate in value-based care while simultaneously reducing program costs.

We believe the program will encourage care coordination. During our discussion with the PRT, we stated our anticipation that care teams would evolve to implement the APM. These teams could involve a variety of specialists. We deliberately did not prescribe how the per member per month fee was to be distributed amongst the care team because of the multiple models of care that exist nationally. We anticipate that these models may vary based on geography, practice size, patient demographics, as well as hospital affiliation. Different care teams could even form within the same geography as dictated by local circumstances. We purposely have allowed for flexibility in care team development to accelerate widespread adoption

of the APM.

We believe that the use of CCM Codes to facilitate surveillance is not feasible for two reasons. First, as illustrated in the budget that is supplied in the proposal, the CCM fee will not cover the specific costs necessary to ensure compliance with surveillance protocols. The environmental scan and literature review reported that there is a high degree of patient anxiety and fatigue associated with surveillance protocols. This can result in transfer from surveillance to active surveil -- active intervention for non-clinical -- for non-clinical reasons.

I'm sorry. I lost my spot there. I think I'm missing a page -- for non-clinical reasons.

Secondly, for -- in addition, the data indicates there's a high degree of variability in both compliance with follow-up and adherence to protocols. These issues are more pronounced in African American men and in economically disadvantaged communities.

Second, for the majority of clinicians nationally, using the CCM for this purpose is not possible. Sharing revenue outside of an approved APM construct could constitute illegal fee splitting under state and federal statutes. Implementation and compliance surveillance protocols requires the dedicated resources provided for in

this -- in this APM.

We disagree with the PRT's suggestion that, if adopted, this proposal should not include historical practice benchmarks. There is broad regional variation in surveillance rate, and this is likely multifactorial in nature.

Selecting national high-performing practices as a benchmark is not prudent nor valid. Furthermore, this approach is counter to the design of existing APMs such as CJR (and OCM. The LUGPA APM accounts for these variations by benchmarking performance on a practice's historical performance plus an increasingly weighted regional benchmark. Not only is this approach more clinically and practically relevant, it also ensures that practices would be incentivized to continue to improve their performance over time.

Neal, can I have the last page? I'm sorry. Are we missing a page?

We believe that characterizing urologists who are not optimizing use of surveillance as over-utilizing active intervention is inappropriate as it underestimates the complexities of shifting patients from active interventions from cancer to a program of surveillance. The -- we're missing a page. I apologize.

CHAIR BAILET: It's all right. We've been there. Take your time. It's important.

DR. KAPOOR: John, do we have the last page?

DR. PATEL: And if not, just speak from the heart.

DR. KAPOOR: Well, I had this wonderful quote by Secretary Burwell, but we'll -- I'm going to have to wing it then. So as I said, the excellent article by Loeb cited in the literature quantifies and identifies eight different factors that may impede the performance of active surveillance. These factors are greatly amplified in -- in certain minority populations and in underserved -- in underserved communities.

As a consequence, migrating patients from a program of active intervention to a program of active surveillance is fundamentally counterintuitive to the patient. We need to be able to provide resources for the clinicians to be able to do this.

Furthermore, it's a mischaracterization to state that we're trying to just simply reform the behavior of a specialty. It is not one specialty that is involved in the management of prostate cancer. There are medical oncologists involved, there are radiation oncologists involved, and there is massive institutional spending on

prostate cancer. We can cite hospitals in the New York metropolitan area whose operating budget is almost entirely supported by their prostate cancer program. So what we're -- what we're looking at is a fundamental paradigm shift in the thought process by which -- by which we're approaching cancer, and this paradigm shift is not only for providers, but it's for the patients as well. And with the amount of headwind that we face in implementing these -- in these proposals, it's extraordinarily unlikely that without proactive intervention that we're going to be able to move the needle to the degree that we want to.

The simple fact is that if you look at the national data as reported by Dr. Cooperberg, who is one of the leading authorities -- and it's in the material you have -- approximately one-third of patients with low-risk cancer are presently being enrolled in surveillance protocols in the United States today. That's disgraceful. When you compare it to a country like Sweden where 80 percent of appropriate candidates are being enrolled in surveillance, we simply are lagging hugely far behind.

As far as the notion that physicians should not be paid for doing guideline-based care, if this was something that we had been doing for the last 30 years and it was established -- and one of the PRT commentators

likened it to the use of a vaccine, and I have to respectfully disagree. This is far different than utilizing a vaccine. This is an evolving clinical paradigm, and right now we don't know precisely who should be surveilled, how they should be surveilled, or when or why we should stop surveilling them, and what we should do with them. We don't precisely know what the risks are for those patients and what their probability is of losing their window of opportunity for cure. And one of the biggest reasons why we don't know this is that there's no way to tell who's being surveilled. There's no proactive diagnosis code for active surveillance. It's always a diagnosis -- determination of exclusion.

So what we're proposing to do is for the first time create a mechanism by which we are collecting data that will allow us to more accurately ascertain the status of surveillance, include patients in the decision-making process, reduce the disparity that exists in surveillance in different ethnic and socioeconomic communities, while simultaneously engaging thousands of physicians presently excluded from value-based care in the process, and reducing hundreds of millions of dollars of program costs.

We believe that this strongly aligns with not only the letter but the spirit of MACRA, and we ask that

the Committee recommend this proposal for implementation with a high priority.

I apologize for the confusion with the paperwork. I did the best I could. And the team will be happy to address any questions that you may have.

CHAIR BAILET: Thank you very much.

Harold and then Rhonda.

MR. MILLER: Thanks. I think your goal in terms of trying to address this area is very commendable and very desirable. I think at least the questions I have are about the payment model, so let me break them into a couple categories.

The first question is sort of just overall, when you looked at trying to create a payment model for this, did you look at multiple options and then narrow it down to this being the best? Or did you start with this because this looks like what CMMI has done in other things?

DR. KAPOOR: It was a combination of both. You know, as Dr. Shore alluded to -- and he can speak to it further -- we were looking to identify a mechanism. Right now, according to CMS data, only 88 urologists -- 88 in the entire United States, and there are 12,000 urologists in the country, but a number of those are non-practicing, and many of them don't address Medicare. If you look

specifically in the Medicare data, about 9,000 urologists have actually billed Medicare over the previous -- the three years from 2012 to 2015. So that's the body that we're talking about. Only 88 of those physicians are eligible for alternative payment models.

MR. MILLER: Well, I understand that. My question was: “Did you look at multiple models and conclude this was the best? Or is there a different model that you thought would be better but rejected because you thought it was less likely to get approved?”

DR. KAPOOR: Well, I think that -- what we were looking for is to identify what was -- what Medicare seemed to be asking of providers, and that was to engage in a two-sided risk -- in a two-sided risk model. And once we were identifying that there was a two-sided risk model, we said we were committed to saying, okay, we have to have bidirectional risk in order to make this meaningful to the system. And once we started with that premise, then we said, how do we go ahead, where is the opportunity for upside savings for the practitioner versus where do we have the downside target? So --

MR. MILLER: If CMS hadn't been sending those signals, is this the kind of model that you would have picked?

DR. KAPOOR: Well, since -- if CMS hadn't been sending these signals, we probably still would be doing fee-for-service medicine. I don't know that I would have thought of it at all.

MR. MILLER: So let me ask you two questions about then what you've done. So it seems to me that there's two pieces to this. One is there is the care management fee, which is -- to Jeff's and my earlier exchange, it sounds to me like there is a gap in what's being paid for. As you said, nobody's tracking this, there's nothing specifically to support that particular process. It sounded to me like what needs to be done is there's a shared decision making process, which takes time to be able to do well, particularly given all the patient concerns about this. This is not something you sort of whip off in a 15-minute visit whenever you're doing something. You want to spend time with the patient, education materials, et cetera. And then if, in fact, they agree to go into active surveillance, there is a process of making sure that it's active. This is not watchful waiting. It's active, and I have some questions about that.

But when I read the model, it didn't seem to match that. It was $75 a month, which had nothing front-

loaded to represent what seemed to be a big of upfront time, and then as Grace mentioned earlier, there's not something to be done every month of any great significance. And it seemed to me that if you end up -- if the total adds up to the right amount, you almost inherently need to keep the patient in sort of just to be able to recoup those costs as opposed to saying let me pay you for what you're doing.

And then part two of that question, I guess, is I didn't see any sense of a standard of care associated with that that says if I'm going to get that $75 a month, I actually went through this process, I actually am making sure that they're getting the biopsies and everything. It's just kind of like I'm going to get paid that, you know, for -- because you said they were in active surveillance.

So I guess tell me about those two things. Does this $75 per month really in your sense match the way you will incur costs? Or is there a reason why it doesn't? And what's the standard, performance standard simply for getting that?

DR. KAPOOR: I appreciate the question, and it's important to understand when you talk about the concept of front-loading the cost, the costs for managing surveillance

are actually -- it's counterintuitive. It's not front-loaded. It's back-loaded. And the reason for that is that if you take a look at the data, it's very clear that at the point of initial decision, those patients that choose surveillance at the point of diagnosis have a relatively lower level of anxiety than those patients that have surveillance. And when you think about it, that makes sense. If you're less anxious about your disease, you're more likely to say, "I'm going to live with a cancer in my body." And those patients that choose intervention tend to be much, much more anxious.

So when you have the initial conversation, you can do that in the context of an hour-long conversation, then some follow-up visits. But if you look at the data subsequently, those curves actually diverge. Those patients that opt for surveillance have progressively greater levels of anxiety about their disease as time progresses; whereas, those patients whose PSAs go down to zero after radical prostatectomy or the nadir level after radiation, they have progressively less anxiety about the disease.

So with respect to what you're saying, I understand that when you say shared decision-making, that must be the biggest cost. It is the biggest cost, and

that's why if you look at the budget that we propose, the ongoing counseling of the patients plus the revision of the care plan to that patient, as well as the first criteria that we have, actually constitutes more than 50 percent of the annual -- the range, the average was $919, but actually constitutes more than 50 percent of that cost. So we did actually give that a great deal of thought, and we feel -- when you look at what happens with surveillance, even those patients that are appropriately put on surveillance initially, the compliance with surveillance protocols is very, very poor. And a lot of that is because nobody really knows what the right protocol is to start with. And we felt that monitoring the time on active surveillance was actually a very valid approach because -- and each one of the aspects of the proposal really cannot be taken in a vacuum, right? Because in the beginning, we're collecting all the histopathological data, because one of the concerns -- and we had -- we literally had calls every week for nearly two years about -- this proposal was a long time in the making. We were very concerned about the possibility for practitioners to game the system. How do you go ahead and prevent people from inappropriately taking patients that should be on AI and putting them into AS? And that's why we want to make sure that we collected the

histopathological data, so you'd be able to analyze each case of an individual practice, and then you'd be able to assess those practices longitudinally in terms of if you've got a very low risk patient and you are unable -- your data metric is that you're keeping, let's say, at 24 months 75 percent of those patients on, and your peer group is keeping 62 percent of those patients on, why, you're doing something that's better than everybody else is doing. And we anticipate that those -- that people are going to be benchmarked, and that's where the bidirectional risk component of these things will come in.

So we did give that a lot of thought, and I think that we did weight the fee. I think Dr. Shore wants to make a comment as well.

DR. SHORE: Yeah, I really appreciate the question, and I hope I'm not -- you were asking about models, and we frankly as an organization, LUGPA, we've been addressing the balance of treatment for newly diagnosed patients for several years. In fact, a very large genomics company gave us an unrestricted grant several years ago, so we've been already interrogating our active surveillance rates as an organization, recognizing this enormous unmet need.

Everyone around this panel would recognize,

whether you're an oncology-based physician or not, it's an evolving industry, and it's an evolving educational paradigm. So we chose this because we were already in this space. And, fortunately, with the edicts from MACRA, we saw this as a very logical way to go forward.

MR. MILLER: I'm not disagreeing with any of that. I want to make sure everybody else has time to ask questions. Your goal makes sense. I'm trying to get clearly at what the gaps are that need to be filled, whether this is the right way to fill them. So care management fee fits -- fits one of the gaps. I guess then my question is about this total cost of care approach, and I'm not sure what that's there for, other than to try to get yourself classified as an advanced alternative payment model. So I want to understand whether there is something -- is that actually offsetting a loss for the urology practice? So if you could explain to me how much of the active intervention the urology practice is doing and losing money on when it does surveillance, because I'd be worried that if the urology practice isn't doing that and it's found money, in a sense -- right? If the patient was active intervention and they went off to some other -- to the radiation practice over there, or they went to the surgeon over there, which I assume in some cases maybe are

the hospital, that all of a sudden there's a very large bonus for the urology practice for not having the patient who needs to get active intervention get it.

So I'm trying to understand why that's there and whether it wouldn't be better simply to have a more modest measure of are you doing active surveillance for the people who need it, particularly given that it's evolving --

DR. KAPOOR: Yeah, and I think it's a fair question. We talked about the total cost of care metric, and the reason why we opted to do it, it would be -- it would be disingenuous for me to say that we did not want to be an advanced APM. Of course we want to be an advanced APM. It's not likely to meet the overall financial requirements, but if we can be exempt from certain reporting requirements for MIPS, that encourages participation in this model. So, yes, clearly we want to be an advanced APM.

When we looked at the total cost of care for -- the total cost of care metric, when you look at the patients on active intervention, which constitutes the majority of people that we're going to be addressing right now, the total cost of care metric presently is about 70 percent of the first year.

Now, remember, that total cost of care only

applies to year one of the proposal, and that is something that sort of has escaped the discussion.

MR. MILLER: Well, I'm worried about that part, too, but that's a separate question.

DR. KAPOOR: You know, but -- so if you're looking at the total -- moving patients appropriately from surveillance to intervention, most of those costs are going to be incurred by decision-making that's directly impacted not only by the urologist but by the care management team. When you talk about is it going to be found money for the -- let's just look around the room here. There are many clinicians, and the clinicians practice in different payment models. So if you're in a multispecialty group that has a radiation oncologist and a urologist and maybe even be affiliated with an institution, you're going to put together a care team that's going to do that, and the shared savings are going to come in. You can allocate those shared savings any which way that you want to. If you are an integrated urology practice that may have incorporated radiation oncology services, you may be able to participate in a greater percentage of that, and then work with one of your local institutions that is willing to create a value partnership for those patients that need radical prostatectomy.

One of the things that I particularly like about the proposal is that if you are in neither of those situations, which is the majority -- if you look at the demographic data, and I believe it was provided in a response to the PRT. If you look at the AUA census data, the overwhelming majority of practitioners in the United States, urologists, are in neither one of those circumstances, but are in small independent practices. So my anticipation in that type of --

MR. MILLER: So, just to clarify, in those cases would the urologist likely be doing the radiation or the surgery themselves?

DR. KAPOOR: Well, let's be clear. Urologists never do radiation. Urologists may work with the radiation --

MR. MILLER: In their practice, in the small practice, they wouldn't be doing the radiation --

DR. KAPOOR: Correct.

MR. MILLER: Would they be doing the surgery?

DR. KAPOOR: Typically -- well, in most practices you'd have somebody that would be capable of performing either an open or --

MR. MILLER: Yeah, okay.

DR. KAPOOR: -- robotic prostatectomy.

MR. MILLER: So, in other words, in the practice, if the urologist didn't do the prostatectomy, they would lose the surgery fee for that patient.

DR. KAPOOR: Correct.

MR. MILLER: They would not lose any fees for not having done the radiation for the patient.

