PHYSICIAN-FOCUSED PAYMENT MODEL
TECHNICAL ADVISORY COMMITTEE

PUBLIC MEETING

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

Tuesday, April 11, 2017
8:00 a.m.

COMMITTEE MEMBERS PRESENT:

JEFFREY BAILET, MD, Chair
ELIZABETH MITCHELL, Vice Chair

ROBERT BERENSON, MD
PAUL CASALE, MD, MPH
TIM FERRIS, MD
HAROLD D. MILLER
LEN NICHOLS, PhD
KAVITA PATEL, MD
BRUCE STEINWALD, MBA
GRACE TERRELL, MD, MMM

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  PRT: Len Nichols, PhD (lead),
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PROCEEDINGS

[8:00 a.m.]

CHAIR BAILET: Welcome. Good morning. Thank you for coming. My name is Dr. Jeff Bailet. I'm the Chair of the Physician-Focused Payment Technical Advisory Committee. I have the privilege of welcoming Secretary Dr. Thomas E. Price, who was sworn in as the 23rd Secretary of Health and Human Services on February 10th of this year. He is the third physician to hold this position. He brings to the department a lifetime of service and dedication to advancing the quality of health care in America, both as a physician and a policymaker.

After his training and residency, Dr. Price, who is a third-generation physician, following in the footsteps of his father and grandfather, began a solo medical practice in Atlanta, Georgia, which would eventually grow to be one of the largest non-academic orthopedic practices in the United States.

Most recently, Dr. Price served as the U.S. Representative for Georgia's 6th Congressional District. He held this office from 2005 to 2017 and earned a reputation amongst his colleagues for being a tireless problem solver and the go-to expert on health care matters.
Committed to advancing positive solutions under principled leadership, Dr. Price remains a fierce advocate for a patient-centered health care system that adheres to six key principles: affordability, accessibility, quality, choices, innovation, and responsiveness. As Secretary, Dr. Price remains committed to these principles, administering a wide array of services, supporting lifesaving research, and protecting and serving all Americans.

Please join me in welcoming Secretary Dr. Price.

[Applause.]

SECRETARY PRICE: Thank you, Dr. Bailet, very much. What a kind introduction. I appreciate that.

Good morning to all. It is wonderful to be with you, to welcome you to the Great Hall here in the Hubert Humphrey Building. I'm incredibly honored to serve in this capacity and remarkably humbled by the opportunity that presents itself. So I want to welcome you this morning, Dr. Bailet, Ms. Mitchell, the entire PTAC committee, for the work that you have done. I want to thank you for the work that you've done and appreciate the opportunity to address you this morning.

I know the sacrifices that you all make. You all have other jobs. I know that people remind you of that
frequently when you're back home. So what you're doing is a service not just to health care in our country, but to every single citizen, and I thank you for that.

I also want to take time to thank the staff who have been engaged in participating and helping these folks do their job and do it better. We rely on a wonderful, wonderful staff here at HHS, and I am privileged to be able to help guide them as we move forward.

I am honored today to join you for this first PTAC meeting to deliberate and vote on physician-focused payment models, and, again, I want to commend you all for the work that you've done, and especially commend those who have submitted plans. It is a foreboding task to be asked by your federal government to devise a payment model for physicians and be out there in what I call the "real world" and to think that anybody's not just going to pay attention but going to care what they think, and so I want to commend the folks who have submitted payment models and encourage others to do the same. And we'll talk a little bit more about that in just a moment.

I met with the Committee just for a few minutes earlier this morning, and I mentioned to them that I think I'm probably in a fairly unique position as it relates to
this task before us, and that is that I served in Congress, as Dr. Bailet said, from '05 to just January or early February of this year. And so I had the opportunity to work specifically on the MACRA legislation. And with my colleagues, we felt that it was incredibly important to get physicians involved in defining or assisting in defining what kind of payment model they felt would be the most appropriate to facilitate their care of patients.

And so the PTAC was one of those things that we were adamant about, we wanted to make certain was put in place, because we wanted physicians to be able to have that input. And now to have the opportunity to serve on the administrative side, on the executive branch side, and to try to put in place that vision that we had on the legislative side doesn't always occur, and so it's an incredible privilege for me to have that opportunity.

Physician-focused payment model, you know, when you think about what this was named, "physician-focused," and you think, well, of course, you know, that's what we ought to be doing, isn't it, the folks providing the care out there? But if we're honest with ourselves, as a nation, it's important that we appreciate where we find ourselves now as it relates to the physician community.
And many physicians -- you read stories about physician burnout. You never read stories about physician burnout 20 or 30 years ago, and now you read stories about physician burnout. And we need to step back and say, "Why is that?"
Part of that reason, I believe, is the payment model and the payment apparatus that docs find themselves working under.

Dr. Bailet mentioned that I'm a third-generation physician. My dad and my granddad were docs. My grandfather practiced medicine until he was 94 years old. Some said he probably shouldn't have practiced medicine until he was 94 years old, but he did, and he inspired in me a love of medicine. But you don't hear about physicians, by and large, practicing anymore into their 80s or 90s, or even their 70s. My peers, when they've reached 50, 55 years of age, a lot of them were looking for the exit doors. And you think about the intellectual capital that we're losing as a nation when docs 55, 60 years of age say, "How can I end this professional run?" And so I want to commend again the Committee for working in this arena and being focused on what physicians feel out there.

And then payment model, I think it's incredibly important to appreciate that what we're looking for is not
just a single payment model. And sometimes -- when I read
that earlier with my legislative hat on before, I thought,
well, are people going to think we're just looking for one
size fits all? And the answer to that is no. We want to
make certain that folks far and wide across this land who
are caring for patients have an opportunity to have input
into what a model for their care of their patients and the
payment for that care ought to look like.

So PTAC is incredibly important. The work that
you're doing is incredibly important, especially at this
vital, vital time. You will have the opportunity to
validate really exciting plans that folks have come up
with, and so I once again commend you for what you're
doing.

Dr. Bailet also mentioned the health care
principles that I've talked about, and they kind of morph
depending on what kind of focus we're putting on issues.
But accessibility, everybody wants a system -- and these
principles really run across the ideological spectrum.
Everybody wants a system that's accessible for everybody.
We want a system that's affordable for everybody. We want
a system that's of the highest quality, provides the
highest-quality care. And we want a system that innovates,
that incentivizes innovation, because that's the only way that you maintain the highest quality of care, and then a system that empowers patients. And in order to empower patients, we've got to have a system that's transparent and accountable and provides choices and is responsive to those patients.

So this Committee actually runs across many of those, whether it's accessibility, whether it's affordability, whether it's the kind of quality that you look at and try to determine whether or not a different payment model will continue to incentivize the highest-quality care, and then obviously the innovation that is so necessary for our system. So I want to urge you to make certain that you're looking far and wide across the models that are coming before you.

I also want to urge others who may be listening or may be responding to the call to propose a payment model to not be bound by old ideas. This is a time of really great innovation in health care on the clinical side. We need to make certain that we're also innovating on the non-clinical side, on the side that allows us to have the finest and highest-quality health care system in the world.

So I want to call on physicians and other
providers all across the land, truly far and wide, to think about what payment model might work better for them and their patients, and to utilize the opportunity to put forward that payment model, especially those in the rural and the underserved areas. I know that the docs out there in small communities, in the underserved areas, they oftentimes feel that the rules that are coming down from on high here from Washington are for those large, integrated groups, that they're for the folks who are in the large practices and have all of that administrative help beside them. But I think there has to be a way -- if we're listening to the folks actually providing the care, there has to be a way to be able to allow them to have input into a system that would work much better for them and for their patients.

No more important time to do this than right now, the opportunities that we have as we transition to a model that, again, tries to identify and adhere to those principles of health care, but make it so that we've got a system that works from a financing and delivery standpoint much more efficiently.

So the practicing doc out there, we need your help. Your participation is absolutely vital to the
success of this wonderful, marvelous group that we've got before us with incredible experience and expertise that they bring to the table. They want to hear your ideas, and I would urge you to make certain that you provide those ideas and models for them as we move forward. This only works with everybody's involvement, and so I encourage you to do that.

I look forward to your recommendations. I look forward to your continued work. And as I mentioned before, we look forward to assisting you to make certain that we're able to allow you and encourage you to do everything that you can to come up with positive, positive solutions to the challenges that we face in health care financing and delivery.

It's an honor to be with you today. Thank you very much. God bless you.

[Applause.]

[Pause.]

CHAIR BAILET: Good morning, everyone, and welcome to this April meeting of the Physician-Focused Payment Model Technical Advisory Committee, or PTAC. We're delighted to have you all here. As you know, this is our first series of meetings that will include deliberations
and voting on Medicare physician-focused payment models submitted by members of the public.

We would like to thank all of you for your interest in today's meeting; in particular, thank you to the stakeholders that have submitted models, especially those that are here today. Your hard work and dedication to payment reform is truly appreciated.

We spent the past year establishing our processes and procedures for receiving and reviewing physician-focused payment models. We want to stress that our process is shaped by input from stakeholders.

Although we begin deliberating and voting on proposals today, we are committed to listening to your feedback and evaluating our processes accordingly. We value your comments at every level, especially as they relate to our receipt and review of proposals.

We also wanted to remind all of you that PTAC is a committee of 11 members, not a committee of one. To the extent that questions may arise in the process as we consider your proposal, please reach out to staff through the PTAC.gov mailbox. The staff will work with me as Chair and with Elizabeth Mitchell, the Vice Chair, to answer your questions.
In the interest of consistency and responding to submitters and members of the public, please reach out to us through this process that we have in place.

Today, we will be deliberating on two models. Discussions of each proposal will begin with presentations from our Preliminary Review Teams, or PRTs. The PRT reports are from three PTAC members to the full PTAC and do not represent the consensus or positions of the PTAC. PRT reports are not binding. PTAC may reach different conclusions and a different recommendation from the one that was contained in the PTAC report.

And, finally, the PRT report is not a report to the Secretary of Health and Human Services. PTAC will write a new report that reflects the deliberations and decisions of the full PTAC, which will then be sent to the Secretary.

Following the PRTs' presentations, some initial questions from PTAC members, the Committee looks forward to hearing comments from the proposal submitter and the public. The Committee will then deliberate and vote on a recommendation to the Secretary of Health and Human Services. It is our job to provide the best possible recommendations to the Secretary, and we are excited to
begin this process.

I will turn to Elizabeth for any additional comments and then any from our Committee.

VICE CHAIR MITCHELL: Thank you, Dr. Bailet, and I wanted to just thank everybody.

As you’ve heard, we are very committed to an open and transparent and fair process. We are eager to hear from you, and our Committee has been very, very committed to making sure that we are inclusive and really looking to make this as successful as possible, understanding that these are ideas from the field, and we are hoping to expand the portfolio of models that are available.

CHAIR BAILET: Do we have any other opening remarks from our Committee members?

Tim.

DR. FERRIS: Jeff, I just wanted to add that it occurred to me during yesterday's discussion that not everyone in the audience knows that we abide by the FACA rules and do not deliberate on any of the proposals, except in this public setting, and so have not discussed any of these proposals, except within -- the PRT has. And I just wanted to clarify that because I think that might not have been clear yesterday that we are truly talking about this
as a group for the first time, here, now, in front of the
public.

CHAIR BAILET: Thank you.

Seeing no other comments from the Committee
members, I think it would be nice to start with
introductions and also disclosures of conflicts, and I'll
start with myself -- or just disclosures that we are
required to make to address any conflicts or impartiality
issues.

My name is Dr. Jeff Bailet. I'm an
otolaryngologist. I am the executive vice president of
Blue Shield of California. I am privileged to be here and
leading this esteemed, impressive group.

Elizabeth.

VICE CHAIR MITCHELL: Thank you.

Elizabeth Mitchell. I am the president and CEO
of the Network for Regional Healthcare Improvement, and I
have no disclosures on this proposal.

DR. FERRIS: Tim Ferris, internist and primary
care physician at Mass General Hospital, senior vice
president of Partners HealthCare in Boston, and no
disclosures.

DR. PATEL: Hi. Kavita Patel. I'm an internist
here in DC, and I have no disclosures.

DR. BERENSON: I am Bob Berenson. I am a fellow with the Urban Institute and no disclosures.

DR. CASALE: Paul Casale, cardiologist at New York-Presbyterian, Weill Cornell, Columbia, and I have no disclosures.

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

I have helped over the past year, the American College of Allergy, Asthma, and Immunology on a payment model for asthma, but I have no financial interest in that model, and I do not see any conflict between that work and the proposal that's here before us today.

And I think also it's probably important for people to know that there is no limit on the number of proposals that the PTAC can approve, so it's not like as if this is a competition amongst a proposal.

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

DR. TERRELL: I'm Grace Terrell. I'm a practicing general internist at Cornerstone Health Care, a
multispecialty medical practice in North Carolina. I'm on
the board of a population health management company called
CHESS, and I am the chief executive officer of a
biotechnology company called Envision Genomics in
Huntsville, Alabama. No disclosures.

MR. STEINWALD: I'm Bruce Steinwald. I have an
independent consulting practice in health care financing
and Medicare issues. I'm a former government official in
numerous positions, and I have no conflicts.

MS. PAGE: I'm Ann Page. I'm staff in the Office
of the Assistant Secretary for Planning and Evaluation,
PTAC staff, and also the Designated Federal Officer for
this FACA Committee.

MS. STAHLMAN: And I'm Mary Ellen Stahlman, also
with the Assistant Secretary for Planning and Evaluation.
I'm the staff director for the PTAC staff supporting the
Committee.

CHAIR BAILET: Thank you.

We are now going to turn the meeting over to Len
Nichols, who is the lead for the PRT for the COPD and
Asthma Monitoring Project.

DR. NICHOLS: Thanks, Jeff.

I would like to call attention to the lead slide
there and remind everybody I stand on the shoulders of
giants with Dr. Tim Ferris and Dr. Grace Terrell. I don't
know how an economist got in charge of this, but, hey, it's
America. It's an interesting country. We'll do the best
we can.

And maybe even this will work. I'm supposed to
click to the right. Do I point this to the sky? See, I
told you we should have had a doc in charge of this, so it
would work better. We could probably find a human to do it
by hand, if we had to, I would guess.

CHAIR BAILET: We could. That's why they have
"technical" in our name. Right?

DR. NICHOLS: Oh, looky here. Progress is being
made. Thank you so much.

So I'm going to briefly review the PRT's role.

I'm going to talk about the proposal in general, the
summary of our review and some of the key issues, and we'll
talk through then the evaluation.

Basically, the way the process works is a
proposal comes in after a letter of intent has indicated a
proposal is coming. The Chair and Vice Chair of PTAC will
assign three members to serve as a preliminary review team,
and one of those members is tapped to serve as lead
Basically, the first thing we do is read the proposal and make sure that we have the information we think we need, and that includes both questions to the submitter. And I would like to commend the submitter for the response to our questions, which were quite voluminous, and your answers were very good. And we also turned to ASPE staff and some of their contractors to get more information.

After we review the proposal, we get all the information and so forth, and as you probably know, public comments are available at all these stages. They see the LOI. They see the proposal. They see the comments.

We prepare a report of our findings to the full PTAC. That report is posted on the website two weeks prior to this Committee meeting, and it's important to reemphasize, as Jeff did at the outset, that PRT report is not binding. PTAC may reach different conclusions. In fact, members of the PRT may reach different conclusion. We're free to do that as we deliberate and discuss things with our colleagues going forward.

I will also say since the PTAC report became public, the submitters filed a statement in response to
that, which I found insightful, but I think not everybody had a chance to read it before today. But I'm pretty sure my PRT members are reading it as I talk, so we'll keep going here.

Okay. The intervention in general is to look for COPD and asthma beneficiaries, and they would receive a Bluetooth peak flow meter and some software tools to permit data to go to a central server, which through monitoring and management could trigger clinical interventions to reduce early exacerbation and respond quickly to infection detection so that we could accomplish improvements in quality of life as well as lower cost.

The payment model calls for CMS to pay for the flow meters, to pay an inflation-adjusted per-beneficiary, per-month remote monitoring and management fee, to waive copays for beneficiary access to the services, allow collaborating pharmaceutical and device companies to provide beneficiaries with discount pricing and coupons for drugs or equipment that may be prescribed to control their particular pulmonary conditions.

The proposal aims to improve the health of patients, reduce avoidable ED visits and inpatient hospitalizations. Reductions in emergency department and
inpatient utilization are expected to offset the costs of the intervention and thereby lower the total cost of care, and the submitter expects to reduce mortality as well.

We briefly review our preliminary judgments of each of the 10 criteria as specified by the Secretary in the final rule, and you can see pretty quickly, if you just scan through there, they meet criterion on 8 of the 10. On scope, we definitely think they did.

We'll go through these in general.

You see there are two where we didn't think it met the criteria. The first, a high-priority item, is the payment methodology specifics, and then integration and care coordination, we didn't think it met criterion.

We were unanimous on all decisions, except for one on flexibility. We had two vote one way and one another, but in general, the conclusion was it met the criterion by a majority vote.

The key issues that we identified, basically there's no question this is a very high-priority issue for CMS. There are a lot of patients with COPD and asthma, and the framework the submitter has proposed, we think has great merit. And I think it's fair to say we would like this to be a successful payment methodology going forward.
We do think, however, there are elements of this proposal that require further development, and that's why we raised the concerns that we did.

Our first concern, which was clear from the way the documents were presented, there were no quality performance requirements to earn shared savings. In the letter that I talked about that was submitted after the PRT report became public, the submitter has indicated there are some quality metrics, which I'd be happy to connect, and we'll talk about that today as we go forward.

Do all of the PTAC members have that response? I think it was handed out in paper before. Yeah, it was electronically sent, but there were a lot of things sent, so not everybody caught it.

The model does not count some real cost, such as Part D spending and waiving of copays, and we can talk about that as well.

The risk adjustment was the thing that probably concerned me as an economist the most. The proposal was based upon a number of chronic conditions the patient has. This method has not been tested, and frankly, I think it would be too risky to put a risk adjustment regime in place like this, but we do think we can talk about how to modify
And then the clinical concern was mostly that the model didn't seem to have enough detail about how integration would be achieved. Primary care providers would not share in the financial risk or the incentives of the program, and other providers behind the pulmonary subspecialists were not clearly integrated with the care delivery model as well.

So now I'll go through each specific criterion and what our assessment of it was, and where I think it's important, I'll bring in what the response of the submitter was. And then we'll go from there.

So the proposal, as I said, aims to care for patients with COPD and asthma to well-defined and clinically important conditions, roughly 5.4 million Medicare beneficiaries with either COPD or asthma or both. The proposal would cover the daily monitoring. It would utilize new technology, have two-sided risk, a lot of good features we want. It would certainly broaden CMS's alternative payment model portfolio by including pulmonary physicians who are not participants in existing APMs, and of course, it would be a large scope because of the size of the Medicare population.
The initial proposal is for a 2,000-beneficiary pilot, but it could be scaled up over time. So, in our view, there was no question, this met the scope criterion. The second criterion is quality and high priority, and here, I think it's important to pay attention to specific words. We do believe it meets the criterion, but I think it's fair to say we think it mentally met the criterion.

There is considerable literature that investment in programs that enroll well-selected patients with chronic conditions, characterized by frequent exacerbations, resulting in hospitalization can effectively improve quality and cost. However, for this particular kind of intervention, there is really only one study with sufficient end to give us confidence. That study was conducted in Germany, where a few things are different. They have better beer. They also have different prices of devices, and we didn't think that there was enough details specified. And we can go through the details of that, but many of the clinical details remain to be worked out.

However, we thought the promise of the intervention and the plan of the submitter was sufficient
to say it met the criteria, assuming the other criteria were met. We didn't want this to be the stumbling block to success.

The payment methodology is the place where we felt like there were questions that needed to be answered before we would recommend going forward. Just remember the basic approach. There will be a PMPM payment and a shared two-sided risk arrangement, and that certainly seems appropriate for this kind of clinical intervention, but there are too many unspecified or questionable features.

I said in the proposal, there were no quality performance requirements linked to earned shared savings. In the response to the PRT report, the submitter identifies a number of quality metrics, which I will leave to my physician colleagues to discuss when we get to that.

The model does not count some real cost such as Part D spending, which was a concern. I think we can talk about that. When the submitter gets to talking, we will have a back-and-forth. But one issue that was clear to us at least in the way we interpreted the proposal was that the model would waive the copays for the beneficiaries in the project, and that we were afraid those costs did not count in the way they described the model.
In the response to us, they said, "Oh, yes, we meant those costs to count." So I think there was confusion about whether those costs should count against Medicare savings. So, fundamentally, they would have to be made up in order for the submitter to win a bonus, and that's important to understand.

Risk adjustment was the bigger issue, at least, again, in my mind and I think in our collective minds because -- and I think it's fair to say, Mr. Chairman, that this group suffers from the same problem everybody else suffers from. They don't have access to the great data that would enable them to develop a more fleshed-out risk adjustment model. So they proposed using number of chronic conditions, which given the data they had was a reasonable first step.

Our concern is that that has not been tested. Our concern is there may be much better ways to do it if they had access to good Medicare data, and that's precisely the kind of technical assistance we would like to make sure this submitter and others have access to at some point.

The per-beneficiary, per-month amount was not based on the cost to provide these services. It was based upon sort of an adjustment, given a number that had been
worked out for, I think, cancer care or something. So that clearly needs a little bit more work.

And then the cost structure that would guarantee the savings assumed device prices that were based on European pricing, which is where this thing has been done full speed before, and obviously, in the United States, those prices are likely to be somewhat different than they are over there.

And so, for those reasons, we reached unanimous conclusion, this payment methodology does not meet the criteria as laid out by the Secretary.

On value over volume, we thought it certainly did. There's no question that it would enable clinicians to efficiently monitor and manage a patient population with great need, and the early detection is precisely the kind of innovation that we want physicians to bring to fruition.

Flexibility, here is where we had our one non-unanimous decision. We agree about all the facts. We differ on the judgment about what to do with those facts. The proposal is simultaneously rigid and somewhat vague. There did appear to be a reliance on one specific device and data transmission method.

The exact clinical protocols have not been
completely worked out, and that was a concern. But I think the larger concern is that the proposal lacks sufficient detail on how the coordination with other providers would occur given the lack of specificity of the clinical protocols. So two of us were willing to give the benefit of the doubt; one of us was not; and that's why the majority as opposed to a unanimous decision was reached here.

There's no question this thing is eminently evaluable, and here integration and care coordination, which is somewhat related to the flexibility one, we felt unanimously that it did meet the care coordination criterion, but did not meet integration. It does not describe in sufficient detail how primary care physicians will be made part of this and does not describe really that much about ensuring that the financial benefit will flow to anybody other than the pulmonologist. So we thought there was too much unspecified about integration, and this decision was unanimous.

Patient choice, the patient enrollment is optional, so it's kind of hard to argue with that. Patient safety, again, there's a lot of focus on preventing early exacerbations and infections, so we think patient safety is
strongly supported.

HIT, I think it's fair to say there's a lot of work to do here because the specific software and device interfaces would need to be developed, and for those of us who have banged around these systems, that's not a simple thing. But, again, we thought this is certainly all doable and, therefore, we felt like the judgment was correct that it did meet the criterion of the Secretary.

So there you have it.

CHAIR BAILET: I want to thank you, Len, and also thank the members, Tim and Grace, for their efforts on this PRT and all the heavy lifting that they did in your analysis and summary. Thank you very much.

I'd now like to ask the Committee members if they have any questions for the proposal review team.

Seeing -- oh, Bob?

DR. BERENSON: Yeah, I was hoping somebody else would go first. In their proposal, they say the following: "Based upon the review with the peak flow meter findings," et cetera, "any recommendations for medication change will be sent through the primary care provider. Alternatively, if the PCP allows the pulmonary specialist, the CAMP will make these changes, and they will be recorded in the
patient's EMR."

Did the PRT pursue this at all to determine accountability for the patient's well-being? That's a concern I have. In the questions, I didn't sort of see anything additional to sort of ask -- find out how this would work. I could imagine responsibility falling through the cracks in this kind of a situation.

DR. FERRIS: We agree, and that was precisely why we --

DR. BERENSON: The integration [off microphone]--

DR. FERRIS: The integration. We did not --

there was not an explicit plan for the integration of care between multiple providers. Those patients with COPD don't just have COPD, so it's not only the primary care provider for whom this specific question you ask, Bob, but also other specialists. Very frequently have cardiac disease, it's very frequent for COPD patients to have a cardiologist.

So the proposal, I think it's fair to characterize the proposal as being fairly robust in the specific area of care for patients with COPD and asthma, but much more limited in its description of how you provide in this model patient-centered care that involves the
integration of all the other physicians who are taking care of the patient.

DR. BERENSON: I mean, this, I guess I could reserve it for later, but in the clarifying letter, which is a helpful letter, in the current model we envision using medical assistants supported by pulmonary nurses, IT software engineer, two nurse case managers, a behavioral psychologist, a respiratory therapist, a statistician, and a medical director, but no pulmonologists are mentioned. And it seems like it's not a physician-focused payment model. It seems to me it's disease management support. And that's one of my concerns about it. I will mention some others when we get to the later discussion.

DR. FERRIS: Can I respond [off microphone]?
CHAIR BAILET: Please, go ahead.

DR. FERRIS: So because of where the proposal is coming from, I think we gave the proposer the benefit of the doubt that this was pulmonology-focused since that was the ostensible platform on which this is working. And I would say that the team of people identified in that list is precisely the kind of practicing at the top of your license, have the real work done by physicians, and have the constant contact associated with other monitoring
systems through IT or outreach to patients that helps stave off remediable exacerbations. That's precisely the kind of team that one might put together to enable that kind of performance. So I think we -- while I agree with you it's not explicit, I think we read it as part of a whole in this setting.

CHAIR BAILET: Harold?

MR. MILLER: This I guess is somewhat related to the question Bob raised, but the issue that -- this is also related to the proposal yesterday. So we have an applicant who is, in fact, a physician practice who has a particular approach to changing care, in this particular case using or wanting to use Bluetooth monitors and, you know, respiratory techs, et cetera, et cetera, et cetera. But the payment model, if I understand it correctly, is to pay a per-beneficiary, per-month payment. It is not specifically to pay for Bluetooth monitors or to pay for respiratory techs. And if this particular practice would choose to use the PBPM in that way, that would be their choice. But if the payment model is a PBPM, then some other practice could choose differently to be able to do that and would then be accountable for the outcomes.

So I just wanted -- and I'll ask the applicant
this, too, but was your understanding of the model that it was to give the practice a per-beneficiary, per-month payment, and then they could decide, whoever got it could decide what to do with it? Or was the payment model to pay them specifically for this particular defined technology and intervention?

DR. NICHOLS: So part of the payment model was to provide the Bluetooth meter to the patient, so that's a given. The technology is a given. And the PBPM was to provide the resources for the team that Bob just articulated in addition to the pulmonologist to manage those patients.

MR. MILLER: Right. There were two pieces --

DR. NICHOLS: Certainly -- and there's also a third. There's a shared savings component against the target --

MR. MILLER: But the PBPM would not be tied --

DR. NICHOLS: No.

MR. MILLER: -- to a specific structure of --

DR. NICHOLS: That was not my understanding. It would be flexible from the clinician's point.

DR. TERRELL: Although there was some -- in the questions, some discussion of particular algorithms that
they had developed or would develop with respect to how the
management of these patients would proceed with the team
that they were involved with. So whether it was a specific
algorithm or care pathway or another or some other way,
whether there was flexibility in the model, I think your
questions, both of you, are getting at how much of this is
proscribed is a good one.

There was work that was alluded to with respect
to the fact that they have some of this fleshed out and
have developed algorithms in place that were particularly
tied to a care pathway. This gets back to what we talked
about a little bit, I think, yesterday with respect to care
models versus payment models and the concern that I
expressed then that this is going to continue to be the
thing that we've got to understand the relationship between
the two. So I think your question is a good one.

MR. MILLER: Well, and particularly when we have
a practice with a particular approach coming in and saying
the payment model would allow this, but the payment model
then would also potentially allow other things, which is a
-- and that's one of the issues on the flexibility is, is
there the flexibility to do it differently or does the
payment require use of that algorithm and does the payment
require this particular staffing structure?

DR. TERRELL: And the other side of that from my point of view is you really have to have very robust quality and outcomes measures as part of a payment model if there's flexibility in what it pays for. And the supplementary information that we receive that you all have in front of you on paper today, we're seeing some of those outcomes measures laid out, hospitalization, ED visits and all of that. But the real need in the situation where there is flexibility and some people could potentially use it for other ways of doing care management has to be around very, very vigorous outcomes measures, in my opinion.

CHAIR BAILET: Elizabeth, your question links to Harold's?

VICE CHAIR MITCHELL: Yes, thank you. I think it's actually very similar, but I just wanted to get a little bit more precise, because we're talking about a specific product. And as we talked about yesterday, that might not always work in some practices.

So you say that this same model could work if another product offered the same functionality, so you could endorse the model without endorsing the specific product?
DR. NICHOLS: Yeah, that was a concern we had when the proposal came, and, in fact, when the proposal came at that time, the device had not yet received FDA approval, which even made me nervous. But we asked CMS about this notion of having one particular supplier of a given commodity, whether or not it had FDA approval, and they said, "Well, you know, in certain circumstances we could work it out." And they sort of implied it really depends a lot on what kind of price they're going to charge and other things.

Since then, in the communication we got after our PRT report was posted on the website, it's clear that the submitter understands and would like us to understand you could use different technologies to do -- you don't have to have that one machine. And, by the way, it has now gotten FDA approval.

VICE CHAIR MITCHELL: Thank you.

DR. NICHOLS: But yes, you could use different...

DR. FERRIS: I'd also respond just to add on to that. I think maybe building on Grace's comments about the care model and the payment model dynamic that I think we saw yesterday and we're going to see more of, you know, it's fairly easy for someone to propose, a physician to
propose or a group to propose, just give me a fee and I'll
figure it out, put me at risk and I'll figure it out. And
that's the payment model, right?

Having the submitter specifically explain what
they're going to do lends credibility to the proposal, or
not, if what they propose to do doesn't seem credible. But
having the care model -- so the application appears to
present us with very specific -- like we will use this
Bluetooth thing. I think when you think about the payment
model, I'm reading the application as this is a credible,
or not credible, clinical intervention that is going to
provide greater outreach for a group of unstable patients,
and that's going to reduce their rate of hospitalizations.

But once you propose that, I don't feel when I'm
evaluating the payment model like I'm tied to the very
specific care model that they propose, because that care
model works in that practice and in that situation. And so
specifics on the care model are important, but not
determinative of whether or not the payment model is a
viable payment model. That's just sort of the way I'm
thinking about it.

CHAIR BAILET: Thank you, Tim. Kavita?

DR. PATEL: So I'm going to ask questions to the
PRT, but I found also that it might be helpful to hear what Jeff and Elizabeth think. I'm struggling a bit what to do because it does seem like the responses clarify some of the issues specifically around the quality metrics, cost metrics, and that may or may not -- I mean, for me at least changes a little bit on kind of how I think about that section on quality, cost, and potentially the value over volume question. So I'm not sure -- kind of I'm out loud kind of questioning, you know, do we kind of take this information and how would you kind of process responding to what I think is clarified? So that's a little bit of a process and substance question.

The second question I -- oh, go ahead.

DR. NICHOLS: Well, let's just get one at a time.

How about that?

DR. PATEL: All right. Go ahead.

DR. NICHOLS: Because I think that's a very important place to start, because let me just say this is why I'm glad I'm not a doc. I think that Tim and Grace should respond first, but all of you should talk about the proposed quality -- because we saw the absence of that -- in the response letter you just saw, they said, "Oops, we meant to include it," you know, whatever. So here we are.
So I think you should look at it specifically and draw your own conclusions, and I'd be glad to learn from your thoughts.

CHAIR BAILET: Tim.

DR. FERRIS: I guess, Kavita, I, too, found their responses very helpful, and they now put us in the realm of plausibility. But they actually don't tie -- there's no formula to tie them, and as we know, tying them to the model is actually a nontrivial exercise. So what I would say is it's very helpful and directionally appropriate. But I'm still not sure that the response constitutes a payment model, at least in a payment model insofar as it is specifically evaluable. Like I still can't say would this work or not because there's no math there to -- there's no formula.

CHAIR BAILET: Kavita, also embedded in your question was a process issue.

DR. PATEL: Right [off microphone].

CHAIR BAILET: We have spent considerable effort lining up the evaluation, communicating with the submitter, working with the proposal review team, drafting the recommendations. A lot of distillation of information has occurred. And, again, we operate transparently, and we
want to have the back-and-forth with our submitters and our stakeholders. Everything is put out for public comment. That's the other thing that is digested by the proposal review team.

Our challenge -- and this is really not specific to this proposal -- is that as a Committee, when you get a six- or seven-page letter with exactly the kinds of information that will help us sharpen our thinking on this proposal, the timing makes it very challenging for us as a Committee to digest this information thoughtfully and then be able to have a rich deliberation, as you see playing out before you this morning. That's a challenge, that's a process challenge, and I don't profess to be able to solve that today. But that is something that we're going to have to address going forward, because we've had -- you know, it's not just this proposal, but we have a similar circumstance with some of the other proposals as well.

Harold, and then Grace.

MR. MILLER: I think it would be good just to spend a minute on this, just to build on Jeff's invitation to people who are listening to send us suggestions about how we might improve our process, because it seems to me that there's at least three options one might do to address
One is that the PRT report, the draft PRT report, needs to come out farther in advance of the meeting, which would then give people an opportunity to respond to it and then to have it potentially revised, but that would delay the process.

The second option would be to have a process for tabling something at a meeting and saying we can't make a decision today because the new information that we've gotten is more significant, or to have some kind of a rapid revision, resubmission, and re-review process afterwards so people don't sort of get a no and then have to completely start all over again. And I'm not sure at all which of those is the right approach to use, and it would be, to me, useful to hear from, you know, people who are thinking about this and watching the process kind of what their reactions are so as we consider the options, we could take that into account.

CHAIR BAILET: Grace, and then Len.

DR. TERRELL: One of the issues, therefore, is, is the process we have of our review adequate or not to where these things could have been put forth earlier? So, I mean, you can question this for any of the reviews -- the
one later this afternoon, this one, or the one yesterday -- well, why are we getting information at the last minute or later than sort of the process that may be changing our mind or allowing us to have a richer set of things?

We set the process up with 20 pages only so that we wouldn't get hundreds of pages of stuff that wouldn't necessarily get us to where we needed to go. And then we have a review of that information, research that we do. And then we have a series of questions back-and-forth. And I've participated in two of these now, and they have been based on some free-form conversation between the members of the PRT saying, well, I've been thinking about this, and you've been thinking about this, and developing a series of questions, some of which were, you know, 39, 40 questions, of which we got very good answers back.

But maybe that's not -- maybe that's really a problem in the process right there. That needs to happen, and then there needs to be something much more specified that would get there. I don't know. But it would seem to me that as we're evaluating this one in front of us now, we based our initial assessment and reports on the information that we had after going through that process, and then we've got other information here just like we did yesterday.
that elaborates on that. I'm not sure that's a bad thing. It could potentially always happen but -- simply because you learn as you go along. But whether this changes the outcome today or not really is going to depend on as we go through the rest of this process.