DR. KAPOOR: That is correct. But my anticipation under --

DR. BERENSON: Can I interrupt on that one [off microphone]? I thought there was that -- it's common in independent practices, at least for IMRT, to bring in radiation oncologists to actually do the radiation but that the revenue goes to the practice, and that that's been one of the recent problems that --

DR. KAPOOR: Unfortunately, that is incorrect. You can have -- you can integrate radiation oncologists into the practice, but the nature by which the revenues need to be distributed are strongly prescribed by Stark Law. If you look at the --

DR. BERENSON: There's an exception, I thought, for self-referral for IMRT.

DR. KAPOOR: It's not for IMRT. There's an in-office ancillary service exception, but you must meet very specific criteria to meet it. But the broader question is

how much of the radiation in the United States is being provided for prostate cancer, and the answer is probably about a fifth. So, 80 percent of radiation services for a prostate cancer in the United States are done by either freestanding radiation oncology centers or with the bulk of it being done actually in institutions. So, the notion that the majority of prostate cancer radiation is being performed by urology practices with the ownership of the technology is simply incorrect.

DR. BERENSON: Well, yeah, but nobody said that. You said that there's no loss to the private practice for doing radiation --

DR. KAPOOR: No, he said that if you didn't own -- if you did not own radiation oncology, there's no loss to the practice. That was the question.

MR. MILLER: I was actually asking for the small practices. I said it would not be typical. But, okay, let me ask one more --

DR. KAPOOR: I was just addressing the question that was presented.

MR. MILLER: -- question and let other people talk, because I don't want to dominate this.

So the final question is: You have this total cost model for one year, and then nothing, which now all of

a sudden creates on the 13th month -- and I know you have in there we're going to sort of -- somebody's going to watch for that, but it would seem to me to suddenly say, okay, I can get the best of both worlds, I get shared savings in year one, and in year two I'm going to go and do the prostatectomy. And I'm wondering what would be wrong with a model that said rather than total cost of care, that it's cost associated with prostate treatment for a multiyear period, that if, in fact, over a three-year period there is less expenditure on prostate treatments, that can clearly be managed by the urologist. We're not worrying about their cardiac complications and everything else and all this stuff we were talking about, care coordination, disappears. You would dramatically reduce the notion that I'm going to shift the treatment across the 12-month boundary, and the actuaries, I'm sure, I would think would be nervous about that if they were trying to cost this model out. Would that -- How would that compare in your mind to what you propose?

DR. KAPOOR: So I'd like to just answer your first question because I didn't have an opportunity to do so. The small practices, I think that the way we had envisioned it is that if you are in a small practice, you're in an area where different practitioners have

historically worked together, that you could form perhaps even a virtual group, which is now being allowed for by Medicare next year. And you would -- it would not just be the urologist acting unilaterally, although it's certainly possible, but remember that we all function as a -- particularly in smaller practices in communities, and if you're going to -- if you're going to act in a way that disadvantages other practitioners in your community and you're not going to include them, we're urologists, we depend on referrals from other practitioners for a living. That would sort of be cutting off your nose to spite your face. So we think that those care teams will form between different specialties that are involved in prostate cancer institutions.

MR. MILLER: That's why I wanted to make sure that it wasn't that you'll get the surgery next year.

DR. KAPOOR: Well, and I think that it's funny -- it's kind of ironic you mention that, because the first approach that we took to this was a 36-month model of care, and we have actually -- we actually had two different meetings with CMMI during the course of the proposal to kind of say, “What is the various workabilities of this?” And we looked at all the existing proposals that existed, and there is simply not a multiyear proposal that's in

existence. So we were actually counseled --

MR. MILLER: Maybe you should be first.

DR. KAPOOR: You know, I've always found that that makes me very nervous.

[Laughter.]

CHAIR BAILET: All right. So, Rhonda, you had your card up. You don't have a question right now? Great. Okay. So, then Grace.

DR. TERRELL: Thank you for your proposal. I am not in this role anymore, but I was the CEO of a multispecialty group that had urologists in it. For 16 years I was in that role. And your particular specialty has been on a roller coaster with respect to the way that the revenues come in as the technology changes over time. And I thought that you very specifically talked about something that was very relevant with respect to the anxiety that the patients have with respect to choice.

But the urologists themselves also have some skin in the game with respect to the choices that they make, and I've seen the revenues go up and down over time.

One of the things, though, that's true -- back when we were pure fee-for-service in my organization, and then we were an ACO -- is that a prostatectomy is a one-time payment that's a relatively good amount, could have

been better, could have been worse, changed over time. And what you're proposing is for ongoing care. I mean, that's the whole point of this, is the ongoing care piece of it.

A lot of the questions that I was asking the PRT were respect to the actual cost of that ongoing care because it's intermittently -- it's intermittently rendered, if you will. In other words, if you've got a registry -- you got the registry, there's some -- you know, there's some analytic work that's being done. If you're doing the actual work of -- the very, very difficult work of talking patients through the shared decision making, you're not doing it every day, and you're not doing it every month.

So I'm trying to justify in my own mind the two different payment models as it relates to the actual practice of urology. So sometimes it's better to do a prostatectomy; sometimes it's better to refer to a radiation oncologist.

My first question is: Have you actually modeled out what this would look like to just do a fee-for-service unit model of the cost of care with some additional on top of it relative to this longitudinal payment that you've got, just take the alternative payment model off the table, but just the cost of it as a unit over time model?

DR. KAPOOR: So I assume that you're not talking about CCM, but you're just talking about just tacking on some additional E&M codes for --

DR. TERRELL: Whatever it would be. There would be some sort of fee that would cover the services, allow you to stay in business, and do this type of therapy approach whenever it's the chosen choice of the patient and the urologist thinks it's clinically an appropriate thing to do. Have you modeled out that as a unit cost as opposed to a longitudinal payment?

DR. KAPOOR: Well, each one of the -- when we talk about the longitudinal payment, it is a -- each one was a collection of unit cost that we simply aggregated together, because on any particular month, for example, you know, you're going to see this patient or that patient or the other patient. You may not see them every month. Sometimes you may need to see a patient that is particularly anxious every three months, sometimes every six, sometimes every month, depending on the unique needs of that patient. And we anticipate that you're going to have a care coordinator or some type of individual that is going to be a non-urologist that's going to be coordinating that type of service because, candidly, urologists as surgeons, that's not necessarily what we do best. We need

the assistance to monitor that process, whether it be a nurse navigator or whether we incorporate a social worker to be working with the patient and their family on whatever their specific needs are.

DR. TERRELL: The cost of those [off microphone].

DR. KAPOOR: Yeah, so there -- I don't -- and perhaps it's my lack of sophistication with the coding. I am not aware of a mechanism by which as a -- the way fee-for-service medicine is constructed, that we could create -- that there exists at present CPT codes that we could bill for that particular thing, other than just continuing to bill E&M visits when we're not actually seeing the patient, which isn't really appropriate.

DR. TERRELL: So my next question is related to what a urologist does versus what somebody else could do as it relates to technology and scarcity of resource and other things. So I mentioned in my questions to the PRT that you can actually do active surveillance if you have an evidence-based protocol with a -- with something that doesn't require urological surgical treatment. Whether that's the right thing for every patient, I'm not arguing with. I mean, you could say that in certain communities it would absolutely be standard of care to send everybody to a urologist; in others it would not. And in other areas of

the country, there may not be any urologists at all except distantly.

So there's a couple of things about that that are important. Number one is shared decision making might not always occur in a facility. There's tele-education and other types of things that might be able to be done that would have a different cost as the technology changed. And I could actually conceive of others wanting to get into this business, whether they're medical oncologists who, you know, do this and then they just, well, it's time for the biopsy, let's send them to the person skilled in that.

You made this very specific for your specialty based, I presume, on wanting to own this disease, believing that you're the best ones to do it, that you've got the overall focus on this. But my -- what I would ask you to do is could you comment on the aspects of this that could be done in alternative ways and how you would relate that to this particular payment model.

DR. KAPOOR: Well, I appreciate the question and really the thoughtfulness of the notion. And to be clear, we weren't really thinking of it as the specialty. We were thinking about it as the disease space. You know, this is a specific disease space. So, you know --

DR. TERRELL: So it could be somebody else in

theory, so long as --

DR. KAPOOR: Absolutely. In fact --

DR. TERRELL: -- they have the ability to --

DR. KAPOOR: -- while we were chatting, when you mentioned the things that were remote, we didn't even think of it up until now, but, you know, this would be a perfect opportunity to incorporate telemedicine, you know, that we could -- that we could have novel technology that -- where devices may be able to be put into -- you know. So from what you're thinking -- I'm thinking about this care management fee and how we could actually utilize it for other things that we candidly hadn't even discussed. And that is -- Dr. Patel had mentioned the entrepreneurial nature of the group, and urologists are a very entrepreneurial specialty. And I think that when you provide a vehicle for something to happen -- right now there's no compensation for this to occur.

DR. TERRELL: Right.

DR. KAPOOR: You know, in this great country, if you say, okay, here's an opportunity for you to -- here's a business opportunity for you to devise the mechanism to track these patients, and the way care management fees go -- it certainly is true in CCM -- you're allowed to delegate that to a third party. You're allowed to delegate

OCM management fees to a third party. I could see clearly how there could be independent organizations that would be forming specifically for the purpose of doing these type of things. So I think it's a great idea.

DR. SHORE: So your point is well taken. Things are changing, right?

DR. TERRELL: Right.

DR. SHORE: So an interventional radiologist could do the biopsy and then send it to a primary care physician or a medical oncologist. And at the end of the day, our proposal is agnostic. It's --

DR. TERRELL: Okay. That's what I wanted --

DR. SHORE: The North Star is for better patient care and cost savings and risk, and that's -- so I think your proposal would be fantastic.

DR. TERRELL: Okay. Yeah, the PRT had talked about that it tended to be focused on urology as a specialty, and so that's why I was getting at this. I was trying to think through the services that could potentially be done in a collaborative way when and if that was appropriate to do so. And what you're telling me is that you believe this model would do that.

DR. KAPOOR: Well, you know, it sounds like a urologist, because the overwhelming -- the triggering

episode is the prostate biopsy, and we attribute the patient to the physician that does the prostate biopsy. It happens to almost always be a urologist, but it doesn't have to be. You know, it could be an interventional radiologist as part of a care team.

So the triggering episode, it sounds urology because at present it is urology. But it doesn't have to be urology.

CHAIR BAILET: Tim, you put your card down?

DR. FERRIS: It was mostly -- I think Grace covered it very well. Two very quick points. One is, did PROMs play any role in your -- it's a big deal right now in urology because of the -- it's really -- patient-reported outcomes really is the way you assess success in much of what urologists do, and I didn't see that in here, and I just wondered, are they -- does the coordination fee help to collect PROMs data, for example?

And the second thing, I guess maybe just drilling into what Grace was saying about the intersection with primary care, and more specifically around ACOs. So say you have an ACO that's defined by a primary care population that's in the region of a urology practice, and just as you said, Dr. Shore, you know, you've got an interventional radiologist doing the biopsies. They're sending the

results to their pathology and primary care is actually doing this. So in a lot of integrated delivery systems, they're one EHR. That EHR has registries built in, fairly straightforward to manage, to input reminders in for active surveillance. Actually, that's pretty standard in ACOs, active surveillance of multiple different conditions, chronic -- and so in some ways this is just the same way, same -- analogous to managing any chronic condition. That's what active surveillance is about.

And so I was trying to understand how your model would interdigitate with a primary care group that actually has the registries, has the active surveillance, has the care coordination, because actually that's part of what an ACO does. And is there any -- what's the overlap? What issues are created by a fee going to one group that's claiming that person for a specific thing and then another group that is actually getting in a contractual agreement to manage the totality of that care?

DR. KAPOOR: Yeah. So one of the notions that we've strongly considered as urologists, as other surgeons, surgical specialties are, we have the capacity to participate in more than one accountable care organization, and so we -- one of the notions that we consider is sub-capitated risk, where if you have something -- and we

mention the interventional radiologist going from the primary care physician. That's a theoretical construct, so we have to understand that that actually happens, perhaps there, but it is not how the overwhelming majority of the services in the United States are performed. And so the idea is that I don't believe that the two things are necessarily mutually exclusive.

So, for example, let's talk about your ACO environment, and your ACO has a hospital, and within the hospital -- and in addition to the hospital, it has some freestanding radiation centers. The ACO in a fee-for-service world could simply ship the radiation business from the inpatient institution to the outpatient facility, reduce the cost of the radiotherapy services by 40 percent and not do anything whatsoever, so, in a way, have their cake and eat it too. They would have the shared savings from reducing the cost by simply reallocating to an off-campus -- a non-accepted campus provider, with CBD, whatever it's called, and still maintain that revenue stream, which is still very substantial, simultaneously collect the shared savings, and do absolutely nothing that benefits the -- encourages the use for active -- of active surveillance.

So we can create in any construct a vehicle by

which somebody can work around the system to game it in some way. What we wanted -- and we talked a lot about that when we developed it, and it's our very strong -- because one of the things that we haven't really talked about is the shifting diagnostic patterns in this.

What we saw, what we're seeing right now is really a rather remarkable decrease in the number of prostates biopsies that have been performed, starting from 2012 when the United States Preventative Service Task Force issued it Grade D recommendation against prostate cancer screening.

Even though it did not get anywhere near the same degree of public attention, in May of this year, the proposed -- they changed that for men ages 55 to 70 and actually said -- and changed the Grade D recommendation to a Grade C recommendation.

We have already started to see in these prostate cancer screening a tremendous uptick in the number of patients that are showing up for screening. So I think that we can anticipate that that historical trend downward in the number of patients that have been biopsied has probably nadired, and we're going to see it start going up again as patients with abnormal blood tests are coming in.

Consequently, the need for such a proposal, when

we're going to presumably start seeing a higher number of patients that have relatively low-risk disease, I think the time is optimal for this right now because we need a mechanism to make sure that those patients are appropriately routed to the right form of care.

You know, again, only a third of patients that are candidates for -- you know, we can talk about the fact that active surveillance rates are increasing. They're increasing only for a relatively short period of time and are still at very, very low numbers. One-third of eligible patients receive surveillance. That's the fact, one-third, and that is data from last year from the largest urology data registry.

So what we're trying to do is just move away from -- trying to buffer the headwinds that we're facing.

CHAIR BAILET: Okay, Tim. Okay. Bob and then Kavita.

DR. BERENSON: Yeah. As I indicated earlier, I want to just understand a little more what the range of services that are not currently reimbursed, what they consist of, and I am particularly interested in understanding more about what a non-physician's role would be in this.

I have this sort of sense that we keep assuming

non-physicians, non-clinical people can do what we've assumed physicians are and should be doing, and with something like cancer, I'm just wondering when the patient has a trusting relationship with a urologist, whether some of the other personnel who might be involved actually can accomplish what is hoped for under a care management regime.

So, let me go through the bullets that you've laid out that are the range of services, and I want to get a little better idea of what's involved.

So the first one is tracking active surveillance beneficiaries to ensure compliance throughout episodes. What is -- compliant with what, I guess is my question. That they keep appointments? What is involved, and who does it?

DR. KAPOOR: Well, again, who does it may vary with the care management team, but long-term compliance with surveillance protocols has been demonstrated to be particularly challenging. And this is particularly true in socioeconomically underprivileged areas.

If you take a look at the demographic of patients that are on active surveillance in the United States, they have two common characteristics. They're white, and they're affluent. And that is the overwhelming majority of

people that are on surveillance, which is really a deficit in care.

So ensuring compliance for patients, particularly those that are needy in terms of making sure that they get to their appointments, to make sure that they actually even do something simple like get their blood work done, these are things that need to be done. And I don't think that that is something that a clinician would need to do.

DR. BERENSON: I understand. So that's what's involved is really for that population to get -- I mean, is it standard, as I've read in the literature, that it is typical to have an every-six-month visit? Obviously, there are exceptions, but is that sort of the standard? That's what our consultant said.

DR. SHORE: That's absolutely not the -- there is no standard.

DR. BERENSON: Okay.

DR. SHORE: And to say that there would be a standard would show a certain naiveté.

You know, it really depends upon the age of the patient being surveilled. It depends on the patient's education. It depends upon if they're in urban, rural, suburban populations, regions of the country.

And one of the things that has been abundantly

clear is the lack of adherence, and perhaps a big part of it is that we're not seeing these patients more enough. You know, it goes back to this -- you were going to use a quote, and the quote I -- actually, if you've ever read anything by Susan Sontag on "Illness as Metaphor," it's one of her books on cancer. Once patients hear this word "cancer," suddenly their hair is on fire, and they're running for the hills. And then some can read an article and say, you know, everyone gets prostate cancer, no one dies of it. The fact of the matter is that certain different populations, the heterogeneity is marked.

Somebody highly educated, the folks perhaps at this panel would say, "I get it. I'll come back in six months. I don't need to be bothered." Others, particularly those who are educationally challenged, geographically challenged, they need more care. They need their family to come in. They need their support team to come in. We have done miserably in that; thus, our adherence rates to active surveillance are atrocious, especially, as you alluded to, to most European, Scandinavian countries.

So, this would be a wonderful opportunity. We don't have -- our model doesn't have everything in it. Your notion about PROMs, health economic outcome reported

data as well, we look forward to using this for further information, and so the answer to your question, no. It wouldn't be every six months for everybody. Some, it might be, it could be, but not for everyone. It really just truly has to be individualized.

DR. BERENSON: Okay. Tracking lab results longitudinally, isn't that standard? And, I mean --

DR. KAPOOR: Regrettably, no. You know, one would think that in an electronic health record era that the labs just come in and they get tracked. We find that -- so, for example, we have one EHR. Our EHR database is huge. We have 1.542 million patients in our urology database, and how data comes in is very often non-discrete.

So, we can't always prescribe where our patient gets blood work done, which laboratory that they choose, how that data gets sent back to us. Very often, it's sent to us in a fax. It's non-discrete, or it's sent by mail. So this all has to be collated together and put together longitudinally because one of the things about tracking patients that are on surveillance is that there are different sets of parameters that you have to interpret when you're looking at longitudinal PSA values, and there's different triggers that exist for you to consider whether or not you may need to do some additional testing, such as

multiparametric MRI or an interim biopsy or whatever the case may be.

So having the capacity to have longitudinal discrete data for these patients is really of critical importance, and every clinician in this room who deals within electronic health records has dealt with the frustrations of getting non-discrete data and try to integrate that in.

DR. BERENSON: Yeah. Well, that was my -- every doctor has that challenge for all their patients, and so I was just wondering what's unique here.

The third one is continually educating beneficiaries. What does that mean? What's continually?

DR. KAPOOR: Well, you say you're wondering what's unique. What's unique is that this is a patient that has an active genitourinary malignancy. That if you miss a nuance in a change in their lab values, they may lose the opportunity for cure.

DR. BERENSON: I see. Okay, okay.

Continually educating. What is "continually" meaning? Does that happen at that visit that occurs, either every six months or every two months or --

DR. KAPOOR: Oh, I think that happens much more often than that. I think that it is imperative that the

patient on surveillance be continuously counseled because --

DR. BERENSON: Who does that counseling?

DR. KAPOOR: Well, I think that that should probably be -- we use Nurse Navigators. I think it could also be a social worker or some other individual that would become involved from the beginning.

I can let Dr. Latino -- she manages the Nurse Navigator program in our practice, and our Nurse Navigators get involved at the time of diagnosis.

So, Kathy, can you address that?

DR. LATINO: Yes. I think it's very important that you integrate everyone in it. Sometimes it's the urologist. Sometimes it's the Nurse Navigator. Occasionally, it's a social worker.

What you have to realize is a lot of these patients, too, you tell them they don't need treatment, they'll go home and say, "Oh, my doctor said I don't need treatment," and they forget about it. That's where this is so important that you have to continually educate --

DR. BERENSON: So do you call them on a routine basis or see them on a routine basis, or what is it that you actually do?

DR. LATINO: Or have the Navigator follow up with

them on the phone. It depends on the individual patient.

DR. BERENSON: I see. Okay.

Social services and coordinating care across practitioners. The social services could be provided by an external social service agency, or is that something that the practice actually provides?

DR. KAPOOR: I think it depends on the scale of the practice.

DR. BERENSON: Right. Okay. And the coordinating care across practitioners, was that referring to the high costs associated with Medicare patients to be involved with -- or what is that about? I won't prejudge. What practitioners are involved?

DR. KAPOOR: Well, I think that depends on the individual care team. We can't prescribe that because of the multiple different models that exist.

We're asked to say what are the potential things that these things could be used for, and I think that providing resources for that care coordination is an important component.

But what it would look like in my practice or Dr. Shore's practice or in a multispecialty group or in a hospital-based practice --

DR. BERENSON: I see.

DR. KAPOOR: -- I think would look very different than those places.

DR. BERENSON: All right. Let me then ask -- I'll finish with this last question, which is a more provocative one, I admit. You've made a strong case that active surveillance is underused, that interventions are overused. To what extent would you help change that behavior by identifying overpriced interventions and reducing prices to fund the active surveillance? In other words, to what extent is the profit motive so great for some other interventions that it would help get a better result if you narrow those differentials somewhat?

DR. KAPOOR: I appreciate the question, Mr. Berenson, but I have to -- Dr. Berenson -- but I disagree with the fundamental premise of the question, and that is that what is the overwhelming driving factor preventing surveillance is a profit motive.

There are enormous factors that are there. As I said, the environmental scan and literature review did pick up an outstanding article by Stacey Loeb, who is in New York, identifying eight different factors that are there, which financial incentives are only one.

Clearly, the highest-cost intervention that's associated with prostate cancer therapy is radiotherapy.

So when you take a look at -- now, the reimbursement for radiotherapy has already been cut massively. So the reimbursement for radiotherapy over the last decade and a half, the per-unit for intensity-modulated radiotherapy has been cut by more than 50 percent already. The reimbursement for radical prostatectomy has been reimbursed -- is very, very nominal.

So if you take a look at the overall cost, the total annual cost, the total cost of care for these patients on intervention is $1.76 billion for prostate cancer. The total professional spend for urology, for everything that urologists do, is $1.1 billion. If you look at what's only being done for the surgical therapy of prostate cancer, it's actually about $15 million a year.

So you have about $15 million a year that's being spent on surgical therapy, about $660 million that's being spent on radiotherapy, and about $4 to $500 million that is being spent on inpatient costs that are nonprofessional fees, the DRG codes, that are associated with it.

So when you talk about a profit motive for a urologist, remember of the total spend in prostate cancer, only a tiny fraction of that right now is actually being consumed by the urologist. It's really systemic spending, but the urologist that wants to modify the decision making

is facing all these headwinds to go ahead and do so. And what we're trying to do is realign the incentives to provide the resources to address those headwinds while simultaneously, it's a misnomer to view this, that we created this -- that we got together and we said, "Let's put our collective heads together and think of a way that urologists can go ahead and extract all this money that other people are previously making." As practitioners, we wouldn't exist in our communities for very long if that's how we approached it.

We need to have care management teams that will allocate that shared savings in the first year and then continue to work together on an ongoing basis to make sure that the appropriate patient stays on surveillance, and so that really is the driving motivation here.

DR. BERENSON: Can I ask one more, which is should you be -- should you have care management teams for the whole range of urologic problems, not just for localized prostate cancer? Is this just -- I mean, should that be the ultimate goal?

DR. KAPOOR: Well, you know, it's fascinating that you say that because even though -- I know you find me extremely terse with my answers so far, but if you'll indulge, all doctors like to think that their specialty is

different than every other specialty. So I'm going to tell you why urology really is different than every other specialty, and that is because typically patients are referred to a urologist not with a diagnosis but with a sign or a symptom, and so -- and this is the thing that attracted most of us into urology.

We do the diagnostic work. We order the x-rays. We order the labs. We interpret them. We come up with a diagnosis. If the medical therapy is warranted, we institute it. If surgical therapy is warranted, we institute it. And in most circumstances, certain practice models notwithstanding, urologists actually then performed a longitudinal follow-up.

So I refer to urology as kind of a clinical cul-de-sac. Once you get into the cul-de-sac, you sort of stay there, but in certain avenues like this, you do require -- this is a -- cancer is a multidisciplinary model, and prostate cancer has always been a multidisciplinary model.

We cannot -- Dr. Shore, myself, any other urologist that's there, we cannot do a radical prostatectomy in our office. We do not have the wherewithal to buy a robot that costs umpteen millions of dollars for the finite number of radical prostates that we do, and we don't -- and it's not technically feasible.

Most urologists in the United States, probably 85 percent of them, do not have the wherewithal to do radiation therapy. They need to work in conjunction with facilities and with other caregivers, and so in this particular avenue, a care management team is really important. But for the overwhelming majority of genitourinary services, the care is -- the diagnosis, the medical therapy, the surgical therapy, and the follow-up is really confined to the specialty.

So the short answer is, no, it's not necessary.

CHAIR BAILET: So, Kavita and the Paul.

DR. PATEL: Just three questions. The first one has to do with something you brought up and also in the proposal with this very clear racial disparity between especially black males and largely, it sounds like, white males with as -- are there any -- is there -- I didn't see any, like, specific metrics or anything that could track kind of other than just, you know, ethnicity data, kind of how you would reach that, and so a question is, is this a function of there's just geographical patterns of largely predominant African American populations who served by groups of urologists who just are not doing this or within a practice? And that's what I just can't tell is this kind of -- does it matter. It's within a practice. There tends

to be a divide, and if that's the case, I'm not sure how -- I want you to point me to where what you're doing --

DR. KAPOOR: Right.

DR. PATEL: -- can help to reach that.

DR. KAPOOR: Yeah. And I think that's a very important concept. We know three things to be true. African American men get surveillance less often than other races. African American men get followed less closely than other races, and African American men drop out of surveillance -- actually, we know four things -- drop out of surveillance more often, and prognostically, they do worse. We do not know why any of those four things occur, and part of the problem is that I can't write down a CPT -- an ICD-10 code for surveillance, or I can't write down -- I can't -- you know, there are some 47 different ICD-10 codes that describes spacecraft accidents. There is one ICD-10 code for prostate cancer, and it doesn't matter if it's low risk, high risk, intermediate risk, very low risk. It's irrelevant. It's just one code. So we can't use claims data to do that degree of differentiation at this point in time.

When you take a look at the studies that are involved in surveillance, African American men are massively underrepresented in those studies, and the idea

behind the proposal is by bringing more patients into the registry, that one of the barriers, one of the headwinds is clearly an educational barrier that exists. Providing resources for that education and providing resources for these individuals to be longitudinally tracked, we hope to be able -- since we're collecting the histopathological data at the time of diagnosis and we'll be tracking the PSAs on an ongoing basis -- for example, Dr. Cooperberg was particularly existed, although we're not endorsing one QCDR, the AQUA Registry, we would be able to put all this data, and that would be an outstanding mechanism for this to be done. We'd be able to put all this data into a registry so we could have a better understanding of what are the -- because right now, one of the hot areas of debate is do we need a different surveillance protocol for African American men. And since there's simply not enough patients in the cohort, we just don't know, and that is one of -- I don't want to even say a corollary benefit, but a main benefit of the proposal is for the first time have some organized methodology for collecting longitudinal data on laboratory values, histopathology, and outcomes on patients based on a variety of staging and grading as well as age, ethnicity, regional demographics, and so forth.

DR. SHORE: Just one other quick comment. So

while it's been an incredible blight on the health care system, the African American cancer disparity -- and Tom Farrington will be speaking later today representing that organization -- let's not forget about African Caribbean. Let's not forget about nonwhite, Latino, huge racial disparities, as well as the changing immigration policies here.

We've done -- there's a lot we could do with a proposal that we're offering here that would be of really proactive benefit, so I think it's not just African Americans, although it's clearly huge. There's many other racial disparities.

DR. KAPOOR: And socioeconomic disparity as well.

DR. PATEL: I had three, and I'll truncate it to just a second point. If the Oncology Care Model did not have a chemotherapy trigger, would this be able to be done in the OCM?

DR. KAPOOR: I'm not an authoritative expert on OCM -- Is it appropriate for either of you to answer that question?

MS. PELIZZARI: I think the challenge that comes with answering that question is the number of other things about the OCM that would have to change if it didn't have a chemotherapy trigger, what is triggering it just at

diagnosis. They'd have to change the whole price-setting methodology because of the variation in --

DR. PATEL: You're trying -- I understand that. I'm asking a very basic question --

MS. PELIZZARI: Mm-hmm.

DR. PATEL: -- because it has a monthly care management fee, which is actually quite higher, much higher, as a total cost of care metric. It does all the things that we're describing here, but it requires a chemotherapy trigger. So I'm asking the question. If there were no chemotherapy trigger, would that be a potential avenue?

DR. KAPOOR: Well, the OCM is closed. I suppose that if there was no chemotherapy trigger and it was open --

DR. PATEL: But the reason I get at this is because we were on the PRT, and that very first question talks about scope. So I know it's a closed APM, but if you looked at the recent CMMI RFI -- and I'm not sure -- they allude to not only potentially kind of either opening up that model, but potentially even expanding it to kind of cancer like at time of diagnosis.

So I was just curious because I'm sure you've talked with CMMI or at least a long time ago probably

talked to them in the original kind of version of this. I'm just curious kind of how you would think about that.

DR. KAPOOR: Well, candidly, we didn't because it wasn't an available option. There were four urology -- to my knowledge, there were four urology practices in the United States that are participating in OCM.

DR. PATEL: Did you respond to that CMMI RFI? I'm just curious. Did LUGPA respond to that recent RFI?

DR. KAPOOR: I don't recall if we did.

DR. SHORE: I don't think we did.

DR. KAPOOR: I don't think we did.

DR. PATEL: No, okay.

CHAIR BAILET: Okay. Paul.

DR. CASALE: Just a couple questions. One was when Bob asked you to go through each of the list of activities, you know, the tracking, the beneficiaries, tracking lab results. So would you agree that it might potentially be more efficient for primary care, who is also tracking their hemoglobin A1c and being sure to get their diabetic eye exam and have their colonoscopy and get their mammogram, to be doing this activity again in communication and coordination with urology, as opposed to urology being the one doing that?

DR. KAPOOR: I don't think we prescribe who does

it. As we said, stated I think rather emphatically, we believe that care management teams will form, and if it is most appropriate in a particular community for primary care physicians to be doing this to avoid the duplication of blood work and avoid the duplication of sticking people and the discomfort associated with the venipunctures and sharing the results with the urologist, by all means. I have absolutely no objection to that whatsoever.

DR. CASALE: Okay. When you answered Bob, it sounded a little bit more like you thought it was important for the urologist to do it in order to be sure.

DR. KAPOOR: No, I thought --

DR. CASALE: Fine. So you're thinking that this could be primary care?

DR. KAPOOR: No, the tracking of the data, it's more -- it's important, and I apologize if I was unclear. It's important for the data to be longitudinally tabulated in a fashion that the urologist can interpret because I have -- the ultimate respect for primary care physicians, quite candidly, how everybody -- how primary care physicians can keep the myriad number of things that they have to keep straight, is beyond me.

I'm just a urologist, and I can just focus on what I do, but the interpretation of these PSAs, I would

respectfully state in the surveillance population is probably outside the scope of a primary care physician's knowledge base.