It doesn't, I believe, eliminate the essential problem we saw with this particular proposal, and that is, they needed help that we weren't able to give them because of the constraints we're under. And that is, had they had some ability to under -- had some technical help that would have allowed them to maybe flush through some of the issues with respect to the payment model particulars that we then critiqued them for, it could have made it stronger. That's what we've got to get better at. This is a good example of a proposal that has some very, very, very good things. We desperately need in this country ways of providing better care to COPD patients, that is, probably several types of innovative care models linked to payment methodology that will allow physicians to do that. But the actual details that they needed to get there, as we've talked about earlier this morning, were not part of our process, and we weren't able to help them do that, as you know.

CHAIR BAILET: Len.
DR. NICHOLS: So I would just pick up on Grace. I think, in fact, this is working. I sort of don't think that we need to necessarily change it. I'm not sure I'm convinced it's broken.

What I think has happened is that we got the proposal. We asked a bunch of questions. They answered the questions. We asked questions of professionals who know more about data than we do. We thought about it. We wrote the PRT report.

I think the PRT report, if you will, sharpened the mind of the applicant in a way, "Okay. That's what they're worried about." Boom, boom, boom. This thing right here is a good piece of information.

I don't think it came too late for us to be able to think about it. It did come in email. It's just that I don't think everybody on the Committee got that email. I think that's where we are.

And so, to me, this is the way it should work. I totally agree with Harold. If the information was sufficiently game-changing, I might want to table, but I don't feel like that's required today, given everything else that we've got.

So, in some ways, the only thing I would suggest
we'd change in the process -- and I think this might have
been proposed at one point. I'm looking at Mary Ellen,
because you probably thought of it, and we probably nixed
it. Maybe we should send the PRT report to the submitter
before we go public and have a little more time, one more
round of back-and-forth.

I think my concern was, oh, my God, that will
delay it, but if these guys respond as fast as this man
did, I don't think we've got a real problem with delay. So
I think maybe we should reconsider that.

CHAIR BAILET: I want to make sure, Kavita, you
have another section to your question, but I think, Paul,
if you're going to respond to the original --

DR. CASALE: Yeah, this will be quick. I'm sort
of with Len. I mean, I don't think that it's really very
broken.

I mean, at some point, you put out the report;
you're going to get a response. We've seen it. All three,
we've gotten responses organically from all three, and I
think whether we send it to them earlier, et cetera, but I
think we need to receive it earlier as a full Committee, to
be honest with you. And I don't think -- you know, if I
had it a week ahead would be fine.
And I just want to emphasize --

DR. NICHOLS: Well, to be fair, it did come in an email.

DR. CASALE: Right.

DR. NICHOLS: -- and I saw it, and Mary Ellen called my attention to it. And I said, "That's interesting. I'll read that next week when we get there."

DR. CASALE: Yeah. Right.

And I guess the other point that I'd want is this is the preliminary report, and I think preliminary is okay. Again, it doesn't have to be perfect and have everything when we get here. Just two points.

CHAIR BAILET: Thank you, Paul.

And Elizabeth.

VICE CHAIR MITCHELL: Yeah, just a quick additional comment. I'm associating myself with Len.

The entire intent of this public forum is to get additional information, and I think we are genuinely committed to incorporating that to the extent possible. I am relying on my colleagues to help sort of evaluate do these new metrics make a difference in your initial assessment, but -- it might be hard to watch, but we really are deliberating in real time, and I think additional
information is really the name of that.

CHAIR BAILET: Thank you.

Kavita.

DR. PATEL: Oh. So the second -- I have kind of a second set of questions around kind of the PRT's reaction, and I know there's some kind of mention to it around the risk adjustment.

If I look at your PRT recommendations and even aside from your recommendations kind of go through each of the criteria, thinking through that -- and we'll vote on that -- I still find myself kind of hung up on -- I found myself kind of troubled by the risk adjustment kind of -- or the -- it's, on one hand, very novel because we certainly -- they made a very interesting argument about kind of using the number of conditions. We know that using HCC -- we know that there are a lot of flaws in current risk adjustment methodology to explain kind of the clinical variance.

But my question to you all is how much of that was a discussion around specifically that section. You reference it in your summary of the PRT kind of section, Len, but I'm just -- and especially now seeing the response from the submitter.
And then I will say I agree with -- I just -- and then the -- kind of a related question is how much of this tension of -- you know, this is a very highly -- you know, unlike the conversation we had yesterday, this is an incredibly prevalent disease, an incredible opportunity to reduce hospitalizations, ED visits. We now see that they are actually thinking about those quality metrics as part of the response. So tell me a little bit about the struggle to think about -- or did the kind of sense of prevalence or impact that this could have on a very kind of burdensome condition kind of come up? So -- and then I'm done. Those are the two questions.

CHAIR BAILET: Go ahead, Grace.

DR. TERRELL: I just have a quick technical point. Because of work that my organization has done in this same area, including developing care models in COPD, I did not feel compelled to have a lot of discussions about that because one of our criteria were Charlson scores or basically identifying people who had five or more chronic diseases as being in and of itself a risk model. So getting the details from them of the stuff that I guess I already assumed was knowledge I had from my own experience, there was not a lot of dialogue back-and-forth. That may
well have been an error on my part or our part, but it was
the risk adjustment, that there is data out there that you
can use number of chronic conditions with an n of 5 being
the number that seems to be a cutoff for levels of stronger
development of care models.

So you can have five stable chronic diseases and
one bad one, COPD or whatever, and that in and of itself
can be a -- for those that don't have fancy data, EMRs, any
other types of things, including registries that many
sophisticated groups have, you can do that with a
relatively simple practice criteria.

To the Secretary's point earlier about smaller
practices or rural practices, that's one thing that's a
very simple way of sometimes doing some of this.

DR. PATEL: So you saw that as a plus? I just
want to make sure.

DR. TERRELL: I saw it as a plus.

DR. PATEL: Because I know that in your
submitter's, I couldn't --

DR. TERRELL: We didn't have that dialogue.

DR. PATEL: -- infer --

DR. TERRELL: I had that dialogue in my own head

so --
DR. PATEL: Okay. Because I couldn't tell from
the questioning back-and-forth if you thought those --
DR. TERRELL: Yeah. There was not the
questioning back-and-forth --
DR. PATEL: -- if you felt that was a detractor
or a -- okay. All right.
DR. TERRELL: -- because I was making so many a
priori assumptions.
DR. PATEL: So that would actually indicate that
this has a novel aspect to it that's not incorporated in
any other current payment methodology, just to clarify.
Okay.
DR. NICHOLS: Oh, I think it's very creative. I
think unambiguously in favor of giving them the technical
assistance we think they need to get to the Promised Land.
I will point out that the letter that came around
in email said they agreed with our assessment of the number
of chronic conditions. A letter that came more recently
did not.
DR. PATEL: Right.
DR. NICHOLS: Well, I'm confused, too, because I
thought this was a printed version of what came in the
email, but this is a different letter. Okay.
CHAIR BAILET: Yes.

DR. NICHOLS: So there are some differences of opinion, and we probably should just table that. I would just say, in my mind, I'm still not in favor of chronic conditions, but go ahead.

CHAIR BAILET: Tim.

DR. FERRIS: Well, I did want to say that, harkening back to our discussion yesterday about what might work for one group and what one group is willing to do, our job is actually to think about the implications of a model generalized. And, again, it's novel. It's really interesting. There are risk adjustment methods where you can simply count conditions, but in this particular setting and in this particular model, this has not been tested. And I would say to base the financial future of a group of physicians on a risk-adjusted model that there is no empirical experience with is a risky thing to do, and that is where it sort of fell down for me.

CHAIR BAILET: Kavita, are you --

DR. PATEL: Yeah, I'm done.

CHAIR BAILET: Okay. Very good.

Any other questions from the Committee?

[No response.]
CHAIR BAILET: Well, then at this time, I'd like to invite Dr. Ikeda up to the microphone, and please introduce yourself for your remarks, which will be in the 10 minutes. Thank you.

DR. IKEDA: Thank you very much.

CHAIR BAILET: There you go. You're good.

DR. IKEDA: Thank you very much.

My name is Daniel Ikeda, and I am a physician from Sacramento, California, in private practice.

I am boarded in pulmonary medicine, infectious diseases, and critical care medicine. I belong to a multi-pulmonary and infectious disease group in Sacramento in private practice. We have about 25 of us, and we operate both in an office-based practice as well as act as intensivists in multiple hospitals in the Sacramento area.

And so when we looked at the changes in MACRA, one of the things that we were anxious to look at is a way to use telemedicine in order to achieve the six goals that Dr. Price had talked about.

We have had -- been very experienced in telemedicine in the intensive care unit, where one of the -- probably the beta site for the VISIQ EICU back in 2003, and through that experience really got a feeling as to what
telemedicine has to offer medicine in general.

Not only are we able to use a single physician to multiple, multiple hospitals for acute interventions, but the data repository developed through this system allowed us to actually look at outcomes to create pilots on various papers or ideas and to see whether or not we can validate these very different things.

Early work in sepsis allowed us to reduce mortality from 40 percent to 28 percent in a matter of months, and we're able to use that experience to then apply protocols throughout the city to achieve similar results.

And as we come to look at COPD, the problem with COPD in the clinical practice is that it's a difficult disease to manage, and the problem with the expertise in the area is that much of us as pulmonary physicians are really drawn more toward a hospital-based practice.

Currently, I spend a week a month in the office because all the priorities for my expertise is in the hospital, and clearly, there is a need out there for better monitoring and management of these sick patient populations.

Now, in looking at this project, I mean, I figure when you create a proposal, you ask for everything you
want, with the expectation you're going to get pushback,
and that's why I'm here.

[Laughter.]

DR. IKEDA: But I didn't know how else to write
the proposal.

But, clearly, the one thing I do want to talk
about is the risk adjustment methodology.

Part of doing risk adjustments, especially when
we're willing to take risk, is looking at what are current
models of risk-based treatments. As you look at history of
capitation, it's all generally based upon a benchmark base,
typically on a mean, and the goal is to improve financial
outcomes based upon that mean.

Now, the problem with that is that in the past,
these types of plans are subject to cherry picking. In
other words, if you can get a population of low-risk
patients and skew your distribution curve to that side,
your numbers are going to look great, but you don't
necessarily provide the care that you really want to do.

So, for instance, in COPD -- and having access to
the chronic condition database, which appear to be very
robust and stable based upon just looking at averages over
years, it provided us at least a thought of an opportunity
to see if we can actually develop a capitation model that doesn't reward cherry picking, because if you think about how this would work under a classic condition, as part of the evaluation, somebody created brand-new tables that were great. I wish I had them when I wrote the proposal.

And among the comments was a fact that based upon their evaluation of a universe of COPD patients with existing COPD, which had the biggest n, the average cost of care was about $24,000.

Now, when we did our proposal, we specifically removed the low-risk patients, patients with Conditions 1 and 2, and by doing so, our average cost of care was $32,000.

Now, it's the same population because we did the calculations both ways, and so that suggests that if this [unintelligible] were to go forward on a classic capitation model, then there is a risk that the whole process would fall apart because of gain-sharing, and that's not what our purpose was.

As a critical care physician, I am very comfortable taking care of very sick patients, and it's really this population of patients in the outpatient that needs the case. In a classic capitation model where I'm at
risk for losses and wins, for every sick patient I get, I want two or three healthy patients, if that's the model of capitation.

But using a model that actually forms separate buckets of risk -- and, in this case, using chronic conditions as that -- informing a mean, a median, knowing what the 99 percent distribution on the high side is for the fat tail, it provides us now a much better ability to skew my distribution curve toward the sickest of the population, which is the population that really needs the service, without the fear that I'm going to screw myself over because I've chosen a [unintelligible] distribution of patients.

And so, as we look at the risk to me and to our group, I am far more concerned about a risk-based model that is based upon the universe of COPD patients because, first of all, the annual cost of care is much lower. Therefore, I would have to actually improve care by a much more dramatic amount in order to achieve savings for Medicare.

On the other hand, if I had a capitation model that actually looked to capitate the high-risk group at their true cost, then reductions in cost related to
reductions in ED visits and hospitalizations will dramatically improve the overall cost in the high-risk group, which will be reflected in the overall cost of care based upon a comparison, an apples-to-apples comparison of distribution of, say, patients with, say, nine chronic conditions or seven to nine chronic conditions. You can probably lump them at that base, because in those tables, Table 1 shows that the distribution of patients from 1 to 20 actually formed a pretty good normal distribution, but obviously, the costs associated with the zero percent versus the 99 percent are vastly different.

And that's why we developed this proposal, specifically looking for a model that we would be willing to take risk in, and the only model that really works is not taking care of the healthy portion of that population, because that would actually cost money to Medicare as opposed to save money to Medicare.

And so that's why we developed this methodology, to really address that question, and based upon that, obviously we have concerns about tail risk in this high-risk population. I don't have an answer to that, except to say that as we did our per-member, per-month fee, we started first with an assumption that, well, what is a
reasonable number to start working with as a benchmark, and so we went to the oncology model. And they suggested about a six percent cost increase. Now, whether that is valid or not, at least it gave us a benchmark that we can put aside and say, well, okay, for 2,000 patients, that's a revenue stream of $4.2 million for our proposal.

Then the question is, is this something we can financially do, make it valuable, but more importantly, can we create a model that is then scalable?

So setting that aside, we have been working on budgeting as to what we would actually need for this process, and part of that is really in the paper that I sent today, where basically outlining what are beneficiary-to-health care ratios that would be appropriate and safe, what are the supervisions, what type of ancillary help I need, setting up a new office, needing health care consultants to help through this process of the data, which is really critical to this type of project.

And our annual budget to maintain the program right now is running about $3 million, proposed. Plus, there is infrastructure cost that started that we probably will estimate at about 5- to $800,000. And then that leaves the remainder, which we felt in order for us to have
a go at this, we would need at least a 20 percent revenue
withhold in order to protect ourselves if the project fell
apart. So we're talking $800,000 to $1 million that we
would basically put in a withhold account in order to cover
our downside risk.

And with that, we felt we can actually do this
project and accept the risks, which are still unknown to us
to a great extent, but create a model by which population
monitoring can now be financially viable.

And that's the key. That's a problem with
telemedicine. There is no good financial model to make it
a viable product, but if this project works, then all of a
sudden, it opens the door for other things.

Now, regarding coordination of care, when I did
the proposal, I realized that if we are talking about
receiving revenue for multiple chronic conditions, at some
point we would have to address the other chronic
conditions. And the dilemma I had in the proposal was not
talking about that because I didn't want to deviate focus
from the primary project. So now we're talking about,
well, we can do telemonitoring for multiple chronic
conditions. And in reality, that's not really what I want
to do right now. I need to validate our assumptions first
with what I think is the easiest of the chronic conditions to actually save Medicare money. You know, as a 30-year expert in infectious disease in pulmonary, this type of system will recognize infections at early stage. It doesn't have to be pulmonary. It could be something else. It will recognize early exacerbations of COPD. And if we can capture that and, more importantly, train patients on a continuing interaction to recognize these things and know what to do ahead of time, we will go a long way in preventing ED visits and hospitalizations.

And so, you know, I find the discussion between the care model and the reimbursement model very interesting because we struggled with that, too. We want the care model, but we have to develop a reimbursement structure that would make it viable, but more importantly, if successful on a limited basis, is it economically feasible to scale up? And that's the input I can give you right now.

And I'm open for any other questions.

CHAIR BAILET: Thank you, Dr. Ikeda.

Tim you had a question, and then Bob.

DR. FERRIS: Well, first just a comment. If more physicians in the United States were so focused on the
integration of a care model that is proactive and attempting to minimize the utilization of services, at the same time so thoughtful about the payment models that are necessary to undergird and support that kind of care model, then we wouldn't have a reason for existing. [Laughter.]

DR. FERRIS: So having said that, I did just want to get your take on a specific concern around -- I'm sorry, this is going to be a little technical, but you seem to be up to it. If you simply count conditions, I'm going to read you five conditions for two different patients, chronic conditions. So the first patient, Patient A, has hypertension, arthritis, gout, psoriasis, and chronic sinusitis. The second patient has heart failure, amyloidosis, stroke, coronary disease, and diabetes. Those two patients are not even remotely similar from either a cost or a care delivery perspective.

And so while I am really excited about the novelty of the method you're proposing, I'm not sure, given those two different scenarios, that there is not still an opportunity for a risk adjustment system to either be abused -- which all of them do; we're not letting the perfect be the enemy of the good -- or that through some
random chance, the risk adjustment system actually might leave a physician's practice in the lurch due to just the variability in the selection of patients that it was unanticipated and uncontrollable. And so I just wonder if you'd comment on that.

DR. IKEDA: So what I will tell you is that, obviously, the two patient examples you gave me, first of all, none of them had COPD, all right? And I think that's critical at least to this proposal.

DR. FERRIS: The comorbidities.

DR. IKEDA: Right.

DR. FERRIS: There was an assumption that they both had --

DR. IKEDA: So everybody in my cohort of patients will have COPD or asthma as a defining condition to enter the program, because that's the area where I have the expertise to intervene. You know, and just looking at the new data tables that came out -- and the one I'll reference is Table 2B. So if you look at that particular table, and you look at ED visits, ED visits related to COPD, hospitalizations, hospitalizations related to COPD, there's a validation that in patients with COPD much of their high utilization costs are due to their lung disease and not to
their other comorbid diseases. And that's the disease
state that I'm targeting to control, and that's why I am
proposing I take all this risk to prove it.

Does that answer your question?

DR. FERRIS: It answers the question in the sense
that you, because of who you are and what you're committed
to, are willing to take on the risk. But it does not
answer the question of whether or not either the system is
gameable or that it could result in adverse financial
consequences to any specific practice given an
uncontrollable risk selection.

DR. IKEDA: So I presume we'll be a guinea pig.

DR. FERRIS: I'm sorry?

DR. IKEDA: I presume we'll be a guinea pig.

CHAIR BAILET: Yeah, yeah. Thank you. Bob?

DR. BERENSON: So let me start by saying that I'm
very sympathetic to what you're trying to accomplish here.
I have a family member who wound up on a ventilator two
consecutive winters for weeks at a time because early
symptoms were ignored, and that's what happens. So I'm all
for it. But I have some concerns.

Let me ask you this: You're in Sacramento. It
is the heart of Medicare Advantage country. Are there
Medicare Advantage plans who have been interested, or capitated medical groups -- there's over 200 of them in California -- that would be at risk and presumably would be quite interested in a technology that could reduce hospitalization and morbidity and mortality. So what's been the experience there?

DR. IKEDA: Well, the answer is there is a great deal of interest. But the question is: At what cost and what reimbursement? That's unestablished since we really don't have -- this is not a viable program as we sit here today. So, you know, part of this proposal from our minds is to establish what is a pricing model that we can use as a benchmark as we go to a Medicare Advantage plan. And I don't know what the answers are related to that, because I know what our costs are going to be, and it's not inexpensive. And so from that perspective, you know, I have two medical directors that want to talk to me, you know, after we get this process done, and we are anxious to look at that.

Down the road, we want to treat asthma in MediCal, or in Medicaid since we're in Washington, DC. And, originally, this project was developed for, I think, the Innovation 2 grants, but I couldn't finish it in time.
to submit for that. I really wanted to treat a Medicaid population using this model.

Obviously, since it was a grant, I didn't know what the payment model would be afterwards and whether it would be sustainable. But that's water under the bridge now. But I think that this type of care is easily replicable for Medicare Advantage plans and capitated plans.

Now, whether it's designed to improve care or reduce costs is a different matter because you can -- because in each individual Medicare Advantage plan, they may not have the sufficient volume of patients in, say, COPD to make it, you know, worthwhile for us to do and for them to entertain, although it may be very viable for them to choose high-risk patients in general and monitor them that way. But then the goals and outcomes would be different necessarily. It's not necessarily to save money -- it is, in one sense it is, but really to provide better overall care and hopefully through that process reduce the costs to Medicare, which are not as predictable as with patients with COPD.

DR. BERENSON: Let me just follow up. My concern basically is that -- well, if I were -- let me just say
If I were a Medicare Advantage chief medical officer, I would be looking for more than a German study to demonstrate the proof of the concept. This strikes me as quite relevant for clinical research to prove the effectiveness. We do know that disease management has potential negative impacts when one organization is doing the disease management and they are not integrated with the practice that's actually responsible for the patient. Those would be the kinds of questions -- so I guess my question is: Have you attempted or thought about the need for doing clinical research to prove that the intervention actually works to improve quality and decrease cost before trying to get a national payment model in place?

DR. IKEDA: The answer is I'm a clinician; not a researcher. And through, you know, our experience with telemedicine as well as in the practice of pulmonary medicine, we strongly believe as a group we will save money. We will prevent people like your relative from hopefully getting sick enough where he ends up intubated. I mean, I see this all the time in the intensive care unit. And when I talk to them after we've hopefully saved their life, I ask them, "Well, how many days of symptoms did you have before you came to the hospital?" And typically
there's this window of time, whether it's two to five days, where patients ignore their deteriorating symptoms and come in where it's too late to intervene at a point where they don't need to go to the ICU. If I can capture these patients early, I will prevent their hospitalization. I know that.

And so based on the studies that we have read, we've seen enough information so that we are willing to take risks on this because we firmly believe we will achieve the outcomes that will provide the six points that all of you are looking for in all your projects. We have that type of conviction.

CHAIR BAILET: Thank you. Harold?

MR. MILLER: Thanks. And thank you for doing all this work. I agree with Tim that this is the kind of thing that we hopefully will be encouraging. I had, I guess, three questions.

The first one in some ways is related to the question that Bob was raising, which is that, if I understand the proposal correctly, the physicians in your group would not actually ever see the patients in person -- you can clarify if I'm wrong about any of this -- and that there would be basically a remote monitoring to support
other physicians, primary care physicians or otherwise, who are the primary care managers for the patient. And as Bob was referencing, most of the experiences with care management programs have shown that unless there is some, a direct patient contact, at least for a portion of the time, not totally, and that there is some real involvement of the patient's primary care physician who's managing the condition, that the results are less successful. I have my own personal experience, having run a project like this, which is getting the primary care physician or whoever is managing the patient to be engaged with the patient, to have them accept that this thing that they're participating in is helpful is important.

So I wasn't quite sure that I understood exactly in reading the proposal how you envisioned that connection sort of from the patient's perspective working. So someone is helping them manage their COPD or asthma. You're helping them manage that. And how would this appear from the patients' perspective? And how would the patient feel like there was really a team working together to support them?

DR. IKEDA: Those are all very good questions.

MR. MILLER: Thank you.
DR. IKEDA: What I will tell you is that everything we envision looks at these issues. The reality of what we actually are going to do still is in flux, you know, because I don't have a specific answer for you.

What we envision, though, is that as patients become linked to us through this daily interaction, what we hope to happen is that they will call us first if they think they're in trouble. And based upon that call, we can intervene, initially remotely, with maybe hourly or daily follow-up to ensure that they're not getting worse. And if they are not getting worse, you know, we will plan to see the patients if they are local.

Now, as we go to a more scaled issue, that's going to be much more difficult, but that's why I believe in scaling. It will require a consortium of physicians to really take over that portion, that role. You know, I think that what this continuous interactive monitoring will do behaviorally is really try to reset behavior, to make patients, you know, adherent to a certain time of day doing certain functions, becoming more educated and empowered to recognize their symptoms, to take presumptive action given a specific set of rules, and to call us and let us know what's going on so that we can make sure they've made good
decisions; and if they're not doing better, to get them to an appropriate health care provider immediately so that they don't end up in the emergency room. And if that health care provider is us, then that's what we're committed to do.

MR. MILLER: That all makes perfect sense to me, and I have seen that in action. The challenge I'm talking about is how to actually get the patient started in that process, to actually be -- because I've seen the problem that patients have had enough of yet another person being involved. So I guess I would just suggest that I think that sort of how you get the patient engaged and how do you have the PCP engage the patient is important.

The second question I wanted to ask is: If I understand it correctly, again, you're proposing a flat per-beneficiary, per-month payment, and the risk adjustment would apply to the spending target, even though it would seem to me that the patients who have more needs and more diseases are, in fact, going to take more time. So I wonder if you think there is still a potential for a cherry picking problem with a flat PBPM.

DR. IKEDA: I don't know the answer to that. You know, I presume that as patients have many more chronic
conditions, that bucket mean cost will be much higher than somebody with three less chronic conditions. Obviously, that sicker patient will have a higher likelihood of going to the ED and being hospitalized. And, yes, they will require more time, but really that's the patient that needs the time. You know, that's why when we look at ratios of providers to patients, we'll get a sense as to who the patient populations are at highest risk of having problems. And, you know, I can't tell you we have processes for that right now, because we don't. But, clearly, you know, if we can identify a cohort, a subset of that patient, that we can say they're going to be in the hospital in the next three months unless we change things, then it's imperative on our part, even if only from a financial point of view, to create a treatment plan designed to attack this in conjunction with the primary care provider, because many of the problems that we may face and I expect to face will be non-pulmonary. And we have to acknowledge that we will play a role in that intervention to get the patient to the right provider.

MR. MILLER: But I'm accurate that you're proposing a flat per-beneficiary, per-month payment --

DR. IKEDA: That is correct.
MR. MILLER: -- and not a risk-adjusted payment.

And the third question, which I was convinced that Bob was going to ask but he didn't -- and probably will if I don't -- is COPD and asthma are both underdiagnosed and misdiagnosed conditions. And I wonder what you have thought -- so, again, when a model like this all of a sudden the payment is based on the patient having the condition rather than a particular service being performed. And I wonder if you've thought about particularly, again, given your, in a sense, distance from the patient, that you won't actually, if I understand again correctly, have seen the patient yourselves and diagnosed the patient, whether you've thought about what problems that might create and whether there are ways to address that.

DR. IKEDA: Well, I think part of it is patient selection, correct? And that's particularly what you're pointing to. You know, we foresee, starting the project, initially looking at our own patient population to see how many chronic conditions they have and whether or not they would fit a program like this. We envision that many of the patients that we try to enroll into this program will be patients who actually are captured through their ED visit and hospitalization.
And so meeting that gold standard of having a disease sick enough to be treated in an ED and hospital kind of skews the population more toward the more at-risk side than to the healthy side.

MR. MILLER: Well, potentially, I guess it does get still to the issue of how good the risk adjustment is, but I just want to make sure I am understanding this correctly.

I thought when I read your proposal, you were talking about providing this support for a broad regional range of practices. This is not essentially we are a pulmonary medicine practice and we want to have this service for the patients that we manage completely ourselves, sort of a specialty medical home concept.

This is the concept where you would be providing a supplemental special service for others who are managing it. So the point is you would not necessarily have been seeing these patients. You would only see them after something bad happened eventually.

DR. IKEDA: Correct.

MR. MILLER: And even -- I'm not even clear on whether then you would see them, because they might end up at a hospital that you don't staff.
DR. IKEDA: That is correct.

MR. MILLER: Okay.

DR. IKEDA: So I don't know what happens when it scales, when we go beyond areas that we physically can service, and to that extent, I am kind of trusting the database because I figure the database is going to be the same, either way, as patients become more remote to us physically, that people all of a sudden aren't going to come up with new diagnosis of COPD in order to get into the program if they lived 90 miles away, at least that's my assumption.

MR. MILLER: Thank you.

CHAIR BAILET: Kavita and then Bruce.

DR. PATEL: Dr. Ikeda, I first wanted to commend you because I can only imagine -- it seems like your imprint is all over this proposal. I can't imagine how in private practice and what sounds like a very typical busy practice, you actually had the time to pull this together. So I wanted to just tell you that I could never have done that, and I'm impressed.

I wanted to ask kind of two -- you've seen now the communication kind of back-and-forth, and it seems like there is some kind of questions about how -- even with your
thoughtful response about the quality metrics, kind of how you're thinking about maybe tying that to the payment model. I respect that your day job is to actually take care of patients, so you don't study payment models on a daily basis.

But do you mind -- just having heard that critique, can you articulate how you may have thought about the linkage in quality with what you're proposing?

And then my second question -- that was just the first one.

DR. IKEDA: Okay.

DR. PATEL: The second question ties to what Harold mentioned about the diagnosis issue --

DR. IKEDA: Right.

DR. PATEL: -- because, as an internist, we know that so many people are misdiagnosed probably by my own hands, and so there's reliance on your ability to do kind of thoughtful pulmonary function testing, et cetera. In whether it's the German study or other studies, have you seen some kind of requirement or criteria that has like a documented basis for the diagnosis?

DR. IKEDA: Well, most of the studies don't talk about chronic conditions, number one.
DR. PATEL: Right.

DR. IKEDA: They talk about COPD.

DR. PATEL: Right.

DR. IKEDA: And most of their entry criteria are based upon spirometry data.

Now, as it turns out, these new peak flow meters actually have spirometry capabilities, and so looking -- and that's why we chose that, because, number one, it would meet PQRS standards daily, and we'd be able to evaluate that to determine if, in fact, we thought patients were misdiagnosed based upon that data. That's not great, but at least it gives us more information to deal with. That's that question.

Regarding the first question, as providers of care in our telemedicine unit in the ICU, we have been dealing with quality standards and metrics for the past 13 years, and typically, our reimbursement for our services are tied to meeting certain benchmarks in those quality standards. So we don't have a problem being benchmarked to quality standards and attempting to meet those goals.

I guess the question is, What are the important quality standards of the person paying me, and what do they want? Because I can propose a list of different quality
standards, and they may not have an interest in those, maybe because I can achieve them so readily. And I'm more than happy to ask the payer, "What are your quality standards, and what benchmarks do you want to hold us to?" And I'm perfectly happy doing that. We're very comfortable with that process.

DR. PATEL: In one of your letters of support -- I want to make sure; I was trying to flip through to find it -- it looked like it was the State of California or DHS, perhaps.

DR. IKEDA: Yeah.

DR. PATEL: So you mentioned Medicaid.

DR. IKEDA: We mentioned Medicaid.

DR. PATEL: We have a letter of support from the state. California enjoys one of the broadest delivery system reform waivers. Was there ever a question or potential for like a State of California Medicaid-level pilot or kind of building a -- Bob talked about MA. I'm just curious --

DR. IKEDA: Right.

DR. PATEL: -- if that came up in --

DR. IKEDA: Well, they were really interested in us getting the grant.
DR. PATEL: You mean getting this to work?

DR. IKEDA: Getting the grant in order to do the pilot.

DR. PATEL: You mean the original CMMI grant that you had applied for?

DR. IKEDA: No. For the Innovation II grant.

DR. PATEL: Innovation II, okay.

CHAIR BAILET: Yes. Right.

DR. IKEDA: And so when that fell through, they were not necessarily interested in creating a funding model for it.

DR. PATEL: Okay. Thank you.

CHAIR BAILET: Bruce.

MR. STEINWALD: I would like to follow up on one of your responses to the question raised by Dr. Ferris on risk adjustment. Clearly, that was an important issue for the Preliminary Review Team.

I want to make sure I got this right. When Dr. Ferris identified these two very disparate patients with five chronic comorbidities and you agreed that they were very different -- but I think you said because they all have COPD and COPD tends to dominate the costliness of the patient, you weren't so concerned that those comorbidities
were very different from each other.

Do I have that right, and if I do, could you remind us on why -- on what basis do you make that assertion that it's the lung disease that really dominates the patient's costliness?

DR. IKEDA: Well, I have to look at the data. I mean, the data with COPD as a primary or secondary condition dominates ED and hospital admissions, at least looking at the data that was provided to the team. That was our initial assumption, quite honestly, is that in patients with multiple comorbid diseases, inability to breathe is probably the single most frequent symptom forcing people to go to the emergency room.

Now, inability to breathe may not be due to COPD. It may be due to heart failure, but clearly that plus infection. So, based upon that, I don't really know how to control a lot of these other chronic conditions like arthritis. Clearly, I know that control of hypertension is good, but it won't necessarily be reflected in any immediate outcome benefit.

So based upon lack of information that control of other chronic diseases adversely impacts the overall cost and utilization, as long as they have COPD, that's the one
variable that I propose to control.

Does that make sense? Does that answer your question, I guess?

MR. STEINWALD: Let me follow up just for a moment. Yes, it's the one intervention that you hope to control, but it also -- as I understood your response to Dr. Ferris, it also makes you more comfortable that the differences in comorbidities of different patients with COPD don't concern you that much because the COPD lung disease dominates, in your view, the costliness of the patient.

DR. IKEDA: I guess the real answer is I don't know.

MR. STEINWALD: Okay.

DR. IKEDA: But I am willing to find out.

MR. STEINWALD: Thanks.

CHAIR BAILET: Grace.

DR. TERRELL: Just a series of questions, some of which are just very quick answers. First one is there's chronic care management codes that are part of the fee-for-service system now. Did you all look at those? Have you used them? If not, why not? Has there been an opportunity to think about that with respect to the processes that
you're doing?

DR. IKEDA: Well, I don't see that code as necessarily being applicable to telemedicine --

DR. TERRELL: Okay.

DR. IKEDA: -- because the proposal, as written, is not really designed to be a chronic disease management skill, although that's incorporated into the process.

If we're being paid a per-member, per-month benefit and taking risk, I don't see why I should be charging an additional charge for chronic care management.

I mean, that seems to be double dipping.

DR. TERRELL: I was just looking at in lieu of that. In other words, right now, without this payment model, there were some other things that are out there. Are you utilizing them, and if not, why not?

DR. IKEDA: Obviously, the whole impetus for us wanting to do this project is to look at MACRA and how as specialists we can participate in some form of advanced payment methodology that would basically allow us to get a five percent increase in our Medicare payment.

DR. TERRELL: Okay.

DR. IKEDA: And that's a very big incentive for us, as it would be for any other provider that enters this
I don't see how using the chronic care management codes achieves that goal, unless you can tell me.

DR. TERRELL: Okay. My next question is, if you were wildly successful with this -- you've sort of alluded to this with some of your answers to some others, and we just were able to really work this out for your group and your region. What steps would you see that we would take to make this a national payment model, given the specificity of your particular situation with your practice resources, versus sort of the Wild Wild West of the entire U.S. health system?

And the reason I'm getting to this, you alluded to it earlier. You wrote, I think, initially a grant proposal that you didn't get in on time --

DR. IKEDA: Right.

DR. TERRELL: -- and used that thought process to actually write a proposal for a payment model, and one of the tensions, I believe, that's going to continue to happen at the level of PTAC are folks who are thinking about their own circumstances and saying, "You know, if I had this particular thing, I could really practice better medicine and achieve things that I can't in the current system,"
versus if we looked at that, how could we roll that out above and beyond just an individual practice? As we are thinking about that at the level of PTAC, that's one of the things that we are really working on.

So any wisdom you have or any thoughts you have as to how we could go from your specific circumstance to a wider policy approach, I would be interested in hearing your thoughts.

DR. IKEDA: Well, what we assumed is that if we were wildly successful, people would find out and re-create the model --

DR. TERRELL: Okay.

DR. IKEDA: -- because the payment methodology would be there, and that's part of the intent.

Do I think I could provide services nationwide? No, I don't think so.

DR. TERRELL: Okay.

DR. IKEDA: I mean, if I can just provide a region-wide, that would be a start, and maybe we'd have some expertise at the end of this to scale up and down California and maybe some of the local states. But my expectation is the economic benefit related to this and the ability to be designated as an advanced payment methodology
will attract other people once they figure out that the real risks in doing this right are small.

Right now, people think I'm crazy to propose a capitation model that's based upon treating the sickest of the sick, but I do believe -- and as a group, we believe -- that we can accomplish this goal. So I hope from that standpoint, we're successful because, if we're successful, the proposed payment model is economically robust enough so that it should withstand, hopefully, the bad fat tail risk that is always going to be out there or ultimately will come to agreement with CMS assuming -- that's one of my questions, actually, is if the proposal gets approved to pass on to the Secretary, it's really my assumption that CMS will look at the proposal and at that point start making changes to the actual implementation of the concept to an entirely different plan, and I was kind of preparing for that discussion at some point in time to see how that works.