DR. CASALE: No, no, no. I agree it would have to be in coordination, but, I mean, the actual being sure that the -- because you said they don't always get follow-up. They don't always get their PSA done. They're told, "Oh, you don't need surgery," and then they go away, and they get lost to follow-up. So I'm just asking, wouldn't it be more efficient for sort of having primary care who they presumably are seeing for their multiple other comorbidities to be the ones, again, coordinating with urology to make sure that you're doing the interpretation of the results, as opposed to you hiring the Nurse Navigator, as an example?

DR. SHORE: Sure. In an ideal world, that could work, sure. I mean, why not?

But as we all know, there's urologists, and then there are primary care doctors of different work ethics and different levels of burden. And to Dr. Kapoor's point, it's not just about following the PSA for the uber busy primary care physician. It's the understanding of the biopsy results, understanding the voiding symptoms, understanding other things that are coming out in terms of

proteomic and genomic testing, et cetera, et cetera, et cetera. It gets unbelievably complicated.

But, yes, in an ideal world, I would say that that would be fantastic. It would be optimally efficient for the patient.

DR. CASALE: Yeah. I wasn't saying they shouldn't be educated through the urologist or shouldn't see the -- I just meant the first two in particular.

And just my last question is around -- I still struggle with this coordinating care across practitioners, and I know you're -- you've been asked this several ways, and I know you are specifically vague because you want to keep it open. But when I think of coordinating care across practitioners, I view that -- you know, we always talk that's the quarterback, right? We talked about it yesterday with the renal -- you know, they changed it from primary care provider to principal care provider.

So are you suggesting that the urologists would then become the principal care provider?

DR. KAPOOR: For all the patient's disease states?

DR. CASALE: For the ones in this model.

DR. KAPOOR: For prostate cancer?

DR. CASALE: For the people in this model, yes.

Active surveillance.

DR. KAPOOR: I'm not following what you mean by principal and such.

DR. CASALE: Well, you say you're getting a monthly care management fee, and one of the responsibilities is to coordinate care across practitioners. So I'm viewing that as that -- they're in this model, and the urologist, being the one likely accepting the care management, you know, the monthly fee, that you're now the quarterback to coordinate the care.

DR. KAPOOR: With quarterback to coordinate the care for the prostate cancer.

DR. CASALE: Well, see -- okay. That's the part --

DR. KAPOOR: Because the care management fee is specifically -- that's why the budget articulates that the care management fee is for the services that we believe are necessary to maintain a patient on prostate cancer therapy.

DR. CASALE: Okay.

DR. KAPOOR: It's not exclusive. For example, if you have a primary care doctor and the patient has six multiple comorbidities, this does not preclude that primary care physician from billing a CCM to manage those.

The care management fee is not for the global

care of the patient. As articulated in the budget, it is specifically for the services that we deem to be necessary to maintain the patient on surveillance because of what we have identified as the longitudinal challenges in keeping the patients on active surveillance.

DR. CASALE: Okay. But then also, you want to -- as part of the model, you'll accept total cost of care.

DR. KAPOOR: For the first year.

DR. CASALE: Right. But that means you're taking responsibility for all the other comorbidities and all the costs related to that, although you're sort of saying someone else will take care of the care coordination around that.

DR. KAPOOR: Well, remember when you say you're responsible for it, you're being measured against the benchmark, against a historical practice and regional benchmark, from -- I'll leave it to the -- the actuaries have gone through this in great detail.

There are risk corridors that are associated with the proposal, and the anticipation is that in any practice of any significant size that your actuarial cost of care over a longitudinal period of time is not necessarily going to be that variable.

So, yes, it's counted in your bucket, but you're

being benchmarked against what your historical was. That's number one.

Number two, as specialists, we're already being held accountable for total cost of care, and that is because right now, there are no specialty-specific measures in MIPS.

So, in 2018, the MIPS score will constitute 10 percent, and by statute in 2019, it will be 30 percent of the total score.

So in the two-step attribution process, what we find is that a very large number of patients that are being attributed to the specialists are being done by the plurality of care model.

So I'll give you -- I'll speak out of school and talk specifically about my practice. Out of approximately 1,900 patients that were attributed to our practice in our QRUR report, about 96 percent of them were attributed to us on the basis of performing the plurality of E&M visits, meaning that they did not see a primary care physician even once.

Of those 96 percent of the visits, our provider was -- 80 percent of those costs were inpatient costs. Our doctors, leave aside being the admitting doctor, even saw the patient fewer than 20 percent of the time.

So right now, the way the model is, we're being attributed total cost of care for patients that we don't even see or we don't even know. We have absolutely no -- and our feeling is that a -- that a physician, a surgeon, any physician would be much more willing to be attributed a cost of care when at least they have some impact on the decision making that influences what those costs of care are as opposed to where we are right now in the MIPS where not only are you attributed the patient, you don't even find out about it until 18 months later.

* **Comments from the Public**

CHAIR BAILET: I want to thank the submitters for your time and engagement.

What we have now is we have four, possibly five folks speaking on your behalf, and the way this would work, I will bring those folks up. They're all here, with the exception of one who is coming, I believe. They're going to step up to the microphone. They all have three minutes apiece, and because of the number of them, I'm going to encourage and really ask that we try to keep it to three minutes.

And again, I want to thank all of you for coming here today and presenting to the Committee. The exchange has been extremely helpful.

So, as you're taking your seats, the first person is Anne Hubbard from the American Society of Radiation Oncology. Good to see you again, Anne.

MS. HUBBARD: Thank you, Mr. Chairman.

Again, I'm Anne Hubbard with the American Society for Radiation Oncology. Thank you for the opportunity to comment on the LUGPA APM for initial therapy for newly diagnosed patients with organ-confined prostate cancer.

The model seeks to implement the AUA, SUO, ASTRO Guideline that supports the use of active surveillance for low-risk, localized prostate cancer.

Reductions in active intervention can help patients avoid the side effects of treatment that may be unnecessary, thus improving quality of life and enhancing care value. While we appreciate the use of the active surveillance guideline, we believe that there has been a significant acceptance and use of active surveillance in the treatment of prostate cancer.

The capture or Cancer of the Prostate Strategic Urologic Research Endeavor database indicates that between 2010 and 2013, 40 percent of low-risk cancers were managed by active surveillance. That rate increases to over 75 percent for men age 75 years or more. These data are already five years old, so it could be deduced that the use

of active surveillance has grown since then due to physician and patient education efforts.

While this model is well-intentioned, we would urge PTAC to consider a broader model for the treatment of prostate cancer.

Thank you.

CHAIR BAILET: Thank you, Anne.

Thomas Farrington. Has he arrived yet? Yes? And he is with the Prostate Health Education Network.

MR. FARRINGTON: Good afternoon, and thank you for this opportunity to present today. My name is Thomas Farrington. I am the president and founder of the Prostate Health Education Network. We are based out of Boston, Massachusetts, and I am pleased to speak to you today on behalf of the LUGPA APM proposal.

PHEN's mission is to eliminate the African American prostate cancer disparity. In this country, black men are diagnosed at a rate 60 percent higher than all other men and will die from the disease at a rate of 150 percent higher. This is the largest racial disparity for all major cancers afflicting men and women.

Despite bringing the issue of racial disparity and surveillance to the attention of the Committee, in our public commentary letter, I was profoundly disappointed to

see that not one single word in the environmental scan and relevant literature review, the expert testimony, nor the Preliminary Review Team recommendation to the Committee mentions the disparity that exists in utilization of active surveillance for prostate cancer.

Clearly, the PRT was aware of this issue. The public document I reviewed in preparation for this statement shows that both racial and socioeconomic disparity and active surveillance was a topic of discussion between the submitters and the PRT.

There's indisputable evidence in the literature supporting the notion that African Americans are offered active surveillance less frequently or followed less closely, stay on active surveillance protocol for shorter duration, fare less well from a prognostic standpoint when compared to Caucasian.

As a prostate cancer patient, I'm a 17-year survivor, and we have our support groups. I work with patients throughout the country, and adherence and knowledge about active surveillance is really a major service gap that we need to close.

There's nothing to suggest that without specific attention and dedicated resources that the racial disparity and utilization of active surveillance will diminish.

Those attention -- and resources are specifically what the LUGPA APM proposal provides.

In an analysis of 10 pool studies, researchers from Dartmouth found a positive effect of shared decision-making interventions on both minority and disadvantaged patients, and in part, a performance metric in the LUGPA APM is ensuring shared decision making occurs. Benchmarking provides providers with such a standardized national tool -- will markedly narrow the disparity in this regard.

If a doctor -- this APM would create a Medicare database collecting information on how surveillance is being performed and for how long, this will substantially narrow the knowledge gap on surveillance that presently exists between black and white men, helping to determine whether the surveillance pathways need to be modified by race.

In summary, I disagree with the PRT that without proactive action, the adoption of active surveillance will proceed unabated. The PRT should strongly consider racial disparity with respect to equal access to medical treatment and the role that it plays in active surveillance.

This proposal will accelerate the use of active surveillance for all men. Without proactive effort, the

racial disparity and active surveillance will not only persist, but may actually widen.

I urge the full Committee to recommend this proposal for immediate adoption by Medicare. Thank you for your time.

CHAIR BAILET: Thank you.

The next speaker is -- I'm going to potentially pronounce this wrong -- Wendy -- how do you pronounce your last name?

MS. POAGE: Poage.

CHAIR BAILET: Poage. All right. Very good. And you're with the Prostate Cancer Education Council. Thank you.

MS. POAGE: Thank you again for the opportunity to present to you today. My name is Wendy Poage. I'm with the Prostate Conditions Education Council.

My organization has screened over 5 million men for prostate cancer in our nearly 30 years of existence. Our two primary objectives are to educate men and their loved ones on the detection and treatment for prostate cancer and also to provide early detection for free across the country.

Men with prostate cancer who are treated with a primary intervention are at risk of developing devastating

side effects, including urinary incontinence and sexual dysfunction, and simply saying those words does not give justice to the gravity and the impact that these side effects have, not only for the men, but for their families. These men are husbands, fathers, grandfathers, and brothers, and those family members of these patients are also severely impacted by the disease.

It's a huge challenge to have anyone in your family diagnosed with cancer, but the burden with prostate cancer is confounded with these primary treatment side effects. We have wives, patients, and daughters calling our office on a daily basis, and they're consistently trying to manage not only the adverse physical outcomes from primary intervention, but they're also working with the life changes that happen on a psychological and burdensome side effects.

The prostate cancer landscape has changed significantly over the years, but we are certain of two things, that early detection saves lives and that not all men diagnosed require primary intervention.

The statements and philosophies based on passively waiting until the use of active surveillance increases is deeply disturbing to me, especially with the current payment system and the history of overtreatment

that is still existing today.

Passively waiting for new standards in medical care to filter down while men and their families suffer is unthinkable. We know that in many cases, the devastating life impacts of primary intervention could be avoided for patients and their loved ones.

We believe that the number of patients who would benefit from the APM is actually far greater than in the PRT recommendation. It is important to understand that the number of men who will be screened for prostate cancer is expected to increase. The PRT report does not acknowledge at all that the increase in screening due to the U.S. Preventative Service Task Force and their change in their recommendation. Previously, they had a D-level recommendation, and that had a chilling effect on our prostate cancer screenings. While the number of cases of prostate cancer decreased, the patients -- more patients were being found with advanced disease.

Earlier this year, the USPSTF softened this position on prostate cancer screening for men between the ages of 55 and 70, and they acknowledged that the screening for at-risk men still remains unanswered. In the few months since this recommendation was made public, we have seen an increase in the number of men that we have tested,

and we know that more low-risk patients will be subsequently identified. And there are surveillance protocols available to better counsel and manage these patients.

In summary, I and the PCEC believe that the LUGPA model addresses a current and growing clinical need. We will improve the lives of thousands of men stricken with prostate cancer and also their loved ones. Passively waiting is simply not acceptable. Aligning the incentives of practitioners and facilities with clinical best practices will ensure that the right patient gets the right treatment at the right time.

I urge the Committee to recommend this proposal to the Secretary of HHS for adoption. Thank you.

CHAIR BAILET: Thank you.

Andrew Saelens. Andrew is with the ZERO-The End of Prostate Cancer. Thank you.

MR. SAELENS: Yes. Thank you all for taking the time to consider this proposal.

When a man hears that he has prostate cancer, the rational reaction is get it out of me. When his family hears that he has cancer, the rational reaction is get it out of me. The practitioners have the unenviable task of convincing some men that the best course of action is to

leave the cancer inside of them and utilize active surveillance.

While we here can objectively understand that this may be the best course of action due to the risks associated with some treatment, it's more difficult for the man hearing that he has cancer. This is especially true for men and families who may distrust health care providers, given episodes such as the Tuskegee experiments.

To convince a man to utilize active surveillance requires trust, and to establish trust requires time. Ensuring a man continues to participate in active surveillance requires persistence. After all, we don't want to lose the men who have agreed to participate in active surveillance and then miss an aggressive warning sign of the cancer progressing.

Molecular testing enables practitioners and patients to make informed decisions about active surveillance or active intervention. Again, molecular testing takes time for the patient to understand and time for the practitioner to analyze.

There are many good reasons to utilize active surveillance for low-risk prostate cancer, including avoiding unnecessary surgery or radiation, which could potentially lower a man's quality of life, loss of time to

treatments, and loss of financial resources to unnecessary copayments.

Conversations between patients and practitioners take time and trust. The ongoing surveillance takes time and skill, the same time and skill and trust needed for active intervention. We therefore support the alternative payment model because it values practitioners' time, skill, care, and analysis and persistence that are all involved in active surveillance. Let's not let the perfect be the enemy of the good. We need to start on some form of APM that helps urologists speed the adoption of active surveillance. We can tweak as we learn from its implementation.

So on behalf of the patient community, we urge adoption of this model. Thank you for consideration of our comments.

CHAIR BAILET: Thank you.

Stephanie Stinchcomb from the American Urological Association. Stephanie.

MS. STINCHCOMB: Hi. Thank you so much for this opportunity to provide the statement before the PTAC. I'm Stephanie Stinchcomb. I'm Director of Reimbursement and Regulation for the American Urological Association.

The American Urological Association, representing

over 90 percent of urologists in this country, wishes to thank the Physician Technical Advisory Committee, PTAC, for their efforts, helping us move forward toward a payment system that incentivizes quality and high-value care for Medicare beneficiaries.

Urologists care for a large percent of Medicare beneficiaries. Today, there are no urologic APMs and few other opportunities for urologists to be part of APMs as we look forward to advanced alternative payment models urologists can participate in when caring for Medicare beneficiaries.

The diverse AUA alternative payment model work group has consulted with LUGPA and reviewed carefully the LUGPA APM prior to initial submission to PTAC. We provided LUGPA feedback about broad participation in the LUGPA APM, the financial modeling, and the clinical appropriateness of the proposed model. We wish to publicly support the model and hope that PTAC recommends approval for implementation.

We want to address a few concerns of the preliminary review team. One, we believe that there are already urologists, particularly in large or multispecialty groups, interested in the broad responsibility for patient care. We expect urologists will be interested in this model, since a majority of care in the first year after

prostate cancer diagnosis is directly related to prostate cancer.

Two, since fewer than one percent of urologists are in APMs and urologists have limited participation in the Oncology Care Model, we believe it's important to have the LUGPA APM available to urologists and urology patients to accelerate improvements in care delivery.