Once those particulars are worked out, then the model is then out there for other people to duplicate.

DR. TERRELL: Okay.

DR. IKEDA: And I think that's the answer I will give you.
DR. TERRELL: All right.

DR. IKEDA: But I think if I am wildly successful, this will scale rapidly because it has all the advantages that we all seek in terms of patient care outcomes, and it's financially viable for whether it's a system-wide health care plan to incorporate and then start using those revenues to treat their Medicaid patients in addition, because if I am correct and we are wildly successful, that's the population I really want to treat, because there is no good payment model for that. And providing the service individually is very expensive.

DR. TERRELL: A couple more questions. One of the things that's interesting about a model that's taking care of the sickest of the sick and doing it in a capitated risk point of view is related to end-of-life issues, and there's a point where integration with palliative care and not doing everything, it sometimes prevents the patients on a ventilator.

How much of the model that you have here --

DR. IKEDA: Envisions --

DR. TERRELL: -- can address that?

DR. IKEDA: Envisions that possibility?

DR. TERRELL: Yeah.
DR. IKEDA: Well, it's interesting that you mention that. One of the Innovation I projects that was completed was a project called AIM, which deals with the last life of care, and that project was performed by Sutter Health, which I'm affiliated with. So I'm well aware of that process. One of my partners is certified in palliative care, and so we've talked about, to some extent, how to incorporate these concepts. Obviously, in doing so, it will increase our mortality --

DR. TERRELL: Right.

DR. IKEDA: -- since in planning for end of life, we have to assume that we're actually increasing mortality over the short term, as documented by the successful study by Sutter, where they did save Medicare in that program a large sum of money.

So, obviously, we're not going to reinvent the wheel there but intend to work with Sutter in this process.

DR. TERRELL: Okay. The final question I have is respect to the quality stuff that initially we felt that your application didn't address adequately. What you've brought back to us today are quality measures that are related to utilization of services. It's hospitalization
and ER and all that. But one thing that's true about the pulmonary and the chest specialist is they've got very specific, more traditional guidelines with respect to quality that have to do with utilization of certain types of pharmacotherapy, long-acting beta-agonist vaccine, many, many other things, when to use pulmonary rehab.

Is there a reason why you did not think about those as being something that should be part of this measure with respect to quality and outcomes? Is that something that you're just already doing? Is that something that the care model itself would or would not be part of? I'm just curious about that because those, I presume, are the things that, at least as far as we know right now, have some impact on long-term management of COPD exacerbations.

DR. IKEDA: Well, you are absolutely correct, and in fact, in the proposal, I listed that we would be using guidelines from these models.

Now, whether or not Medicare would want to benchmark on compliance with these, we're perfectly open for that, because really benchmarking to quality goals is, in our minds, primarily the desire of the person paying us, because we want to be benchmarked to the goals they want to
measure versus the goals necessarily that we want to measure.

DR. TERRELL: Thank you.

CHAIR BAILET: Dr. Ikeda, I share Dr. Patel's earlier comments and applaud your efforts, given that you're a busy critical care physician.

I have a couple of questions. I don't want to get, necessarily, into the weeds, but you made an earlier comment about your experience with the eICU. You were one of the early adopters or worked in a system that had adopted that. Having placed that system within a 2,000 employed-physician group and 15 hospitals, I want to understand that. These initial 2,000 patients, are these your patients specifically, or is this a population of patients that you are going to be monitoring, much like the eICU methodology?

DR. IKEDA: Well, I think for this initial recruitment, it would have to be locally. For the pilot we would have to look into Sacramento County residents. Now, in Sacramento County, based upon the latest data, there are 18,000 people, Medicare, with a diagnosis of COPD.

CHAIR BAILET: Okay.

DR. IKEDA: So the population is there. And so,
you know, we, in our office, see just the tip of the iceberg, which are typically the sicker of the sick, and obviously a number of my patients, in my practice, would benefit from something like this. But we also see many patients that are not as well monitored or cared for, through the emergency rooms at various hospitals, that get admitted, and we envision trying to create a program to recruit and enroll those individuals into the program, and we'll find out how successful that is once the program is running, assuming it's approved.

CHAIR BAILET: Right.

DR. IKEDA: But that's what we envision first, is really, it's that high-risk population where the capture point typically is going to be in the hospital-based setting.

The other component will be an outreach to the varying groups in town, as well as to competing organizations, such as, in Sacramento there is Kaiser and UC Davis.

CHAIR BAILET: Right.

DR. IKEDA: And we want to be open with them as well, to offer the services and allow them to participate in this as well. But I think before I can go to that next
step, I need an actual payment model that I can say, you know, we're going to pilot this. Dr. Louie, you know, at UC Davis, you know, can you -- are you interested in, you know, in doing the research and seeing how this works as an independent provider?

And so I think, you know, we'll be able to achieve that 2,000 through a variety of means, although I clearly don't have an actual number of distribution as to how that's going to happen.

CHAIR BAILET: So, thank you for that clarification, and here is directly what I have a question about. This is new, and I was on the ground when eICU concept came to the fore, and the challenge that we had, which was not necessarily just the challenge within my own practice, was that these patients, if they're not your patients, have very strong relationships, because of their comorbidities and just their sort of genetic makeup, if you will, they are very sticky to other physicians.

DR. IKEDA: Exactly.

CHAIR BAILET: And the other physicians have a very significant influence over what happens with these patients, and what happened in the eICU environment were that you had this cohort of physicians who were not their
physicians but they, by chance -- by just the nature of the program, were monitoring these patients. And there was a lot of tension between the monitoring physician and the physician cohort that actually had a very strong bond, and patients were -- there was a lot of tension. There was a lot of opt-out. There was a lot of challenges in the early adoption.

And so I guess I'm curious, have you thought through -- have you had that experience? You've thought through those challenges, having been in the trenches?

DR. IKEDA: Well, I was the medical director during the time.

CHAIR BAILET: And you're still here to talk to us.

DR. IKEDA: And so I had to talk about the fact that we weren't big brother, and we're not trying to take over the care of their patients. And it took a long time, in some instances. You know, obviously, you know, whenever we did write an order on such a patient we certainly contacted the physician, indicating the reason why we intervened. But over time it worked out. You know, they lost fear.

But regarding this project, you know, clearly,
you know, if we get the green light, one of the first projects is really a physician outreach, town hall if you wish, to find out how do they feel about entering their high-risk patients. What do they get in return? Obviously we want to make sure that any patient that’s entered into the program meets their MIPS PQRS standards, so that they can report that. Clearly, we want to be a lifeguard and a safety net for their high-risk patient population, similar to what we do in the eICU. And, clearly, we want to figure out how coordination of care should occur without the physician on the other end feeling we're usurping their responsibility and their patient population.

So those are all issues that, you know, we look at, and that's why, in part, with the coordination of care I kind of didn't know what to do with that question.

CHAIR BAILET: Yeah, well, and that's something that we'll discuss when that metric comes up a little later. Elizabeth?

VICE CHAIR MITCHELL: Thank you, and thank you very much for the proposal. I have two questions and a comment.

My comment, first, was just to sort of recognize and applaud your statement that said you were ready to be
held accountable for the priorities for whoever is paying
you. Having worked with public and private employers, that
is not always something that people are so bold about, so I
just wanted to recognize that.

My question, one is on sort of the HIT aspect of
this. I think the PRT -- and you said that there is
clearly a technology component that people are comfortable
with. I'm more interested in the information-sharing
aspect of that criteria. And you've acknowledged some
potential barriers created by the, perhaps, lack of
interoperability across the EHRs.

So can you comment on how much of a barrier you
think that will be, and some of your thoughts on how that
will be addressed?

DR. IKEDA: Locally, it shouldn't be that big a
problem. You know, right now, you know, in our private
practice we use an EMR called Athena, which has no
connectivity at all with any of the EHRs from the groups,
so currently we end up faxing and scanning a lot of stuff.
But at least within our region we are now -- it is starting
to coalesce around Epic. You know, the Sutter system has
it. It looks like the Mercy outpatient system is going to
-- or Dignity now -- outpatient system is going to evolve
to it. Kaiser has it. UC Davis has it.

And so for the purpose of this project, we would probably use Epic as our platform, which allows connectivity to the varying providers city-wide. So locally, that's easy.

You know, as we think about scaling it, it does become an issue, and I don't have good answers to how we're going to -- how we would approach and overcome those issues. That's what I think I need an IT, you know, person to talk to, other IT people, about how we can make that happen.

VICE CHAIR MITCHELL: Well, thank you. That actually segues to my other question, which is very similar to, I think, Grace's question about scale, because, obviously, scalability is a key -- well, key part of our thinking. But my question was more focused on readiness. You have been, I think, extremely candid and open about the unknowns of this model, which is entirely appropriate. That's why you're here. But do you have a sense -- and this may not even be fair -- sort of the readiness of others in the field to test this, or how much needs to be learned before it is scalable?

DR. IKEDA: I think a lot depends upon whether or
not we're as successful as we hope we can be. You know, success breeds a lot of interest and taking people off the inertia step. You know, clearly, if we see signs that this is working very well, you know, we can start contacting other major groups in different cities to see if they have an interest.

I mean, you know, as pulmonary specialists we do have a network, and we can utilize that network, potentially, to scale people into their own communities if they have the interest. But everybody is going to be scared in the beginning, because the risk-sharing model I'm proposing is obviously unique. You have concerns about them. They are going to have even more concerns, since it would be their money on the line. And so the answer is, if we are wildly successful then scaling becomes a slam-dunk. If we're not successful, it goes nowhere.

VICE CHAIR MITCHELL: Fair enough. Thank you.

CHAIR BAILET: Paul.

DR. CASALE: Yeah. I will just add my gratitude for bringing this forward. Thank you. Clearly a lot of work has been put into this.

Just a quick question. You know, in the BPCI model, one of the clinical conditions is COPD, asthma. Did
you ever have a conversation or think about, again, within
the physician community that you work in, to participate in
that, and maybe leverage this as part of that?

DR. IKEDA: No, we did not. I mean, we're not
that familiar with that model, to be honest. I mean, most
times I'm in the intensive care unit, and so, you know, I
used to have a big outpatient practice but I don't now, and
from time to time my interests, you know, aren't
necessarily, you know, over there, because I can't -- don't
have the time to spend on it. But since this particular
project is one I created previously, it was easy to dust
off the shelf, honestly, and certainly I could commit to
this to the point where I already told my senior partner --
actually, I'm pretty senior myself --

[Laughter.]

DR. IKEDA: -- my boss, that I'm willing to give
the ICU back to the youngsters and devote time to this to
make it successful.

CHAIR BAILET: That's very noble of you.

We have no more questions within the committee.

DR. IKEDA: Okay.

CHAIR BAILET: Seeing none, I want to thank you
again for your attention and the detail and the effort that
you put in interacting with us and being extremely specific
and helpful in answering our questions, as we consider your
proposal. So that is very kind.

DR. IKEDA: Well, honestly, I found this to be a
very fascinating project. It kind of enlivened my
intellectual side, after just seeing patients day-in and
day-out. And so I appreciate the opportunity to have a
chance to bring this proposal forward and sit before you.
And if Blue Shield is interested, I'm willing to talk.

[Laughter.]

CHAIR BAILET: So, yeah, we'll talk a little
later about that, but again, thank you very much.

DR. IKEDA: Okay. Thank you.

CHAIR BAILET: All right. So our next section of
the meeting is, as we said, being transparent and working
with the stakeholder community, we have opened up the floor
for public comment. We had some folks on the phone who
have been listening in to the entire session, but I'd like
to have James Gajewski step up forward, if he is here, to
present. I think I got that right. You'll thank me for
that.

DR. GAJEWSKI: I do thank you, but you're only
close. It's Gayeski [phonetic.]
CHAIR BAILET: Oh, my goodness. Okay. Well, maybe another couple sessions we'll get it worked out.

DR. NICHOLS: It worked out yesterday.

CHAIR BAILET: Yes. Absolutely. Yes.

DR. GAJEWSKI: Yes. Anyway, I again want to thank the panel for the opportunity to speak. As I stated yesterday, I represent the American Society for Blood and Marrow Transplant. I actually deal with a lot of pulmonary disease, primarily bronchiolitis obliterans, but I take care of my COPD and my asthma patients because, as I noted yesterday, I, for six months to one year, to two years, sometimes, am the primary care physician for this.

Yesterday I made lots of comments about the issues of cherry picking and patient access, and I just want to remind the panel, bone marrow transplant has lived under case rates since 1991. We have some outlier clauses but we live under case rates. We also, since 2005, have had our one-year survivals published by center, and we now are having physicians and groups having to say no to patients, either because we can't get proper compensation or we have to worry about our acuity adjustments issues and our survival.

I have been on the front line to say no to the
patients for therapy when the therapy is their only chance for living. I have also been on the front line for stopping ventilators, many times in my life, in my career as a physician. So these issues are very personal to me, because of the type of practice I have, because I take care of transplants in acute leukemia patients.

So acuity adjustors -- and I appreciate all the comments about risk adjustment and I agree, perfection will be the enemy of the good, and yet we have to preserve access for these patients.

So one of the issues with acuity adjustment is data collection, and everybody here has talked about the robustness of Medicare data and yet many of us, in other settings and venues, will say that the claims data for ICD-10 and ICD-9 is very specious.

One of the issues for these complex patients is that all of us who are cognitive care providers with these complex patients are billing Level 3 inpatient, we're billing Level 5 outpatient. Sometimes we get to bill critical care with these patients, but if I do team-based care I can't bill critical care because those codes were never designed by CPT and RUC for those.

The answer for some of Grace's questions, which
is not the chronic care management codes but maybe
something that was approved this year, is prolonged
service, non-face-to-face time that may capture some of
this work effort. But it is also very hard for us, as
cognitive care providers, to get that problem list into any
sort of claims software to be as robust as it should.

And so as I think about COPD and asthma, and many
of the people at this table, I know, have treated COPD and
asthma, but how many of you have put in chronic hypoxia?
How many of you have put in CO2 retention or mixed acid-
base disorder with primary hypercapnia, because these are
the patients with COPD who are the most brittle, the worst,
the highest complication rate.

Also, as we deal with these COPD-ers, they are
also, like my patients, they have ischemic heart disease,
and there is an interrelationship. Many of them have
diabetes. They also have peripheral vascular disease,
cerebrovascular disease, all of these things.

One of the sad lessons, having negotiated
transplant contracts, both with my honorable colleagues
from Blue Cross but with every major payer in the country -
- I have lived under case rates for commercial payers since
1991. When I was a young man doing those sort of
I tried to write a contract where we would just deal with the disease and any comorbidity we would get a supplemental payment for. The problem is, when you're looking at a three- or six-month payment time period to say that the creatinine is due to the hypertension or the diabetes versus the immunosuppressant drugs I prescribe, you can't do that, and that's why we've had to live with outlier clauses.

But the issue of these comorbidities -- and I applaud the presenters for coming up with an idea, but there is going to be risk stratification with it and it's not just going to be those five comorbidities. The patient with ischemic heart disease who also has an ejection fraction of 30 percent and has COPD is a very different patient than some of the others with five comorbidities, and we are going to have to think about this or there will be this cherry picking, and the patients most in need of care will be denied access of care.

The other issue with a lot of these patients is going to be cognitive decline, and all these new, wonderful systems we're talking about require in-home sort of monitoring with electronic sophistication and usually a

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home caregiver. Well, not everybody has that. Not all these patients, when you hit 65, 70, 75, have a lot of sophistication, and these are patients on 20 meds a day. We can't get a visiting home nurse there every day to help them with medication management. We all try very hard to do that.

I also would say that some of the other issues that I, who takes care of these critically ill patients, struggle with is some of the other requirements under MACRA and some of the things for electronic health care, having patients have immediate access to my notes. My friends who are mental health providers get some protected space of access for their notes, where they can make comments, but anything that affects a patient outcome should be documented in my note.

So as I deal with patients going through divorce, that hurts. As I deal with cognitive decline, patients with what I feel are personality disorders that is affecting their compliance, where they're actually sabotaging their care, I put those into my notes. They have immediate access to them. I get comments back. It is a huge issue.

And so if we are going to do any of these complex
patients correctly, how we do this documentation of the complexity is going to be important. How we pay the providers to do this complexity of documentation is important, because the claims data is not as robust as we would like it to be, and to do this well, to preserve access, it will have to be.

The final issue, as I think about this model, you really do have a dimorphic patient population between COPD, and if you think about the Medicaid patients with asthma, which will primarily be children and adolescents and you have to deal with things of dysfunctional home situations, you have to deal with the inability to get homes cleaned because parents are working or there's family dysfunction and disaccord. All these things, and the emotional health of the environment, will drive a lot of the issues. That's data that's never been coded in claims data, number one. Number two, how are we actually going to have some control or do acuity adjustment for that, and yet we must.

And so, you know, I commend the presenter for all they have done, but I also need to have this panel to think and deliberate about all these complexities, because these are not easy. But this is what it's like taking care of patients in real-life situations.
CHAIR BAILET: Thank you, doctor.

Any other folks in the audience who may want to come forward and provide public comment?
[No response.]

CHAIR BAILET: We are now going to ask the operator to open the lines. I believe there's potentially some folks who may have registered to comment.

OPERATOR: At this time, if you would like to ask a question, please press star and the number 1 on your telephone keypad. We will pause for just a moment to compiles the Q&A roster.

Please press star and the number 1 if you would like to ask a question.

And there are no questions on this end.

CHAIR BAILET: Thank you very much. Before we start deliberating we are going to take a 10-minute recess.

Thank you.

[Recess.]

CHAIR BAILET: We're going to go ahead and please take your seats. Thank you.

We're now at that moment in time when we're actually going to start our deliberations. What we are going to do is we have an electronic voting system for us,
and as we walk through all of the Secretary's criteria and as the PRT shared the report shared earlier, we're going to look at each criteria individually, and we are going to score them as a Committee to help sharpen our thinking, and ultimately we're going to make a recommendation to the Secretary.

Also, I'm asking our DFO, Ann, to read -- because there are people on the phone who will not be able to see the screen. As we go through each criteria, she will read the results as we move through the process.

Are there any other comments from folks before we start deliberating? Is the Committee prepared to begin deliberating at this point?

[No response.]

CHAIR BAILET: I think we're ready to go then. So let's start with the first criteria, Scope of the Proposed PFPM, one of the three designated high-priority criteria. The proposal aims to broaden or expand CMS’s alternative payment model portfolio by either: one, addressing an issue in payment policy in a new way; or, two, including alternative payment model entities whose opportunities to participate in APMs have been limited.

So a score of 1 to 2, Does Not Meet; a score of 3
to 4, Meets; a score of 5 to 6, Meets and Deserves Priority Consideration. And for the purposes of this portion of our deliberation, this is a simple majority?

MS. STAHLMAN: Yes.

MS. PAGE: Yes.

CHAIR BAILET: So we are ready to vote. Yes, please, Paul?

DR. CASALE: Just a question. On the opportunity to participate in other APMs -- and I brought up the question about BPCI -- did the PRT think about whether this could be incorporated into the BPCI with COPD/asthma, you know, condition?

DR. NICHOLS: We didn't think so much about BPCI for the reasons anticipated, but we did talk about another payment model, fee-at-risk. But we talked about it, and it's an idea that would be on the table going forward.

CHAIR BAILET: I want to make one other comment before we vote. Folks who are looking at the screen will see that there are 11. Although there are 10 of us voting, the 11th person is the person behind the curtain controlling the electronics, and they are doing a good job. I'm sure that was just a fat finger.

MS. STAHLMAN: Somebody voted.
CHAIR BAILET: All right. So we're going to go ahead and start over. Ready to go.
Ann?

MS. PAGE: We have zero members voting 1, Does Not Meet. We have one member voting 2, Does Not Meet. We have zero members voting 3, Meets. We have four Committee members voting 4, Meets. We have five Committee members voting Meets and Deserves Priority Consideration, and zero members voting 6, Meets and Deserves Priority Consideration.

According to the rules of the Committee, if a proposal is found to meet a criterion, it rolls down to when we have a majority of six votes, so this would be found to meet the first criterion, Scope of Proposed PFPM.
CHAIR BAILET: Thank you, Ann.
Any comments from the Committee based on the results? We're going to go ahead to the second criterion, Quality and Cost, which is -- oh, Bob?

DR. BERENSON: We can do comments, right [off microphone]?
CHAIR BAILET: Yeah, that's right.
DR. BERENSON: I thought we were deliberating. I have great concerns about the diffusion, potential
diffusion of accountability in abnormal disease management finding. And I know the Committee -- the PRT has identified that issue and put it down under lack of integration. But I think this is fundamental to the model. In some places, the model is a disease management intervention with little role, frankly, for pulmonary physicians. I even had -- I still have concerns that it's not really a physician-focused payment model. But assuming it is, then I think the lack of attention to that interaction and who's really responsible and what happens when a pulmonary physician gets a seriously abnormal result but doesn't have the patient's medical records, et cetera, et cetera, needed more attention. And so that's why I would elevate that concern from whatever, number 7 or number 8, into a fundamental concern that I would have.

CHAIR BAILET: Harold?

MR. MILLER: One of the things I'm struggling with, and I think we were struggling with partly yesterday on all of these, is that whatever the issue may be actually cuts across multiple criteria, and it's kind of hard to figure out whether you -- where you put that. And I was trying to do this yesterday, having reflected on all that, was to try to go back to what the criterion says. And the
criterion says it anticipated to be able to improve quality and reduce costs. And my conclusion from that is that this is clearly anticipated to do that. There's an intervention that it's supposed to support that will do that. There is varying degrees of experience that it can, in fact, do that because we know that this population does get hospitalized a lot. And we know that efforts to try to contact them to encourage them to identify problems early does work.

So, to me, I find that it meets this because it's anticipated to do that. And I think that the quality aspect, it seems to me, is addressed. This issue came up yesterday. I think that if you're focusing on trying to keep people out of the hospital, that that is a quality improvement. It may not be the full set of measures that are needed to be able to do that.

And so I just wanted to say at least the way I'm thinking about this, because I think we ultimately will have to figure out exactly in the future how we apply all these criteria, is that's how I'm thinking about the criteria. My concerns about some of the other issues really I'm sort of going to put into the second -- the third bucket, which is how well is the payment methodology structured to try to protect against potential problems of
CHAIR BAILET: Thank you, Bob, your card is up, but you're done, right?

Any other comments?

[No response.]

CHAIR BAILET: So this is the second criteria. The proposal's anticipated to improve health care quality at no additional cost, maintain health care quality while decreasing cost, or do both, which would be improving health care quality and decreasing cost. Again, a high priority, and we are ready to vote.

Ann?

MS. PAGE: Zero committee members have voted 1, Does Not Meet. Two Committee members voted 2, Does Not Meet. Five Committee members voted 3, Meets. Three Committee members vote 4, Meets. And zero Committee members voted for 5 or 6, Meets and Deserves Priority Consideration. So the majority has determined that this proposal meets Criterion 2.

CHAIR BAILET: Thank you, Ann.

Any additional comments from the Committee based on the results?

[No response.]
CHAIR BAILET: We'll go ahead and move to Criterion 3, Payment Methodology, which is also high priority. Pay alternative payment models entities with a payment methodology designed to achieve the goals of the PFPM Criteria. Addresses in detail through this methodology how Medicare, and other payers if applicable, pay APM entities, how the payment methodology differs from current payment methodologies, and why the PFPM cannot be tested under current payment methodologies.

We're ready to vote. Oh, Harold. I'm sorry.

Harold has a comment before we vote.

MR. MILLER: I'm sorry to disrupt the rapid flow to voting. I wanted to make the observation that I think this risk adjustment issue is going to come up frequently with a lot of models, and we, I think, probably would all agree that the risk adjustment systems that exist today don't work very well, which means that in almost any case it's going to be difficult to say that somebody can bring in something that we know will work.

This one, I was struck particularly with the follow-on letter that we got today. I was originally sort of in the camp that said that -- that is not a pun, "camp" -- in the camp that said that COPD we ought to be risk-
adjusting based on the severity of COPD, not the other things that they have. But I was struck by the argument from the applicant, and I'm recalling my own experience in having run a project focused on COPD, that it was, A, very difficult to measure the severity of COPD. There is no code for that. And, moreover, what we tend to define was that the patients who were the easiest to keep out of the hospital, were, in fact, the patients who sort of just had COPD, and it was the others who had other problems that were the most difficult to keep out.

And so it struck me that it becomes an interesting thing when the criteria applies to couldn't be tested otherwise, is that if, in fact, it's a different approach to risk adjustment, that it merits testing in some fashion, and it's difficult to figure out whether it will work without actually testing it. But I do think that some of the other questions that came up yesterday about a total cost model become more problematic whenever you have a risk adjustment structure based on number of chronic conditions, because if all of a sudden one of those chronic conditions is rheumatoid arthritis and you suddenly have biologic drugs coming in or inflammatory bowel disease or whatever, that's a very different issue than saying the goal is to
try to keep people out of the hospital regardless of what their conditions are.

So I do think that there is going to have to be some -- if the risk adjustment structure is going to be different, there's also going to be a different way of measuring the accountability, the total cost or whatever measure, to be attached to that. Otherwise, it could potentially lead to some patient problems and require more quality measures, et cetera, to go along with it.

CHAIR BAILET: Thank you, Harold. Len.

DR. NICHOLS: So I agree with Harold that the risk adjustment is novel and the proposal is novel and it needs work. And I think the fundamental question we have is: Do we want to do the work before we start running money through it, or do we want to do the work maybe after? And I must say I come down on the side of I think there's enough creativity here, this is worth investing resources in. I don't think it's ready to run money through it. I just feel too queasy about the variation that would go with using this system as it is without it having been run through a lot more testing and alternative ways of capturing that severity, including combining electronic health record data with the claims, if we can get that far,
at least for a pilot. So that's kind of where I come out.

MR. MILLER: If I could ask, what is in your mind about what would be the next steps then? There would be more work on the model done before it would be appropriate for actual testing?

DR. NICHOLS: So we have this letter to the Secretary, and I think what we put in a letter to the Secretary -- I mean, to me, the most surprising thing in the last four hours is that somebody said it didn't meet the scope test. To me, this is big -- five or six of us had it way over here to very high scope, merit, preponderance of evidence for quality. But I think there's concern about lining up and having this very willing gentleman bear this risk without having kicked the tires a great deal more. And so what I think we do first is we give the task of designing a risk adjuster to CMS. That would be my suggestion for the letter. And in the meantime, we work out more of the accountability details with the submitter, and in a sense we start the process of modifying the proposal, but let's come back to that second conversation with a much more robust risk adjuster proposal. There may be two or three, by the way, that we might test.
MR. MILLER: So if I may, again, the point I made yesterday is I'm trying to think about whether or not the revision to the model could be done without actually trying it somewhere. And I'm not convinced in this particular case that it could because it would in many cases rely on clinical data that would be hard to get without actually doing it.

I think the issue about putting the applicant at excessive risk it seems to me could be dealt with by structuring a limited test with a fairly narrow risk order around it, to say we're not quite sure yet and we want to try this initially, anyway, to see how it goes before adjusting that, because, I mean, that would be the way most models, in fact, do start, is kind of with a narrower risk band and then expanding it over time once one is more confident.

So it doesn't seem to me that we should not propose something because of that, because I think the initial phase of a model could be structured, particularly in a limited testing phase, to be able to protect the applicant from that as a limited tester.

CHAIR BAILET: Kavita.

DR. PATEL: So the great thing about this is that
we're all doing this like live, and we've never done this before, so it's like someone has a camera on one of our family dinners and we're all starting to talk about things that you didn't actually realize we would talk about.

My issue with that, Harold, is that I feel like then -- this goes back to something Paul and I and Rhonda struggled with in our PRT. We had to walk the line of kind of doing what was right in front of us. So I kind of read this myself, the black and white. I will say that the additional information helped to change a little bit of my thinking. But I read what was written in front of me, and I feel like what you just said, Harold, is not what was written in front of me. So I don't know how to -- I'm struggling a bit with how much can we do to do what I think Len is suggesting, which is right in my mind, you know, if there was a little more technical -- if there was some vehicle by which there were other people to kind of help with thinking through risk adjustment or a refinement of the payment methodology, that would impact my -- you know, maybe a later decision. But today I have what's in front of me, and I feel like what you articulated is not what’s in the proposal.

But I also don't want to be so over-interpretive
and punitive that we're limited to this 20 pages and not to something else. And I just don't know how to react to that.

CHAIR BAILET: Harold?

MR. MILLER: So if I can respond to that, because I think that's an excellent point. What I guess I was looking at is saying the applicant has proposed a risk adjustment model. We are concerned about how it would work. It's not -- we were originally saying we think it needs to be changed. Now I'm saying, well, maybe it doesn't need to be changed. But the problem is there's risks associated with a risk adjustment model, and what I was trying to think through was, well, could you actually figure out what those risks of the risk adjustment model are without actually putting it in place and trying it in some fashion?

I'm on the fence about that, but what I was saying was it seems to me that if, in fact, one leaned toward the basic concept here needs to be tried, that we could -- and the concern is simply that the applicant would be at very high financial risk, we could protect them against that if we felt that the model should be tried.

I was sort of making that statement independent
of whether one agrees with this specific proposal that they have made, but it does seem that in a case like that, if -- but you're absolutely right, it wouldn't be go invent a whole new risk adjustment model and then try it. My argument was if, in fact, something like this -- if our concern about it is not that the proposal is bad but that because it has never been tried, we have no idea whether it's going to send them into bankruptcy. We could protect them against that in a trial. That was my point.

So thank you for that clarification.

CHAIR BAILET: Elizabeth?

VICE CHAIR MITCHELL: Along the lines of health policy reality TV --

[Laughter.]

DR. PATEL: [Off microphone].

VICE CHAIR MITCHELL: -- we are sort of exploring this out loud. And I was going to save these comments for later, but I have a very similar dilemma. I have no doubt that your practice could test this and probably be very successful. I have not been convinced that others could or would, and we are limited in what we can recommend, our options. So I'm leaning more towards very strong comments to the Secretary that this has a lot of merit, but the
readiness question to me is really significant. So I just -- I'm struggling with the same thing, but I really worry about our range of options.

CHAIR BAILET: Tim.

DR. FERRIS: I think to address Harold's point about whether or not this requires testing to be improved, from my perspective it is very clear that one could do computer simulations of lots of different risk codes at the practice level. We do it all the time, health policy researchers do it all the time. There's no question that you could get an enormous amount of information without actually going through the testing process in this particular case. It may end up in the same place, but that's not a question in my mind.

CHAIR BAILET: Len?

DR. NICHOLS: Ditto, and I think my point would be, Harold, while, yes, we could protect this applicant from the risk, I don't think there's enough confidence that that particular model is going to be the end game that we should do that. I think we should do the simulations, do the experiments, find different ways to calibrate these different variances, not just the means, and then come back with a very stratified structure in order to deal with the
exact patients Dr. Ikeda has focused on. And that's what I think would serve us all much better than starting before we're ready.

CHAIR BAILET: Bob.

DR. BERENSON: This, I guess, is going to be most useful just as a process point, because it's a little late in the game, but one of the Medicare MAPCP -- what does MAPCP stand for? Multi-Payer Advanced Primary Care demos use a number of chronic conditions as their risk adjustor, and there is experience at least there. I don't believe -- well, I won't say what I believe, because I don't -- I might be wrong, but there is some experience, and the process point is that I think we need to do more surveillance when we have issues like this that come up and we just assume that nobody has ever tested this before. I think it has been tested, and so I would just throw that out.

CHAIR BAILET: Len, did you have an additional comment?

DR. NICHOLS: In a primary care setting?

DR. BERENSON: In a primary care setting.

CHAIR BAILET: Okay. Seeing no other comments from the Committee, we will go ahead and vote on Criterion
No. 3.

Ann.

MS. PAGE: Three Committee members have voted 1, that the proposal Does Not Meet the criteria. Five Committee members voted 2, proposal Does Not Meet criteria. Two Committee members voted 3, Meets the Criteria, and zero Committee members voted for 4, and zero voted for 5, and zero voted for 6. So the majority of the Committee has determined that the proposal Does Not Meet Criterion 3.

CHAIR BAILET: Any other comments from the Committee on this criterion based on the outcome?

[No response.]

CHAIR BAILET: Seeing none, we are going to move forward with Criterion No. 4, Value over Volume. The proposal is anticipated to provide incentives to practitioners to deliver high-quality health care.

Comments from the Committee? Deliberations before we vote?

[No response.]

CHAIR BAILET: Let's go ahead and vote, then. Ann?

MS. PAGE: Zero Committee members have voted 1, Does Not Meet. Zero Committee members have voted 2, Does
Committee members voted 3, Meets. Six Committee members voted 4, Meets, and zero Committee members voted 5, and zero Committee members voted 6, Meets and Deserves Priority Consideration. So the majority of the Committee has found that the proposal Does Meet Criterion 4.

CHAIR BAILET: Any comments based on the results?

[No response.]

CHAIR BAILET: We're going to move forward with Criterion No. 5, Flexibility. Provide the flexibility needed for practitioners to deliver high-quality health care. Any comments before we vote?

[No response.]

CHAIR BAILET: Let's move forward. Ann?

MS. PAGE: Zero Committee members have voted 1, Does Not Meet. One Committee member voted 2, Does Not Meet. Seven Committee members voted 3, Meets. Two Committee members voted 4, Meets; and zero Committee members voted 5 or 6 for Meets and Deserves Priority Consideration. So the majority of the Committee has found that the proposal Meets Criterion 5 for Flexibility.

CHAIR BAILET: Thank you, Ann.

Any comments from the Committee based on the
CHAIR BAILET: We're going to move forward with Criterion No. 6, Ability to Be Evaluated, have valuable goals for quality of care cost and other goals of the PFPM. Any comments?

CHAIR BAILET: Ready to vote. Ann?

MS. PAGE: Zero Committee members have voted 1 or 2, Does Not Meet. Four Committee members voted 3, Meets the criterion. Six Committee members voted 4, Meets the criterion, and zero Committee members voted 5 or 6, Meets and Deserves Priority Consideration. So the majority of the Committee has determined that the proposal Meets Criterion 6.

CHAIR BAILET: Thank you.

Any comments from the Committee?

CHAIR BAILET: We're going to move forward then with Criterion No. 7, Integration and Care Coordination, encourage greater integration and care coordination among practitioners and across settings where multiple practitioners or settings are relevant to delivering care
to the populated treated under the PFPM.

Any Committee members? Harold and then Grace.

MR. MILLER: I just wanted to comment on this because, again, I think some of this is going to be relevant for future things, but the criterion says encourage and not require. So an interesting question, it seems to me, is that this, if it was structured the way it was structured, would certainly encourage it because it might be very difficult for anyone to be successful unless they, in fact, integrated and coordinated care, which I think is sort of where the PRT came down in terms of encouraging it without saying exactly how it would be achieved, which in some sense is okay for a payment model if, in fact, you believe that that can be done.

DR. TERRELL: One of the things that we need to be thinking about is the ambiguity of the word "care coordination" with respect to this criterion. So it can be thought about within the context of the care coordination for an individual patient with all the resources that a nurse navigator or other type or telemedicine or any of these types of things can potentially do this, basically, coordinating resources versus care coordination between providers, which I believe we're using within the context.
of integration here. But this is just an acknowledgement or something for the PRT to be thinking about, because we're now seeing two proposals in a row that I think are very much focused on care coordination for the patient in their model that they're proposing, but not necessarily as focused upon the whole integration of care.

So, as we're thinking through this in the future, we may want to either make a distinction in our own criteria or at least be more explicit with that for the applicants, so they can comment on both aspects of it.

CHAIR BAILET: And I guess, Grace, adding to that comment, in this particular condition with the comorbidities being high touch and requiring expertise from a multiple set of disciplines, I do think that while I do acknowledge the patient coordination, which is extremely heavy here, to really maximize the benefit of this model, it is that integration with the other clinical teammates who would be taking care of these patients, so I do think that's important.

Kavita.

DR. PATEL: So, again, I'll just verbalize the things I'm struggling with. When I read what was originally kind of proposed, I arrived at the same --
independently the same conclusion the PRT did. I think when I hear Dr. Ikeda and kind of any colleagues that work with him on this putting into the kind of paper response that we have -- and I'll read it: We've decided that this concern about the coordination is a valid argument and in our evolving care plan will expand monitoring to other chronic conditions, et cetera. We will consult with other and offer care coordination of other chronic diseases in our population of patients with COPD and asthma.

So I'm trying to kind of read to the letter of we don't know what care coordination is, or at least we think we do, but it's not specified in the Secretary's criterion how maybe the PRT might respond to that, or I'll say my response to that is that he is -- or at least the proposal is trying to encourage, even though the intentionality was expressed in this kind of late-breaking document, that there is actually an encouragement of this coordination, although the details have to be fleshed out.

So I would almost just put forward that this could potentially meet the criterion just based on this added inclusion.

CHAIR BAILET: Bob and then Paul.
DR. BERENSON: Well, I'm going to disagree with Kavita. I think that added inclusion gives me more concerns. We're going to have a pulmonary practice essentially coordinating care for a patient’s diabetes and heart failure when the patient is being cared for by a different physician. The whole thing doesn't hang together.

I mean, I think this is added to recognize the need for care coordination, but again, I'll just say a separate disease management program, which is what this is, with perhaps some pulmonary physician involvement to deal with COPD exacerbations is not the place to be doing overall care coordination divorced from the patient's regular source of care.

DR. CASALE: Yeah. Just to comment again, as you pointed out, this Criterion 7 is specifically around coordination among practitioners, so I understand coordination -- care coordination for the patient is critical, but this criterion is around practitioners.

And although in that add-on statement, there is encouragement that there would be more, as Dr. Ikeda said, right now it's relying on faxing. Again, I think you need more detail to try to understand how this would -- or
experience on how this would actually work other than the traditional methods which are currently being used, which we know are ineffective.

CHAIR BAILET: Thank you, Paul.

Len and then Harold.

DR. NICHOLS: So a great thing about being a non-physician is you get to learn from physicians on the PRT, and what we talked about in more detail than anything else on this criterion was a distinction between care coordination and care integration. And, actually, it was integration that we unanimously concluded it was lacking.

Care coordination definitely is encouraged in all kinds of ways, but I think it's integration that we were worried about.

CHAIR BAILET: Harold.

MR. MILLER: So the fact that this applicant said that they were planning to coordinate care does not necessarily mean anything about the model. It's sort of that this applicant was saying that they would do it.

But what it does seem to me to indicate is that, in fact, they felt that the model would, in fact, sort of push them in that direction.

I would distinguish, I guess, if the model was
saying, "We are going to prevent COPD hospitalizations, and that's all. We don't care about anything else. And if the patient is going in for something else, not our problem," and you would have the ordinary food fight that goes on in trying to figure out, so why did that patient get hospitalized, then I would be worried about it. But the fact that they are saying, "It doesn't matter. Whatever they end up in the hospital for, we're going to be accountable for that," certainly to me says you're going to have to figure out somehow how to coordinate care with all those other physicians that are taking care of those things because the pulmonologists aren't going to be terribly expert at managing all that.

So, to me, if it's encouraged, does the model encourage it? Yes. And the fact that the applicant said, "You're right. We're going to have to do that," sort of reinforces that notion for me.

CHAIR BAILET: Tim.

DR. FERRIS: I guess I would ask Harold. We heard from the applicant that they would do it because they think it's the right thing to do. What specifically about the model encourages that behavior?

MR. MILLER: Well, what I just said was that, in
fact, if they -- if the patient is hospitalized for an exacerbation of their heart failure, of their rheumatoid arthritis, of their whatever, they will be accountable for that. So if they're not figuring out how to manage that, then they are going to be at significant financial risk. That seems to me to encourage that. That's at least my interpretation of it.

That's why I was trying to distinguish it that I don't think that a model that said we are only going to be accountable for COPD- or asthma-related things would, in fact, have that same level of encouragement. In fact, it could encourage the opposite, which is finger-pointing to say, "No, it wasn't my problem."

CHAIR BAILET: Paul.

DR. CASALE: As I think about it, just because somebody is willing to accept the risk doesn't guarantee that there is going to be integration or coordination of care, in my mind, without at least seeing some ideas on how that would actually happen in the model, not just "We'll take the risk." To me, that doesn't guarantee. I think the model should describe a little more fully around how all that would work for me to feel comfortable with this.

CHAIR BAILET: Grace.
DR. TERRELL: So that's going to be a crucial question, I believe, this afternoon, is a crucial question in this one as well, which is, is a payment model itself going to, therefore, naturally lead to certain behaviors or a priori are we going to expect certain aspects of the Secretary's criteria to be explicit in the models?

What I just heard you say is that you don't believe that one payment model methodology naturally leads to the other, and it does need to be explicit.

We need to be thinking as a committee about that, not only for this model, but for others that are going to come forth. That's one of the crucial things that we need to understand, each of us individually, what is the relationship between the payment model and the Secretary's criteria for all these other things. Does it naturally lead to it, or are we going to insist, as we make a recommendation going forward that are being explicit, you know, tie, if you will, to that?

So I think that, Paul, your comments are actually extremely relevant to our broader issues that we're going to be struggling with.

CHAIR BAILET: Thank you, Grace.

Any other comments from the Committee before we
vote?

[No response.]

CHAIR BAILET: Then let's go ahead and vote.

Ann.

MS. PAGE: Four Committee members have voted 1 that the proposal Does Not Meet the criteria. Another four members have voted 2, the proposal Does Not Meet the criteria. One Committee member voted 3; it Meets the criteria. Zero Committee members voted 4, Meets the criteria. One Committee member voted 5, Meets and Deserves Priority Consideration, and zero Committee members voted 6, Meets and Deserves Priority Consideration. The majority of the Committee has voted that the proposal Does Not Meet Criterion 7.

CHAIR BAILET: Thank you, Ann.

Any comments from the Committee based on the results?

[No response.]

CHAIR BAILET: We are going to move forward, then, with Criterion No. 8, Patient Choice. Encourage greater attention to the health of the population served while also supporting the unique needs and preferences of individual patients.
Any comments before a vote from the Committee?

[No response.]

CHAIR BAILET: Let's go ahead and vote.

Ann?

MS. PAGE: Zero Committee members have voted 1. Zero Committee members have voted 2, Does Not Meet. Four Committee members vote 3, Meets the criterion. Five Committee members voted 4, Meets the criterion. One Committee member voted 5, Meets and Deserves Priority Consideration, and zero Committee members voted Meets and Deserves Priority Consideration. The majority has voted that the proposal Meets Criterion 8, Patient Choice.

CHAIR BAILET: Any comments from the Committee based on the results?

[No response.]

CHAIR BAILET: We'll move to Criterion No. 9, Patient Safety. How well does the proposal aim to maintain or improve standards of patient safety?

Any comments from the Committee before we vote?

Bob.

DR. BERENSON: Yeah. This is the place, I guess, I get to say what my fundamental problem is, which is that we have an intervention, which I would love it to work, but
it hasn't been proved effective, except in one German
study.

So I do not know whether it would achieve its
aim. I mean, the thing says to aim. It certainly aims to
do the right thing, and it could do the right thing, or it
could result in diffusion of accountability with primary
care physicians no longer -- I mean, I've got a pulmonary
doc who is going to deal with this, and I don't have to
worry about it, and a pulmonary doc who doesn't have the
relevant information. I want to know that the intervention
works, and then I can worry about a payment model. And I
don't think we're at the stage. I don't think we should be
using the PTAC offices to do basic clinical research, I
guess is what I would say, and that's my concern.

So I have difficulty. The aim is exactly right,
but I don't have any confidence that it will be achieved or
not achieved.

CHAIR BAILET: Thank you, Bob.

Harold?

MR. MILLER: I think an interesting aspect of
this proposal is I don't think we can sort of criticize
them on both sides. They actually are not taking
accountability and payment for all of the payment
associated with the patient. So there are going to be other clinicians still responsible for those patients under whatever payment model applies to those other patients.

This model, at least as I understand it, is designed to try to provide an extra overlay layer of help to the patient beyond what they can get today. It is possible, as you say, that that might lead other people to sort of pass the blame or the responsibility on to these folks, but it doesn't seem to me that that is inherent in the model. That adding an extra layer of protection on top would seem to me to be a good thing to do rather than otherwise.

I mean, the converse would be to say that everybody who is responsible for the patient is suddenly in this risk-based model that we're a bit uncomfortable with would be, to me, a higher level of concern about patient safety.

CHAIR BAILET: Bob.

DR. BERENSON: So I would just respond. So why don't we find out by doing a clinical -- doing some clinical research and what the impact is before we decide to do a national payment model?

MR. MILLER: Well, I would just say, I think you
keep referring to national payment models. That's why we are talking about limited scale testing, and I think the issue ends being, in some cases, what does clinical research mean? We've seen that some of the grant programs, to simply fund an intervention, don't really get at the issue very effectively of how do you structure a payment model to support them.

So I do think we have to figure out how to create the bridge between the health care innovation award approach and payment models. And I would respectfully disagree with my colleague, Tim, that you cannot do all this stuff through simulations, because the whole problem is that if you are running simulations you are running simulations against past existing behavior, not how care would change under a different model, and that is one of the fundamental problems in recalibrating risk adjustment models, is because you can only calibrate them against the behavior you're trying to change, which is not a good thing to do.

DR. BERENSON: I didn't think we were talking about limited scale testing, necessarily. I thought that was one of the options we had, and maybe that is where this fits. But I do think one of our options is to even give it
high priority for broad testing. So maybe we can -- we will agree -- I don't know; we haven't voted yet -- but your point is what we're talking about is limited-scale testing. I didn't think that is what we were talking about.

CHAIR BAILET: Thank you, Bob. Tim.

DR. FERRIS: Harold, once again you've mischaracterized my comments, and so I just want to point out that what I said was that we could improve the understanding of the variance associated with the practice level. I stand by that statement. Thanks.

MR. MILLER: With that clarification, I would agree with that. Thank you.

CHAIR BAILET: All righty then. We're going to go ahead and vote.

Ann.

MS. PAGE: Zero Committee members have voted 1, Does Not Meet; two Committee members have voted 2, Does Not Meet; seven Committee members have voted 3, Meets the criterion; one Committee member voted 4, Meets the criterion; and zero Committee members voted for 5 or 6, Meets and Deserves Priority Consideration. The majority of the Committee has voted that this proposal Meets Criterion
CHAIR BAILET: Thank you, Ann. Any additional comments from the Committee? I see Grace.

DR. TERRELL: For the next one.

CHAIR BAILET: Oh, for the next one. Okay. Then we're going to move forward, for Criterion 10 -- you guys are rushing me here -- Health Information Technology.

Encourage use of health information technology to inform care.

Grace.

DR. TERRELL: This issue came up yesterday, when we were talking about this criterion of encouraging the use of health information technology. Everybody went off on interoperability in electronic health records and that aspect of technology. But I think that this particular proposal really talks about other ways of thinking about health care technology. In this case a Bluetooth device that is providing the information back to providers is not integrated across some Epic system, although this was discussed as something that might need to be planned for.

And as we're thinking about this particular criteria in the future, I suspect that we're going to get far more types of beta and innovative new types of
technology that are going to be coming as part of these
models, that are not going to be mature, they are not going
to necessarily have anything except a study from Germany,
because that's the nature of innovation. And so much of
the innovation that's happening right now is happening in
health care within the context of care delivery at the
individual patient level and how to enable their
experience, particularly, to not be so facility-based and
to be based much more on chronic care management type of
enablement tools.

So this particular criterion, over time, we may
find ends up being one that we spend more time thinking
through, as a committee, than some of the others. I may be
wrong about that but we’ve now had two in a row that are
very much in the same mode of a technology that's important
in it. And with this particular one, it's right there on
the edge of the way a lot of the investment in technology
is going.

So we just need to make sure that as we are
talking about our own thought processes, that we don't get
trapped in today's technology and the health systems and
the population tools that are out there now. It may or may
not be mature but it's going to be something that, I think,
is going to continue to come up.

CHAIR BAILET: Elizabeth.

VICE CHAIR MITCHELL: Thank you. I actually am impressed and like the innovative technology aspect of this proposal, but the more we've talked about integration across specialists and others, the more concerned I am about the information-sharing aspect of this, which, I mean, we're talking about HIT to inform care. And, again, through no fault of the applicant, I don't think the answer can be just universal adoption of Epic, because we've got to find ways to get information shared across practices, particularly for something that assumes coordination across multiple practices and specialties. So I'm actually more concerned about this than I was.

CHAIR BAILET: Len.

DR. NICHOLS: So I'll pick upon Elizabeth's point about Epic. I know quite a few systems in Virginia that all have Epic and they can't talk to each other, so trust me, that ain't going to be the solution.

What needs to be worked out, therefore, is a way to parallel track the development of the risk adjust or the development of the interfaces that are going to make this kind of creative technology actually operational across a
wide range, and we need to be working on that simultaneously.

CHAIR BAILET: Thank you. Grace, do you have another comment? Your card is up.

DR. TERRELL: Sorry, no.

CHAIR BAILET: So we're going to go ahead and vote.

If you think you voted, you may not have, so you may want to push your button again. There we go. Ann?

MS. PAGE: Zero Committee members have voted 1, Does Not Meet; two Committee members voted 2, Does Not Meet; three Committee members voted 3, Meets; five Committee members voted 4, Meets; and zero Committee members voted for 5 or 6, Meets and Deserves Priority Consideration. The majority of the Committee has voted that this proposal Meets Criterion 10, Health Information Technology.

CHAIR BAILET: Thank you, Ann. Any comments on this criterion? Any additional comments, based on the results?

[No response.]

CHAIR BAILET: So what we're going to do now is the folks on the information technology side for us are
going to provide a summary slide, which we'll review in a minute, which summates the voting through these 10 criteria, and while we're doing that, if there's any other committee comments, in general, about this proposal, before we actually begin deliberations and vote relative to the recommendation to the Secretary, which is the next phase of our process.

And again, I'd like to just walk the Committee members through that. We are going to use electronic voting, and then we are also going to voice vote by member, because we believe it is important for the community submitters and the public stakeholders to know where we came down on this particular recommendation for the Secretary.

So a vote of 1 means does not recommend to the Secretary. A vote of 2 means recommend the payment model to the Secretary for limited-scale testing. A vote of 3 means recommend the proposed payment model to the Secretary for implementation. And a vote of 4 means to recommend the proposed payment model to the Secretary for implementation as a high priority.

So those are the four categories, and if we're ready we could provide the summation of our criterion
voting, that would be helpful.

Yeah, it just takes a minute for them to transition. Yes, Kavita.

DR. PATEL: Maybe I can ask now, not just the PRT but I'm thinking out loud. I know we'll see all of our criteria and perhaps I'm too, kind of, colored by yesterday. If we feel like they really met a number of the criteria, with the exception of one of the high-priority criterion, that we are all kind of dancing around, like some form of technical assistance, which this committee is not allowed to provide -- we have already covered that -- I actually don't feel -- I struggle because the criterion and the way we voted on them is eerily similar to kind of how we arrived on yesterday's proposal, but that we moved forward for different reasons, for limited-scale testing.

My hesitation is that I think this is like still short of qualifying for limited-scale testing yet offers so much promise and opportunity. So I'm curious, as we only have the three options. We don't have a 2A, you know, technical assistance before limited-scale testing, then pass Go. I'm kind of struggling with how we take something that has a real -- obviously, by our voting, we think there's some real merits to the actual proposal, novelty,
some interesting potential around risk adjustment,
inclusion of a high-priority condition, et cetera, et
cetera. And what do we do with that? We're kind of in an
in-between category space, and that's where I'm struggling,
myself, to be out loud about it.

So is there a 1, 2, 3, and then like a 4, you
know, I'm still struggling, kind of question, because
that's where I'm at.

CHAIR BAILET: Thank you, Kavita. Harold?

MR. MILLER: I think -- well, I'll speak for
myself. Many of us are struggling with that. I guess I'm
struggling with that. I think the -- we've said before
that even if we do not recommend we will provide comments,
suggesting the nature of that, to distinguish between we
really didn't think this was a good idea at all versus it's
a great idea but it's got some weaknesses in it.

At least the way I am thinking about it is that
if there is a sufficiently high level of technical
assistance or revisions needed to get it to the point where
limited-scale testing would be desirable, then I would put
it in the no category, that it really needs to have that
done. If it's in the category where maybe a little bit of
technical assistance but, frankly, most of the stuff it
needs is going to have to be worked out in an actual test, then I would lean on the -- which is where I leaned yesterday, which was I didn't think that the revisions were of sufficient scale to really stop it, and I felt it could move forward.

I feel in the other direction on this. I think, to me, that there are enough things that really have to be refined and clarified about this that you couldn't just say, take that, do a little bit of tweaking, and go test it. But I do think that, ultimately, that no matter what we do, in terms of -- or what they do in terms of revising the methodology, I still think it would need to go limited-scale testing, if it stays in this same kind of category, because it's so different and so potentially -- raises issues that have never been tested before. That's at least where I am.

CHAIR BAILET: Thank you, Harold. Elizabeth.

VICE CHAIR MITCHELL: Actually, I may have just agreed with Harold. I am so intrigued and impressed by the innovative nature of this but I'm with you, Kavita. I don't see the readiness for testing. And so I'm wishing we had more categories, but really, I think, going to be relying on the comments to make that point that technical
assistance, data, everything we've already identified that is needed is exemplified here.

CHAIR BAILET: Thank you, Elizabeth. Len.

DR. NICHOLS: So I agree. I think -- I like the way you framed it and I think of everything as a continuum. And to me the question is: What are the elements of work that need to be done before I would feel comfortable having it tested anywhere? And, here I see three. I see the risk adjuster issue, I see the information technology connection issue, and I see the integration pathway protocol issue. And to me, CMS can do the first two. The clinicians have to do the pathway, but that's precisely what I mean by parallel track, to get us to a better proposal with the technical assistance in hand.

CHAIR BAILET: Bruce.

MR. STEINWALD: You know, we've talked a lot about making recommendations for implementing a model, and wondered about how often those would be accepted by the Secretary. Now wouldn't it be something if we recommended against implementation and they said, "No, we think we will implement it." We never considered that.

[Laughter.]

MR. STEINWALD: All of that is just background to
saying that we have to rely on our comments, and to the extent that we think there is substantial merit to this approach, we want to get that clearly in the record, and hope that CMS could find a way, if not through a re-proposal through PTAC but maybe another mechanism for pursuing that approach.

CHAIR BAILET: Thank you, Bruce. Grace.

DR. TERRELL: It might be useful for us to say here, in public, that the way we set up the PRTs, if any of the three high priorities was recommended against by the PRT, then the PRT did not recommend it to go forward, is sort of the way we've set it up. What happened yesterday is -- and as we have reiterated -- is that the PTAC can overrule that. It can determine that those three high priorities do not, in and of themselves, mean that it can't move forward if there's other merit, and that's what we did yesterday.

So to get to the point that everybody is making with respect to the continuum, we don't recommend but yet we may think that there are some things out there that could make it better, then there is the likelihood that we can recommend for limited-scale testing because it's far enough along, versus the, let's go forward with this with...
all -- you know, all deliberate speed. Those types of things are not necessarily constrained by the don't recommend but they do imply a certain level of readiness that's out there.

What we're now talking about today is in the ability to comment we may be able to provide broader thoughts, even if we don't recommend, it could move something forward, but it's not actually part of the process that we've got right now, and it doesn't mean that the PRT process that has been put in place actually speaks to that per se, although it probably does signal about what some of the strategies are going to be.

CHAIR BAILET: Thank you, Grace. Bruce, did you have an additional comment, or --

MR. STEINWALD: Sorry.

CHAIR BAILET: Any other comments from the Committee?

[No response.]

CHAIR BAILET: So, like yesterday, we are only able to do a voice vote, but I wanted to just remind folks, and folks on the phone, because they can't see the summary slide that is now up. Ann, if you could just summate where we are, and then we will go ahead and do a voice vote, and
we'll start on this side of the room, with Paul, and go around, just to keep it balanced.

Ann?

MS. PAGE: Do you want me to read --

CHAIR BAILET: Yeah, if you could. Yeah, just the summation.

MS. PAGE: Okay. This is the summary of the voting that just occurred on the proposal, whether or not it meets the individual criteria. For Criterion 3 and Criterion 7. Criterion 3 is Payment Methodology, high priority. The Committee voted it Does Not Meet that criterion. And for Criterion 7, Integration and Care Coordination, the Committee voted that it Does Not Meet the criterion. For all the other criteria -- Criterion 1, 2, 4, 5, 6, 8, 9, and 10 -- the Committee voted that the proposal Does Meet those criteria. So 2 out of the 10 criteria were found to not meet the Secretary's criteria, and the remaining eight, the PTAC voted that it does meet those criteria.

CHAIR BAILET: Thank you, Ann. So now we’re going to start with Dr. Casale, for rendering a recommendation opinion.

DR. CASALE: Yeah. My vote is a 1, do not
CHAIR BAILET: Bob?

DR. BERENSON: Do not recommend.

CHAIR BAILET: Kavita.

DR. PATEL: One, do not recommend.

DR. FERRIS: One, do not recommend.

VICE CHAIR MITCHELL: One, do not recommend.

CHAIR BAILET: My vote is one, do not recommend, and one thing we did yesterday that we're not doing today was we provided a little backstop for our thinking on the vote, and I guess I'll maybe -- I feel compelled. I feel compelled to do that. We can do it afterwards? Okay.

MR. STEINWALD: One.

DR. TERRELL: One.

DR. NICHOLS: One.

MR. MILLER: One, because of what I said earlier, which is that I think it does need more technical assistance, but I do think that something like this should be -- if that proves successful, moved forward.

CHAIR BAILET: So maybe we'll come back around starting with you, Len, and provide that background.

DR. NICHOLS: I couldn't agree more. I think this proposal is so creative, we need to nurture it. But I
think we need to protect it from itself, and that's what that technical assistance would do, in my view. And, again, I see three strands. I see the -- I would just say the risk adjustment sector, the information technology connection, that is not trivial. And while some people can do it, not everybody can. And working out how more could do it would be a worthwhile investment. And, third, I really think this care integration pathway stuff is pretty crucial. It could be specialty societies involved and all kinds of stuff.

CHAIR BAILET: Thank you. Grace?

DR. TERRELL: The aspect of technical assistance is something that we're going to have to understand in far more detail and explore. One of the things that was said in testimony today is how helpful he found some of the tables and he wished that he had had access to some of that information prior to being able -- prior to writing the proposal or in the process of that. And if we're really going to get a lot of this type of creative proposals from the medical community, that's going to be something that we're going to have to understand at the level of PTAC but also CMS, is that what type of information that could be available can we provide the broader community, not
particularly an individual but the broader community, that
would allow a far more creative process and once that's
iterative that could go on forward from this.

So as we're making those comments in this
proposal, I would suggest that at our next time to
communicate with one another that we also be thinking about
how we would do that much more explicitly and understand
what the constraints might be on the part of CMS.

CHAIR BAILET: Bruce?

MR. STEINWALD: Despite our unanimous vote on do
not recommend, I think the comments should be framed very
positively, as others have said as well.

CHAIR BAILET: I agree, Bruce. I again commend
Dr. Ikeda for his innovative approach to something that is
extremely needed in this population of patients. But I do
want to make the distinction of our comment about the
grades of sort of hitting the hurdle where we think we
could support a recommendation for limited-scale testing.
And I think in this particular proposal there are still
enough unanswered questions relative to the payment
methodology reasons we've discussed.

I agree with you, Len, relative to the
information technology and the dissemination of that
information, again, because of the complexity of these
patients. But I also want to underscore the challenges
that this model will have with implementation relative to
coordinating with other specialists using the backdrop that
we have now, which is this Bluetooth technology. So I do
think that that needs more work, and I completely agree,
again, with you, Bruce, that this has to be -- I feel
compelled that we should frame this up as something that
needs to be supported to the point where we can get it into
the field. It's just not ready at this point.

Elizabeth?

VICE CHAIR MITCHELL: Thank you. One of the
things I liked best about Dr. Ikeda's letter was his wish
list, and if we had a wish list, I would -- sort of a PTAC
incubator for really promising models. But we don't have
that. So I'm going to, again, just reiterate my
appreciation for the innovative and really just forward-
thinking approach, but my concern about readiness, and I
will pile on to the very positive comments.

DR. FERRIS: The problem with being on this side
of the table is that you've already made all the comments,
so I don't have to make any. Grace says go to lunch.

Right.
I did want to, in addition to agreeing with everyone, just highlight what Bruce said about, you know, CMS saying even though PTAC didn't recommend it, actually it's so important we should do it. That is actually the message that CMS should take from this because if you look at the scale of the problem with hospital admissions in the United States from COPD as a large fraction of those being avoidable, which we've clearly shown in our setting, there actually are few epidemiologic targets as rich as this one is. And so it should be a priority to -- and in addition, one can't imagine -- or I should say it in the positive: One would imagine that whatever solution comes to address that problem is going to look a whole lot like what is in this proposal.

And so you take those two things together, and you come to the unavoidable conclusion that this should be a priority to develop and test this model or some model that comes out of something similar to this. And that should be actually at the very highest priority for Medicare.

Thanks.

CHAIR BAILET: Kavita?

DR. PATEL: The only additional comment I would
make, I guess our own wish list, because we had Dr. Ikeda's, is that with the care coordination, we spoke yesterday -- I'm not sure if you were able to hear it. We spoke yesterday about kind of distinctions between a novel payment -- or a physician-focused payment model such as this one and kind of these concepts like a specialty medical home. Or we even asked today about kind of what are the inadequacies of a chronic care management fee, which is an existing kind of model. In the proposal itself, it references the oncology care model. Just to help think through potentially in whatever next version of this there is, to help think through how can the actual functions of that care coordination, which I think as a clinician you almost take for granted because you know you have to do it, you don't have a choice in any clinical setting, but how that directly ties to the payment model, to the quality metrics. And just as bold as you were about the novelty in the HIT and the novelty in the risk adjustment, think through kind of how to tie that novelty back to what we're tasked with, which is looking at the payment models.

CHAIR BAILET: Bob, final comments? Paul?

DR. CASALE: Yeah, just to -- and, again, at the
end it's hard to add much. But, you know, as I think about it, this model, as everyone has said, is incredibly creative and innovative. This is the type of thing that gets physicians jazzed. I mean, they really get excited because, as Bob related about his relative ending up on a ventilator and Dr. Ikeda said, yeah, he sees this every day, people end up on a ventilator that he could presumably have prevented. And, you know, so this is the type of creative, innovative model that we would encourage.

And again, I think the problems, I think Len has highlighted the three areas that really need improvement. But I think that message to the Secretary should be clear about the positive aspects of this model.

CHAIR BAILET: Thank you. Elizabeth, do you have a final comment?

VICE CHAIR MITCHELL: I don't really want the last word, but this isn't meant as an afterthought, but something that hasn't been said that I think is really important in our comments is that I think the savings from avoided hospitalizations is really important. And so I guess building on your point, Paul, we are getting folks at the right time, and I think the potential for savings are also really significant. So I just wouldn't want that to
not be included in the comments.

CHAIR BAILET: Thank you, Elizabeth, and I thank
the members of the Committee for a very rich, engaged,
spirited discussion.

At this point a lot of the comments that we've
made along the way I know will be incorporated into the
recommendation to the Secretary. But at this point, if
there are other comments as we -- one of the next steps now
is for the staff to work with us to frame up the actual
letter, and that's an iterative process that we'll all be
able to participate in. But if there are additional
comments that haven't been made that you think are
important for the staff to hear at this point in time, this
would be a good time to share them. Len?

DR. NICHOLS: I guess the only thought really is
picking up on what Dr. Ikeda said about how useful -- and
we discussed it today -- how useful those tables were, we
need to figure out a way to get there quicker, and I think
we should put that in a letter to the Secretary, that we're
working on ways to be more proactive. And, you know, we
know why we didn't -- why we got stymied before. We wanted
to do -- and we couldn't. We got to find a way to get
tables to people in the middle of the preparation of the
CHAIR BAILET: Thank you, Len. Any other comments? [No response.]

CHAIR BAILET: So that concludes the deliberation and the recommendation process for the proposal, the CAMP proposal, and, again, I want to thank Dr. Ikeda for coming all the way out from Sacramento. I cannot underscore the value in having you here and hearing from the proposer directly live. I certainly know that — speak personally that I found it tremendously helpful yesterday and today, and I hope that we can continue as a Committee to keep that bridge and encourage folks and actually work with them to make sure that they can come, because it is invaluable to this Committee and our process. So, again, thank you.

I do want to say at the end, because of your comment about BlueShield, I do think it's important for the folks in the room to know that, yes, I am an executive with BlueShield and, yes, I am sure that your practice has relationships, contractual relationships with BlueShield. But I personally have not been involved or talked with your group about this particular model, and it did not influence my voting and reflections on it. But we can have an
1 offline conversation about ways that potentially we could
2 leverage the assets of the plan to work with your practice,
3 again, because I agree with the point made earlier about
4 the invaluable efforts that this will provide to this
5 community and, more importantly, to the patients.
6 So if I in my position with BlueShield can do
7 something that can help accelerate this process, I'm all
8 in. So I'll be following up with you after as well. Thank
9 you.
10 So we are not quite at lunch, and because of the
11 amount of work required to review these processes, I'm
12 going to make a recommendation for my teammates to
13 consider. We could break for lunch now, or we could begin
14 the next review process with the PRT report. We could
15 break at that point. We could potentially -- because we
16 have a number of public comments, we could potentially
17 begin that process and then break. I look to my Committee
18 for their input on what you'd like to do. Bob?
19 DR. BERENSON: I think we just should break for
20 lunch and move the schedule up with the extra 20 minutes we
21 have so that we begin at 20 to 1:00 instead of 1:00, if the
22 people are all around. That's what I'd recommend.
23 CHAIR BAILET: Yeah, okay. And I guess I'd also
float out we could take a shorter lunch, too. We probably
should, given all the work that's in front of us.

Elizabeth, you had a --

VICE CHAIR MITCHELL: Yeah, my only concern is if
people are coming for the scheduled 1 o'clock that we --

MS. STAHLMAN: It wasn't scheduled at 1:00. It
was scheduled immediately following the first one.

VICE CHAIR MITCHELL: Oh, okay. Then I would
recommend a short lunch break, and starting as soon as we
can.

CHAIR BAILET: Okay. Say that again?

MS. STAHLMAN: 12:30 would be 45 minutes.

CHAIR BAILET: 12:30 would be 45 minutes, so
we'll reconvene at 12:30. Thank you.

[Whereupon, at 11:44 a.m., the meeting was
recessed, to reconvene at 12:30 p.m. this same day.]
CHAIR BAILET: All right. If we could kill the music.

[Laughter.]

CHAIR BAILET: Yeah, kill the music. We're going to go ahead and continue. So welcome back, everybody. We are the PTAC, and we have a member who is on her way down but I thought, in the interest of time, what we'd like to do is go around the room, specifically, and speak to any conflicts relative to the Brandeis-ACS proposal, starting with Paul.

DR. CASALE: Do I have to introduce myself or just say my --

CHAIR BAILET: No, your conflicts. We've introduced ourselves --

DR. CASALE: Okay. Yeah, okay.

CHAIR BAILET: -- earlier this morning.

DR. CASALE: Great. I have no conflicts.

CHAIR BAILET: Bob?

DR. BERENSON: Just two things to say. One, I've known Frank for quite a while but I have not, in any way, been involved with the development of this. And it just
occurred to me that I graduated from Brandeis but that was quite a long time ago --

[Laughter.]

DR. BERENSON: -- and the statute of limitations has run out. So I have no conflicts.

CHAIR BAILET: Timothy.

DR. FERRIS: So I, too, know Frank, in multiple situations and, in fact, we co-chaired the Consensus Standards Approval Committee for the National Quality Forum together. But, more importantly, related to this specific application, I submitted a grant application to do a validation of the grouper, and although that was not funded, have known Chris Tompkins for many years prior to the discussions of this, and I have participated in meetings with CMS about this grouper, on multiple occasions.

And based on that prior interaction, not with these individuals but around this specific proposal, although I was not specifically in the development of the proposal, I felt it best to recuse myself from voting, but thought that I could potentially contribute, with full disclosure, to the deliberations, and so have offered, and the group has accepted, that I will participate in the
conversation but will not vote.

CHAIR BAILET: Thank you, Tim. Elizabeth.

VICE CHAIR MITCHELL: Thank you. I would consider myself among the friends of Frank and have worked him on the Measures Application Partnership and discussed Louisiana and alligators and other things, and co-presented before, and I have spent time with Frank and his team, gaining an understanding of this proposal, over the last few years. He came to me, but I think that had more to do with the lobster rolls than the proposal. But I do not believe that that exposure has created any sort of conflict in my review.

CHAIR BAILET: Thank you. And seeing Frank, I met Frank once --

[Laughter.]

CHAIR BAILET: -- about six years ago, but it's wonderful to see you again, and I have no conflicts, based on that.

Bruce.

MR. STEINWALD: Bruce Steinwald, no conflicts.

CHAIR BAILET: Grace.

DR. TERRELL: I've had a great conversation with Frank about alligators, grandchildren, in the airport in

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Delta Club in Atlanta. I have heard him speak about this proposal, or about a payment methodology twice in a public forum and setting. And with respect to Brandeis, I have participated as a speaker and participant at various types of forums on payment reform, in more general terms.

DR. NICHOLS: So I think I might be the only person, living or dead, that's never met Frank. I'm looking forward to this afternoon. I have no conflict.

CHAIR BAILET: Thank you.

MR. MILLER: I appear to be more objective than most because I have never talked about alligators with Frank.

[Laughter.]

MR. MILLER: But I do know Frank professionally, and we have presented together at various meetings. I also know Chris Tompkins from Brandeis, and we've had many conversations over the years about payment issues, but I was not involved, in any fashion, with this particular proposal and do not feel that I have any conflicts.

CHAIR BAILET: Thank you. So, without further ado, Grace, we are going to turn it over to you as the lead reviewer, to hear from the PRT.

DR. TERRELL: Thank you, Mr. Chairman, and ladies
and gentlemen. I want to first thank the rest of my PR team, in Bruce and Harold, and we'll go through, as those of you that have been here the last couple of days, the same type of formatting as we talk about our proposal.

So to remind those of you, again, who have seen this, our presentation essentially starts with a proposal coming forth. This one was in December. It was the very first one to actually be proposed to the PTAC. There is a preliminary review team that essentially is assigned by the Chairman and Vice-Chairman, which includes two to three PTAC members, in this case three, who had no relevant conflicts of interest. At least one physician served on that review committee, and at this point it was me.