Three, although there is growing recognition that active intervention may be deferred in a subset of patients, the use of active surveillance represents a paradigm shift in the care for the field. As such, numerous barriers still exist to modify physician and patient behavior. Consequently, adoption of active surveillance is highly variable. These barriers are exacerbated by a lack of resources to ensure compliance with surveillance protocols and misaligned payment incentives, which encourage active intervention.

Therefore, the LUGPA APM realigns payments with clinical best practices as well as provides resources to manage the surveillance process, which will accelerate the use of surveillance, thereby reducing health cost and increasing the quality of patient care.

Thank you for your time. We appreciate the chance to make this public comment and look forward to a

positive review.

CHAIR BAILET: Thank you.

I just want to confirm that there is no one on the phone, and there is no one else present that wants to make a comment?

[No response.]

* **Committee Deliberation**

CHAIR BAILET: Okay. So I turn to my Committee members. Any additional comments, or are we ready to proceed with our voting on the criteria.

DR. NICHOLS: Vote.

* **Voting**

CHAIR BAILET: All righty, then. So just to revisit, we have 10 criteria: 1 and 2, does not meet; 3 and 4, meets; 5 and 6, meets with priority consideration; and the asterisk is for particular criteria where the Committee members don't feel that it is applicable.

So the first criterion is Scope, high-priority item, aimed at either directly address an issue in payment policy that broadens and expands the CMS APM portfolio or includes an APM Entity whose opportunity is to participate in APMs, have limited -- or have been limited. So please vote.

[Electronic voting.]

CHAIR BAILET: Ann.

* **Criterion 1**

MS. PAGE: Zero Committee members voted 6, meets and deserves priority consideration. One member voted 5, meets and deserves priority consideration. Zero members voted 4, meets. Eight members voted 3, meets. Two members voted 2, does not meet. Zero members voted 1, does not meet; and zero members voted not applicable.

The majority of Committee determines that this proposal meets Criterion 1.

CHAIR BAILET: Thank you, Ann.

Criterion No. 2 is Quality and Cost, another high-priority item, anticipated to improve health care quality at no additional cost, maintain quality while a decrease in cost, or both improve quality and decrease in cost.

So go ahead and please vote.

[Electronic voting.]

* **Criterion 2**

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

The majority of the Committee has determined that this proposal meets Criterion 2.

CHAIR BAILET: Thank you, Ann.

Criterion No. 3 is Payment Methodology, another high-priority criterion, pay the APM Entity with a payment methodology designed to achieve the goals of the PFPM criteria, addresses in detail through this methodology how Medicare and other payers, if applicable, pay APM Entities, how the payment methodology differs from the current payment methodology, and finally why the physician-focused payment model cannot be tested under current payment methodologies.

Please vote.

[Electronic voting.]

* **Criterion 3**

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

The majority of the Committee has determined that this proposal does not meet Criterion 3.

CHAIR BAILET: Thank you, Ann.

Criterion No. 4 is Value over Volume, providing

incentives to practitioners to deliver high-quality health care.

Please vote.

[Electronic voting.]

* **Criterion 4**

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

The majority has determined that this proposal meets Criterion 4.

CHAIR BAILET: Thank you, Ann.

Criterion 5 is Flexibility, provide the flexibility needed for practitioners to deliver high-quality health care. Please vote.

[Electronic voting.]

* **Criterion 5**

MS. PAGE: Zero members voted 6, meets and deserves priority consideration. One member voted 5, meets and deserves priority consideration. Five members voted 4, and five members voted 3, meets. Zero members voted 1 or 2, does not meet; and zero members voted not applicable.

The majority has determined that this proposal meets Criterion 5.

CHAIR BAILET: Thank you, Ann.

Criterion 6 is Ability to Be Evaluated, have evaluable goals for quality-of-care costs and other goals of the PFPM.

Please vote.

[Electronic voting.]

* **Criterion 6**

MS. PAGE: Zero members voted 5 or 6, meets and deserves priority consideration. Two members voted 4, meets. Eight members voted 3, meets. One member voted 2, does not meet. Zero members voted 1, does not meet; and zero members voted not applicable.

The majority has determined that this proposal meets Criterion 6.

CHAIR BAILET: Thank you, Ann.

Criterion 7 is Integration and Care Coordination, encourage greater integration and care coordination among practitioners and across settings where multiple practitioners, their settings are relevant to delivering care to the population treated under the PFPM.

Please vote.

[Electronic voting.]

* **Criterion 7**

MS. PAGE: Zero Committee members voted 5 or 6,

meets and deserves priority consideration. One member voted 4, meets. Three members voted 3, meets. Six members voted 2, does not meet. One member voted 1, does not meet; and zero members voted not applicable.

The majority has determined that this proposal does not meet Criterion 7.

CHAIR BAILET: Thank you, Ann.

Criterion No. 8, Patient Choice, encourage greater attention to the health of the population served, while also supporting the unique needs and preferences of the individuals.

Please vote.

[Electronic voting.]

* **Criterion 8**

MS. PAGE: Zero members voted 6, meets and deserves priority consideration. One member voted 5, meets and deserves priority consideration. Five members voted 4, meets. Four members voted 3, meets. One member voted 2, does not meet. Zero members voted 1, does not meet. Zero members voted not applicable.

The majority of the Committee finds that the proposal meets Criterion 8.

CHAIR BAILET: Thank you, Ann.

Criterion 9 is Patient Safety, maintain or

improve standards of patient safety.

Please vote.

[Electronic voting.]

* **Criterion 9**

MS. PAGE: Zero members voted 5 or 6, meets and deserves priority consideration. Five members voted 4, meets. Six members voted 3, meets. Zero members voted 1 or 2, does not meet; and zero members voted not applicable.

The majority has determined that this proposal meets Criterion 9.

CHAIR BAILET: Thank you.

And finally Criterion 10, which is Health Information Technology, encourage the use of health information technology to inform care.

Please vote.

[Electronic voting.]

* **Criterion 10**

MS. PAGE: Zero members voted 6, meets and deserves priority consideration. One member voted 5, meets and deserves priority consideration. Two members voted 4, meets. Four members voted 3, meets. Three members voted 2, does not meet. One member voted 1, does not meet; and zero members voted not applicable.

The majority has determined that this proposal

meets Criterion 10.

CHAIR BAILET: Thank you, Ann.

Do you want to summarize our voting, please?

MS. PAGE: The Committee has determined that the proposal meets 8 out of the 10 Secretary's criteria. The two criteria that the proposal did not meet are No. 3, Payment Methodology, and No. 7, Integration and Care Coordination.

CHAIR BAILET: Thank you, Ann.

Are we ready to proceed with the recommendation to the Secretary? Yes.

So, again, here it's an electronic vote, and then we'll go around, and every individual will describe how they voted. There are four numbers: 1 is not recommend; 2, recommend for limited-scale testing; 3 is recommend for implementation; 4 is recommend for implementation with high priority. And the asterisk represents a not-applicable proposal, and then we will then describe how we vote personally. But please vote electronically at this time.

[Electronic voting.]

* **Final Vote**

MS. PAGE: Zero members voted to recommend the payment model to the Secretary for a high-priority implementation. Zero members voted to recommend the

proposed model to the Secretary for implementation. Three members voted to recommend it to the Secretary for limited-scale testing. Eight members recommended that it not be recommended as a proposed payment model to the Secretary, and zero members voted not applicable.

So the two-thirds decision of the Committee, which is determined by eight votes, is that the proposal not be recommended to the Secretary.

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

CHAIR BAILET: So thank you, Ann.

We'll start on this side of the room with Rhonda and work our way around, please.

DR. MEDOWS: So I voted in favor of recommending limited-scale testing. I wanted to be able to see if the impacts on the care management and the close monitoring of the patients and see more specifically whether or not it actually did adequately address the concerns around racial disparities, ethnic disparities, and ongoing care.

CHAIR BAILET: Bob.

DR. BERENSON: I voted 1, do not recommend, and I was somewhat conflicted because I think the care management component is actually quite potentially useful for a subpopulation. My concern was that for many patients, I think an established coding will be completely sufficient,

but that there is a -- that is actually an advantage of free schedules, is that you only apply certain codes when they are needed. So I'm concerned about windfall profits for affluent practices and when we want to really target this to a population where there is a real disparity issue.

I think the total cost of care is a nonstarter completely. I don't think that we should be holding urologists accountable and give them random rewards or penalties based on what happens to the costs of their patient population, which mostly has nothing to do with the prostate.

So I guess where I'm coming out is I don't think we're there yet, but I actually think this is something to work on. Whether it's an APM or whether it is to try to figure out how to modify or develop new coding in the fee schedule so that the support is there when it's needed but not when it's not needed, I don't have the solution right now. So I don't want to just send this home and never see it again, but I think this one doesn't quite make it.

DR. PATEL: I actually voted limited-scale testing, but I want to make it very clear in the comments to the Secretary that it's exactly for the reasons Rhonda underscored, that I do think that this notion of this tremendous disparity in care has to be dealt with.

I do not think the model, the way it is on paper, is exactly the way to deal with it, but I want to send a strong signal that given the preponderance of prostate cancer in the Medicare population and kind of the blind neglect in making sure that we have not just, as I think was pointed out by the submitters, African Americans, Africa Caribbean, Latino, basically kind of ethnic minorities of any kind, that we have some way to do this in the current program. So that's honestly what convinced me to go from a 1 to a 2.

CHAIR BAILET: Len?

DR. NICHOLS: So I voted to not recommend, but I would echo the sentiment and the statements that, in fact, what I have learned, including what I learned today, is that -- I mean, I knew the disparity issue in general, and I certainly learned it from the presenters. But I think hearing the public testimony drove it home in a way that made it more urgent, and so I would hope that what we could do in our letter is sort of articulate what Bob said.

This isn't it, but we ought to be working on this. The Secretary ought to be working on this. I am 40, maybe 60 percent convinced we could do this with a proper code, and they could tell us how to make the code. And believe it or not, the code might be quicker than what we

could do for you. But in any event, I think it should be expressed in no uncertain terms this is worth pursuing -- was bigger.

CHAIR BAILET: Elizabeth, you're on the line?

VICE CHAIR MITCHELL: Yep. I voted to not recommend. I was concerned it would not meet our criteria that it improve quality without reducing cost.

I had trouble connecting the payment change to the care change proposed, and then Paul's questions about coordinating and integrating care across providers, I was concerned about that as well.

I am completely in agreement with the need to urge attention and action regarding disparities and would like to include those comments in our letter.

CHAIR BAILET: Thank you, Elizabeth.

And I also voted not to recommend. Where I was challenged was, again, like my other colleagues before me, that the payment, I do think with some diligence that we could come up with some codes to reflect the effort that is required here. And I think if that focus is there, I'm confident that codes could be designed, and I think it was potentially Len or possibly Bob that talked about the speed to which we could get there based on where we sit and alternative payment models.

I think that potentially codes could take us there a lot quicker, but I echo previous comments about the need to do this for the disparity reasons, but also people are doing the work today. That's clear, and so I think they need to get recognized for their efforts and support it.

Thank you.

MR. STEINWALD: I also voted to not recommend, but I admit to being on the fence and might have been close to being persuaded to go the other way for two reasons.

One is I could imagine myself being a patient candidate for a model like this, maybe all --

DR. NICHOLS: It's not hard.

MR. STEINWALD: Not hard, right.

[Laughter.]

MR. STEINWALD: And I would like to have a care coordinator. I mean, I went through the experience with my mother-in-law that some of you know about, and having a care coordinator was really beneficial. And I could imagine it being beneficial to me personally.

I also buy the argument that we heard that it's maybe not enough just to let active surveillance evolve into being the prevalent treatment, not only to take care of the minority disparity problem, but also just to hasten

the movement there. I can imagine it needs a boost to get there.

But I also agree with Bob and others that it might be faster to get there with existing tools within the payment system as opposed to a brand-new model.

DR. CASALE: Yeah. I also voted 1, not to recommend, and like others, I'm fully supportive to the care management piece. I think that makes a lot of sense, but not supportive of urologists assuming total cost of care, and also, to Harold's point about, well, what happens after a year, since that was only for a year, which can also create some unintended consequences.

But emphasizing to either come back with a prostate-specific model with care management or look for a way to get a change in the fee schedule, again, it makes a lot of sense to me and fully supportive. And I think that message needs to go to the Secretary, you know, again, regarding the challenges around disparities and others and the importance of care management, given the ongoing needs to keep people sort of in the system. But it's that other part that I think made me decide on not supporting because of the total cost of care piece.

CHAIR BAILET: Thank you, Paul.

Harold?

MR. MILLER: I voted not to recommend. I do think it's important that we be clear to everyone why we said that, and I think others have said it well. But I'll just say it from my own perspective. I think the issue is important and needs to be addressed that there needs to be attention to encouraging active surveillance and supporting active surveillance particularly for the populations where there is a disparity.

I think that there needs to be a payment model to support that, I think, because to me there are two potential barriers. One is lack of adequate support for the shared decision making, patient surveillance, support, et cetera, and I think because of the financial disparities for the providers in terms of doing one versus the other.

So I think there needs to be payment model, and I'm not convinced that simply putting some codes in will do it.

I am troubled by having sort of just a flat care management fee. It seems to me that there -- what everybody has said is that there are disparities, which says to me that there probably needs to be some degree of risk stratification in that to suggest that people who have more challenges, et cetera, may need higher payments, and so that we don't end up saying, okay, we put a code in, and

guess what? All of the white middle class people are, in fact -- you know, now they're getting paid for the things that they were already doing for those people, and the others still aren't because there's not adequate payment for that. So I think that it needs something more than that.

I think we have to -- From my perspective, others can disagree with that, I think we have to send a strong signal that this notion of care management plus total cost of care, shared savings, shared risk is [not] a good idea, that it is not a good idea. And the fact that CMS has been doing this does not mean that everyone else should follow.

I fear that we will be down the road someday. Today, all we talk about is how bad fee-for-service is. We could be in five years talking about how bad all of these total cost-of-care models are that have been implemented because that was the flavor du jour in 2016 and 2017, and I think that we need to move beyond that to things that are more patient-centered, and that is not a patient-centered model. And having everyone fighting over total cost of care is not a patient-centered model.

And I believe in this particular case, there are some fairly severe risks to the patients. While we may be encouraging active surveillance by paying for it, we may be

under-encouraging treatment where it's necessary because of the notion that if we delay your treatment by a year, we'll save a bunch of money and be able to get a bonus. And I think that is not a patient-centered model, and I don't think it's appropriate.

My concern with this proposal is not only that I think that it doesn't make any sense, I think it's actually problematic in terms of patient safety and patient choice to create such a strong incentive in the other direction.

So I think it needs to be fixed. I don't think it -- I don't -- my perspective, it shouldn't be tested as it is proposed. I think it should be fixed, and I would strongly encourage the applicant to come back in with one of those options that they were thinking about but didn't propose, to come in, and I would further say that I think the goal should be getting good patient care and adequate support for physicians, and that the goal is not getting five percent bonuses and getting out of MIPS. And I think that the people chasing being an advanced alternative payment model, without adequate concern for the patient, concern, I think we need -- we need to stop that.

So, anyway, I think we need to send a message that we need better payment models than that, and this is a good opportunity to do that.

CHAIR BAILET: Grace?

DR. TERRELL: I was one of the people that were on the fence and ultimately voted not to recommend.

My concerns had mostly been articulated with respect to the payment model just wasn't right.

On the other hand, the amount of thoughtfulness and care with which they had actually fleshed out the care model was far more flexible than I had gotten just from reading the material. So I thought that the public testimony today was very helpful not only in articulating the disparities and the issues around that, but in a very thoughtful approach about how this could be more flexible than I had thought with respect to some of the coordination and integration with other providers. So I very much like that.