The PRT identifies any other information that's necessary. After reviewing the proposal, additional information is provided by the submitter, and in this case we had a series of rounds of conversations that started with some questions and then subsequently went to a phone conversation -- a phone conference that lasted -- those that involved recorded conversation to get further clarification. We then had a series of meetings at the PRT level and prepared our report, which we will summarize for you, with respect to the criteria that are set forth by the
MS. PAGE: Does your clicker work?

DR. TERRELL: Yeah. I just hadn't used it yet.

I'm just waxing eloquently here. My clicker works.

[Laughter.]

DR. TERRELL: So this proposal is quite different than the other two that we've heard about, with respect to both approach and scope. So it is based upon episode-based payment models, where the episode groupers are defined by updated versions of an episode grouper developed for CMS previously by Brandeis University.

The proposed model targets procedures and conditions broadly, including over 100 procedures and conditions that are designated as payment episodes, identified for potential focus. This includes a breadth of conditions, as far as upper respiratory tract infections, appendectomy, colonoscopy, cataract surgery, acute simple fibrocystic or dysplastic breast disease, juvenile arthritis, lung resection, coronary artery bypass grafting, open heart surgery, liver transplant, heart failure, and cancers.

The initial implementation was proposed to focus on over 75 procedures in 10 clinical areas involving 75
separate medical specialties.

The advanced alternative payment model entities would enter into risk-based contracts with Medicare and take accountability for the cost and quality of episodes of care. The entities could be single-specialty practices, multi-specialty practices, or convener groups of small provider practices with or without ties to particular facilities, as long as the entity is able to perform its management and fiduciary responsibilities.

Contract with CMS would involve Medicare payments for every instance of a procedure or episode or condition defined in the contract during a performance period for which the entity's affiliated qualified payments provide a service paid for by Medicare, and each entity participating in the model would identify its affiliated, qualified providers who would participate under the business agreements. Physicians would participate by contracting with the alternative payment model entity.

Physician payment continues in the usual fashion through the Medicare Physician Fee Schedule, but the APM entity is at financial risk, based on participating physicians' attributed role in providing care. Attributed roles are determined by clinical algorithms that
retrospectively identify all clinicians who participate in the care of a patient for each type of episode, and infer the nature of each clinician's role. Savings or losses attributed to each participating QP are based on the episodes he or she is involved in and his or her specific role in that care.

Retrospective bonus payments and penalties are paid for to -- or paid by the APM entity, based on the differences between observed and expected spending for the episode. The APM entity would engage in gainsharing with affiliated qualified providers as agreed upon in their business agreements and guided, at its discretion, by the team-based physical attribution framework.

When spending exceeds expected amount, participating providers may be required to contribute to repayments to CMS, and the model will build in stop-loss provisions to protect against catastrophic losses.

With respect to quality, improvements in quality and efficiency are expected to result from the financial incentives and use of the clinical affinity groups or sets of clinicians who regularly participate together in episodes of a given type. These decisions and services are intended to influence the way in which patients are treated
for a type of episode.

Quality measurement is focused on two categories of measures: episode-based quality measures and all-patient-based quality measures, but measures are not specified. In the early transition period of the model, accountability would be focused on reporting of quality measures to allow participants to transition into the model and set a baseline for performance-based payment adjustments in later years. Over time, the Secretary would set a minimum threshold of performance on quality measures.

So the summary of the PRT review team, with respect to the 10 Secretary's criteria, is that we were unanimous on all of the criteria. It met all of the criteria per our assessment, with the exception of number 2, Does Not Meet criteria with respect to Quality and Cost, which is a high priority, and number 4, Does Not Meet criteria with respect to Value over Volume. As is the current policy of the PTAC, whenever a proposal does not meet one of the high-priority criteria, then it is not recommended by the PRT.

So, in conclusion, we have 10 criteria. We did not recommend to go forward because we did not think that it met two, and we will go into greater detail in a minute.
about our thoughts on all those, but I wanted to stop at
this point and give both of my other reviewers a chance to
comment if they wanted to.

MR. STEINWALD: Just to emphasize what you said, in passing, this is a very different proposal from the two
that we have reviewed so far. It's different in structure,
and I would say it's different even in philosophy, so it
should be a very interesting conversation.

MR. MILLER: I thought you did a great job with
your summary, Grace. Thanks.

DR. TERRELL: Wow. Amazing. A miracle has
occurred in Washington.

[Laughter.]

MR. MILLER: Well, then no.

DR. TERRELL: All right. Let's get into the
actual criterion.

So for Criterion 1, this is a high priority. The
scope of this is related to the broad aims to expand on
CMS's current alternative payment model portfolio by either
addressing an issue in payment policy in a new way, or
including alternative payment model entities whose
opportunities to participate prior to this had been
limited.
So our conclusion with this is that it meets the criterion. We believe that there is broad-scope model -- that this is a broad-scope model that would provide a payment mechanism for a large number of clinicians covering a broad range of services, from time-limited procedures to ongoing management of patients with chronic conditions, in inpatient ambulatory and outpatient facilities, which is not currently possible with most of the grouper methodologies that are part of Medicare's portfolio.

Initial implementation proposes to focus on 75 procedures in 10 clinical areas involving 75 separate medical specialties. This is additional evidence of this criterion being met. Expansion into acute and chronic conditions would increase the scope of the model with potential for over half of all clinicians in the country to have greater than 75 percent of their professional fees covered by this methodology. So the scope is quite broad.

However, details were missing on how the model would impact provider payments and patient care in specific areas. Information lacking about how the APM would function for the majority of episodes described was missing, and the nature of this particular thing was about the breadth and scope, and we did not get as much
information about -- from a specificity point of view.

Support for the model has been indicated by physicians involved with surgery and the hospitalist, but an episode payment model for many hospital procedures that are recommended in this model are already being tested by CMS, such as the Bundled Payment for Care Improvement Initiative is already in there. So there are some other things that would partially involve some of the things in this model but not all of them.

Criterion 2 was the crucial one with respect to Quality and Cost, another high priority. The proposal is anticipated, if it is met, to improve health care quality at no additional cost; maintain health care quality while decreasing cost; or, number three, both improve the health care quality and decrease cost.

Our conclusion was it did not meet the criterion, and the points we would like to make about that is the current MIPS quality measures identified as the starting point for quality reporting, that the proposal basically stated that current MIPS reporting data sets were unlikely to produce clinically meaning improvement in outcomes of care, when rigorously evaluated, yet that's where the current proposal was starting.
There were no penalties for reductions in quality in the payment model, and quality primarily was based on reporting on processes rather than outcomes. Moreover, initial requirements were for reporting, not performance on measures.

There was insufficient assurance of adequate quality protections to offset the financial incentives for lower spending. Spending could be reduced in ways that would not be beneficial to patients.

The proposal asserts that new grouper software takes into account all spending in an episode of care, but it does not describe how physicians will control cost of services they do not deliver directly, such as post-acute care cost, and does not explain whether the risk adjustment methodology adequately addresses differences in patient needs that can affect cost.

The cost participation is optional. Less than full participation would leave Medicare at risk for the portion of spending attributed to physicians in the episode not participating in the clinical affinity group.

Overall, the PRT felt there was insufficient information describing the ways in which care delivery would change in order to improve quality and reduce costs,
and the reasons those changes could not occur under current payment systems.

Criterion number 3 is high priority and it is about Payment Methodology. The criteria is that it would pay APM entities with a payment methodology designed to achieve the goals of the physician-focused patient model criteria. The payment model criteria addresses, in detail, through this methodology, how Medicare and other payers, if applicable, would pay the APM entities, how the payment methodology differs from the current payment methodologies, and why the PFPM cannot be tested under current payment methodologies.

The PRT conclusion was that this proposal Met this criterion. The payment methodology is described in sufficient detail with respect to its general principles and specific examples were provided in response to follow-up questions. However, the payment methodology is dependent upon CMS updating the episode definitions in the episode grouper methodology, over time. The methodology is asserted to be applicable within other payment models, such as ACOs, for most types of providers, in most settings, and for most procedures and chronic conditions, but no specific examples were provided describing how the model might be
successfully implemented in such a broad range of settings.

Because the same basic methodology is intended to be customized to each of a large number of conditions, procedures, and settings, additional details will need to be developed before it can be implemented for all of those conditions, procedures, and settings.

The model proposes to assign each clinician involved in patient care one of several designated clinical roles. These include primary provider, principal provider, episode provider, supporting provider, and ancillary provider.

Each clinical role a priori would be assigned a fixed portion of savings amount determined by policy, yet no information supporting the proportions proposed nor any process defining how those proportions might be adjusted over time were included in the information.

Criterion 4 was Value over Volume, and this proposal criterion is about anticipating to provide incentives to practitioners to deliver high-quality health care. The PRT conclusion was that the proposal Did Not Meet the criterion. The proposed models could incentivize efficient provision of services within episodes of care where there are opportunities for greater efficiencies.
However, quality of care is neither rewarded nor penalized unless savings occur. Insufficient mechanisms to ensure that savings are not achieved at the expense of quality or to encourage or reward quality even when no change in spending is present. Use of retrospective episode groupers is intended to provide information and standards for individual providers, episodes, and patients for accountability. However, reducing spending within individual episodes does not necessarily achieve savings in total cost of care unless accompanied by methods of controlling a number of episodes provided or ensuring clinical appropriateness of episodes.

Although the proposal indicates that utilization of procedural episodes would be controlled through their nesting within condition-based episodes, the proposal would not restrict procedural episodes to only be implemented inside condition-based episodes, nor is there any requirement that the physicians who would be accountable for managing utilization under condition-based episodes would actually participate in the model.

Criterion 5 of the Secretary's criteria is Flexibility in that it should provide the flexibility needed for practitioners to deliver high-quality health
The PRT conclusion was that the proposal meets the criterion. The model could be used in inpatient, outpatient, and ambulatory settings for multiple procedures and chronic conditions involving multiple types of providers. The model permits flexibility with respect to the number and types of physicians who could participate in clinical affinity groups.

However, some issues need to be resolved, we believe. It's unclear how independent practices in different specialties with overlapping but not identical service areas could effectively participate since not all patients in one practice in a clinical affinity group would be in other practices in the group and vice versa.

The proposal asserts that rural, critical access, and small group providers can participate under the umbrella of a new corporate entity or convener group. However, the proposal does not describe how to overcome the logistical challenges or potential regulatory or monetary hurdles to accomplish this. The model does not appear to provide for direct payment for innovative services not eligible for payment under the current payment systems and does not explain how physicians would provide such services.
without payment. It's unclear whether and how physicians
would have greater flexibility to control post-acute-care
costs and other types of non-physician services.

Criterion 6 is the Ability to Be Evaluated by
having evaluable goals for quality of care, cost, and other
goals for the physician-focused payment model. The PRT
concluded that the proposal Met this criterion. An
evaluation could be performed by comparing changes in
spending under the episode, group, or model for
participating versus non-participating practices. However,
the model would be very complex to evaluate because not all
clinicians in a clinical team are required to participate,
and there may be many different combinations of physicians
participating in clinical affinity groups. While creating
flexibility in implementation, this increases the
complexity of evaluation because of the potential for
multiple configurations of clinical affinity groups and for
interactions between variations in care delivery and
variations in the clinical affinity group composition.

The model depends upon the ability to identify
members of the care teams accurately with respect to the
role -- primary provider, principal provider, ancillary
provider, et cetera -- and their contributions across

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settings and the ability to report quality measures of
greater specificity than is currently required by payers.
Criterion 7 is specifically about the Integration
and Care Coordination, and it is designed to 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 physician-focused
payment model.
The PRT concluded that it did Meet this
criterion. The model includes innovative ways to support
multiple clinicians working together as part of clinical
affinity groups. The model aims to increase integration
across specialties by identifying clinicians who regularly
participate in a given type of episode for measuring and
reporting utilization and quality data. However, no
apparent minimum threshold for the level of integration is
required, nor is there any way to encourage or require
support by and coordination with the physicians who are not
part of the alternative payment model entity. The
voluntary nature of the involvement of members of the care
team may result in less integration and care coordination
than would be desirable or necessary to successfully reduce

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spending and ensure quality.

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

PRT did conclude that it met this criterion. The patients are not limited in which physicians and other providers they can choose for the different components of care included in episodes. There is no requirement for gatekeeper arrangements or narrowed networks that would limit patient choice.

The model may improve attention to individual differences in patient characteristics by including social needs conditions and health-related preferences, for example, by incentivizing attention to the social determinants of health outcomes as a driver of adverse variances in cost and quality. However, it was not clear whether the risk adjustment methodology would adequately protect against participants avoiding high-needs patients.

If the model allows a wider range of clinicians to participate in advanced alternative payment models than what exists in the current CMS models, then expansion by demographical, clinical, or geographical diversity may be
Criterion 9 is Patient Safety, and it is designed to answer the question, How well does the proposal aim to maintain or improve standards of patient safety? We concluded that the proposal Meets the criterion. The model aims to address patient safety by ensuring that episode spending measures include costs resulting from excessive, delayed, or avoided care, and poor outcomes of care.

Because episode definitions would include cost of treatment of complications, there are implicit penalties for an increase in patient safety problems.

Process measures used for the quality component would also help ensure patient safety. However, the initial quality measures only provide incentives for improvement if there are savings, and the model does not describe how disruptions in care transitions and care continuity would be addressed if all clinicians involved in services prior to and after the transition were not participating.

Criterion 10, Health Information Technology, is designed to encourage the use of HIT to inform care. We concluded, Mr. Chairman, that the proposal Meets the criterion. The model requires at least 50 percent of
eligible clinicians in each alternative payment model
to use CEHRT for clinical documentation, communication, and patient care, similar to the requirement for advanced alternative payment models. The model does not restrict current health information integration efforts and may incentivize the use of technology that promotes improved care coordination in monitoring the factors affecting rates of complications. The model requires identification of providers as either primary, principal, episodic, supporting, or ancillary; and its required reporting of quality measures may require enhancements of current coding practices for claims reporting. However, the need for technology to identify high-risk patients or technology-enhanced care innovations is not directly addressed in the proposal.

In summary, key issues identified by the PRT, our overall conclusion was the proposed model should not be recommended because it did not meet one of the high-priority criteria pertaining to quality and cost of care, and it does not meet the criterion for value over volume. The broad scope of the proposal and the limited detail in how it would affect individual conditions and procedures make it difficult to determine whether it would meet the
criteria for physician-focused payment models in all cases.

The PRT does not recommend limited-scale testing because the proposal did not identify a small number of specific clinical areas, episode types, and venues that would be appropriate for limited-scale testing. And the PRT believes that models could have considerable impact if these concerns were adequately addressed in a revised proposal.

Since the writing and presentation of the report, we have received additional written material from the proposers, and I'm going to ask Bruce Steinwald to sort of summarize some of our thoughts on that.

MR. STEINWALD: Specifically, the letter dated April 7th?

DR. TERRELL: Yes.

MR. STEINWALD: Yeah. Well, you heard me say earlier that this is a very different proposal, both in scope but also in philosophy, and let me illustrate that latter point by example. In our response or in our preliminary report, we express some concern that we're unable to determine how clinical care would be changed by the implementation of a model of this type, what specific kinds of changes would be made. And in the proposals we
reviewed already, it was pretty clear. It was pretty clear that they were talking about a subset of Medicare patients with a specific condition that are treated in a certain way now and how that treatment could change as a result of the clinical model that underlies the payment model.

In response to what we said, their response in this letter of April 7th was, "The ACS-Brandeis model does not begin with predetermined care redesign or formulate in advance the strategies of mechanisms for change. We designed the model to allow providers and provider groups to find their own way toward high-quality and high-value care. The model can provide opportunities for numerous specialties in diverse settings to participate in an APM. Instead of laying out a prescriptive care pathway, the ACS-Brandeis model provides new incentives for the delivery team to evaluate each episode of care individually for variation in quality of cost and then drive innovation."

In other words, the philosophy here is create a set of incentives and allow those incentives to operate differentially depending on the condition, the diagnosis, the nature of the care provided, and even the venue of care. So they don't want to be prescriptive of how they expect care to be redesigned. They want the clinicians on
the ground to make those decisions and be influenced by the
payment incentives that the model provides.

DR. TERRELL: Mr. Miller, do you want to add
anything?

MR. MILLER: I'll add one thing, which is that we
are evaluating physician-focused payment models as defined
in MACRA, and MACRA includes physician-focused payment
models as an alternative payment model. It further defines
an alternative payment model as something that is
implemented under the Innovation Center's authorizing
language or the shared savings program. And, interestingly
enough, I don't think a lot of people realize this. The
Innovation Center's authorizing statute does not actually
mention payment models of any type anywhere. It doesn't
mention episodes; it doesn't mention bundles. It doesn't
mention anything like that.

What it actually says that it is authorizing is -
- this is language from the statute -- "payment and service
delivery models where there is evidence that the model
addresses a defined population for which there are deficits
in care, leading to poorer clinical outcomes."

And one of the things that we struggled with with
this proposal was that it did not clearly identify where
the deficits in care were with poorer clinical outcomes that were going to be addressed and how they would be addressed. On the one hand, I think the broadest level one could say, well, you know, there's evidence that there's deficits everywhere and that there is something to be done. But we felt that it was difficult to really evaluate against the criteria without some information about that. And that does not translate into a -- we thought that it needed to prescribe the exact intervention, but that it did need to identify what kinds of things could be potentially improved through the model and some indication that the model, in fact, would remove whatever barriers existed today if there were any. And that was where we struggled a bit, was to understand that given, as Grace said, the breadth of the model, which was proposing to do this across a wide range of conditions and a wide range of specialties, without that level of information.

DR. TERRELL: So to go back to the comments to Paul that I made or in response to Paul's comments this morning that I made earlier before lunch, we have been talking for two days about care models versus payment models, and in the other two proposals that we evaluated,
there was a very defined care model for which sometimes
there was a struggle with respect to a payment model that
might fit it. The clinician started with an idea about how
their particular services that they perform could be
greatly improved, wrote about that in both cases, I
believe, quite eloquently, and then many of the issues that
we had were around the payment model.

This particular situation, to Bruce's point, is
the opposite, and it's philosophically opposite. And that
isn't necessarily bad or good, but it just means that you
have to think about it very differently when we're
evaluating it. So if this works, this could be the game
changer because it applies -- does apply to so many
specialties, so many forms of care, inpatient, outpatient,
all across the sort of traditional medical spectrum,
multiple specialties.

So our instinct, I believe, was to try to get
details and examples of how it might work with particular
examples so we could get our arms around it because of the
breadth of it.

So the response back that -- well, not the
response back, but what we got in this letter since our
report came out is basically saying that the philosophy is
that this payment model, does it necessarily a priori need
to start with a care model? I don't know that I disagree
with that or that the rest of the PRT disagrees with that,
but there's criteria that the Secretary put forth with
respect to this specifically talking about quality and
other things that are related to patient care per se. So
it kind of goes -- and we go back in that direction.

So as the entire PTAC, I believe, today is
deliberating on this and the specific criteria, a broader
question that we have is if indeed this is correct, you
start with the payment model and everything else shall fall
from that if the payment model is the correct one. How
will we be able to know that, evaluate it, or make
recommendations? Because I believe that as a Committee we
started from a very different point of view, perhaps.

So, with that, Mr. Chairman, we've finished our
report to you.

CHAIR BAILET: Thank you, Grace, and the other
members of the PRT Committee. A lot of material. It's
clear that there was significant dialogue, including a
transcript of the phone conversation, among other
interactions with the team, and I'm impressed by the scope
and scale of the work that you guys did to try and provide
the background for us to have the kind of deliberation that
this model deserves.

Before we get into asking specific questions,
Kavita, you were out of the room when we declared potential
conflicts, and just to complete that requirement, if you
could.

DR. PATEL: So I've heard this proposal presented
in meetings and have had conversations with Frank over the
years about the summary of the proposal, but not ever in
this detail as it's currently presented. Mostly in the
form of presentations to larger groups.

CHAIR BAILET: Thank you. So I'm going to turn
it over to the Committee colleagues to ask clarifying
questions, comments regarding the proposal to the members
of the PRT. Kavita?

DR. PATEL: Can I just -- because I found myself
riveted by the transcript that you all had with, I think,
Frank, with Dr. Opelka and Dr. Tompkins. But I just want
to make sure I am reading it correctly.

In your PRT recommendation around the -- there
was an issue the PRT had with the quality metrics.
Actually, let me go back and state that in the kind of
value -- in the quality conversation, we've never really --
the criterion does not go into any detail about process versus outcome measures. There's really just quality. So I would just push and understand a little bit of why there was that pushback about the process measures when, as we known, in quality most of what we have, unfortunately, are process measures.

But then if I read the transcript, it does appear that Dr. Opelka in the transcript kind of highlighted that there's a novelty to the measures that they're thinking about that would also lead to kind of potential registries and PROs, and that, in fact, they are looking at kind of building that out. Am I describing that accurately?

DR. TERRELL: So this is actually pretty relevant to the conversation that you all were having yesterday where you had what was in front of you and said this is where it is now and then as opposed to aspirations, and I think a lot of where we were was that they were starting with what there is right now out there with respect to MIPS.

We were pushing them a little bit on trying to get some sense of granularity as opposed to the general types of quality measures that are out there versus ones that -- how would you have a methodology to do this for all
these different types of specialties?

And then what they talked about is ways that they aspire to how this might go forth in the future, but it's not there yet.

The other thing that I probably should have emphasized more in my report is that they very much see this as a process, that we are starting somewhere. We need to get the entire physician community to another place, and it's not going to be flipping the switch. It's going to be incremental stages.

Our critique was not with what they were aspiring to, but with the lack of granularity that we could get to because of their general principle that it would come sort of from the grassroots efforts of the individual practices and societies and the concern that at the initial stage, there was not a quality requirement, per se, unless it was tied to savings.

MR. MILLER: Well, just let me add two. There's sort of two separate issues. One is what would the quality measures be, and then what would be the standard performance?

I think we felt that the goal was a good goal to try to move to outcome measures, but as a practical matter,
they weren't available virtually anywhere yet. They were proposed to be developed, and they said explicitly somewhere that that process was just starting for them.

The second issue was that under the quality framework that, initially, it was simply pay for reporting, even with whatever there was that existed. And so the concern was that in the initial years, there would be these financial incentives to reward people for reducing spending, which could come in good ways and bad ways, and that the only quality adjustment for that that we saw in the proposal was that if people had reported measures -- it didn't matter what they did on the measures. If they reported measures, then they would be okay to receive the savings, and the applicants may clarify or correct that if that's not right, but that, I think, was our concern. It was that, in the long run, the model might well be desirable and work, but it wasn't clear when the long run would occur.

CHAIR BAILET: Elizabeth.

VICE CHAIR MITCHELL: Thank you.

Bruce, you have said that this is, in part, a different philosophy, so this is a potentially philosophical question. This model seems very strong in
flexibility, choice, improvement, but how would you evaluate it in terms of accountability, whether it's the sort of pay for reporting versus pay for performance? Can you speak to that at all?

MR. STEINWALD: I can start. So remember the model doesn't change the way -- it doesn't change the Medicare fee schedule. It doesn't have a per-member, per-month. It doesn't pay for services that are currently not paid for.

It relies on the entity that the physicians participate in to drill down the incentives to the individual physicians and other qualified providers to change their behavior, but to change their behavior in a way that's particular to the condition and to the nature of the care, surgical, non-surgical, and also probably the geography of it.

So, in a sense, they can't -- this is my interpretation. They can't specify exactly how those incentives would work at the individual provider level because they might be very different, depending on the condition and other circumstances.

And now to get to accountability, because that was your question, and I obviously didn't answer,
therefore, in my mind, it's hard to specify accountability when you can't specify the incentives at the individual practitioner level.

MR. MILLER: So just to elaborate on that, there is clearly accountability in the model for spending within an episode. There is not accountability for the number of episodes, depending on what the episode is. So the episode could be as narrow as a surgery, or it could be as broad as managing a condition. There's not really a distinction in the model, but it is not required that anyone pick the full range of things. Someone could simply be doing the surgical episodes, so then there would be no accountability for whether the number of surgeries went up, et cetera.

The second issue is that there is only accountability for a portion of the spending in the episode based on how -- which of the clinicians were participating. So there's an allocation of the dollars. X percent goes to this provider, and Y percent goes to that provider. And if they're not all participating, then only a portion of that spending gets allocated to the entity. The rest stays with Medicare.

And then the third issue is there is not clearly accountability for quality performance, at least in the
short run, because of it being a reporting of measures rather than outcomes, if that helps.

CHAIR BAILET: Bob and then Len.

DR. BERENSON: Yeah. I want to follow up. I feel a little bit like Denzel Washington, who played the lawyer in Philadelphia, who said, "Speak to me like I'm a 10-year-old," because I don't understand some basic things about how the payment actually works and the role of the grouper.

I'm looking at various tables in their proposal, and there's a column that says "expected cost." Where does expected cost come from? The grouper? Let's just say it is a -- oh, I don't know -- a hernia repair. How do we know the expected cost? What is that? Where does it come from? Is it from the grouper?

DR. TERRELL: Yes.

DR. BERENSON: All right. So the grouper tells us what -- all right.

[Laughter.]

CHAIR BAILET: Could you dumb it down for us, Grace?

DR. BERENSON: "Yes" is good. "Yes" is good.

The actual cost, then, is what? The actual
billings that were submitted with the usual prices that Medicare uses for paying the relative -- whoever submitted, whether it's the physicians or a hospital or whatever? And so the incentive on the recipient, the APM recipient, or whatever they are called, is to generate behavior that produces that savings, and the role of the grouper is then to establish the baseline. Is that how it works?

DR. TERRELL: Yes.

DR. BERENSON: All right. That helps me a lot, actually, because I didn't quite understand.

CHAIR BAILET: You're pretty easily satisfied, Bob.

DR. BERENSON: My second question is, to what extent do we know anything about the effectiveness of the grouper? Now, this is a modified CMS grouper, and as I understand it, working with the people who helped develop the original CMS grouper, but what do we know about the performance of it, the validation that the grouper actually does what we want it to do? Because that seems to be a core part of this whole proposal.

MR. MILLER: Well, I'll say -- and, again, the applicant can clarify this, but I would say not much do we know.
We have seen a description of how the grouper work is supposed to work sort of in general. We have not seen really the detailed clinical logic behind the grouper. We've seen some information about what codes are in, et cetera, but not the actual -- there's a detailed logic as to when a code is in and when a code is not in, under what circumstances, et cetera. We have not seen that.

And I have not seen any actual statistics showing issues of variance, et cetera, how wide was the variance on that and how often did the individual cases occur and were there different patterns around the country, et cetera, et cetera, et cetera. We have not seen any of that.

DR. BERENSON: All right. Because what I'd like to have some clarification on -- we heard from CMS a while ago, CMMI, that they're not actually using the CMS grouper, perhaps for the resource part of what was the value-based modifier and now the resource component of MIPS, but not for its own BPCI or its own bundles. And I never got a straight answer as to why not, but I would ask the question. If it's not good enough for CMS, is it good enough here with a new version?

Do you want to contribute?

DR. TERRELL: Yeah. I want to just -- I don't
know that I'm answering your question, but it may give some
clarification. If you think about the current grouper that
CMS is using, it is only DRG-focused inpatient.

DR. BERENSON: Okay.

DR. TERRELL: And one of the things that this is
about is it was developed by Brandeis for CMS to basically
be thinking about groupers outside of that context. So we
should have probably emphasized that this was developed to
think about could you do groupers that were ambulatory,
that were chronic condition outpatient-based, and create,
if you will, bundles of bundles within that context, that
you could have broad application for multiple conditions
and episodes.

So CMS went far with that, fairly far with that,
to my understanding. However, the types of payment models
that they determined that they would put in place ended up
being all inpatient.

Subsequent to the work to develop this by CMS,
there has been additional work that we do not have the
specifications on with respect to some of the questions
that were answered that was put forth by the American
College of Surgeons on top of the other work that had been
done.
DR. BERENSON: Okay. That's helpful.

MR. MILLER: I'll further clarify. So CMS has two groupers that it has developed. One is this one. One is a different grouper process that Acumen has been developing for it, and they've just announced a new set of clinical committees to develop new versions of the grouper under Acumen.

We asked CMS what their intentions were with respect to the different groupers and did not get a clear answer on that. My impression was because they had not clearly resolved that and were not able to say that.

And we can again ask the applicant this, but my impression is that from what we've seen in terms of CMS behavior right now is that the episode grouper for Medicare is not the default model that CMS is using, I think to your point.

So that's a long-winded answer to say this does not appear to be the model that CMS has chosen to use in its own resource measures.

MR. STEINWALD: Okay.

DR. BERENSON: But one of the -- I have two quick -- oh, did you want to respond?

MR. STEINWALD: Yeah. This will be a good
question to ask the applicant when he has an opportunity to come to the table about the grouper and its central role in the payment model.

DR. BERENSON: Okay.

MR. STEINWALD: It would be good for you to prepare that.

DR. BERENSON: Okay. But, I mean, one of the attractive parts of this is now this grouper isn't inpatient only. Right? And that is one of the attractive parts.

My final question is that the applicant, the proposal -- I mean, a lot of the sort of notion here is that you can do a large number of episodes, both procedural episodes and conditions, and embed procedures within conditions, et cetera. But are they interested and willing to see this tested with a manageable number of episodes?

DR. TERRELL: You can ask them directly, but the implication that has been from my point of view, yes, I believe.

DR. BERENSON: Okay. Thank you.

CHAIR BAILET: Thank you, Bob.

Kavita.

DR. PATEL: Bob asked some of this. I'll just
ask, in your PRT section on quality and -- sorry, not
quality and cost -- on value over volume, you mention that
some of this issue with like the nesting within condition-
based episodes, that the proposal would not restrict the
procedural episodes to only be implemented inside
condition-based episodes, nor is there a requirement about
physicians being held accountable, a little bit to
Elizabeth's point for managing utilization.

It strikes me in reading through all the kind of
voluminous information that they had really tried to kind
of boil the ocean, so to speak, with so many permutations.

So my question in my own reading of this with
what was in front of me, it seemed like there were so many
like possibilities that it was almost hard to kind of grasp
your hands around kind of how would this play out. They
offered some examples, but you could probably conceive of X
to the nth degree of those examples.

So is that what really hurt? In your discussion
around not meeting the criterion -- because I find this to
be potentially like a huge game-changer with what you said,
the ability to coordinate, the ability to not be dependent
on MS-DRGs for a lot of the problems that those convey
inside current bundles, which are still largely facility
based. And so can you just go through -- did you all
struggle with that, or did it really just come down to the
need that the applicant should really have tied this to
better accountability?

DR. TERRELL: You know, I think for me -- and the
other two reviewers can answer individually -- I believe
the question that you're asking is actually intrinsic in
their methodology, and so if you believe that this is a
methodology that allows really maximum breadth and
flexibility, then part of what they're saying is that,
"Well, we can use it for just almost anything if you accept
our methodology as being something that allows physicians
to be held accountable for cost and quality of care."

So what we tried to do in all of our questions
back to them was to get very focused on specific examples,
so we could get our heads around it.

But I think for the PRT or for CMS, whomever
would go forward with thinking through this, one of the
central questions will be, Is that true? Will it work just
as a methodology for any possible situation? That's what
would make it a game-changer if suddenly you have a way of
having intrinsic, in a payment methodology, the ability to
make sure that doctors' behaviors were maximized for
patient benefit.

So what our reservations were, were twofold, I think. One was show us. Show us really, really specifically. Don't boil the ocean, but give us a small vessel where we can really see all the pieces of it. But because the way that they were conceiving it was broader with the maximum amount of creativity at the local level, we didn't quite feel that we got that.

So the question is, if the methodology itself is adequate, do you worry about it? One of the statements in their letter that they just sent to us that I presume we all read says, "Well, we don't think you're thinking of -- that this methodology may not actually work for your criterion." Well, they're not our criteria. They are the Secretary's criteria, so there may actually be a disconnect between that, and if that's the case, we need to understand how the PRT would actually function to make recommendations if it doesn't meet criteria as they were set forth by the Secretary.

MR. MILLER: I would just add two specific things. So on the issue of value and volume -- and this is, in a sense, where the flexibility of the model becomes one of its weaknesses, is because it's conceivable that,
certainly, people who are well motivated could pick this and do exactly the right thing with it. It's also possible otherwise, and so on the volume side, there is the possibility that someone could save some money inside of an episode and decide that it's really profitable to do that episode now and to do more of those episodes, which would then encourage more volume. That's a possibility. It doesn't mean that that's guaranteed to happen. It could, possibly.

And then the other possibility is that within an episode, somebody could stint on care to generate savings for which there is no quality measure to protect against that, which would mean that value would potentially decline.

There could be many other similar examples I could cite where this would actually support higher value over volume. The problem was there was no assurance of that, and because it was kind of up to people to pick what they wanted to be in, they could clearly, if they wished, pick ones that might not achieve that versus ones that did. That was sort of an additional concern.

CHAIR BAILET: Tim.

DR. FERRIS: That's a great conversation because
I want to pick right upon that point and just ask the PRT, if it's of value -- if there's any reason to think that it is not valuable to know whether or not, in the context of the implementation of this model, total cost of care went up. So if, in the context of a measurement -- ongoing measurement of total cost of care, or volume associated with any one of the chosen -- and I understand that this was not part of the proposal, but I'm now thinking from an externality perspective, in the context of a measurement of the implementation of total cost of care writ large, or a more narrow cost of care around the volume of the specific chosen -- and this comes up, by the way, in all the bundled payment issues. But I'm not trying to problem-solve.

Is there any reason why one couldn't measure that larger cost or largest sets of volume metrics in order to be sure that the implementation actually didn't produce those negative consequences that you guys just described as being possible?

MR. STEINWALD: Well, the answer, I think, is yes, but -- like so many other answers are. So it's hard to generalize. You know, I'm sure if you constructed the right kinds of episodes and measurement you could measure what needs to be measured. But when you're in the ocean,
you know, it's hard to generalize an answer to a question like that.

MR. MILLER: Well, the -- their model actually does incorporate that, because they have an episode measure for the bigger episode. So you could say, if I'm worried that there is going to be too many orthopedic surgeries delivered, there is an episode definition for osteoarthritis. Again, to Bob's point, we don't know how well that works but there is one.

But in the payment model for knee surgery, if only the surgeons and the anesthesiologists, et cetera, are participating, as least as I could tell there is nothing that says that there is any sort of way that that -- I mean, the interesting thing is you don't have to invent one. They have it in the model, but the payment model per se doesn't seem to -- again, we can ask them, but it doesn't seem to connect those two together.

DR. FERRIS: That's interesting. Thanks.

And I guess the other question is around -- maybe stepping back from this proposal a little bit and thinking about this as the third of our deliberations. We've been talking a lot about payment model and care model and the need or lack of need for a connection between those two,
and I just wondered, your response in sitting here, again, as Kavita was saying earlier, thinking out loud. It seems as though if you have a -- if we have a very narrowly focused proposal, we need a credible care model, but it also strikes me, being someone who lives in the ACO world in which we took risk in an ACO, and I will say, on Day One we didn't exactly have a care model. We just sort of, like -- you just started doing stuff.

The broader -- it's possible, then, that the generalizable rule here is that the broader -- the incentive system across total costs of care, the less you need to be prescriptive about a reasonable accountability for the care model, like something plausible in a care model. And I just wondered if you thought that was nuts.

DR. TERRELL: I think that may not be nuts, if you think about those of us who are foolish enough to be in some of these at-risk from Day One ACOs, such as you and such as me. The freedom that we had to develop things was just part of the broadness of it.