But ultimately, the concepts around tying this to the total cost of care, to my mind, looked like a stretch as it relates to becoming an advanced alternative payment model, which like Harold and some of the others of you have articulated, I think is problematic in general.

Having said that, I think from what I was also hearing, the current chronic care or counseling -- because there's something different between chronic care management and counseling, and one of the things I was hearing in this

was that what their work product is, it's more than chronic care management as it's currently construed in the codes. It's almost to what Bob was getting at, the real function in the doctor-patient relationship -- it may be another provider doing it -- about walking them through one of the most difficult decisions that they have to go through when they're -- in their lives, which is how am I going to either live knowing that I've got a cancer and just go through a trusting process with a provider to sort of take this watchful waiting approach or go for sort of a potentially curative intervention now, which can lead to some very, very profound side effects that we're all aware of.

So I think that perhaps one of the things to be thinking about, when I encourage you to bring another version of a care model forward would -- really to articulate this very unique function that you're talking about, which is more than chronic care management, per se. It's the counseling, behavioral, doctor-patient interaction and how you would value that in a way that would get at all the concerns that many of the public speakers articulated quite effectively.

CHAIR BAILET: Tim.

DR. FERRIS: So I voted for limited-scale testing

for exactly the same reason that my other colleagues voted for it and mainly to highlight the issue of the -- I don't think it's too strong to say the national disgrace about the disparities in care for prostate cancer.

So while that was the rationale for my difficult choice between the two, I also agree with all my colleagues who made a decision not to recommend for exactly the reasons that they chose.

I think slightly different than what Grace just said. So I counsel patients about active surveillance for prostate cancer all the time. Most primary care doctors, most internists do.

My patients who have elevated PSAs and get intermediate biopsies talk to their urologist, who tends to have a particular recommendation, and actually, they go to different doctors, and they get different recommendations. And that creates a really interesting dynamic among providers.

And so one of the things that I liked about this in the coordination aspects of what they are proposing in theory was that actually getting the doctors all on the same page is essential to the choice of the patient because the doctors -- if the doctors are giving -- it's hard to imagine a urology patient not having more than one doctor,

meaning at least a primary care doctor and a urologist and maybe an oncologist and a radiation therapist.

If those doctors are giving a different message, the default will be to treatment, and so while I am very sympathetic to the model, the care model, I didn't see the articulation -- and I think Paul was pointing this out -- most specifically among the different providers because if it's just the urologist -- and I want to be careful here. They didn't say that the model itself could be just for urologists, but the model itself didn't actually propose making sure that all the different providers were on the same page, and that to me is the core of the decision and the patient's decision about active surveillance versus an intervention, getting them all on the same page.

So I saw mismatch between the proposal and the goal of the proposal, and therefore, I couldn't actually see the way in which the proposal would actually end up doing the job of reducing the disparities and getting more people on to active surveillance.

But I will also say I don't know what -- as someone else, several other people said, I don't know what the answer is, and so limited-scale testing, sure, like absolutely, because we've got to try something, and we've got to try it soon because, as I started off by saying, it

is a national disgrace to have the situation that we're in today.

I do also have to say -- and I think a couple people said this, but it makes me uncomfortable to recommend that we need a payment to do the right thing. I find that to be a problematic situation, and I get where we are now in that the situation is not the way it should be, and so I agree that passively waiting is not acceptable.

There's something about this situation that we don't understand when there's clear guidance about what the right thing to do is, and such a large proportion of physicians in the United States are not following that guidance. There's something else about this, and maybe it has to do with the fact that our patients are getting multiple different opinions. And so by not being on the same page, the default is to be what I'll call conservative and go for an intervention.

So sorry for going on and on.

CHAIR BAILET: Thank you, Tim.

Adele, I think it would be helpful if you -- well, maybe before we do that, if we could just -- I've heard several points along the way where people wanted to go on record and make sure that the letter to the Secretary contained certain specific comments and positions, and

maybe we should just spend a minute because we want to make sure we're clear on that. And I don't know whether it would be Adele or Ann -- or Adele would be the best person to go ahead and try and capture that for us.

DR. SHARTZER: Sure.

So there was a clear indication that the PTAC feels that this is an important issue, that work should continue, that their decision not to recommend this is sort of the close of the chapter, in part, because disparities in prostate cancer treatment are such a disgrace, so that will be a key point.

I will also mention that the PTAC was concerned about the total cost of care in this model, and that potential revisions by the submitter would be considered, and that HHS as a department should continue to think about ways to support AS for patients. Those were the big ones.

There was some mention that existing tools that are within the realm of CMS may be faster and in fact more effective at addressing this issue.

Is there anything else? Okay, go ahead.

DR. FERRIS: Yeah. I just wanted to emphasize the point that I think the actual coordination among physicians caring for an individual patient is a critical component of getting patients onto AS, and that that should

-- again, we'll have to decide if everyone else agrees, but to my mind, any proposal that comes back needs to address that, that point, from my perspective.

CHAIR BAILET: Harold?

DR. NICHOLS: I don't think we said it, but I'd like to say it now, so thanks for this opportunity.

You know, the presenters talked about this registry database, and I believe the statement was we know these four things, but we don't know why. We should damn well be answering the question why out of that database to the degree we can. So I would encourage us to put that in the recommendation to the Secretary as well, because that's something that could be done while we work on the codes.

DR. SHARTZER: There was also some support for the care model that was portrayed, so I'll mention that.

CHAIR BAILET: Harold.

MR. MILLER: I want to endorse what Tim said and just to add onto it just as more color commentary, if you will, is I think that -- while I think it's great that we have specialty societies bringing us models, but I do think that when there are multiple specialties involved in a particular aspect of care, that it will be helpful to have all the specialties supporting what's being done and involved in that approach.

The other thing that I said that I want to make sure is captured if everyone agrees with it is I think there should be some thought given to stratifying the care management payments because I think in some sense, it gets at this issue that Tim also raised, which is that if it's easy to do, then it should just be done. We shouldn't be paying as an incentive to get it done, but I think there are -- clearly, we've heard that there are challenges to doing it, and that the patients who need that support, that there needs to be adequate payment for that.

So instead of -- to me, the notion of simply paying for everybody the same amount, I think having some differentiation. Whether that means nothing for some and something for others or whether it means something for everyone, but a higher amount for people who have more challenges, and how that would be defined, I'm not sure, but it seemed to me clear from what I was hearing that there were different populations who had different intensities of needs. And if we're trying to fill a gap, not give incentives – we’re trying to give incentives, but I think we're trying to fill a gap. We should have the gap filled and match the cost of filling that gap.

CHAIR BAILET: Thank you, Harold.

Bruce and then Bob.

MR. STEINWALD: Just to maybe elaborate a little bit on what you referred to as the tools that currently exist, I think what we were getting at -- and I'll use Harold's language, if others agree -- is to urge the Secretary to determine if the payment system as it's currently formulated can be adapted to accomplish the goals that this proposal articulated, and that could also be expanded to include to directly address the disparities issue. So it's sort of a two-part process. First, let's see if we've got what we need to accomplish the goals within the current payment system, and then if not, then move on to developing a payment model that gets at those objectives.

CHAIR BAILET: Bob?

DR. BERENSON: And that picks up where I was going to be. Harold suggests we really need an alternative payment model with a care management fee, which is then -- I mean, which is stratified for different populations.

Grace suggests that -- which I agree with, that the E&M codes can be used for counseling, and I don't really know to what extent that would cover Navigators and others incident to.

This just brings up the same issue. I don't think it goes necessarily in this report, but we have no

communication directly with CM. I think it would be -- both for technical help in trying to figure out what is doable, perhaps through the Secretary, something would go to them, but this whole -- our whole operation is focused on CMMI and alternative payment models, and we keep coming up with, well, maybe we can accomplish this through the fee schedule, and yet we don't have the technical knowhow in some cases to really answer that question.

So we've all said, well, maybe this can be accomplished through the fee schedule, and I don't know how we're going to institutionally have access to the decision-makers over there to get them to work with us and the proposers to try to figure out.

Now, my guess is that there are some urologists doing active surveillance who have done some work-arounds with the Medicare fee schedule to get some payment, whether they're using established coding or being creative in the use of some codes, but once we sort of understand the limitations, but also the potential, I think we'd all be in a better situation.

Everybody is coming to us to solve a problem. Now, I don't know whether they actually did go and try to get some coding and that never -- so I guess all I'm basically saying is I think organizationally we've been

sort of put in with alternative payment models, and we need somehow some -- I mean, I think it would be very useful if, for example, there was somebody from CM who works -- there's only nine people, as I understand it, who work on the physician fee schedule, whether they could actually be here for two days while we were doing these reviews. We probably could have a debrief with somebody. That to me would be much more effective than just sending in a letter to the Secretary to say here was the problem, here is what we want to pursue as -- can the fee schedule currently or with some modification be used to address this issue.

Do you see what I'm saying?

MS. STAHLMAN: Sure.

I wonder, Bob, if you think it would be helpful to bake some of that into the PRT process, so it happens earlier and not here.

DR. BERENSON: I think that's right.

DR. NICHOLS: I mean, in a way, Kavita did research this to the degree she could on her own, right? And that's what happened, and so I totally agree with baking it into the PRT process.

MS. STAHLMAN: And somehow the PRTs have --

DR. BERENSON: Yeah. No, getting some technical expertise early on as to what are the limitations, what is

the potential.

I mean, clearly some of the shared decision-making activities, I would think would be covered by the sort of variation of the E&M coding which permits more than 50 percent is counseling, you bill it.

MS. STAHLMAN: Some of the PRTs clearly have reached out to CM, either directly or through the staff, and we should maybe be encouraging the PRTs to do more of that, and so we'll be doing that.

DR. BERENSON: Okay. So that's all I'm suggesting. I don't think that goes into the report.

I honestly don't know whether the right way to do this is through an APM or whether it is through just some coding because coding allows you to say, "Well, for this patient, I don't need to do that. For that patient, I really do need to do that," as opposed to stratifying a care management fee, which is an alternative way of doing it.

CHAIR BAILET: Kavita.

DR. PATEL: Just really briefly, we heard already the submitters put two-plus years of effort into this, so saying that we do not recommend, I want to underscore -- I think Paul said it, Harold said -- several of us have said that there is a very ripe window of opportunity to revise

and -- and am I going to get myself in trouble here? Can I say revise and resubmit? But highly encourage this group to not let these two-plus years kind of go to waste and to consider taking some of this to modify and I think making this more appropriate for us to then be able to recommend to the Secretary.

MR. MILLER: And please don't take away any bad feelings you have about the experience so far to discourage you from coming back in with a second proposal.

CHAIR BAILET: So I personally want to thank LUGPA for the efforts, the public members who came and spoke on behalf of their proposal. This is an issue that needs to be addressed. We're going to use, as best we can, the tools at our disposal to make these challenges known because clearly it's not working as best as it can, and we need to lean in where we can. And resubmission, the Committee stands willing, ready, and able to work with you as you think about potentially refining this proposal. We're here, and we have a commitment for resubmission, a resubmission process that's streamlined, and we're here, ready, willing, and able to work with you on that.

So, thank you.

We're going to take a 10-minute recess before we get to the last proposal. Thank you.

[Recess.]

Minnesota Birth Center: A Single Bundled Payment for Comprehensive Low-Risk Maternity and Newborn Care Provided by Independent Midwife-Led Birth Center Practices That Are Clinically Integrated with Physician and Hospital Services

*** Committee Member Disclosures**

CHAIR BAILET: Okay. We are going to go ahead and complete the proposal reviews for this public meeting, which the last one is the Minnesota Birth Center, a single-bundled payment for comprehensive low-risk maternity and newborn care provided by independent midwife-led birth center practices that are clinically integrated with the physician and hospital services.

Rhonda Medows, Dr. Medows, is the PRT lead, and before I start, we are all going to go around and talk about conflicts of interest and introduce ourselves again.

Jeff Bailet, EVP (executive vice president) of Health Care Quality and Affordability with Blue Shield of California.

And we're going to start with Tim and then with Rhonda, and then, Rhonda, you got the wheel. Go for it, Tim.

DR. FERRIS: Tim Ferris, primary care internist

at Mass General and CEO of the Mass General Physicians Organization. No conflicts.

DR. TERRELL: Grace Terrell, general internist at Wake Forest Baptist Health and Chief Executive Officer of Envision Genomics. I have nothing to disclose.

MR. MILLER: I have a thing I have to read, and I didn't have it. Sorry. Harold Miller. I do have a disclosure.

So I have provided, for whatever worth it was, pro bono assistance to the Minnesota Birth Center and its founder, Steve Calvin, at various points over the past eight years. I'm very familiar with their proposal, and I've invited Steve to give presentations about various conferences I've helped organize and moderate.

I have not been directly involved in preparing the proposal. I have actually encouraged many payers and maternity care providers to pursue similar approaches, but I have had no involvement in this particular proposal. It wouldn't have any direct effect on me, but I'm going to recuse myself from participating in the vote on this because of my past involvement, because I don't want any impression of bias. So.

And Harold Miller, CEO of the Center for Healthcare Quality and Payment Reform.

DR. CASALE: Paul Casale, cardiologist, executive director of New York Quality Care, and I have no disclosures.

MR. STEINWALD: Bruce Steinwald, a consultant here in Northwest Washington -- actually, we're not in Northwest. We're in Southwest. So. But, anyway, I have nothing to disclose.

CHAIR BAILET: And I have -- Jeff Bailet. I have no disclosure, and also Elizabeth Mitchell, who will be joining us momentarily, she is the CEO of the Network for Regional Healthcare Improvement. She has nothing to disclose.

Len?

DR. NICHOLS: My name is Len Nichols. I direct the Center for Health Policy Research and Ethics at George Mason University, and I have nothing to disclose.

DR. PATEL: Kavita Patel, general internist at Johns Hopkins and a Fellow at the Brookings Institution. Nothing to disclose.

DR. BERENSON: I'm Bob Berenson. I'm a Fellow at the Urban Institute, and I have nothing to disclose.

DR. MEDOWS: I'm Rhonda Medows. I'm executive vice President for Population Health at Providence St. Joseph Health. I have nothing to disclose.

*** PRT Report to the Full PTAC**

DR. MEDOWS: And we will move forward with this discussion.

We have before us a proposal from the Minnesota Birth Center. It is entitled, as Jeff has already read, "A single-bundled payment for comprehensive low-risk maternity and newborn care provided by the independent midwife-led birth center practices that are clinically integrated with physicians and hospitals."

We can start with our usual protocol about the Preliminary Review Team, its composition, and role. The chairman and co-chairman actually have appointed three members to this Preliminary Review Team, which includes Dr. Grace Terrell, Dr. Len Nichols, and myself. The team itself has the ability to request additional information to help in its review and assessment of the proposals. We have taken advantage of that and asked through ASPE for additional data to be pulled to us on the volume, the number of patients who have been pregnant in the Medicare population, as well as doing some follow-up work to try to help assess the number of low-risk pregnancies in the Medicare population.

In addition, we've had some information come in from a consultant, an OB/GYN from University of Penn.

We also want to recognize the input provided by members of the public, including the American Association of Birth Centers, the Minnesota and Washington chapters of the industry association, as well as individual certified nurse midwives, some of whom are actually owners of birth centers but are independent.

The review team met several times to discuss this proposal. Our findings in our report are opinions of our own. They are not binding for a PTAC. PTAC will then hear our presentation today as well as from the submitters themselves and any public comments available and then reach its own conclusion.

So if I can talk about the actual summary of what the proposal includes, I will have to tell you that this is a proposal that we had much discussion about for several reasons. But starting with the model overview, it is proposing in concept a bundled payment for perinatal episodes of care. The perinatal episode of care includes women, their nine months of pregnancy, as well as eight weeks postpartum, as well as newborns for the first 24 hours of life. This is a provider-directed proposal led by certified nurse midwives that are the leaders in the care.

The applicant also describes having an integral physician involvement and also describes having a

subcontract with hospitals and hospital-based clinicians.

Low-risk pregnancies was defined by the applicant's list of 15 areas of exclusion. We did receive additional information from the American Association of Birth Centers, as well as the OB/GYN consultant, as well as some other additional information coming in from some of the submitters, public submitters.

The care model being proposed is that there would be cohorts of 250 to 300 pregnant women who would receive care from a four-to-five-member team. The members of that team would include certified nurse midwives, doulas, patient educators, lactation specialists, et cetera.

And the applicant describes their use of a collection of services that are used today in a BirthBundle that is used for self-pay patients. That BirthBundle, the collection of services, are not, however, used in payments received by them from Medicaid or commercial payers. The applicants do note several times throughout their proposal that Medicaid and commercial are the primary payers of care for pregnant women and for newborns, and they acknowledge that Medicare is not the primary payer.

Key to our discussion today are several issues that you can probably call right off the bat. Number one was the concern about scope. We initially received the

application -- if I can be as frank as possible, we were concerned that this was not an appropriate venue for a bundled payment model for a population that is really traditionally treated -- I'm sorry -- paid for through Medicaid and commercial itself.

However, we decided to do two things. One was to confirm that what we believed was probably true, that the number of pregnancies in the Medicare population would be low, that the number of low-risk pregnancies would be incredibly small, given the eligibility to criteria for the Medicare population, including age, chronic condition, and disability.

We also wanted to make sure that we had the opportunity to have some discussions with some of the members not only in the community, but also get some input about what we were hearing, and that was the consideration that CMS may decide to include Medicaid as a payer in addition to Medicare on MACRA or other payment models that were being proposed. And so we took a little bit of time to get the data pulled together. We learned that there were 22,000 pregnancies paid for my Medicare in 2016, 261 of them in Minnesota itself, the home of the applicant. But we also understood and found that for every patient that we identified, that the majority of them had comorbidities,

had chronic conditions that basically would not allow them to be categorized as low risk. Most would be high risk, as we suspected.

In the interim, we actually did learn from CMS and from our ASPE contact that the CMS final rule on MACRA and alternative payment models did not move to include Medicaid as a payer in the program.

At that point, we came to having some really engaging conversations amongst ourselves on the PRT, and that conversation went something along the lines of this. This isn't an appropriate model for us to review now that we know that there are very few actual patients who would be served in this, under this model, and very few patients I am talking about are pregnant women.

But we also recognize that the newborns that are included in the model would not be covered by Medicare because they are not currently part of a Medicare eligibility category.

What we decided to do was to proceed with evaluating what was put before us and commenting on that, what we thought were the strengths of what was in the proposal, and then to speak to those things that were missing or that could be beefed up in a subsequent proposal to an appropriate payer.

We did have the conversation and wondered, and so we can ask the question when the presenters -- when the applicant comes about what were the next steps in terms of engaging Medicaid, whether it be the Medicaid managed care programs, the state Medicaid program, or the federal CMS Medicaid program about payment models and their development.

We also thought that we would also ask them about commercial partners, whether or not they had pursued that again.

Okay. Here is the other problem, the other issue that came up, and that was in the proposal, even though the applicant speaks to the concept of a bundled payment, the bulk of the rest of this part on payment methodology focused on asking us to help them create the payment model itself.

They spoke to some of the benefits of having a bundled payment, which is basically the effort to actually focus on care, low intervention, and basically trying to reduce unnecessary services -- interventions and hopefully have a better outcome. However, there was no actual payment model proposed.

The request for us to co-create or create with them a payment model is something that you understand we

would have to decline. We are in the business of evaluating payment models proposed but could not co-create one.

In addition, we noted some of the concerns that they had expressed, and they did talk about in their payment application -- I'm sorry -- in their proposal the part about being concerned that if they were to pursue a payment model with Medicaid, the concerns that it would be based on Medicaid previous rates, current low rates, the concerns about whether or not some of the outliers could be addressed in other insurance products or other methodologies, and then the concerns and probably a more realistic concern about whether or not partial payments could be made up front or at least midway through a pregnancy to help take some of the financial burden off of the caregivers.

I'm going to skip this part and go right to individual categories.

For Criterion 1 on Scope, the PRT reached a conclusion that this was not meeting the criteria. While we think the concept is truly worthy of further consideration and development, a bundled payment model for low-risk maternity care and newborn care seems best suited for Medicaid or commercial payers. It does not seem to be

appropriate for the Medicare population given the exceptionally low volume of pregnancies that could be determined to be low risk.

In addition, we believe that the inclusion of the newborn actually is out of bounds, as newborns are not covered by Medicare.

The PRT found that they did not meet the criteria for scope, one of the high-priority areas.

Criterion number 2, Quality and Cost, where the goal is to actually either improve quality or to maintain quality while reducing cost, the PRT reached the conclusion this also did not meet criterion.

We appreciated that the applicant proposed that it be mandatory that a birthing center be licensed and accredited to ensure some level of proficiency and actually effective treatment for perinatal care, but we noted that there was a distinct absence of any quality measurements, commitment to quality improvement, targets for quality improvement, or very specific performance measures for cost management or cost reduction.

They did have a great deal of discussion about the potential for cost reduction that would be related to lowering the number of interventions safely and to also reducing facility fees for those pregnancies that could be

delivered in the birthing center as opposed to the hospital.

The PRT's conclusion was that this did not meet the criteria.

Criteria 3, Payment Methodology, I've kind of discussed with you. While they talked in concept about bundled payments, they did not actually propose a payment model for our review and assessment. We noted several of their concerns as well as issues being brought forward, but again, no payment model was presented for review.

The PRT reached a conclusion that this did not meet the criteria.

Criteria 4, Value over Volume, the proposal discusses the importance of actually providing high-touch, low-technology care, the importance of having prenatal care be delivered in a manner in which the patient, meaning the pregnant woman, has a preference for, but also making sure that there is not overuse of ultrasounds, continuous fetal monitoring, et cetera.

The model does address financial incentives inherent to actually improving the care for the patient as well as actually being able to use in these cost savings by more appropriate low -- and low-tech care to then be used and redirected for those few instances where there was more

complicated care and requiring higher cost settings, such as a hospital.

Criterion number 5, Flexibility, the proposal does discuss the flexibility within the care team at the birth center. It discussed flexibility between the certified nurse midwives as well as the doulas, the patient educators, lactation specialists, et cetera. It does discuss also the coordination between the care team as well as the perinatal hospice in the event that there is a poor outcome after a delivery, and it also discussed the subcontract role with hospitals as well as hospital-based clinicians.

However, in the submitted comments from the public, there were concerns expressed by certified nurse midwives in smaller practices as well as those that are in practices that are not associated with hospitals or physician practices, that this would not be a model that would be inclusive to them. They had concerns that this would be changing the way that they approach the care of the patient.

We would like to see in any kind of a follow-up, or in the next iteration for whichever payer they are providing information to, that they actually kind of map out what the relationship would be for the hospital, for

the clinicians that they are working with outside of their care teams.

For Flexibility, the Committee did not believe that this met criterion.

The Ability to Be Evaluated, Criterion 6, this is where we reached the point where we realized that without an actual payment model, without quality measures, without cost reduction measures, it's pretty hard to evaluate whether or not this would be an effective model.

We did note their mention that they had different sources of information, that they did collect data and report it to the American Association of Birth Centers, that they did do a consumer survey. However, it's very difficult to say how we can evaluate the effectiveness of evaluating them without, again, a model.

PRT conclusion is that this did not meet criterion.

Criterion 7, Integration and Care Coordination, this proposal did discuss, once again, the care coordination that would occur between the actual birthing center care providers themselves. It discussed the importance of care coordination. It discussed the importance of making sure that they coordinate with perinatal hospice. It does not, however, discuss a very

specific plan to improve care coordination or integration. This is an opportunity for them in subsequent proposals to actually address very specifically their efforts to do care coordination between themselves, hospital-based clinicians, and as one submitter did present in the public comment, coordination between the providers taking care of the mother along with providers taking care of the newborn.

The PRT conclusion was that this did not meet criterion.

Criterion number 8, Patient Choice, this was one of the areas where we felt that the applicant discussed multiple times the importance of patient choice, the opportunity that there be options other than traditional perinatal care, the opportunity to use birthing centers, to use a whole host or different array of different health care providers, including the certified midwives, the RNs, the LPNs, the physicians themselves, as well as a choice of setting.

We believe that this particular criterion was met.

Criterion number 9, Patient Safety, while the proposal does speak to, again, licensure and certification in terms of level of quality of care being provided and it discussed low-risk pregnancies, we did receive additional

information that made us think hard about the need to expand the list of exclusions that were given to us by the submitter.

The submitter listed 15 different chronic conditions and situations that would actually basically move the patient from low risk to high risk, but we received additional expanded lists from the American Association of Birth Centers as well as from the OB/GYN consultant. When we looked at that list, we felt that this proposal needed to be further enhanced to be more inclusive of those items, those issues that would actually raise the risk of the patient.

What was also missing from this proposal was we would like to have seen recommendations as well as measures for improving patient safety actually for the care that they would receive in the birthing center, the care coordination between the birthing center to the hospital when complications arose, and overall performance measures that actually would indicate good outcomes for the patient, meaning the woman, as well as the newborn itself.

We believe that this criterion was not met.

And finally, Criterion number 10, Health Information Technology, the applicant speaks to the grassroots nature of their efforts pulling this together.

They mentioned briefly their use of AthenaHealth Tool. They did also mention that some other groups were using the Prometheus analytics, but they did not present this as a proposal for recommendation to be included in the model.

We would like to have seen a recommendation and a plan to actually improve how health information technology can be used in this model.

CHAIR BAILET: So I open it up to the other colleagues who participated on the PRT for any additional comments.

Tim?

UNIDENTIFIED SPEAKER: [Speaking off microphone.]

CHAIR BAILET: No. That would be Grace and Len.

DR. TERRELL: I think Rhonda summarized in great detail and have nothing in particular related to this proposal to add, but I did want to broaden it in terms of thinking about our approach to this versus the approaches yesterday that were not applicable with the two other models because I think you can tell from Rhonda's presentation that we did a considerable amount of work on this, even though we more or less determined up front that it wasn't applicable, relative to what we learned was our sort of charge, which is much more of a Medicare-centric population, with scope being only one of the problems.

But nonetheless, we went through the details of going through this criterion by criterion. So irrespective of what happens with this, as we have our broader conversation about yesterday and that methodology that we used, this, to your point, Bruce, is a different perspective and approach to that. I think it will enrich us as a PTAC to have had this experience today relative to the others, and so that we can, as you said yesterday, learn from what might be an efficient approach in the future.

CHAIR BAILET: Bob?

*** Clarifying Questions from PTAC to PRT**

DR. BERENSON: Yeah. Just to follow up on that, if you had known like right up -- in retrospect -- in retrospect, if you had known the statutory state of Medicaid, that it wasn't included, would you have gone through the whole review, or was it that you were already down the road, so you figured you'd just continue?

DR. MEDOWS: Would you like me to answer that question?

DR. TERRELL: Yes.

DR. MEDOWS: Okay. All right.

We were trying to accomplish multiple things. We wanted first to actually have an opportunity to encourage a

bundled payment model for perinatal care, even though we felt we -- and we got confirmation that the Medicare program would not be the appropriate place for it.

We were actually hoping that the alternative payment model would be expanded, but when we realized that it would not be, we kind of figured we were pretty far along at this point. So what we thought we would do is we would evaluate what was given to us in the proposal and then come up with those -- the information or concept that we would relay back to the applicant about how to improve.

But here's kind of the issue, Bob, also. We're talking to them about how we would improve it based on our own criteria, with the understanding that in actuality, it's going to be a Medicaid issue or a commercial issue, and there may be completely different criteria that they would have to hit, but we can only tell them what we know.

So we know that they need to have concrete quality measures. We know that they have to have some kind of a way to not only assess but also plan how cost reduction should occur if that's part of their model.

They have to have all these things laid out, and so we thought the least we could do is actually speak to those things that we believe that they would need as a basic element of a model.

Does that make sense?

DR. BERENSON: Yeah. No, it does, but let me ask now a substantive question. There is a code for maternity care, which is the whole nine months, the whole nine yards, and then separately, after delivery, care for the infant is by a pediatrician. This also includes the facility fee, which I think might be a flashpoint for some.

I guess my question is: “What is the problem that this would solve?” I mean, there's a reference to fragmented care. So do they use the code for the maternity, and that is not fragmented, but then it is this hand-off problem? What is the problem here?

DR. TERRELL: I'm not sure that we completely got that answer in our evaluation.

Some of it, I thought might well be associated with the place of service itself being birth centers relative to hospitals and other places, where codes are, but I don't know that we know that for sure. It seemed to be a lot of it was focused on the unique nature of not only their care model, but their site of service. I could well be wrong about that, though.

DR. MEDOWS: As well as their focus on lower interventions.

DR. TERRELL: Yeah.

DR. MEDOWS: There were high-touch low interventions, and they wanted to propose something that actually would take the perinatal care, the newborn care, the actual delivery itself, and put it into one combined model, hopefully at a lower cost. But I can't really say that because, again, I don't have a payment model.

DR. TERRELL: Yeah.

DR. BERENSON: Were there -- and I'll stop with this question. Did they have support from the relevant pediatric practitioners and facility, the birth center, that they wanted to be part of this model, or was this just the birth -- the practitioners, the midwives?

DR. TERRELL: They got it from the birth center.

DR. BERENSON: I see, okay.

DR. TERRELL: I don't recall anything --

DR. MEDOWS: So there were multiple public statements that came in. All of them were around the birth centers or the certified nurse midwives.

DR. TERRELL: Yeah.

DR. MEDOWS: I did not see any responses come in from pediatricians, family medicine, OB/GYN specifically, but there was conflicting opinions in those submissions.

DR. BERENSON: Oh, okay.

DR. MEDOWS: Some in support and some raising

some concerns.

CHAIR BAILET: Are you done, Bob?

DR. BERENSON: Yes. Without my microphone on.

CHAIR BAILET: Okay. Very good. So, Tim.

DR. FERRIS: So picking up on the line that Bob was going down, I think I read six months ago in a JAMA paper about the explosion of birth centers in the United States, and what I see is an economic driver, which is there is a nine-month bundled payment where if you -- you actually can make a margin in a birth center, whereas in hospitals, it's not so much.

And so without knowing the state of play of the industry, based on reading that one paper, I was under the impression that what was being encouraged in this model is actually happening. And so I was confused by the fact that there was sort of new -- hospitals are opening up birth centers near the hospital in every city in the country, and so I just wasn't -- what problem -- and this is what -- I guess what Bob was asking. What problem is it we are trying to solve here?

And if it's the role group issue, it seemed to me the incentives are also aligned with that. So having the clinical nurse midwives doing the work of the delivery, I'm also told that is sort of exploding across the country

because, again, the economic model already encourages that, to have sort of an OB/GYN supervision for that crash case that you need, but that basically otherwise the OB/GYNs are not the principal caregivers.

DR. MEDOWS: So, Tim, I have to tell you that we are in -- personally, we are in different states that have different levels of acceptance of the model, and then we have different levels of acceptance by payers.

I know that we have payers, commercial payers, that will actually support this kind of a model, but based on what was in the proposal, not so much where the Minnesota Birth Center was concerned. They were not getting that level of support.