Having said that, if this is going to be broadly applicable for, what, 75 percent of clinicians in a -- you know, in most settings that we traditionally provide care right now, it would seem to me there needs to be the
ability to actually demonstrate, to the question that was asked, that Bruce answered, that, in this particular situation, if not ahead of the time for all people in all places that care is provided, some way of actually demonstrating that as opposed to "if you build it, they will come," or they will save, or they will have high quality.

We've done that, round one. You and I are victims, or poster children, or whatever, of the successes and failures of that approach. But I believe that part of the purpose of PTAC is to have a different approach and a different level of scrutiny and say, get specific with us so that we can help the Secretary get better at designing these things to be as maximally successful as possible.

And part of the issue, since they're doing an incremental approach, is how do you measure that when there is incrementalism, because that's where you get into some of these quality concerns that we had, is if you're starting off here and eventually want it to be far more, you know, 10 years from now in a far more ideal situation, you're measuring during a stage that is under perpetual change. And as a result of that, we felt that there just needed to be some specificity that would allow at least a
direction for -- where there could be some testing or analysis that could be done to give us more comfort with that.

MR. MILLER: I would also add to that, I think there is now a reasonable body of evidence that says that a pure pay-for-performance model or a pure shared savings model does not automatically result in success, that some people have been able to use it for success and some have not. So I think that's part of the concern here, is that there is some experience with that.

And we are -- you can say that there are kind of two things that one can do under one of those models. One is that if one thinks there is simply overuse going on, and this now encourages people to reduce it, then it's good enough, and there are references in the proposal to that being a focus, but there's not really any explanation of exactly what those things are that says here's the thing that would be reduced.

However, one thing that is not in the model at all is that there is absolutely no change in the underlying payment system, and we've just seen two proposals come in with people saying, "I need to get an up-front payment to do something differently, I think, to be able to achieve
these things." And so this model doesn't have that. And so what that says to me is that under that structure, what it's really doing is it's focusing on areas where we think there is simply overuse for the sake of no good reason, that this will now encourage the reduction of. But it's kind of across the board and it doesn't -- there's not a good way to distinguish, are you reducing the actual true overuse and not ending up getting a little bit of underuse built in there at the same time.

DR. TERRELL: But I would add to that, not just over- and underuse but lack of coordination. I mean, I think one of the real merits and strengths of this proposal is the fact that it allows the creative, non-siloed collaborations, almost spontaneous collaborations between those that are already naturally involved with the care of patients as it's currently construed. And part of their argument, and I think it's a good one, is that, you know, you basically have everybody motivated around these general principles and you allow them to be in entities where they can put these things in place, then it's not just over- and under-utilization but it's let's figure out how to actually work in integrated ways where you get improvements in quality and savings naturally as a result of not having
what is the perpetual complaint about the U.S. health care system, which is its siloed effect, and that is sort of intrinsic in fee-for-service, where you have the individual payments.

CHAIR BAILET: Len.

DR. NICHOLS: So I'm trying to figure out the signal we're sending, and what I think we're saying is don't try to bring us a unified field theory of civilization. This is too complicated. There's too many potential applications.

But here's what really kind of got me curious about what we really want to say. The judgment of the PRT is the payment methodology meets criteria, but somehow we don't get quality and cost improved and somehow value over volume doesn't work, and that really makes me think, maybe we're not looking at these criterion right, or maybe the criterion don't fit this particular configuration.

So I want to ask you two questions. Would you be more inclined to support something like this if, in addition to the bundled business, it essentially said I have a total cost of care constraint that I'm going to hold myself accountable for, and are we not then saying you've got to take into account total cost of care?
And the second obvious question, maybe, is, would this not have been met more favorably if they sort of spent less time explaining how it could apply to everything and more time showing exactly how it would apply to a particular maybe payer or situations?

DR. TERRELL: I'll answer the second half of the question, which is that seemed to be what all three of us were craving, was to -- if we bought the concept that it was broad and if it was successful it would be the Holy Grail, then you had to give us concrete examples, and I think we really, really dug to try to get that and couldn't get it to the level that we wanted. And it wasn't that we felt that those concrete examples were going to define it per se, but we needed to get our arms around it, using them. So I think that that assessment of -- our assessment is correct.

MR. MILLER: I would add that we -- and, again, we are learning as we go, all of us, on this, right? -- but the way at least I think, and Grace and Bruce can disagree if they want to, but I think we tried to focus on the payment methodology criterion as to whether we thought it was clearly and precisely enough defined that we could understand exactly how it would work, as opposed to the
other criteria where we tried to assess what result it
would have, and whether it met those criteria.

DR. NICHOLS: Yeah. Okay.

MR. MILLER: And I think that may be a little bit
different than the way we were doing some of the other
proposals, but, I mean, clearly, with the others, we
thought there were flaws but it was also that we really
just weren't quite sure exactly how it worked. I think we
concluded, we were pretty clear about exactly how they
meant to make it work.

And the issue, to me, with the examples, was that
in the absence of clearly defined quality measures, you
know, outcome measures, et cetera, and some of the
protections that we talked about, if it had been clear that
lots of work had been done, saying here's what we expect to
happen, here's people who have signed up, here's what they
are planning to do, we would have said, okay, well, clearly
maybe there might be some weaknesses but there's lots of
positive stuff that's clearly already lined up to happen,
but we couldn't see that.

And then when you say it's a jump ball and
somebody might sign up to do the wrong thing and somebody
might sign up to do the right thing, and we don't know
which one is going to sign up, that said, boy, we're just
not comfortable saying -- again, I think I'm speaking for
myself, but that's kind of where at least I came down.

MR. STEINWALD: Yeah. The other two proposals,
you know, we were all impressed by the clinical reforms
embedded in their proposals and then they were found
deficient in trying to overlay or partner a payment model
with the clinical reforms, where the payment model would
support and expand and courage the kinds of clinical
transformations that their models envisioned.

So this is very different. I mean, we thought
that the payment model, even though it was not without some
issues of what to do about non-participating, and how do
you make sure that the clinical affinity group has got what
you want in it, but giving that the benefit of the doubt
and saying, okay, we understand the payment. Now what we
don't understand is how you can partner that payment model
with any number of clinical transformations in different
clinical areas, different kinds of episodes, different
geographic areas. How do you make that shell of a payment
reform work for all of those different kinds of clinical
situations that you could envision?

And, by the way, there's probably some overlap.
As we've talked about, there's always overlap between these criteria. There's probably some overlap in the difficulties we had with Criterion 2 and Criterion 4, very similar reasons.

Chair Bailet: Paul.

Dr. Casale: So one area I guess I'm struggling with is this team-based fiscal attribution -- and I know you highlighted that in your report; it was in one of those "howevers," amongst the howevers -- in terms of the clinical roles. And, you know, I mean, I see the table and I can imagine how that might work, or does work even now in BPCI, with an elective hip replacement or something. I would struggle more in a complex Medicare patient who is acutely ill, who comes in -- who may then be involved in multiple episodes within here. And even one of the letters, I think, from the radiation oncologist was like, "Well, you have me in the supporting role." I know these are examples, but sometimes I'm the episodic provider, whatever, you know.

So in the model, they mentioned about clinicians identified through billed services, assigned by algorithm, and there are issues in that with PCP assignment in ACO, right? I mean, so how exactly would that -- and
alternatively they say providers could designate
themselves, but then you worry about the food fight, as
Harold likes to bring up, about, well, you know, who's who.
And then is there an opportunity for patients to identify
who their providers are?

So, anyway, I was wondering what kind of
conversation you might have had around all that.

DR. TERRELL: We had some conversation around it.

My understanding is that there is some proprietary
algorithm that's part of what they've developed, but we
didn't get into the details of that. Part of it would
probably have to be self-identification or coding within
the context. They gave some very good examples, in fact,
one in cardiology with respect to, you know, you could have
a primary care provider who is managing hypertension and
lipids, and then they end up with an acute event, and
there's a cardiologist, and then they end up with, you
know, CT surgery or whatever. And they were able to
basically give very specific examples of how that whole
thing might work, and I thought that was a great example,
in broad ways, where somebody could pop from role to role,
depending on the particular patient and their particular
role in it.
It would seem that they're basing this on methodology that's been developed that we didn't get the specific details of, on claims, and on patterns that they can identify from broad, you know, access to claims that have been there for a long period of time.

The types of things that you are talking about -- well, what about the identification, what's going to happen within the clinical affinity group with respect to this -- I don't think that was answered. You could still have doctors fighting internally over the dollar, depending upon, you know, the usual types of incentives or lack thereof that are in there.

But it appears that, I wouldn't call it machine learning but they have obviously got big data knowledge that informs this model and would likely get better over time, as they're able to do analysis of patterns with these new types of identifications put into the model.

With respect to patients -- we actually asked it probably more related to patient choice -- a patient wouldn't necessarily say this is my primary provider or my episodic provider, but the patients have complete choice. They could go to a particular primary care physician who is not part of the clinical affinity group, and that piece may
be carved out of the overall payment model that the clinical infinity group would have, or not. There was, again, that flexibility in there, but it did not preclude patient choice. But it appeared that there was some sort of deep knowledge that was based upon some stuff that's already been developed, with respect to the Medicare database.

MR. MILLER: I'll just clarify. If the clinical affinity group, which I think is a wonderful idea, was constituted in the maximal sense, that everybody who was involved with the episode signed up and was part of the alternative payment entity, then they would basically be collectively accountable for all the spending, however the episode was defined, and then they would be under the model, completely free to figure out how they wanted to divide up the money.

But if they're not all involved, then there are some default rules, and the default rules include both sort of the -- I believe sort of an attribution rule in the model that says, so how do I decide whether you're the primary or you're the episodic, or whatever, and then they get it. That's somewhat irrelevant if everybody was involved, because whatever the grouper said whoever it was
it wouldn't matter because you'd get the whole thing and
then you'd have to divide it up, and again, the applicants
can clarify that.

But that was one of the complexities that made it
difficult to assess this. If you had said we're only going
to do this when the whole clinical affinity group signs up,
it would have removed one degree of complexity but all of a
sudden now you can be assigned -- you can pick whatever
episode you want and you can have whoever in your clinical
affinity group, and it may or may not be all the key
people, and that really starts to create some interesting
questions about what's really going to happen here.

DR. BERENSON: I will be asking our guests when
they're up here, but I just wanted to pursue a little more,
the grouper and what it does and doesn't do.

So Harold has already surfaced the issue of
appropriateness and the potential for value and growth when
you are paying for procedures.

On the condition side, we haven't talked as much
about that, although Harold mentioned it, that the concern
that conditions will come out of the woodwork, that people
will have conditions. Is there any logic in the grouper
that determines that a patient who is being treated -- I
mean, who is being billed for congestive heart failure
actually has parameters consistent with congestive heart
failure that they actually have the condition, as far as
you know?

DR. TERRELL: It's a claims-based system.

DR. BERENSON: Oh, okay. So we still have that
issue, then, that we would have, and any condition-based
payment episode, we have the issue of having to establish
sort of the minimum severity.

All right. Then final question.

DR. TERRELL: Having said that, Bob, again, what
I alluded to with big data or knowledge or machine
learning, if you see somebody who's having certain bundles
of services performed, you may well be able to infer that
they have congestive heart failure, even if somebody never
makes a claim to it, or if they’re on Lasix and they've got
pulmonary edema listed as a diagnosis in others.

So we didn't get very -- into the details with
them about the specificity of that, but I believe my
understanding from what we did get from them was that the
way this is built out, oftentimes -- and it should get
better over time -- you should be able to, by sophisticated
analysis of patterns of data, get pretty good at
understanding who really has certain things.

I mean, if somebody is coding congestive heart failure, but they never have a chest x-ray, an echocardiogram, or prescription for an ACE inhibitor or something, then that may well be something that the type of methodology that they have would actually protect against, which is something that some of the other methods don't have.

DR. BERENSON: All right. So --

MR. MILLER: I don't believe that's in the model as it's defined today, and we can ask them that.

DR. BERENSON: And I just wanted to sort of go back to Len for a second. When you mentioned earlier total cost of care, you were referring to total cost of care for the episode, for total --

DR. NICHOLS: Yeah.

DR. BERENSON: -- because it seems to me -- go ahead.

DR. NICHOLS: Well, because what I understood the critique to be, you can't control the number of episodes if you only focus on the cost inside the episode, therefore the inference being you've got to have some more global metric to feel comfortable about control of episode.
DR. BERENSON: I see. Okay. I got your point.

To me, one of the advantages of having an episode grouper is that you can hold people accountable for what they have control over rather than things that have to do with all sorts of other conditions, and that is a --

depending on who you're paying for what purpose, you either do want to do total cost or you want to say you're responsible for back surgery --

DR. NICHOLS: I'm with you.

DR. BERENSON: -- and we're not going to hold you accountable for congestive heart failure.

DR. NICHOLS: I take your point.

DR. BERENSON: Okay.

DR. NICHOLS: All I was trying to get to was the thinking in the PRT about why --

DR. BERENSON: And to be able to deal with the volume issue. Yeah, I got that. Okay. That's a tradeoff.

Thank you.

CHAIR BAILET: So I don't want to truncate the dialogue, but I do want to make sure -- no, Kavita. You're going to be the last. I'll call on you, but you will be the last Committee participant until we can have the presenters come and also hear from the public. I just want
to make sure we have enough sand in the hourglass to have
the deliberation that's required.

So, Kavita, you've got the last shot.

DR. PATEL: Very brief. And I'll ask Dr. Opelka.

This is proprietary to Brandeis. They were awarded the
kind of episode grouper by CMS. There are obviously other
commercial groupers. This kind of riffs a little bit on
the proprietary notion that we've talked about with other
models. Is it such that your exploration has kind of
deemed that this is incredibly tied to that proprietary
use, or could there be some ability, flexibly, which gets
to maybe like Criterion 5 with the ability to bring rurals
and kind of overcome these monetary hurdles? Did you talk
about that?

DR. TERRELL: So the issue is if it's a grouper
that's actually a Medicare-CMS product, probably something
would be proprietary.

So, for example, if we ended up with the overall
principles of this particular proposal were accepted by us
and accepted by CMS and wanted to go forward, then, in
theory, there could be other types of other products that
could provide the same service. But since it would
actually be at the Medicare level, how that would be done
and administered likely -- whomever got that, likely there would be a Medicare contract involved.

DR. PATEL: I guess a different way of asking is, is the burden of the cost for that -- I mean, right now, that's being borne out by Medicare because they're using that in the QRUR and VBPM. I mean, so is there -- I didn't see any reference that there would be any cost for that methodology to be taken up by CMS. I think that's the assumption. I just want to make sure I'm clarifying that.

DR. TERRELL: You can ask the proposers, but I was assuming that the methodology in the grouper methodology has to reside in those who actually make the payments as opposed to an intermediary.

MR. MILLER: We are not clear on how that progresses. If Medicare were endorsing it and maintaining it as their public use grouper, it would be a different thing. It's not clear that they are, and then there are enhancements to it that we're not quite clear, the nature of what that is.

CHAIR BAILET: All right. Thank you.

If we could now call Dr. Opelka and the ACS team. As you come up, if you could identify yourselves. We've got opportunity for 10 minutes of comment.
DR. OPELKA: Good afternoon. Frank Opelka with
the American College of Surgeons.

DR. TOMPKINS: Chris Tompkins on the faculty of
Heller School, Brandeis University.

DR. OPELKA: I'm going to make a few brief
remarks, and then I am going to ask Dr. Tompkins to make a
few more.

First of all, I want to thank you, the PTAC, and
particularly the PRT for the job you've done. We certainly
didn't make it easy on you, and we really appreciate the
depth at which you've approached this.

I was going to make a few remarks, which most of
you have already made. So I'm going to stay away from some
of those and focus, if I can, on the question of quality
over cost and value over volume for just a few seconds,
because I think these two go together, and we're missing
some subtleties that's in the proposal in the way that it's
been discussed.

The way the model works is we would identify
within an episode whether the team that's engaged in that
episode has actually established shared savings or whether
or not there are losses relative to an individual patient
risk-adjusted expected cost. So that's an individual
patient risk-adjusted expected cost. Did you save money, or did you lose money on that deal?

That then translates into four tiers of quality. There are four tiers of quality, and those four tiers only exist if you're in the episode-based measure framework, which is a new measure-based framework proposal we've put forth to CMS. That measure-based framework proposal includes high-value process measures, such as the goals of care. It also includes outcome measures, which are currently in the MIPS program, and it has, now in developmental phase but will be ready by this fall, PROs that are specific to the episode. So if there was a goal of this episode, did we meet that goal in a PRO? So there are, indeed, outcome measures.

That creates four tiers. If you're on the savings side, you must not just participate to reach the highest tier. You must perform. You must be in the top decile of performance. So it does have performance level built within it along with participation. It also has new levels of participation we've never seen before. Fifty percent of that episode must have a PRO. We've not reached that in anything else we do.

Now, if that particular episode that's in use
doesn't yet have all the elements, which all those elements were included in the proposal for measurement, but if that particular episode doesn't have it, we default to the MIPS measure set, which we don't think is optimal. It does not allow you to reach the fourth highest -- the highest tier, the fourth level. You can only get to a score of good.

In all four of those tiers, it influences whether you're on the losing side or you're on the winning side.
So if you're in the loss column and you score in the top decile, your loss is forgiven, but if you are in the lowest measure, then you pay and bear the full risk of the loss.

If you're in the positive, in order to get the full positive, you've got to be in the top decile. If you are unacceptable, even though you had shared savings, you get nothing.

So quality is influenced in both the upside and the downside risk of the model, and I don't want that to be lost. So this model has within it a whole new set of measurement, which has gone through the NQF process and is continuing to emerge and develop, and it pushes an entirely new envelope in where we are in measurement today.

So let me turn to Chris for a few other comments.

DR. TOMPKINS: First of all, thank you for a
gracious opportunity to be here.

Twenty years ago, almost exactly, I had a gracious opportunity to brief a few senior leadership in this very building with regard to a design report that we had just submitted to the Office of Research and Demonstrations in which we had devised a payment system we called the Medicare shared savings payment system. Twenty years ago.

Now, that was the Roaring '90s. In the Roaring '90s, managed care was trying to displace the culture of health care that had grown up organically in prior decades. And those of you who were there remember the outbreak of schizophrenia, which was the term of art, where you had delivery systems that were well entrenched in their productivity measures and compensation systems, and yet you had this aspirational call of managed care backed up by concrete contracts saying, "We don't want your productivity measures. We want the nascent concepts of value."

And the Medicare shared savings program was an attempt to cure the schizophrenia because the biggest anchor holding back the delivery systems was the fee-for-service Medicare system, especially for specialists who were doing quite well, thank you, under the productivity
Now, that was the Roaring '90s. Managed care was the impetus then, and now we have MACRA. We are believing that MACRA is a new impetus for reform that will create demand on the part of MIPS-eligible clinicians to try to seek refuge from MIPS and in APMs when they can actually be effective.

I've had doctors say this to me, "If you're going to ask me to do so much, please let's make it worthwhile," and we're trying to open up the space that doesn't really exist well. It is space. It's empty space. We're trying to fill it in the APM space where specialists in particular, but emphasis is on team-based care, where we have every clinician's role in every episode for every patient they see, for every service they provide, and every dollar that they spend and every dollar that they save or lose is accounted for in the system.

It's an x-ray machine that everybody steps into, but it's an opportunity to show your effectiveness, so yes, it pitches a -- call it a bundle price, target price, expected value, expected cost, and it says under the almost universally panned fee-for-service system with all of its lack of coordination and all of its fragmentation, this is
what you see. This is what Medicare spending -- this is what's not sustainable. This is what led to SGR. This is what led to MACRA. This is what has to change, and here is your opportunity to do it.

Now, back in the day when we did the Medicare savings program, we sort of like created a blank canvas. Tim, you referred to that. Right?

Game on. The ACO. Now, what is your care plan? Right? Well, you had some ready to go, but it wasn't all out there. This is a little bit more like paint by numbers, because now instead of just a blank canvas, we have every condition known to humankind catalogued and grouped, and all the major procedures and all the clinically relevant services that pertain to those conditions are encoded in the clinical logic by their clinical relevance and association to the clinically meaningful episode framework that it's all designed around.

Now, it wasn't easy to anticipate what to speak on, but I was flying into Washington. It seems like yesterday, but this morning. And knowing I was coming into Washington, I decided that I had to organize my comments around an acronym, and so the acronym I decided was SPRINT, just so I could remember it without referring to my notes,
without putting on my glasses.

Now, the first S is -- this is now the implementation plan. So the S is specifications. We've done all this. You've done most of what you've done, and we've done most of what we've done without contact. Very much of it was CMS. At some point, there has to be meat on the bone. There has to be the specifications that only CMS can provide because they have the authority to do it. They wrote the QPP regulations. They know what has to fit, and the two things that they have to weigh in on are what are these entities, what are their governance, what's the rules, minimum case size and so forth. We're certainly willing to give the technical backup for that, but they have the authority and the perspective to make that decision.

The second one -- and I watched you all on TV yesterday, so this is my second day. Maybe I missed it, but I don't remember very much discussion about qualified participation in advanced APMs. When you read through MACRA and when you read through the QPP, the idea isn't that a MIPS-eligible clinician puts a little toe into the APM world but otherwise stays in MIPS. The idea is that the body of your clinical work is carried over into the
APM, and on top of the grouper, this APM has what we do call the fiscal attribution logic, but what it does is it tracks every clinician's work every day of the week.

There are some clinicians who maybe do the same thing every day, every day of the week. Most don't, and so if you're trying to capture the body of work that most clinicians do, you have to be able to follow them as they go from this condition to that condition or into the OR or maybe consultation, maybe surgical consultation, and you need to track all that. And that becomes what we call the episode clusters that are defined around each clinician.

Those clinicians affiliate. They become qualified participants in advanced APM entities, and that's where the risk is born. And those of you who have read the proposal know that that's the case.

So I'll go faster now. Those are the specifications. One of the things that the PRT asked us several times was, "Well, who is interested? Who is going to participate?" So that's the P in SPRINT, participation.

CMS has thrown demonstration parties before, and nobody shows up. We don't know in advance, and without those specifications, nobody is going to say, "I commit to this model." If there's an eight percent downside risk,
what's the upside risk, and what kind of industry is going
to form around this? And industry has formed around ACOs.

The I -- and you'll be glad to know two letters
that are taken up in my next category are called
"information protocols." This provides a tracking of every
single dollar, savings or loss, in the clinical framework.

As I said before, CMS is now in a position to push out
information data formats that they don't do right now.
They give raw data out, but now for CMS's own internal
monitoring and evaluation purposes and for the sake of
participating organizations, they can say, "Here it is.
Here's the x-ray results."

And working with the information protocols with
CMS around what kinds of ways to frame it, what patterns to
reveal and so forth, now suddenly the lights are turned on,
and you have the cost drivers for all the episodes you're
participating in and all the patients you're seeing.

So lastly in my SPRINT acronym is tracks, t-r-a-
c-k-s, because it isn't necessarily true that we just turn
the switch and this whole thing, the whole blossom opens up
all at once. No. Some grounded experience seems to be in
order, and again, this is where CMS could weigh in as well.

What are the tracks? You could have a procedural episode
track, so you have surgicals, specialists, anesthesiologists, radiologists, so forth, who form around
procedure episodes because that's what they do, but that's actually not all they do, and that's not all they want to
do. They give surgical consultations, and they give follow-up visits as well. But nevertheless, one track
could be procedural episodes. Another could be acute conditions. Another could be chronic conditions, or you could cut it another way.

But the point is in a rapid cycle adoption process, step up to the game-changing Holy Grail, as has been referenced by various people around the table.

CHAIR BAILET: Thank you both for your comments and participation in helping create this proposal.

I'd like to turn it over to the Committee now for questions specifically to the submitter. Thank you, Bruce.

MR. STEINWALD: You touched on this under your S in SPRINT, the role of the grouper. But I wonder if you could expand on that a little bit, and especially identify the unique features of the grouper and how its essential role is in the payment system that you propose.

DR. TOMPKINS: Well, you know, when we started developing the episode grouper, we realized that existing
groupers really were not designed for the Medicare population where you have simultaneous conditions and simultaneous episodes happening all the time. So it was designed with that in view.

First of all, it exists. That's an advantage of having it. It does the accounting whereby through the clinical logic and the episode construction logic, you're able to take a whole stream of administrative claims sorted by beneficiary and sorted by data service and say why was this service done. And so, therefore, the episode grouper for Medicare -- I won't get into too many of the technical details. It's a SAS program, but some earlier questions were asked about this. It was designed by -- it was developed at CMMI with oversight from the Office of Information Services, which puts quite a lot of high standards on software that's developed by or for CMS. And we had a professional software development team at Booz Allen Hamilton that complied with all of those OIS requirements and all the testing requirements and all the documentation requirements, and CMMI would tell you right now it's the best, most tested, most openly tested and best documented grouper bar none in the industry.

It has some tricks up its sleeve, which others
don't. For example, it can allocate services to multiple episodes co-occurring, but it will divide the dollars and allocate them so that when you're attributing actual costs to the episodes, you're not double counting dollars.

It recognizes by way of clinical logic and association that the procedures are done with respect to the indication, which are the conditions, and you can roll it -- yes, the procedure episodes can stand alone for their own analytical and payment purposes, but they roll up into their conditions, which are the indications for that patient. Sometimes procedures are done for different indications. The grouper knows which indication it was, so you can roll it up to the condition episode. Similarly, when you review the condition episode, all of those procedures are now rolled up into it.

There's another episode association we call "sequelae," which are -- we borrowed this definition from Merriam-Webster, which are the aftereffects or secondary results. That is, if you're having a condition, other conditions can emanate from them. Heart failure can emanate from an AMI. Post-surgical infection can emanate from a surgery. These are formed by way of their episodes. Some of them can be used for analysis. Maybe some of them
only serve the purpose of capturing the services relevant to that clinical concept and then rolling it up into the parent or causal episode.

So, without double counting, across all episodes, all the complexity in the world, we can keep track of dollars, every dollar, without double counting it. Also the savings and also the losses.

CHAIR BAILET: Paul?

DR. CASALE: Thank you for presentation. You know, when I think of episodes, I always first think of BPCI, you know, because that's my initial thought. So when I look at BPCI and those 48 conditions, I mean, people are speaking with their feet. Most are doing elective joints and CABG, right? Not very many are doing chronic conditions. And as I think through your motto, again, I'm always trying to -- I sort of need some reality. So I think of the elderly patient with sepsis who then has an MI, ends up with a PCI, then has a vascular complication and ends up with an embolectomy, then gets a small bowel obstruction. I mean, you know, so the episode and the -- I struggle a bit on how all of this comes together without getting ultimately to including the total cost of care.

So I don't know if you could comment on that,
because I do struggle with how this all works in these complex Medicare patients as opposed to what's currently going on in BPCI, which is mostly around elective --

DR. TOMPKINS: Well, I'm not sure what -- I'll take a stab at the -- the grouper would acknowledge all of those conditions, right? Each one gets triggered. Each has a certain duration. It will assign services by way of clinical relevance to each one. If clinicians have decided that there are relationships among those episodes and it's not spurious or just happens to be, there's no all-cause here. If there's a connection made, it's because clinical reviewers have decided that there is an appropriate connection to be made. So the grouper will do all that in the background.

Now, the question about BPCI, when ACA was passed, that launched a lot of things. Some things were parallel inside of CMS, and BPCI as a bundled team or a portfolio started underway, just like as authorized under ACA, the episode grouper formation had its own track. And so they sort of grew up organically differently. BPCI is pretty much hospital-based DRG.

Philosophically, not to go down this road too far unless you want to, philosophically, we think that the
triggering moment, the definition, should be as early as possible so that you maximize the chances for arbitrage.

And most things don't appear out of nowhere in the hospital. So for one thing, to be able to go upstream and recognize that physicians have ambulatory practices, too, and those patients are often seen there, the grouper has already tracked that, and the patients with those denominators, with those conditions, now are at risk for going in the hospital. The grouper will keep track of that.

BPCI has grown up sort of out of convenience, I would say, piggybacking on the DRG system. I don't think that the DRG per se would meet our criterion for the label which occurs at the earliest possible moment before those arbitrage and opportunity, because as we all know, the DRG label is put on, and the DRG dollars are out the door even after the discharge has occurred.

Now, do you --

DR. CASALE: Yeah, I think a bit. I think a couple things still that I struggle with is ultimately when you get the dollars down to the physicians, so who is -- you know, which role are they playing in these very complicated --
DR. TOMPKINS: Right.

DR. CASALE: -- condition, you know, episode within episode within condition.

DR. TOMPKINS: Right.

DR. CASALE: And then second is around, you know, if this is -- in terms of creating -- you know, as Bob always says, what triggers the condition, so will people end up with more conditions that might encourage, you know, more episodes within the episodes?

DR. TOMPKINS: Well, we've had -- I think even some of the go-around with the PRT involved questions about specific anecdotes. We had one with CMMI, too. The patient who has this and then this has this. If we had more time, which we don't right now, but if anybody wants to submit it as a question, we can actually deconstruct that and say, well, this was this episode, here was the care team for that, here's this episode, here's the care team for that.

But let me go back to 1997 for a minute, which is when we had the Medicare -- again, my comments about that. The idea was a cultural shift. It was a cognitive shift. It was to say however we're organized, however we behave, whatever our clinical thresholds are for what we do should...
be governed towards the prime objective of value and not productivity and volume. So whether you happen to be the supporting provider here but you're the episodic then, and then you're an ancillary here but over here you're the medical specialist who's the primary, the idea here is that we are trying to manage our patients towards value.

So even though the grouper has to sort of keep up with all that detail, the clinicians hopefully are rising above it and saying this is our patient, and even though this is a sequence of events and there's some caregivers that are coming and going, the general thrust here is to give excellent care at the lowest possible cost.

Now, the question about -- I mean, I made the joke about the epidemic of schizophrenia, so now you've generalized it, right? If you had an episode for schizophrenia, then suddenly everybody has it. That's sort of the notion here.

Well, the grouper can -- in the grouper there's a component called the "episode identification rules," which have to do with what are the diagnosis codes which are the triggers for the diagnosis. You can also add additional criteria to it. You say I'm not going to recognize this, or I'm going to stratify this condition if it -- we're not
going to recognize it unless the test was given before a confirmatory diagnosis was given or if a definitive service is provided in addition to the diagnosis code. That option is there. But let me just take that one example and make a general reference back to some other things.

It's a SAS program that's constantly reading clinical metadata tables, so those trigger codes are often a table, which can be reviewed and modified. And we can test or we can review and modify those codes and those tables as necessary in order to optimize against the occurrences of a rise in diagnosis codes and so forth. But let me tie it back up, because I'm now trying to touch on everything.

The entirety of the Medicare population experience in dollars is poor -- you know, is represented in the claims and is organized by the grouper, and you can put to the test the incidence rates, the prevalences, the cost profiles, and so forth of any- and everybody you want to. So you can monitor for the existence of undue occurrences or occurrences of conditions that don't seem to have the supporting services of the cost profile. But if physicians are going to, you know, be so concerned as to undermine every effort, then, I mean, I can see that that's
an unintended consequence. This is something we want to monitor. But I don't think at this point, with the implementation of MACRA, I think we take our best step forward and then we try to monitor for maybe things we don't want that are unintended consequences.

CHAIR BAILET: Tim.

DR. FERRIS: Great. I want to pick up on that last comment because I really liked your analogy of the blank canvas for the ACO and the paint by numbers with this. And all analogies fall down and misrepresent the complexity of what's going on, but just given that, the paint by numbers here, it seems to me, if I understand our PRT's evaluation, which I'm sure in many ways I don't, it's really -- it's safe to say it's really, really complicated. And if I read between the lines, there is some anxiety about unintended consequences which can't possibly be anticipated given the myriad number of interacting parts within this model.

And so one of the things about the blank canvas and the ACO is that what people do in order to achieve ACO is -- it's actually a small whole number. They do care coordination, they do site of care, they do -- and, actually, in surveys of what ACOs are doing, they come up
with 12, maybe 15 things, and you can look at those 15
things and say, is this likely to hurt patients? Are they
likely -- you know, what's the potential unintended
consequences?

I don't think any brain is capable of -- with
such a complicated system, of thinking through what the
potential unanticipated consequences are of such a
complicated -- at least certainly my brain isn't. And so I
wonder, given that set of -- that characterization, which,
please, tell me if you think that -- in what way that
mischaracterizes the comparison. What would you recommend
to PTAC given all the uncertainties about how those
uncertainties are managed, the uncertainties around
unintended consequences? How does one think about the
testing and implementation of such a complicated model
where the unanticipated consequences are - can’t be
anticipated.

[Pause.]

DR. OPELKA: So I'm stalling while he's going
brilliant on me.

So we think a model like this is something you
roll out. You begin with a starting spot, and we thought
it would be easier to begin in the procedural episode world
as the initial place to do this, and beginning with the
various team members that are within there and build this
out from there.

The challenge that we have -- and there are many.
We could list 100 challenges with this model as we think
through it. When the world has told us leave MIPS and go
to APMs, well, when I think of it, just for general
surgery, I've got 10 different types of general surgeons
out there. Am I going to build 120 versions of the COPD
model in the individual siloed APMs? We'll never finish.
We'll never get it done.

We needed a framework that we could build upon
that meets the practice model, first of all, of a general
surgeon. The second part of this was I as a general
surgeon, in the world today of Medicare, we don't practice
alone. These patients are far too complicated. There
needs to be a connection across this episode, this time
window of care that everyone is coming together and we're
all going to measure cost and we're all going to measure
quality and we're all going to have shared accountability.

Now, can I create that initial rollout that
starts with the small enough group that we can build on the
way we practice, that we can put that construct together?
And the long view of this is actually -- it is to learn enough about how big I can build the episode, how I can get out of just procedural episodes and build the condition, and then build larger conditions so that I'm heading toward the ACO construct. The closer I get to that ACO construct, the more I can get into population health-based payment systems. So that's the overall plan.

Now, how do I start that small enough and at the same time be able to account for where people will try and game this, where we're stepping off? And how do we actually keep up with the ability to leverage what's happening in the clinical data world to backfill this? We don't think claims-based alone is a big enough solution, but once we start making that connection to the clinical world with the claims world, we've referred to it affectionately as "walking in the cold fusion," someone else called it "unified theory." We think both are correct. So if we can have cold fusion and unified theory come together, we can do that. But that's where we're going. How do I take the clinical knowledge that's out there and says you have to prove to me you have this so that you belong in this episode? That gets more complicated the deeper you go into these episodes. So
what's the initial starter set that I can start to build
the framework, that we can start to shift the logic, that
we can start to move the culture?

So we chose what we thought were rather tight
episodes that people could plausibly understand all the
services that are in there, and they could plausibly come
together to figure out how they're going to optimize care.

Do you want to add to that?

DR. TOMPKINS: Well, I'm certainly not the
clinician around the table, so I -- no, we are opening up
space here, and there's plenty of room for innovation and
some of it could go wrong. The cold fusion I think is a
part -- the episode framework for the first time at least
points toward the capability of borrowing in the clinical
information that clinicians already use surrounding
virtually the same clinical concepts and episodes. And so
additional information can be brought for severity
adjustment, for clinical outcomes, and so forth.