When they come up, they can kind of speak to what their engagement has been with commercial payers, and they can speak to the engagement that they have had with Medicaid, whether it's the managed care plans or the state, et cetera. That's probably one of the burning questions on our minds.

But the model is going toward the lower cost center, so much so that I know that in some of our hospitals for some of our OBs, they actually have created their own birth bundle payment that's at a lower cost, where they actually basically have to eat a little bit of

the facility fee, kind of drop it down to be able to be competitive, right? But at the same time, one of the smarter things that I think folks -- we've done is not only made the case for it being lower cost, comprehensive package, bundle for prenatal, but to look at the cost savings, particularly for the Medicaid populations overall, not just at the price of those services.

DR. NICHOLS: If I could --

DR. TERRELL: One of the issues, though, is our lack of ability to analyze data because our data was limited to Medicare. So a lot of the penetrating questions that you all may be curious about, we had limitations in our ability to actually investigate once we concluded that the scope was outside of what we thought was within our purview.

CHAIR BAILET: Len.

DR. NICHOLS: I think we should ask the applicants, but, Tim, I think the situation was that the Minnesota Medicaid didn't agree to go with the bundle for these people, and so they had hoped that we would see the wisdom in the bundle and thereby inspire colleagues to adopt a similar approach.

CHAIR BAILET: Bruce?

MR. STEINWALD: Yes. So I'm having this feeling,

and I'll express it this way, that a defense attorney representing a client says, "Your Honor, my client was 100 miles away when the crime was committed, and besides, it was self-defense."

[Laughter.]

MR. STEINWALD: You've heard that? Well, maybe now.

DR. BERENSON: We have now.

MR. STEINWALD: So what do I mean by that? So I'm not sure why we should be discussing what the problem is that they were trying to solve with a proposal that doesn't really fit within our purview. It's just barely a Medicare scope, and even that's arguable. And then they didn't present a payment model.

So I guess I'm back to where Grace started out, and it's sort of asking, “What did we learn from this? Is there something that really distinguishes this from the ones that we evaluated yesterday and said were not applicable in just about every respect?” And I guess I'm not feeling it, not really.

I understand when you were down the road a piece and you decided to go the rest of the way, but I guess I'm still wondering about the lessons learned.

DR. TERRELL: Yeah. We didn't know any better.

You all took one approach, and we took another. My remarks were sort of a compare/contrast the usefulness of it, I think would be the way to think about it.

DR. MEDOWS: We could have gone either way. We could have said not applicable, but I can't say that, so we went with the path of least resistance.

But in all seriousness, we wanted to also make sure that we were very cautious about not giving a negative view to something we still think has merit that needs to be fleshed out, needs to be built. Because of the populations involved, it's just simply that it's not a Medicare population that needs this.

CHAIR BAILET: Any other comments from the Committee?

[No response.]

CHAIR BAILET: Then not seeing any, I'd like to bring the submitters up to the front here.

Dave, are you flying solo?

DR. CALVIN: I am flying solo.

CHAIR BAILET: All right. Very good. Welcome.

DR. CALVIN: [Speaking off microphone.]

CHAIR BAILET: Yeah, please.

*** Submitter's Statement, Questions and Answers, and Discussion with PTAC**

DR. CALVIN: Very good.

So I just had a brief statement as well. Mr. Chairman, members of the Committee, I'm Steve Calvin. I'm an internal fetal medicine physician specialist and Medical Director of the Minnesota Birth Center. About 40 people work there. There's one other Y chromosome. He's the IT guy. The rest are all X chromosomes.

Like a good birth, I will keep my comments brief, and that would be a good -- a quick birth for both mother and care provider, with a minimum of pain.

[Laughter.]

DR. CALVIN: So the Minnesota Birth Center does appreciate the review of our proposal for bundled payment for midwife-directed maternity and newborn care for low-risk pregnancies using birth centers and then integrated with the medical system.

We know that the members of this Committee serve as volunteers, and we do appreciate the long hours that you provide in this important work.

We appreciate the work that the PRT did in the initial assessment of our proposal and the complications that I think that we have put into that. The PRT conclusions on our proposal were not entirely unexpected. We knew that the PTAC is focused on Medicare, but we had

hopes that this summer that Medicaid would eventually be included in the purview of the Committee. And as I have been walking around Washington today and being on the East Coast, being a person from the West and the Midwest, in some ways submitting our proposal is akin to Ben Franklin's 1752 experience of flying a kite in a thunderstorm. We hoped that our proposal wouldn't attract too much lightning, but that it would be a beneficial experience that advanced the goal of improving maternity and newborn care.

Our willingness to make this proposal was tied to this summer's request from CMS for comment on the inclusion of Medicaid maternity services in the purview of PTAC. So we and others submitted comments encouraging that change, but unfortunately, the rule change was not adopted.

And we do understand the criticism that our proposal was not detailed. The grassroots nature of our model explains the fact that our proposal was more narrative, and it was not as thorough as it could have been if we had more resources.

We have spent most of the last seven years developing a midwife-directed primary maternity care model that has attended more than 1,300 births in a system that is well integrated into the obstetrical and neonatal safety

net system.

Because I spent 25 years doing maternal fetal medicine, so I tell people I know every bad thing that can happen to a mother, although if I wait a week, I can find something else bad that happened.

However, as daughters and daughter-in-law started to have children and we have grandchildren now, I also understood that the system doesn't serve low-risk women very well.

Fortunately, our clinical model has gained traction, and it has drawn attention from payers in Minnesota, and with the support of these payers, we are on our way to being able to provide this higher-value care to more satisfied mothers.

The expansion of our service will allow us to provide much more detail on the quality and financial outcomes of this payment model in the future, whether this Committee or in other venues.

Each year, nearly 2 million, half of all U.S. mothers and their newborns, receive -- 2 million women, more than half of all U.S. mothers and their newborns receive pregnancy care paid for through Medicaid. My obstetrician colleague, Neel Shah at Ariadne Labs in Boston, is the leading advocate for improved maternity

care. He points out that total spend on maternity and newborn care is six-tenths of a percent of total GDP. That's a percentage that really gets the attention of economists.

But financial concerns aside, the primary impetus for our work is the goal of maximizing the chance for the birth of a healthy baby to a mother who has a safe and satisfying birth without unnecessary interventions, all while appropriately aligning payment.

We believe that work like ours and that of many others will be able to improve newborn outcomes while bringing the primary Cesarean section rate down to about 24 percent from the current rate of greater than 33 percent, and again, we do appreciate your review of our proposal.

I also appreciate Harold Miller's recusal. I have pestered him many times over the last few years for his volunteer input. I would even refer to him as, in some ways, the godfather of this model, and it has been invaluable. I don't blame him; I thank him.

[Laughter.]

DR. BERENSON: [Speaking off microphone.]

DR. CALVIN: Yes, that's right.

CHAIR BAILET: Steve, thank you. Thank you for that.

And I'm going to open it up to the Committee members to ask some clarifying questions.

Bob, it looks like you're a go.

DR. BERENSON: Yeah. No. Well, as you've seen, our PRT does -- said you didn't meet our -- except for one, I guess.

DR. MEDOWS: Choice.

DR. BERENSON: Yeah. Choice was the only one. Does it matter to you if we voted that you failed all the criteria, or that we said it was non-applicable because your proposal really doesn't fit into Medicare, and so we really didn't review it for purposes of evaluating it?

DR. CALVIN: Right. And after reading the PRT evaluation, it was not a surprise. It was during this summer we were hoping maybe that Medicaid would be included, and so I just thought it was worthwhile.

Much of what I've been doing has been just to advance this. Our midwives have privileges at the hospital. We have collaborative obstetrical groups. Neonatologists are on board as far as putting together a bundle, all of those things, but I just felt, well, we put the kite up in the air. And I do see -- you know, I saw some thunderstorms. Even the comments were not ones that -- I took them, you know, with the way they were intended.

DR. BERENSON: But I'm trying to get at if you're going back to Medicaid or to a commercial insurer and you have the PTAC saying you failed versus the PTAC saying we didn't really review it, does it matter to you?

DR. CALVIN: Yeah. No. Well, it does, and I think the criticisms of lack of specificity and a real clear payment model -- we're in the process of developing it with payers in Minnesota. So whatever you decided to do would be okay with me. We wouldn't leave terribly disappointed. We would entirely understand that when -- We knew there were under 30,000 women who gave birth with payment from Medicare, so that was not a surprise. And it was more a matter of just sort of putting a marker and saying this is something that we should really -- this seemed to be the venue.

I feel like I maybe came to a golf tournament with a croquet mallet.

[Laughter.]

DR. CALVIN: I'm not a golfer either. But it's that sort of thing where you just feel like, well --

DR. MEDOWS: So can I rephrase his question a nicer way? Which is going to be more helpful to you? You're an applicant. You put in a proposal. We have proposals that we are calling atypical, meaning they just

don't fit perfectly. Is it more helpful for us to say something is not applicable or to say something does not meet criteria? Does it matter to you? When you are taking this information and going to other payers, other potential partners, which is more helpful?

DR. CALVIN: I think saying that it's not applicable, that would be most helpful, and I do appreciate the positive reinforcement about -- from my perspective, I know this is how things are going to be paid for, for maternity care, in the future.

DR. MEDOWS: Can you speak a little bit about any interactions you've had with Medicaid, either the health plans or the state? Are you able to share any of that in terms of their willingness to work with you on this?

DR. CALVIN: Sure. So there's the state situation. In Minnesota, we have a fairly -- we’re a purple state. We have a state legislature that's currently in the hands of the Republicans and a governor's office that's a DFL. And there is currently a bipartisan committee of five state senators from the Republican side and four from the Democratic side, and they're working together on trying to come up, "What are we going to do the next legislative session?"

We've actually floated this bundled payment

proposal for the 30,000 mothers out of the 70,000 births in Minnesota that are paid for by what we call medical assistance, but it's Medicaid. And the current way that it's paid for, it's not working out really well.

I think care is provided pretty well, but the managed care organizations are finding a hard time making it all work.

So, all of this has just -- it's been part of the process, and I would think -- so on a state level, each state has its own politics. I've had some conversations with people that are currently in the Medicaid and CHIP area of CMS to just make an initial contact, and it was only recently. And that's been a good contact because one of the people there actually has expertise in this area.

So I figure whatever exposure we can provide for this model and for others like it is a good thing. So if just saying it's not applicable, it would be helpful.

CHAIR BAILET: Great.

So, Steve, just one thing I am thinking about. I think if the Medicaid -- I think if Medicare decided to throw Medicaid in, we'd be having a different conversation today. That was clearly the driving force behind submitting or at least getting us this far.

As I look at the process -- and again, I'm not

trying to truncate the discussion, but I just think we need to be transparent and think about downstream ramifications. We are completely prepared to go through our process criteria by criteria and render an opinion. That generates a report to the Secretary. The Secretary, by statute, is obligated to publicly respond -- and as I think about the value of that and how it positions where you want to take this, the other thing I would -- I think we should just transparently consider would be do we want to go through that process, and I'm not -- I'm here. We're all here. We're ready, locked, and loaded to go forward, but I think it's just a question I'd like an answer to. At least we go in with our eyes wide open.

DR. CALVIN: Yeah. I think that the comments already made by the PRT are adequate. I don't think that there's any reason to go further, just based on what I know to be the reality right now of Medicare and where we're at.

So, in a way, it's probably like withdrawing or just acknowledging. This is something we floated the trial balloon, and I think that it's a good one. So I don't know how to --

CHAIR BAILET: Well, so I can help you relative to -- if that's where you're going, if that's where you're thinking about landing, there's a formal withdraw. You

wouldn't be the first person who's come before the Committee and withdrawn their proposal in flight, if you will.

DR. CALVIN: Sure.

CHAIR BAILET: But there is a formal process. It's really generated from yourself, and again I would perfectly -- I mean, I'd like to hear from other Committee members who potentially have a point of view before we call that question, but we have a formal process.

Rhonda?

DR. MEDOWS: So does the process mean that he has opportunity to withdraw now before the vote?

CHAIR BAILET: Correct.

DR. MEDOWS: Okay.

CHAIR BAILET: Grace, you had your --

DR. TERRELL: I just wanted to make one comment about the quality of the Medicare data because I do think it's going to be important going forward with your very important agenda for us not to have tripped you up any, which is really what Jeff is getting at.

So, an example was with the very small number of Medicare patients that were there, one of them who was pregnant had prostate cancer. So I don't know about the maternal fetal aspect of this or the science about it or

whether this was a transgender person, but it implies that the data was terrible with respect to at least part of it in terms of what we might learn.

So one of the things I think that would be pretty important as you're going forward and thinking about what you're doing is to make some very important things happen. The data that might need to happen from Medicaid or commercials needs to be clean, and it needs to be done in a way that would not obstruct where you need to go with things.

DR. CALVIN: Point well taken.

CHAIR BAILET: Please.

* **Withdrawal of Proposal**

DR. CALVIN: So I would say that my inclination is that I would like to withdraw the proposal just because -- not to -- "waste" isn't the right word. You've spent a lot of valuable time in discussing these things, but I think it would be -- time would be better spent doing other things at this point. We've already -- it's been out there. It's been commented on.

CHAIR BAILET: So we -- as a Committee, we are willing to accept your request for a withdrawal.

DR. CALVIN: Yes.

CHAIR BAILET: And we will truncate our process

today. Again, Steve, the good work of what you're doing and what your intentions are going to do and what this process hopefully has provided some insights to help you sharpen the next steps you're making.

We thank you again for coming --

DR. CALVIN: Thank you.

CHAIR BAILET: -- and presenting this model, and I think it's caught the eye of commercial payers. You've already said that, and hopefully, this right here, this discussion today will increase that visibility. And on behalf of our colleagues, thank you for presenting this to us.

DR. CALVIN: Yes. Thank you very much.

CHAIR BAILET: You bet.

So as we wrap up as a Committee, I just -- again, I want to commend all of you for your incredible dedication to this process, and it's a volunteer effort. We all have day jobs. The level of engagement, I just -- I'm proud to be partnered with all of you.

Before we leave, are there any other open items that while we're here deliberating publicly that we want to cover? I know Tim has got a plane to catch, but if there is anything else --

MR. MILLER: I just wanted to say I want to thank

Jeff for being on the hot seat, being the Chair and doing a nice job of chairing over the past two days, so thank you for that.

MR. STEINWALD: Good job.

CHAIR BAILET: Thank you. Thank you.

Yes, Len.

DR. NICHOLS: I would like to second your earlier praise of our staff that have done an amazing job making our lives better and making us look smarter than we are and making it flow as smoothly as it has. It's truly been an amazing curve of improvement.

CHAIR BAILET: That's great.

I don't know if Elizabeth is still on. Elizabeth, did you want to make any closing comments?

VICE CHAIR MITCHELL: Only to thank all of you and the team. I'm sorry I couldn't be there, but I think it's just really an honor to be part of this work.

CHAIR BAILET: Harold?

MR. MILLER: Since we're thanking people, I don't know quite who to thank, but I would note that this is probably one of the only meetings I've ever been in that went on this long and the microphones actually worked. Every single microphone worked for two whole days. That is actually really rare, and I've been in a lot of meetings in

a lot of places. I have no idea what is happening behind the cameras, but I know the microphones are working, and that's really --

CHAIR BAILET: Harold, you didn't get the memo. We have the A team here, okay? So I want to thank all of you guys. We did earlier, but it's worth doubling down on that.

So, without further ado, I'm going to go ahead and formally adjourn our meeting today. Thank you. Thanks to the public. Thank everybody.

[Whereupon, at 5:26 p.m., the PTAC meeting was adjourned.]