But like I said, even compared to ACOs, all the
services are now catalogued, so this is not like, you know,
hiding or moving around in the dark. This is not -- I was
going to say that's where you would want to stay in MIPS,
but I won't necessarily make that comment. But to step out
into the APM where this is really so carefully articulated in terms of what the clinical context was and which physicians were involved and what was the role and where do they bill and what do they do, now match that with cold fusion when you have the clinical information pouring in that shows much even richer -- you know, at some point I think we trust most of the clinicians and innovators to do the right thing with this opportunity. And at the very least, it takes away the nefarious incentives that have been probably pushing for a lot of unintended consequences right now.

CHAIR BAILET: Len.

DR. NICHOLS: So, Frank, I'm glad I met you. What I want to get to, though, is the ability of this grouper to learn. It seems like there is a lot of magic baked in here, and here's my paint-by-number attempt to grapple with the complexity here. It seems to me the genius of it is you can map every configuration of professional patient interaction and pull it up in these different directions, episode or clinical, aggregate, all the way up as far as you want to go.

The flip side, what's not so pretty about that, at least to my economist mind, is that, therefore, we are
setting, as targets, or the benchmarks, or the goals, or whatever, the bundle against which you judge yourself, today's fee-for-service activity, and yes, beating that's better than doing it, but how do we learn to have better goals? Can your grouper -- is it dynamic in that sense?

DR. OPELKA: And I'm sure Chris will probably want to jump in here, too.

From a clinical sense, what woke up the community -- and I used to just think it was the surgical community, but a lot of other specialties have come inside the grouper and sat with us, and looked at this -- what woke us up is we had no clue, in an episode of care, how many different tax IDs are hitting that episode of care, and how many of them were not apparently warranted. We had no idea, and I would say that the average physician is completely clueless. This was the first attempt for us to see why is a coronary artery bypass in one community got 18 tax IDs and another got 65, and yet, risk-adjusted, they're the same, and the outcomes and length of stay are the same.

What's happened here is just patterns of behavior have just emerged and never gotten cleaned up, so can we create a logic, using the grouper, that then provide analytics back to the field? If the analytics don't come
back, if they just tell you're an outlier to the bad, good
luck, we've not done anything.

DR. NICHOLS: Right.

DR. OPELKA: But if I can show that you are out-
imaging everyone else, you're out-consulting everyone else,
this is where a lot of the questions we got from the PRT
was, give us the formula that goes in here. Well, on these
one-off APMs, that's easy to do. There is a care plan.
But the variation is so different, in different markets,
for different reasons. We don't want to be prescriptive.
We'll ruin the opportunity to get people to actually look
inside and understand what's different. We actually want
to get that feedback. We want to create the learning
cycles that share with everybody, just like the ACOs share
as much as they can about where they found and save money.
We think this allows you to go inside an episode and begin
to wonder, why are we different? Is this warranted or not
warranted? Does it influence the overall outcome of care,
and how do patients feel about it in the PRO sense of the
word?

So that's the linkage we see, that if we start
making these changes, we have to have an episode based to
measure framework, and it has to tie back to the patients.
It has to have the PRO, or we're not going to have the kind of feedback we want.

And the other side of this is we made this argument to the PRT, so we've been looking at the standard quality metrics we used in surgical care, and they don't allow us to get to the kinds of confidence intervals that I can't tell you something isn't random. And so the standard outcomes, like mortality and SSI, I'm tortured by small numbers. In order to make this work, I need the PRO. I really need the patient input in this whole cycle.

So all of that -- we can't make this work by just pulling it out and saying let's just look at the grouper. All of those components have to come together -- the feedback loops, the learning environment, and measurement that ties back in to the patient experience of care.

Do you want to --

DR. TOMPKINS: Maybe a footnote to that. Len, your question -- I was tracking part of it -- was just to say that right now, your beating historical or current standards, because the grouper acknowledges that all these clinically relevant services, although in many cases unwarranted, shall we say, are included in the expected cost, and so, therefore, the motivation and the opportunity
is to beat that. And I think your question was, in the next chapter.

DR. NICHOLS: Yes.

DR. TOMPKINS: Right. Well, if the grouper is still doing what it's doing, then it will still assemble the clinically relevant services, but the margin will go down, and the margin will go down to the point where the "expected cost" -- in other words, what's the norm -- is actually correct. I mean, if you -- the pressure right now is to move -- is to push on the efficiency frontier, right?

DR. NICHOLS: Right.

DR. TOMPKINS: And as long as you can push on the efficiency frontier, and beat the norm, the expected cost, then there's a margin there. With hundreds or thousands of clinical laboratories working on the innovation and moving the frontier, there could be a time when that margin really gets to be very small, which is a nice place to transform the payment or the expectation into a prospective payment, without relying on the savings, you know, the comparisons and so forth, and the shared savings to drive the difference.

So you could, with the innovation, if you pounded all that excess out, then you could actually reach the true
efficiency frontier for treating that condition or
providing that service, and then you're golden, because now
you know what to pay, and you're not going to pay more than
that because more than that is not warranted.

DR. NICHOLS: And you would know you hit that
frontier by the fact the variance across the country just
got to be zero?

DR. TOMPKINS: The variance would get to be zero
and the average would get to be, you know, correspondingly
lower. But I look forward to that day, right? I mean,
that presumes a lot of success here.

CHAIR BAILET: Elizabeth.

VICE CHAIR MITCHELL: So my question is on the
present, and after a couple of years I think I've gotten my
head around the theory. I get it. But this is potentially
a very basic question about practice that probably has an
obvious and maybe brief answer.

So you're talking about the feedback loop, this
incredible information that illuminates where every dollar
went, who did what, the x-ray machine. Where does that
information go? Who gets that and then assigns dollars,
risk, performance? Is that just sort of your average, or
maybe above average practice manager? Does that require
sort of super powers to understand these reports? Do you need a Tim Ferris? I mean, who governs this? Where does the information go?

DR. OPELKA: So this has been part of the dialog we've had with the Innovation Center. How do you structure this with the APM entity? How do you allow that APM entity to get into the ability to consume and educate and build the clinical affinity groups?

What's happening is the grouper to the APM entity is pretty prescribed, but then what happens from the APM entity down to the point of care, that's where things start moving, and that's where, when we saw the ACO industry come out, there was a whole new industry that got around this. How do we get around this, understand this, and begin to do this?

We think that these kinds of changes have lots of different elements to them, including not just the claims-based information but the quality-based information. And when you take risk in this environment it's not just insurance risk. It's operational risk. Before I jump into an episode of care, do I have the team to do it? Because now I'm at risk in a loss environment, do I have the team to perform on quality?
So those elements of assuming that operational risk, along with the physical risk that's involved here, all have to be constructed. Part of that’s on the specialty society. How do we come together and teach each other in this new model? How do we distribute that and get the field ready for this kind of work?

CHAIR BAILET: Bob.

DR. BERENSON: Thank you. So there's a lot that I like about the approach, so I don't -- consistent with my style, I'll go to the stuff I don't like and ask you about that, actually, partly to try to solve these problems and see if we can't get those taken care of.

So one is this issue of appropriateness. Now you said, and I agree completely, that there's practice variations with lots of different ordering patterns of imaging, different numbers of doctors, et cetera, et cetera. We also know from Dartmouth and elsewhere that there's dramatic variations in the incidence of procedures. Similarly, it's not like this is a theoretical problem.

It's a real problem, and in your responses to the PRT you basically said, well, until we get measures of appropriateness there's not a lot of progress we can make.

So are you dismissing things like expectations of
following evidence-based guidelines, or having second
opinions outside of the bundled payment? I mean, are any
of those process requirements, something that should just
be dismissed and we should just sort of do our best to
respond if we find that this becomes a problem?

DR. OPELKA: No, and I think this is a keen area
of focus. It's been, I think, pretty much under-invested
by the industry as a whole, and probably because the
current solutions that have been put into place are so
difficult to put forth and develop that it will take us too
long to do. So what alternatives do we have?

First of all, for a proxy, the first proxy that
we put in place is to try and develop these goal-of-care
initiatives. So if there is a procedure out there, what is
truly the goal of care, get agreement by the whole team
with that goal of care, including the patient, and then
link the assessment of that with the PRO. So we think
that's a poor man's version of the first step toward
appropriateness. That would be a dramatic shift from where
we are today, but we think that's a great first step.

Rolling in things like the clinical pathways,
guidelines have not yet strong enough. They've been
guidelines and not really harsh pathways. Can we break the
problems that we have with the HR companies and get these interoperating and moving into the clinical environment? I think there are a small number of specialties, us being one, that's working on how do we build that into the workflow solutions, and we think that gets us a step closer to appropriateness of care. But we're not going to solve that in this payment model. We may get more improved measures, but to get into a RAND-style type appropriateness measure scale is -- it takes a long time to develop those measures and there's probably not going to be as much bang for the buck if we can get through some IT solutions. So we are all in favor of it. Where we are today isn't far enough, and we're more than happy to move that direction. It's just not going to happen overnight.

DR. BERENSON: Let me ask one other, which is, as I was reading this, one of the concerns I had was it's -- even though it's a dramatically new approach to payment through episodes, to some extent it is still based on current patterns of billings. And then I found, actually, Steve Wiggins' letter to us. So I just want to get your comment. He's from Remedy Partners and he actually spoke to us about BPCI last month.

"The proposed APM examples include an implicit
assumption that allocation of risk and reward is appropriately tied to the physician's relative billings. We believe this is an erroneous methodology for attributing savings. Spending and quality outcomes are most often controlled by practitioners billing far less than surgeons."

How would you respond to that kind of criticism?

DR. OPELKA: Well, the model that -- and, Chris, you may want to jump in here, too -- the model that we're putting forth isn't just physician billings. It's all Part A and Part B, and if you gave us Part D we would have rolled that in too, because we think -- one of the key points of this methodology is we're looking at as much cost as we can, within what we think is an episode, and within what we think plausibly assigns to that episode, not just what I, as a clinician, can influence, but we, as the team, can influence. And we can build in larger components to this team, other than the clinicians. The APM can partner with the hospital. The hospital could form the APMs. So could an ambulatory surgery center. We're not excluding anyone from coming into the risk environment and being part of looking at the total spend, and trying to figure out what's warranted and what's unwarranted, and how do we
maintain or improve quality in that process.

DR. BERENSON: But I'm referring, more specifically, to at least the perceived existing distortions in RBRVS-based fee schedules that pay lots more for people doing the procedure than perhaps the people who say we don't need a procedure, as an example. There's no sort of -- I mean, an alternative is to give an entity a bundled payment and let them make the decision about how to allocate the dollars, rather than just accept the established billings that come in. Is there any way to change that?

DR. TOMPKINS: Well, just to clarify, I think what you're referring to, or he's referring to, are the proportional allocations in the fiscal attribution model, where the surgeon gets 40 percent, and the -- that's what you're referring to. Well, we never said, and it's actually not true that those were derived from "the physician billing profiles." And I'm not saying that our method was necessarily worse, or better, but it wasn't that. So just from a factual point of view, that was never the point.

So I think that the question here, Frank, is how do you -- this is an optimization problem. Right? You
have a dollar saved or a dollar lost. You're all accountable. How many cents on the dollar are you versus her versus him? And so it's an optimization problem that has to do with how much of the responsibility and the ability to effect outcomes resides in one person or one role versus another? And Frank, you've had a lot of conversations with --

DR. OPELKA: Yeah. So we -- there are a couple of different parts of this. So first of all, the initial attribution model that came together is just inferential and it was sticking a flag in the ground. We think that's an area that should go undergo ongoing governance. How do we think about different episodes and how might we allocate them differently? And we're fully in favor of that but we had to start somewhere. And believe me, when I presented this to the surgical boards, and I said, you know, "This is where we want to go," they wanted the surgeon at 85 percent. And then when I reminded them there was a downside, then they wanted the surgeon at 15 percent. So everyone is acting out of their own self-interest here, and I get that. But we just set a point of reference to begin with, and we think that these episodes can evolve in this regard.
Secondly, a lot can happen at the APM Entity. This attribution is part of the payment between the payer and the APM Entity, but the APM Entity may reallocate that whole risk entirely differently, depending on where they feel the effort is within a community. And we've seen this within the peri-operative surgical care, where a primary care may say, "I'm doing all this pre-op work and I'm taking care of the patient in the post-op period. Why aren't they being appreciated for that?" and they can. But that is a negotiation that is at the community level, at the APM Entity, and that was baked in as part of the flexibility of this program, because care is so different in each part of the country.

DR. BERENSON: So that theoretically could apply, then, not to just the allocation of the risk but to the allocation of the dollars in the bundle. Right? In the episode.

DR. OPELKA: That's correct. That is absolutely correct.

DR. BERENSON: And let me ask the final question and then I will move on, is you've got lots of surgical subspecialties endorsing the model, at least for testing. Do you think it's feasible to find a geographic area where
you could actually get a broad interest in demonstrating more than just one or two episodes but really trying to test the model, which is very broad-based?

DR. OPELKA: We actually got this question from the PRT, too. We've not gone out, as the College of Surgeons, and done some kind of market assessment. We don't really have that tool or that instrument or that capability. We've had a lot of interest from different private sector payers, who have been interested in the model, and we've had interest from ACOs, who look at this model as something that would be very useful to them in trying to understand the working episodes that are within an ACO.

So that's been our limit. We've been focused on trying to get the model through the process here, and, you know, we, of course, are very flexible with how do we begin a rollout and learn and expand the rollout, whether that's regionally or on some other different scale. We've been willing to work with the Innovation Center with regard to that. We're not closed up.

CHAIR BAILET: Harold.

MR. MILLER: Four questions. So we'll stipulate that there is clearly variation in care around the country,
and unwarranted care. Although various and sundry efforts to try to look at that more deeply have been found that some of that variation and unwarranted care is actually warranted care, because there were things about the patient that weren't being measured, that whenever you looked more deeply found that, in fact, the variation was appropriate, which goes to the issue of the difficulty of risk adjustment.

So it's one thing to have this episode grouper as an analytic tool, to say we need to give information to people to see where there are opportunities. The challenge becomes when you try to turn it into a payment model and you base payment on it.

So this gets into the question of kind of what's the protection for quality. And in the letter that you sent just before this meeting, the pages aren't numbered so I can't tell you the page, but it's just above the 4(b) criteria and value over volume response. You have the statement, "The model effectively prohibits participating providers from benefitting financially from reductions in care that lead to poor performance and quality — prohibits," which is a powerful, strong statement, but does not seem to me to be consistent with the quality structure.
you described earlier.

So could you explain exactly how it prohibits that from occurring?

DR. OPELKA: Well, in the sense that the quality is measured, in both process outcome and PROs, we're not stopping anybody from what they're doing, but they will pay -- they will -- if they underperform in the quality space there, then bearing the risk of that underperformance.

MR. MILLER: But they could, if they reduced spending and they were not in the worst quality, but they had also diminished quality somewhat, my understanding of the model is they will get some savings back, just not as much savings. So it's not prohibiting them from benefitting financially. It might reduce what they might otherwise get. Am I correct? Because it doesn't say you have to maintain--

DR. OPELKA: You're looking at the same coin. I'm looking at the head; you're looking at the tail. It's six of one, half a dozen of the other.

MR. MILLER: I'm not sure it's six of one and half a dozen of the other, but okay.

DR. OPELKA: Seven and five.

MR. MILLER: So there are other episode
approaches that try explicitly to distinguish between the
desirable care and the undesirable care, and to distinguish
those in the model, as opposed to saying here's the total
spending in the episode, and if you reduce that, you get
some share of that; but say if you reduce the undesirable
spending -- and it sounds as though in your model you
actually do have some of the undesirable sequelae
identified.

Did you think about structuring the model that
way potentially initially to say that we would just focus
on the undesirable -- what we measure to be undesirable
care, hospital admissions, readmissions, complications, et
cetera, as opposed to it being based on total spending?

DR. TOMPKINS: I'll start. No, not really. The
grouper actually forms three different dependent variables
and can calculate risk-adjusted sequelae costs for any
episode. So if you're interested in knowing the extent to
which there's a larger excess in a sequelae cost than would
be presumed or expected because of the risk-adjusted
results for that patient, you can do that.

The reason I give the short answer first, no, is
because we didn't think that as a payment model we wanted
to at all divide, because we think the inferences, the
scientifically based inferences about the cost performance at the patient level are all inclusive with respect to cost, and we thought that managing both the sequelae costs and the directly assigned services, what we called them, were all part of the same bundle or episode and ought to be equally available for -- but clinicians looking at it would probably have an eye at the sequelae costs and say, "This is what we want to avoid. Who wants this to happen?"

MR. MILLER: But one could structure a payment model slightly differently than what you did that would do it that way because the episode grouper would, in fact, support that.

DR. TOMPKINS: It would be -- yes, if one would want to, then one could because it does, yes.

MR. MILLER: The third question is several years ago Medicare did commission some analyses of the commercial episode groupers around the market then to try to see whether or not they were grouping sensibly or not, and it had some clinicians look at them also and found that in a number of cases they were -- because of the problems with the claims data, were assigning things badly, that cases were being assigned to an episode that just did not really make clinical sense when one went back and looked at that
I don't really understand. What has been done in that sense to validate the grouper that you have? Because you've developed it with clinical input. But has there been an effort to run specific cases and then take a sample of them and look at them to be able to determine whether or not the results made sense to clinicians so that they would say, "Yeah, boy, that's working perfectly. What that group didn't do makes sense to us?"

DR. TOMPKINS: As part of the development process, I had a number of subcontractors -- I mentioned the software developer Booz Allen, but we also had the New York QIO IPRO, which was part of our clinical team, and we also had subcontractors which were the AMA PCPI and ABMS, and we had external clinical reviewers who were looking at the codes and the logic and some of the output. Was it thoroughly satisfying and did we -- no. It was interactive, and it was part of the cyclical development of the episodes. We're now embarking on similar parallel projects to further kick the tires and vet it even locally to have data from a particular organization look at the results of the grouper, the organization has those physicians and has those patients and has that history, and
we'll be validating the results from that perspective. So
it's an ongoing discovery process. We --

MR. MILLER: So you're planning to actually look
at actual cases and how well it worked, but haven't done
that yet. Okay.

Final question --

DR. TOMPKINS: Well, we look at actual cases. We
have what we call "patient vignettes," where the actual
claims history of a person is looked at in every degree of
detail, and then we cross that to "did the grouper trigger
an episode here, did it trigger" -- if so, which, which,
and it opens it up to become a matrix, and you now know all
the episodes that are open at any given time, and then you
further follow the chronology of services, and you can
follow the footsteps of the grouper to see which episodes
that service was assigned to. And that process has -- was
part and parcel of the --

MR. MILLER: What I was really getting at was if,
in fact, the model is implemented, people will be getting
assigned episodes, and the question will be: Will they
feel that those episodes that they got assigned made sense
to them? And the question is: Has sort of a sample run of
that been done so people got a report on what would have
been their episodes had the grouper been in place and said, 
"Yep, boy, that makes sense to us, what we got assigned"?

DR. TOMPKINS: Well, the fiscal attribution logic, which followed after the episode development, is where a lot of that happens. And as you know, we don't assign an episode to a single clinician. A clinician doesn't get assigned a clinical role in an episode unless there's an actual bill that says this is the service I performed that's clinically relevant to that episode.

There could be some breakdown. But, I mean, this was looked at very closely, and part of the overall enterprise is to maintain, I think this -- I would say this is a national resource. This question about proprietary came up. CMMI developed and paid for the software. They own it. But somebody needs to -- you know, we all get updates to our apps on our phone and everything else. Somebody needs to stay on top of that development. The clinical data tables have to change for no other reason than clinical practice changes and coding systems change.

So instead of having everybody sort of scattering and working on their work and doing all this over here, if we all contributed a lot of that effort towards the single resource that articulates the clinical logic and the
relationship between services and episodes, et cetera, then
that in turn benefits everybody.

DR. OPELKA: So just to add to this, as part of
this project, what we did was we took the data files that
are part of every episode, and we pulled together the
clinicians who are involved in the episode, and we walked
through an in-depth exercise about all those data files,
asking the clinician what is appropriate and what is
plausible. And they could narrow these episodes down very
tightly with appropriateness of care, but then we wouldn't
find the variation. So we had to work with the clinicians
and say, "But what would plausibly be out there that we
ought to include in this episode?" So that as the episodes
were built, we can actually bring up and appreciate where's
the waste? From a clinical perspective, let the physicians
look at this and say, "Yeah, I know that happens all the
time. It shouldn't happen, and it's happening all the
time, and it needs to be in that episode because we need to
know about it."

So we built these episodes with another
generation, because there were several already, generations
that had reviewed this. But all of these were refreshed
with all the specialties who were willing to participate,
and we continued to open it up to more who want to come in and review the data files to update them. Those need to be kept current. Care changes. New drugs come out. New treatments come out. All kinds of thing change. So episodes are dynamic, and they need to be managed.

MR. MILLER: Final question. If a small physician practice came forward and said, "We'd really like to participate in this for managing a chronic disease," so a gastroenterology practice says, "I'd like to manage this for" -- "manage my inflammatory bowel disease patients," or a pulmonology practice wanted to manage their COPD patients, and said, "We've looked at the data. There's nothing that we're over ordering here, but our patients are, in fact, showing up in the hospital more than we think is necessary or desirable, and we think that we could do something different to try to keep the patients out of the hospital, but it would require us to be able to hire additional staff, et cetera, which are not supported under the current fee schedule," there's nothing under this model that would pay them differently. How do you anticipate that a practice like that might be able to participate? Would they have to look to some larger alternative payment entity that would front money for them? Would you see
potentially there being additions to the fee schedule that would only be billable if they're in this alternative payment model, or what?

DR. TOMPKINS: I mean, this is a parallel question that's come up in the ACO world where the original conception was that if you really believe in what you're going to do and generate the savings to come up with a business model, an ROI calculation, and borrow from your savings or get a bank loan, because if you're that confident, then it will eventually pay for it through the shared savings.

As the portfolio of ACOs over the time, they've explored other options, and just like that, it's possible that CMMI would consider a portfolio of models that operate generally under this umbrella, where there's an advance payment or other kinds of billable services that are only allowed by the demo, and they're added to the actual cost, and when the shared savings reconciliation is done, those are netted out. And the cash flow has been preserved by the practice, and their hypothesis has been proven true, and the savings allow them to reconcile with a net positive.

DR. OPELKA: I think there's --
MR. MILLER: So that is not part of your model now, but it could potentially be if that was a barrier to small practices participating.

DR. TOMPKINS: Yes.

DR. OPELKA: So I think there are many ways from a behavioral economist standpoint as to how to get engagement, and you're describing one. And we know it's very effective.

MR. MILLER: Well, I wasn't talking about engagement. I'm talking about a barrier, that they face a specific barrier to being able to deliver the care, and the question is: How would they get the resources to do it?

DR. OPELKA: So, again, you could reduce the downside risk. You could increase the upside reward. You could gain other partners who would be willing to share with them. Or you could frontload them. There are multiple different ways to create that incentive for engagement, and we have not been prescriptive to say this is the only way. We're working to listen to whatever incentivizes the payer to help move this and get it going.

CHAIR BAILET: Thank you, Harold. Kavita.

DR. PATEL: I'm just trying to brush up, because I remember, I think, Chris, you wrote a report for CMS on
the groupers. I'm trying to make sure it's the same report
that's included in here.

DR. TOMPKINS: We included the design report in
the original submission.

DR. PATEL: That's right, and so I just wanted to
make sure it's exact -- because I remember reading that
report before it was in our appendix. I just wanted to --
because I know one of the criticisms around the groupers
has really been the risk adjustment piece. So just tell me
-- it seems like given that we're using claims, so there's
that limitation, that you've done as much as you could
sequentially to kind of enhance the validity of this risk
adjustment. Do you feel like you're -- and there's
criticism of the current kind of bundles model with MS-
DRGs. Can you just talk about maybe in comparison or
contrast to how this is a bit more robust?

DR. TOMPKINS: Well, if you -- I don't know, take
a reference point. You could take BPCI, which basically
just allows the DRG and --

DR. PATEL: Right.

DR. TOMPKINS: Or you could take another
reference point, ACOs, take your pick, which has the HCC.
In contrast to either, or both, in each EM there's a risk
adjustment component that tries to get as much information as we can from the claims. So, for example, there are two features. One's called a "stratification feature," the other is called a "risk factor table."

So, for example, if you were to have a surgery episode for hand-wrist-forearm, that surgery isn't just put out there, and whether you do only fingers or only hands, you know, it articulates what we call subcategories. So if for this patient it was as finger surgery, that is different than the next patient for whom it was a wrist. And also the surgical technique is available in the stratification, and etiology, the indication. So there are a lot of ways in which we sort of set it up with as much information. That's the stratification.

Now on the risk factor table, there are demographics. The default is HCC for most of the episodes that are running in the background. But for the episodes that we call forward for profiling or for payment, they're all built on -- they're all customized. You know, the HCC just looks at total cost. That's the dependent variable. Here we say no, it's the episode-specific. We want to predict COPD costs for the next 90 days. So, in other words, it's very time specific. It updates every 90 days,
and it looks at the patient's history at the time of the onset of that 90-day period, and also looks -- so, for example, if you were guessing about the expected costs of a patient with COPD, you would probably want to know whether or not that patient today has pneumonia. The grouper knows that, call that an "open risk factor." You probably also want to know whether the patient had pneumonia recently but it's over. The grouper knows that, preserves that as a recent episode.

So whether it's a procedure episode or whether it's a condition episode, the grouper with its formation of 500-plus episodes and over 1,000 clinical concepts allows all of them potentially to be risk factors for any episode that's in the library.

In the process of developing the customized risk adjustment model, what we did was we had a claims base of millions of Medicare beneficiaries. We looked at all the instances in which that particular subject episode was triggered. And we allowed the grouper, the software, the statistical software, to look for the comorbidity factors or the recentness of these various things, and we did Monte Carlo simulations 500 times each, and we'd only include a risk factor if it was found to be statistically significant.
in the same way in at least 80 percent of those Monte Carlo runs. And then the variables that come from that process are subject to clinical review as a last pass to make sure that they have face validity, clinical credibility, and they're not just a way in which a spurious correlation has been found.

So all the episodes that refer to the 100-plus episodes have customized risk factors that were designed in that way. The episodes that run in the background that are not necessarily called forward for payment are amenable to the customized risk adjustment models, but otherwise rely on demographics and HCCs.

DR. PATEL: And you mentioned that obviously CMS has this software, so the burden -- just to clarify, the potential burden of the cost, the updates, et cetera, would not necessarily be part of an APM -- you know, part of a barrier to participation because there's an assumption that this is CMS's responsibility.

DR. TOMPKINS: Well, there's an assumption that CMS, going on other payers, we hope, would see that, again, the common resource that everybody benefits from. So, for example, if you were to take prostate cancer condition episode, that's a condition episode that ought to be looked
at very closely by the oncologist. But treating that type of cancer or other types of cancer, there are surgery episodes that can pertain. There are external beam radiation episodes that can pertain. There's implanting radioactive material in the tissue that can pertain.

Every time somebody works on the episode that pertains to their clinical work, everybody benefits. So the radiation oncologists benefit when the medical oncologists clarify the chemotherapy and the other services relevant to that, and likewise when the surgeon clarifies the services that are -- the codes that are relevant to that. So when you have a complex unfolding of simultaneous treatments and episodes, again, everybody benefits from the other's work, because when you clarify the competing or contemporaneous episodes, it's to everyone's benefit to clarify what actually should belong in the subject episode.

DR. PATEL: And then one more question, and I actually wanted -- I meant to say this: I think one of you -- both of you may have mentioned all the models that we review are not meant to be advanced alternative payment models, so our purview -- I guess just as a -- it's something that actually we had to kind of go back to statute and remind ourselves that -- I think there's been
an assumption that anything PTAC recommends would potentially qualify as an advanced alternative payment model. Our obligation was really physician-focused payment models, which would qualify potentially as an advanced -- sorry, an alternative payment model and potentially an advanced alternative payment model. So I thought that was just a point of clarification.

And my last question is for Dr. Opelka. There are some letters in here that offer pause and some criticism. You have obviously -- I think everybody's wrestling with what feels like there's something really genuinely just kind of as I said game-changing there, but it's incredibly complex. And then no disrespect to our government colleagues in the auditorium or listening. It feels like once you hand this over to a bureaucracy, that potentially there are errors that might occur as part of implementing such methodology.

All right. We can put that aside for a second. Can you just speak to -- you mentioned that you haven't really looked at a geographic market. You haven't really kind of gone out and solicited, you know, will this practice be willing or will this group of surgeons at this employed facility be willing to do this. Can you describe,
just because I know you've been doing this for years, in
talking to your colleagues, kind of describe how you think
this model can actually change the way -- you know, the
behavioral economics of it, change the way people are
practicing. What's really kind of motivating you to keep
working at this? I know you've talked to CMS -- you know,
I know you presented nationally about this. Where do you
see something that could really fundamentally change the
way we practice medicine?

    DR. OPELKA: So I'm not sure we're going to
fundamentally change the way we practice medicine. We want
to change the way we pay for it. We don't think that the
current fee-for-service environment in the RBRVS world does
a patient any favor. It silos the care. It pulls the team
apart. It doesn't bring the team together.

    We believe that most of the surgical care that's
out there is team-based care, particularly in the modern
era of all the different options we have and all the
complexity of patients we have. I don't know anybody who
really says, "I really, truly just practice alone" anymore.
There is so much involved with the primary care physicians,
with the medical specialties, with anesthesia, with the
post-op care, and all the post care choices now, that this
has all got to be a team. And everyone seems to get into
their own little focus and then they don't pay attention to
how are we coordinating all across each other. And the
government has been trying to do that in the current fee-
for-service system, using a measurement system which we
don't think has gotten the engagement.

So our fundamental basis was prior to us even
having MACRA, we began building the episode-based
measurement framework, because that's how we practice. We
practice as teams of physicians, gathered around a patient,
trying to optimize their care. And we looked at surgery in
phases of care. We think there's a pre-op phase, the peri-
oper phase, and intra-op phase, the post-op, and a post-
discharge phase, and there are critical, crucial events
that occur in each one of those phases, and they're all
team-based and related care.

Along comes MACRA and says, hey, we will actually
allow for alternative payment models and we're going to try
and incentive people to move away from fee-for-service, and
then the MIPS program. That fit our core belief in
building team-based care, clinical affinity groups, around
an episode basis.

So with that, I have been working with Dr.
Tompkins when he first began on this journey with the EGM, and we said, boy, we think there's a fit here. Can we bring these two together and can we do it in such a way that it actually is a race to optimal care? Can we create that, and we believe we can.

So that's what put us forward. When we talk to our members, and we go out and talk to the different fellows of the College of Surgeons, they get this. It's how they practice. They're not tracking the current measures that are out there, but this is how they actually practice medicine. So there's a lot of interest in the rank and file in saying, I really want to see that model take shape, because they know it's closer to how they practice.

Now, the whole element of asymmetric risk, yeah, they have more upside than downside to get people to engage, those carrots that you have to put out there. We're not expert in that. We're trying to figure that out ourselves. We're working with the Innovation Center to figure out where are their swim lanes, how far can they go to make this work, and we're learning as we go here.

CHAIR BAILET: Thank you. Grace and then Bruce.

DR. TERRELL: So a couple of things. One is I
just wanted to, as a point of clarification, you had
asserted earlier that one of the things that the PRT had
been asking you for was a formula. I don't think that what
we were asking you for was a formula but something that was
actually a little different, which was a -- it could
certainly be hypothetical but a highly specific
hypothetical example of how this might look in a clinical
affinity group or a region, to the level that we could
really dig into the details. And I still think that's
important, not within the context that that particular one
would be the way it all worked out, but because it may be
the way your surgeons get it, but the level that CMS has to
get it or the health care ecosystem has to get it, in
general. There's a lot to that, that still, I think,
requires people to get a lot around their head.
The other thing that I wonder about -- two quick
things. One is, with respect to the cognitive
professionals -- so I could give an example of an
infectious disease consultant who make come in for 10
minutes on a case, happen to notice that a person has a
particular risk, or is getting ready to be septic, or
something like that, orders a blood culture or orders an
antibiotic and saves somebody from a sepsis episode that
could have been devastating. And within the context of bundling, I still wonder if sometimes that type of quick cognitive work that many, if not all physicians do in ways that aren't currently measured is still something that needs to be thought through in a little bit more detail, which is one of the reasons I thought it would be helpful to understand, at a broader level, how something like this might look. So just little things like that could be thought through.

The third, and this is actually the question rather than the comment, is you have made the point, both in writing and here today, that this is very different, and I agree, to some of the other models that we've seen, and where you're talking about a single specialty or small or something that starts with a clinical idea.

So my question for you is not as rhetorical as it sounded, but if this particular methodology were put in place, would we need a PTAC? Okay, and by that I mean, if this solves most of the issues, where we're looking at the others, would all these other things be subsumed in what you're doing?

DR. OPELKA: Well, first of all, let me go back, before I tackle that question. I think your points that
you make about a concrete example and walking it through, that's going to be crucial to implementation. It has to be in the package to help everyone, and I think the PRT made that point today, even better than in our discussion on the phone. So that, to me, was very, very helpful. How do we build out an example of claudication with all the elements that are in there, or how do we build out an example of a real procedure with all the elements and subtleties that are in there? It won't be all the permutations of where the waste and savings are. It would just be, how do you actually go about thinking and changing your mind frame into a clinical affinity group? So I think that's very helpful.

We're not at all trying to replace the PTAC. We think this process has been enormously valuable. I know that there was a thought or a discussion earlier today that, to me, you are trying to deliberate and build out who and what you are. It's almost like you are building the car while we're driving it, and I think you're doing an incredible job. And I think that looking at these different aspects of different alternative payment models, this is just one --

DR. TERRELL: That's what I wanted to hear.
DR. OPELKA: -- and it may pick up a whole bunch of different other types that want to fit within this construct, but there are others --

DR. TERRELL: Okay. That's what I wanted to know.

DR. OPELKA: -- and this is not the only one.

MR. MILLER: I'd like to quickly remind those listening at home that PTAC is not paid, so putting us out of business would not lose our incomes in any fashion.

[Laughter.]

MR. STEINWALD: Dr. Opelka, a while ago you referred -- and let's see if I got the language right -- to an initial starter set of tight episodes for rolling out the model. I may have mischaracterized that. But my question is, do you have a sense of what the minimum would be -- clinical areas, types of episodes, venues? What would -- you know, in contrast to the other two proposals, where we've actually talked about testing and small scale, what kind of scale do you think would be necessary to test your model? How would you characterize that?

DR. OPELKA: So there are hundreds of episodes. We've submitted the minimum starting set. That's our proposal. That's where we're ready to begin. The concept
of a geographic area to do that, that's another question
altogether, and we would sit down with the Innovation
Center to begin that. But we think the starter set is what
we've put on the table today, the 54 procedural episodes
that are in the proposal. But you could go to 100, to 200,
shortly thereafter, depending on the level of interest, and
call for it in the market.

CHAIR BAILET: Great. Good discussion. I want
to thank both of you for hanging in there with us and not
only the work you did here today but also all the work that
you've done, not only creating the proposal but working
with the PRT to help us sharpen our thinking on it.

So now it's time to open up the floor to public
comments. We have several people here who want to make
comments. We also have, potentially, some folks on the
phone. So I'm going to go ahead and work through the list.
If you could come up to the microphone and identify
yourself. I believe that's Francois de Brantes from
Altarum Institute.

MR. DE BRANTES: Good afternoon. Yes, Francois
de Brantes from Altarum Institute, and thank you for
allowing me these few comments.

I was reflecting, really, on the last question about
putting the PTAC out of business, and pondering on why even
are we all here today. And we are here today for several
reasons, one of which is that despite what was promised in
the payment innovations from the ACA, the last
administration really failed to put out any type of robust,
comprehensive, physician-based payment models, and that's
the opportunity that is in front of you today.

Chris mentioned that there were a number of subcontractors
that worked on the episode grouper for Medicare. For
reasons that I won't get into, my prior organization, the
Health Care Incentives Improvement Institute's name was
redacted from the final report, but we were instrumental in
getting the team together to develop the initial prototype,
the result of which, Harold, actually did distinguish cost
between typical and avoidable complication. So I can tell
you that the ability to do that in EGM is absolutely there,
and to hone in on for clinicians on those feedback loops,
Elizabeth, on what exactly they need to pay attention to.

But what I really wanted to kind of assuage your
minds of is that you're looking clearly at something that
is very broad in scope, and potentially has multiple layers
of development. And when we started doing our work,
everyone looked at us and said, "Boy, jeez, you know, what
you guys are doing is really complicated." And I now tell
them, "No, it's not complicated. It's sophisticated," and
there's a difference between complicated and sophisticated,
because brute force simple hasn't worked in this country,
and with this model that has been presented to you, by the
combination of the American College of Surgeons and
Brandeis, you have a highly sophisticated model that has
been not just sprung up over the past couple of months but
has been curated for seven or eight years, has been vetted
extensively. And, Bob, if you're worried about, you know,
how is this going to play out in the field, it's playing
out today, because the Prometheus payment model and the
work that we're doing is the first cousin of EGM, and we're
deploying it today in market after market. The feedback
that we get from providers is always positive. And even at
a large scale, like in New York, under the Medicaid DSPR
program, we're now -- there are several layers of value-
based payment programs, all of which are based on an
episode-of-care model, some of them around mental health
and substance abuse, comprehensive chronic care episodes,
and the providers are organizing themselves to do good care
for the patients.

So, yes, I think that at the end of the day the
payment model does drive the care transformation. The
providers organize themselves around the needs of the
patients. They deliver on those needs. And what we can do
in payment is basically make sure that we're not getting in
the way of clinicians doing the good work.

The ACS and Brandeis model accomplishes that
role. We've been waiting in this country for physician-
focused payment models at a large scale, that can get us
out of the rut that we're in, and that's the opportunity
that you have in front of you today. I plead with you --
do not waste this opportunity. The American people deserve
it.

Thank you.

MR. MILLER: Can I ask Francois a question?

CHAIR BAILET: Go ahead.

MR. MILLER: So do you believe --

MR. DE BRANTES: I didn't know that was allowed.

[Laughter.]

MR. MILLER: We are making it up as we go along
here.

Do you believe that an episode model that
separates typical and avoidable spending is better than a
model that simply has a total episode cost, or do we not
know and we should try both?

MR. DE BRANTES: No. I think the evidence is fairly strong that it does work better, because you can hone in your feedback loops. When Elizabeth asked who gets this information, the front-line clinicians get this information, because they're the ones that are going to change the care patterns. And that information about what's working in your area, which patients are experiencing more hospitalizations, more ED visits, how much utilization is going on in delivering better outcomes, is going to vary in Tennessee as it does in North Carolina, as it does in New Jersey or New York, and the information feedback loop that goes to the clinicians has to be highly actionable and reliable.

EGM does that, and it gives you incredible -- I mean, when Chris talks about it as an x-ray, that's what it is, and it's no different than what we've done. Adding a little flag on some of those elements that are avoidable complications, you know, which we've defined and it's for free, it's on our website, and it can be incorporated in the EGM model tomorrow, is the easy stuff. The difficult part is coming up with an episode construct, rules of service assignment, a clinical logic that makes sense to
clinicians when they get those reports, and that's what we've accomplished over the past seven years, and it's a monstrous feat.

So there is this unbelievable asset that the United States of America, the Federal Government owns, that has been sitting on a shelf, and that can be deployed tomorrow, to power probably one of the best alternative payment models for physicians in the world. Let's give it a try. Let's give it a try.

CHAIR BAILET: Wait. One more question before you sit down. Sorry.

[Laughter.]

CHAIR BAILET: We're just wearing a hole out of the floor there.

VICE CHAIR MITCHELL: Sorry Francois.

CHAIR BAILET: Sorry about that. Go ahead, Elizabeth.

VICE CHAIR MITCHELL: So about 10 years ago I invited Francois to come share his model with some fairly sophisticated physician executives, and they said, "It's very compelling but it gives me vertigo." That was one of the quotes. It was so complicated. Now, I think you've made remarkable progress. I think we have overcome some of
that, but I'm going to ask the same sort of question. How does this maximize the information? It's great reports, great analytics, but how do you get it to change practice? How do you use the information, practically, in a real-life medical practice?

MR. DE BRANTES: Well, I think it starts by not forcing physicians into artificial constructs. So if you start with what are your patients, what are their needs, what are the problems, what's the constellation of episodes that creates the markers around them, and you provide them with that information, and you provide that in the context of an upside/downside risk model, they have pretty much everything that they need to figure out how to organize themselves.

Where we get into the vertigo part is in the example that Paul mentioned earlier, where you've got the sequelae of all of these little things that occur, and, my gosh, how am I going to find myself back into this portion and that portion? The reality is that it happens today. In other words, the interaction of the different clinicians with the physician along a continuum of care exists today in nature. It exists today in the fee-for-service world.

The only thing that EGM does is capture that
activity and then apportion the responsibilities and the
upside and downside according to the effect of the care
that the individual clinicians have given to the patients
along that continuum. In doing so, you're creating, again,
this absolutely essential feedback loop.

I don't know -- and Frank mentioned it -- I
remember the first bundle payment programs we did, we'd
show the clinician -- and Paul was in some of this, in
Pennsylvania -- we'd show the clinicians what the total
episode cost was. They couldn't believe it, right, because
the surgeon is used to seeing $2,500 bucks and the episode
for knee replacement is $25,000. Where does the rest of
the money go? Well, suddenly you realize where the rest of
money goes. Once you figure that out and once you have an
incentive to change that, it's incredible what happens.

The reason people had vertigo is because there
really weren't -- there wasn't an underlying, fundamental
incentive in the country to do anything. Ten years ago, it
wasn't Prometheus, it was Sisyphus, and today it's a
different story because of MACRA. Right? Today it's a
different story because of MACRA, and the thirst for this
information is phenomenal.

We see the reports going on in New York State,
for individual value-based contractors -- FQHCs, individual practices and IPAs, et cetera -- and they're transforming the way they care for patients.

So I'm really not worried about this, and I know you ought to be because that's your responsibility. But your responsibility is also to say, are we doing something that's going to significantly improve the quality and affordability of health care in America, and I'm here to tell you, yes, you are. And let -- you know, yeah.

Kavita said you give it to the feds, who knows what happens. Well, I think that's our joint responsibility to make sure that the administration implements it way it should, and I think the physicians in the land -- I mean, let's -- I think you should take pause and kind of think about this. Tens of thousands of physicians across the country are standing up and saying, "We're ready to be accountable. We're ready to take on financial risk in the management of our patients." When, in our lifetimes, has that happened before? That's the responsibility you have. Thank you.


DR. BERENSON: Francois.

MR. DE BRANTES: Yes.
[Laughter.]

DR. BERENSON: I mean, there's tens of thousands of docs in ACO shared savings programs as well.

MR. DE BRANTES: Two-thirds of them, by the way, are saying now that they could the job just as well outside.

DR. BERENSON: Well, okay. They're saying to whom? I mean, that was my point. You're giving me testimony. Have there been formal evaluations of the outcomes of Tennessee and all the other places, New York --

MR. DE BRANTES: Yeah, and Arkansas I would say is probably the most advanced, Bob, in their evaluation of their program. They continue to show important results in the improvement of the management of patients. You know, the case studies that we've published on, for example -- I mean, I can go from maternity bundles to other procedural bundles to chronic condition bundles -- all show the same thing, which is fundamentally what you guys talked about earlier. This isn't -- and Tim mentioned it. This isn't rocket science. It's about care coordination, understanding how to manage patients, and then deploying the resources around it. And the payment model just gives you the incentive to do that. That's all.
Now, you can look at it in a redacted construct and in a very tight kind of surgical space or a larger one around a condition or an even larger one around total cost of care. I think our experience and contention and evidence is that when you do it at a level that matters to the front-line clinician, change happens a lot faster.

DR. BERENSON: So you're going to send us those evaluations?

MR. DE BRANTES: Yeah.

DR. BERENSON: Okay. That would be great.

CHAIR BAILET: Francois, un moment.

MR. DE BRANTES: Un moment.

CHAIR BAILET: Len.

DR. NICHOLS: Thanks for coming.

[Laughter.]

DR. NICHOLS: This is really a question for the room, I mean really, but you're here and now I'll start with you. Two things.

It seems to me what you've built is a vehicle to do the world's best micro simulation of medical transformation, so, A, has anybody played out what costs would do over time and behavior and how that could go and how agent-based modeling might help us get there? And if
we haven't talked about that, we can talk about that offline.

MR. DE BRANTES: We can talk about that offline.

DR. NICHOLS: Okay. The second question is:

This is all great, but if it's so great, why hasn't CMMI just done it? And why are you coming to us? What's up? What's their deal?

MR. DE BRANTES: All right. So I'll give you their answer.

DR. NICHOLS: Okay, good.

MR. DE BRANTES: For three years running, when we had the bundled payment summit here in Washington, there was always someone from CMS showing up to explain, you know, the great work they're doing and the horrendous Bundled Payment for Care Improvement. And I would always ask: When are we going to have condition-based episodes? When are we finally going to have episode of care payment that matters to physicians?

The answer from CMS during the Obama administration was: That is the role of an ACO. That is the role of an ACO. That is why we stand here today. That's why we don't have physician-focused alternative payment models in this country to date, apart from the
ACOs, because the evidence suggests that most ACOs simply jack up prices on the commercial sector. The philosophy was that's where care coordination belongs. That's where the management of patient belongs. Our contention is that the management of patients belongs in the physician's hands.

CHAIR BAILET: Thank you.

Next up -- I am going to get this name right today -- Dr. Gajewksi. Is he still here?

DR. BERENSON: He left [off microphone].

CHAIR BAILET: Did he? I know he was here, and he was planning on presenting. But he's not here.

So Steve Black-Schaffer from the College of American Pathologists.


CHAIR BAILET: Well, I had some help here. I've got some really good staff.

DR. BLACK-SCHAFFER: Very good. Given the hour and the day, I will only talk about the one thing that we thought was interesting, and I must say I think everything possible just about has come up. But let me talk about our concern with regard to this model, which we also think is rather cool in most ways, and it has to do with the payment
methodology.

We applaud the submitter's aspiration -- and I'm reading it so I don't go on forever -- to quantify a large number of measures and qualify a large number of physicians for APM participation. We share, however, a concern that was expressed several times around the table about the key last step in the model, which is the proposed fiscal attribution framework. And, yes, obviously, everything can be readjusted at the end, but there is a presumptive attribution mechanism, and we think it's not only suboptimal, it's potentially dangerous.

The model is built on clinically relevant determinations of expected versus observed costs. However, to achieve efficient and coordinated care, good information has to be provided at the clinical actors, and this information must be sufficiently specific to point towards appropriate use and to point out inappropriate use, whether that inappropriate use is out of ignorance or avarice.

As proposed, the model misses this crucial behavioral economic opportunity. It does admirably detailed work at the whole episode level to provide whole episode information on observed versus expected costs. And then it stops just short of bringing observed versus
expected costs down to the more granular and clinically actionable level of the actual clinicians involved in the model.

This key gap in actionable information exposes the model to a tragedy of the commons, and it fails to incentivize the clinicians at the granular level required most intelligently to inform their individual actions in a way that ensures their common interests are actually aligned.

Instead, the model proposes the surrogate use of clinical responsibility roles. These exist merely to approximate the clinician's opportunities to manage financial risk. And by using these, it fails to take advantage of what I agree, and I think pretty much everyone around the table has agreed, is the essential strength of this model, that you actually have real information about the observed versus the expected costs of those clinical actors and all the resources involved. This is what we've been being told, and it sounds really significant.

It is this real specific information which should be used to attribute fiscal responsibility. With such attribution, there is a remarkably coherent system available to us all here, and I second the people who are
speaking about it enthusiastically. However, I would observe that without it, opportunities for coordination are lost. Coordination does depend upon information, and opportunities for gaming the system are introduced. And other than that, I would like to thank everybody for their attention.

CHAIR BAILET: Thank you.

Nick Bluhm from Remedy Partners.

MR. BLUHM: Thank you so much for this wonderful discussion. I believe that most of our concerns were raised, either verbatim or otherwise, and I would say perhaps what -- instead of sticking to the script, I would say in response to some of the comments that were made about complexity versus sophistication, if we look at the BPCI initiative and the uptake, it was in part due to its clinical relevance; that is, we can parse out whether episode triggers should be before or during hospitalization, but physicians understand that the episode began at hospital admission. And I feel like to move the episode grouper for Medicare, which -- and I remember fondly my time with Dr. Perloff and Dr. Tompkins at CMMI -- to move it into the realm of sophisticated but understandable, it will be important to have the technical
specifications, what everyone has been sort of circling around, out in the open and to have, you know, the best data scientists running a full set of claims through it to understand how it works in practice. I think that is a crucial step, and we think that it's a solid foundation, but one that would benefit from that open public dialogue based on analysis with the claims data set.

Thank you.

CHAIR BAILET: Thank you.

And Stephanie Stinchcomb from the American Urological Association.

MS. STINCHCOMB: Hi. I'm Stephanie Stinchcomb, director of reimbursement regulation for the American Urological Association, and I'm presenting for the AUA.

The American Urological Association, representing more than 90 percent of urologists in the United States, wishes to thank the PTAC for their efforts toward a payment system that incentivizes quality and high-value care for Medicare beneficiaries. Urologists care for a large percent of Medicare beneficiaries, and we look forward to advanced alternative payment models urologists can participate in when caring for Medicare beneficiaries.

The American Urological Association, through our
Alternative Payment Model Work Group, has worked extensively with the American College of Surgeons and Brandeis teams as they have prepared, modeled, and revised the ACS-Brandeis advanced alternative payment proposal and wish to publicly support the model. The AUA requests that PTAC considers this model for testing or implementation. We believe the model has the following strength:

It incorporates a broad range of specialties who already work together to provide coordinated care for Medicare beneficiaries.

It is comprehensive in scope and flexible in design, which we believe will help us adapt the model to best meet the needs of Medicare beneficiaries.

The framework is attractive to specialty care providers because it allows individual specialties to help craft the condition-specific models most appropriate for their patient population.

The model ties quality to resource use, and as a society, the AUA is very committed to quality measurement and believes that quality measurement is a necessary component of any advanced APM.

We appreciate the opportunity to make this public comment, and we look forward to positive approval of this
proposal. Thank you.

CHAIR BAILET: Thank you, Stephanie.

We're now going to open up the phone lines. I'm not sure who's out there, but we'll find out momentarily. Operator, could you please ask if any of the folks on the line want to participate?

OPERATOR: At this time if you would like to ask a question, please press star, then the number 1 on your telephone keypad. Again, that's star-1.

And your first question comes from the line of Brooke Zollinger from Leavitt Partners.

CHAIR BAILET: Go ahead, please.

OPERATOR: Your line is open.

[Pause.]

OPERATOR: Your next question comes from the line of Joshua Lapps from Society of Hospital Medicine.

MR. LAPP S: Hi, my name is Joshua Lapps from the Society of Hospital Medicine, and I'm offering comments on behalf of the society.

On behalf of the more than 57,000 hospitalists now practicing in the United States and on behalf of the Society of Hospital Medicine, the medical professional association representing hospitalists, we want to express
our strong support for the proposal of the ACS-Brandeis advanced alternative payment model. The model seeks to provide novel incentives and tools for providing both efficient and effective care by improving quality of care and reducing costs. SHM and many of our national thought leaders have been partners with ACS and Brandeis in the development and evolution of this unique alternative payment model, and including providing input in the development of the model over the past year.

Under the model, financial risk would be attributed to providers based on their individual role in providing care to the patient, and payments can be adjusted based upon the quality of care delivered. Unlike existing CMS episode-based payment models, the ACS-Brandeis model does not necessarily require hospitalization, which allows for the inclusion of a myriad number of procedures performed in the outpatient and other settings, as well as episodes for acute and chronic conditions cared by for medical specialties.

While the initial proposal is primarily for the surgical patient, we believe that this patient-focused approach, which has an emphasis on the team-based nature of care, can be expanded to be for more than just surgical
care and could easily be translated to other forms of specialty care, including the medical episodes for hospitalists and the care that hospitalists are providing every day.

If implemented, it's our belief that this model will provide opportunities for participation in advanced APMs to providers who have now lacked options for meaningful participation under MACRA. This will enhance the ability of many physicians to participate in transformative delivery system reforms in a way that is designed to be clinically meaningful to them and to the patients they serve.

And so, in closing, SHM is strongly in support of the ACS-Brandeis advanced alternative payment model, and we hope that the PTAC will vote favorably in support of advancing the model forward.

Thank you.

CHAIR BAILET: Thank you.

Operator, is there anyone else on the line?

OPERATOR: Again, to ask a question, please press star-1.

[Pause.]

OPERATOR: And there are no questions at this
CHAIR BAILET: Thank you, Operator.

Before we move into the next phase, I would ask that we take a 10-minute recess, and we'll be back at the top of the hour. Thank you.

[Recess.]

CHAIR BAILET: All right. There we go.

PARTICIPANT: A gong [off microphone].

CHAIR BAILET: A gong, okay. All right. I'm just going to let my Committee colleagues get their coffee. I want everybody appropriately caffeinated here for this next phase.

DR. NICHOLS: We need bourbon for this one.

[Laughter.]

CHAIR BAILET: All right. We have one public commenter who I believe is here, right? Yeah, I see him as well, yes. I thought that was him, but now it's you.

MR. TERRY: Oh, I didn't register, so if you want him to go first.

CHAIR BAILET: No, no. Please, go ahead.

MR. TERRY: Okay. Great. My name is Dave Terry. I'm CEO of Archway Health. We work with dozens of providers across the country who are active in all of the
Medicare bundled payment programs. We've been doing this as a team since 2011.

I love these discussions. We're a bit more practical, I think, than policy-oriented, although we follow the policy very closely. In our experience, these programs are working quite effectively, and we're in support of the ACS-Brandeis program because anything in the market that we see that engages the specialty providers we think is a big step forward. I've worked for a lot of ACOs over the years. I think these models are complementary, not competitive, in that we always struggle within ACOs to find ways to engage specialists, and these models really help us engage specialists in different ways.

I also say it's complicated and sophisticated, as Francois said, but these programs are much simpler to manage than an ACO because we know the patients who are sick, and we're only working with populations of people who we know need care, have very large budgets, we can assess them and provide specific care plans for those patients.

Having managed ACOs, population health, I would be at risk for everyone in this room -- and I have no idea where the health status is of most of the people in that program. So while it's complicated to set up, they're much
easier to manage than ACOs, and we think complementary to ACOs.

Just a couple comments on some of the things that came up in the discussion. In relation to kind of care plans and protocols, in our experience accountability and data drive innovation, particularly for specialty providers who have a lot of volume. We like to work with specialists who focus on a few areas and do it a lot and really, really well. And they then innovate when they're accountable and they have data. And the guidelines often aren't that helpful for that group, to be honest, because when we talk to the specialists, they see the guidelines as more a lowest common denominator tool as opposed to letting them innovate in an environment of accountability and data.

Addressing one of Elizabeth's issues, in terms of how to get the data to the providers, in our experience a little bit of data goes a long way. They don't have a lot of experience looking at this information. It's actually not that hard to get meaningful information in the hands of the frontline clinicians and to help them work with it. And then they innovate, and we get out of the way. And that's the most fun and impactful part.

The last thing I'd say is I think small practices
work great in our experience. We work with small practices who have more volume in their specialty area than some large hospitals. So we have a small group of orthopedic surgeons that do 500 knees a year. That's more than many hospitals.

And so they do need help spreading the risk, and there are more reinsurance products and tools to do that. But we're strongly in favor of any models that encourage the specialty providers to take on more accountability and have more opportunity to innovate.

I thank you for the opportunity.

I understand, yes, please. Three minutes.

I see. I understand. Thank you. But I also complimented you, Harold, earlier. Anyway, thank you very much.
much, and thank you for getting my name pronounced correctly. The third time was the charm.

I don't want to re-emphasize much of what I said, but I do think as you deal with this sort of model, dealing with the complex outlier patients and having outlier clauses will be essential. You take one of my types of patients to a surgical procedure with thrombocytopenia, neutropenia, on immunosuppressant medicines, there is no coding adjustment or acuity adjustment things out there for them. You take those patients with some of the mental health issues, the poor psychosocial systems that we've never captured in any claims database, their post-operative management is going to be more complicated, and there will be failures. So how we deal with that, again, becomes a problem.

The other issue, again, if right now we are spending 35 to 40 cents of every health care dollar for management of the costs of the transaction, how we can do something about the cost of analytics, because everything right now, for all these -- any program under MACRA to be successful, we need more analytics. That was one of the essential lessons I took from the MACRA summit. But how we compensate for these analytics is important.
It is also very unclear to me, because I have tried to get nursing personnel to actually enter a bunch of this data into the EHR that I've been using, and they have balked. They say that's got to be a doctor function for all the details. And I see the frown, Harold, but, you know, to get complex metabolic acid-base disorders with hypercapnia in there, borderline personality disorder, the nurses do not want to take accountability for that. They demand that physicians do it.

Thank you very much.

CHAIR BAILET: Thank you.

Robert?

DR. BERENSON: I know we're supposed to be heading towards voting. I'm going to make a suggestion and see what people think, that this is too important to vote today. This depends so much on the grouper, and I don't know what the grouper does. I would like to have the time, a postponement of our vote until the next meeting probably, so that we actually can get a demonstration of it, to actually see how it works. I would like to see the studies that Francois says exists about the external evaluations. I would like to know from CMMI what concerns they have and whether it does reflect a bias against episodes in favor of
ACOs, to hear a little more about that.

And, ultimately, the sort of endorsements and the notion of a complete transformation of health care through payment is so important that I think we should take the time to do this right. And I would not know how to vote today if I had to vote. I regret I'd probably not be as favorably disposed as the endorsements of it would have me be if I could get more confidence by actually looking at it in operation. Now, a two-, three-hour demonstration, asking questions, may not be enough, but at least I'd feel more confident that I knew what this black box was.

So I don't know what the urgency is for us to vote today, and so that's the idea that I have, to ask the PTAC's opinion about whether that makes sense.

CHAIR BAILET: Grace?

DR. TERRELL: I think that's relevant to the comments that I was making earlier, that the PRT was really feeling a need for a level of specificity that we never quite felt that we got. And if it is possible to do that, then I think that it would be -- I would agree with Bob it would be useful. It potentially would have changed the PRT's recommendation, I think, had we been able to have looked at something with more granularity. But I don't
know what -- some feedback to us as to why the questions that we were asking didn't seem to elicit that, what were we not asking adequately might be useful for us for future proposals as well.

CHAIR BAILET: I would ask other Committee members to provide input on Bob's proposal. Len?

DR. NICHOLS: I want Tim back if we're not voting. But I mean, really, if we're not voting, let's go get Tim and see what he thinks about this matter. But, look, I'm always in favor of learning more. What I'm trying to figure out is what am I going to know that's going to change the way I feel, and I'm not sure I get that, because it seems to me -- I mean, maybe we should just have a little bit of a discussion.

The promise here is amazing. The specificity is lacking. I don't know that I can figure out anything from two hours. I can imagine that a two-hour webinar can help me have a more concrete vision of what the grouper does, but it seems to me we ought to be more specific about what we ask him to do. Okay? And I would submit part of what some of us feel like we want -- at least I'll speak for myself -- would be show me how it would work on a smaller scale to start, and I don't know if smaller scale is one
set of conditions, one set of episodes, one set of -- one
geography. I will leave that to you all. But that to me
would be one thing.

And then the second thing would be, yeah, I'd
like to hear from CMMI, but I'm not sure -- they can't tell
us that, short of a two-month wait, because we don't meet
again until June, right? That's what I'm kind of feeling
like. If we're going to do the information session, let's
do it in the next 30 days and specify exactly what we want
them to show.

DR. BERENSON: Could I respond?

CHAIR BAILET: Please.

DR. BERENSON: I'm only asking for a postponement
until June, and the demonstration would have to happen
certainly early in that period. And I would absolutely
want it to be as effective as possible. I don't know
exactly what that implies. I don't know if we can run
claims through as one of the suggestions was. But I think
that the PRT in particular, but anybody else who can
contribute to that, can help figure out what we need.

And what was the other point? That was basically
the point I wanted to make. I would also like to hear from
-- now that this is -- well, no, that's fine. I'll leave
CHAIR BAILET: Bruce.

MR. STEINWALD: First, I'd like to ask the staff if there are any unintended consequences if we postpone voting?

MS. STAHLMAN: Such as?

MR. STEINWALD: Does it create a hardship for you? Does it somehow mess up the procedures that we've laid out in a way that would --

MS. STAHLMAN: I don't think so.

MR. STEINWALD: -- cause a problem?

MS. STAHLMAN: Not that I can think of. I think that if we wanted to put it on the agenda, the June meeting is June 5th and 6th. So it's a Monday and a Tuesday. It would probably be the Monday here in the --

MS. PAGE: Have to ask the submitters if they can make that.

MR. STEINWALD: Well, hearing that, then I have no objection to putting it off, and that's not quite saying -- I don't know about the rest of you, but I know your doctors are used to getting up when it's dark, but Len can verify this. Economists generally aren't, so --

[Laughter.]
MR. STEINWALD: It might not be a bad thing to do just for the quality of our deliberative conversation.

CHAIR BAILET: Thank you, Bruce. Harold?

MR. MILLER: I don't -- Bob may feel this way. I don't personally feel that seeing a demonstration of the grouper will in any fashion help me make a decision about this. I am still troubled by the lack of specificity in other respects that makes it difficult to approve a model that is going to have PROs but we don't know what they are yet, and that initially is just based on reporting quality measures, not based on any actual performance on those quality measures, with no minimum quality standard and the potential of achieving savings by stinting. Those are the things that concern me.

If the submitter said that they would be able and willing to fill those things in by the next meeting for enough specific things to argue how that would be an initial test, and I think that would make to me a significant difference in the way we would approach it. But I don't personally feel that a demonstration of the episode grouper would solve that problem. I mean, I think I understand maybe because I think I understand how the episode grouper works, and it's not clear to me that seeing
a demonstration of it answers any questions about that. I think this may be a theme of mine, I guess, but I'm not sure we will really know how the episode grouper works until it's actually put into practice and you see how it works in reality.

CHAIR BAILET: I think given the significance of the proposal from Bob, maybe we could just go around to the other Committee members and just provide input, if you have any input. Len?

DR. NICHOLS: So I don't have input, but I have a question. What did you ask that didn't get clarified, if there was some specificity that you were looking for you didn't get? I think that will help me understand what we want them to do next time, if we want them to do anything.

DR. TERRELL: Sure. We and other members, I think we asked things that would give us a specific example, show us, you know, how this would work. They gave us some examples in their original proposal that were related to cardiology and CT surgery and that. They came back with one that was specific, I believe, to colonoscopy. But the thinking about it more as an ecosystem, if you will, where there was a specificity around how the entire - - how it would work with that as it related to how would
somebody come up with the way it actually impacted cost and quality.

So what we've heard today is by virtue of having access to information, it will naturally lead to improvements in cost and quality because people will see their data, and then they will make choices related to that. And I believe what we were asking for was something that would be far more specific with that. Okay, we can provide this type of information. Some of that was provided for us in tables. But the next pieces of it, sort of the analog piece that's the final stages, if you will, after all the digital stuff, we didn't quite get, at least in my opinion. I don't know about the other two of you, but that was my need.

MR. STEINWALD: Well, I'll say this in response to that. First of all, it was only the three of us asking questions, and now there's 10 people asking questions, and they don't all have the same perspective that the three of us had.

Having said that, though, we've already asked an awful lot of this proposer, and I think they would be within their rights to say, "You know what? We've done enough."
On the other hand, they have had the benefit of listening to the conversation over the last three hours and might have a clearer idea themselves of what would be responsive to the concerns that they heard expressed around the table.

And so I guess I'm suggesting that before we table the vote, we ought to ask the developer whether they'd be willing to go one more round with us.

CHAIR BAILET: Let's hold that question. Paul and Bob.

DR. CASALE: So as Bruce said, I wouldn't object to it, but as Len said, I'm not sure seeing how the grouper works would necessarily change my concerns, a lot of the concerns that Grace just articulated. But if there are other members of the Committee that would feel more comfortable -- of course, getting more information is always helpful, but I'm not sure it's going to allay some of my concerns, again, that particularly Grace articulated well.

CHAIR BAILET: Bob?

DR. BERENSON: Yeah, I mean, this is going to involve asking a question of a couple of our former presenters here, is to what extent what, Francois, you were
talking about as successes in New York and Tennessee, et
cetera, is using the same methodology as what ACS and
Brandeis are proposing, I mean, is it -- would we be able
to talk to some of the physicians who are being paid under
this method as a way of seeing how it functions in the real
world? Or is what they're proposing different enough so
that that would not necessarily be useful for us, I guess?
If I could ask both parties to comment on that.

DR. OPELKA: Well, I can't speak to the model
that Francois is talking about, so I have no knowledge of
contractually how those arrangements, those business
associate agreements are run, how the risk model works. So
I can't tell you that the detailed specifics are -- how
comparable they are, how comparable they are not. But from
the perspective of giving more information and answering
more questions, you know, I don't personally have a problem
with that. The more we can inform you about it, the
better. We don't want you uncomfortable in your decision
making process. We, too, feel this is very important and
giving --

DR. BERENSON: Do you think it's possible to do a
useful demonstration with Q's and A's in a few-hour period?
Is that something that is doable and useful?
DR. OPELKA: To the extent of the grouper?

DR. BERENSON: Yes.

DR. OPELKA: Yes. Now, we didn't really talk about the different groupers that CMS has, and that was part of the question that came up earlier, but it didn't come up in our own discussion. This particular grouper, the reason this grouper has so much value is it measures all Part A, Part B. The other groupers that are out there narrow things down to that which clinicians know they can influence.

We want everything, so we would be showing you a demonstration of what looks at all the possible costs we can attribute to an episode, because we think that's -- when you're looking at APMs, we think that's the way to go. When you're looking at MIPS, where you're trying to protect people from penalties, that's a different world, and that's a different grouper.

DR. BERENSON: Francois, were you just talking in positive terms about the concept of condition-based episodes, or were you talking specifically about a methodology that is comparable, in some specific way, to what you understand they are proposing?

MR. DE BRANTES: [Off microphone.]
CHAIR BAILET: It's not on.

DR. TOMPKINS: The logical features of the group that Francois uses and the build-up of the episode construction logic in the code specifications, they're consistent. Are they identical? No. They're consistent. So if the question is, can you give actionable information to delivery systems of physicians so they feel more comfortable about the cost world in which they're living, through his lens it would be qualitatively similar to this lens.

CHAIR BAILET: Did you want to make a comment, to answer Bob's specific question?

MR. DE BRANTES: Yeah. Chris captured it. I refer to it as not necessarily siblings but first cousins. So it's qualitatively the same.

DR. BERENSON: I mean, if we did go to what I'm suggesting, I think we would want to establish some subcommittee or PRT with others who wanted to join, to really figure out what would be the best use of the extension. I don't think we could do that at this moment here, but it sounds like there's things to be learned both from a demonstration of the grouper and perhaps some conversations with physicians who have been functioning
with the grouper in the states where it's in play. But I think we would need to brainstorm a little bit.

CHAIR BAILET: Yeah, how best to do that, and we also have our staff to help us guide us through the actual appropriate process, but I would Kavita, and I saw Len's card up, and Grace, but I also like Elizabeth. So, Kavita, do you want to just make a comment real quick?

DR. PATEL: I, too -- I mean, so when Len asked the question of what, like, what would change, honestly, I would have a better sense of what this looks like. I mean, I feel like I have read everything several times, and I'm still -- maybe I'm the 10-year-old also. I just can't wrap my brain around this. And so what it inclines me to do is to default to what is currently the PRT's recommendation, which is to not recommend, and they also made a comment about not even recommending limited scale. I am calling that into question, but in order for me to make the decision about potentially advancing this to limited scale, I feel like I need that extra piece of information.

I'll also say, that in the transcript, I didn't see anywhere that we talked with anyone at CMS. I know that several times it's been mentioned that it's just sitting on a shelf, you know, not getting updated, not
getting used. I don't let my own decisions be influenced by what the agency is thinking, but I'd like to understand what have they done, just to get a sense of what is it that they have done, because that has not come up. So I don't care what their opinion is about it, but I would like to understand that, and that will all help me make that decision.

So I'm just being honest about what would change my deliberation.

CHAIR BAILET: Thank you, Kavita. Elizabeth?

VICE CHAIR MITCHELL: Thank you. I actually could support the postponement, and would participate in a demonstration. I think I could get quite a lot out of it, but would ask even more specific questions about the PROs that are planned for use. I think understanding those outcomes and how -- outcome metrics, and how they would be integrated would be very helpful. And, additionally, if there's time, just a bit more information on the data access piece.

CHAIR BAILET: Len.

DR. NICHOLS: So I think we've graduated to what do we want to learn, right, from the future. Okay. I'm persuaded if folks want more time then I wouldn't mind
having more time either. I'm just always pushed back
because we've come so close.

So what I would like to know would include not
only how are current physicians, how they would view all
the implications of the allocations that you're proposing,
I'd like to know how, if you will, a fresh set of
clinicians, maybe from a multispecialty group, how they
would view it. Because here's what I'm worried about, two
things. Maybe they're both wrong, but one is, how do we
implement this without making it difficult to do anything
else in the same area?

Because what I remember reading quite a bit in
the proposal was a notion of free choice. We want every
doc to voluntarily join or not. Well, what if the surgeons
all love it, and what if the urologists all love it, but
what if primary care and six other specialties don't? Then
what have we got? That's what I'm having a hard time with.
How do you make it jive with this world of voluntary.
That's why I naturally, just simplistically, overly
simplistically gravitate to can we find one little corner
of Buffalo, or some darn place, to do it, you know, or
Tennessee or Arkansas, whatever. See what I'm trying to
say? I want to see how it would play out.
DR. OPELKA: Well, there's --

DR. NICHOLS: And so -- if I could just say one more thing, Frank.

DR. OPELKA: The College of Surgeons is a finite resource center. We are not a payer. Now I would take my reserves out of my payer and go model this and mock it up and do everything you asked, but there's only a limited amount of services. And all these questions are great questions, but who's going to finance it? If it doesn't get off the dime, you're never going to get the answers to these questions. We don't have the resources to gather in an advanced delivery system all these questions. We're not that body. So that's where the payer and the partnership with the Innovation Center comes into play, but we can't get there if you're not comfortable enough to get there.

The Innovation Center is ready to go. They keep saying, "Let's get going." Well, now we're saying, "No, it'll hold until March." No, now it's going to hold until June. Once we go past June, it will hold until 2019, because they've got to be working on the 2018 rollout. So there's a part of this that says if you want to get going, somebody's got to take the step. Someone's got to have a little faith and make the move. But if you're not ready,
then we're backing up -- when we go to June, we're really backing up to 2019.

DR. CASALE: So along those lines, are you suggesting we look at the Prometheus experience as a reflection of what would happen in your model, since it's qualitatively similar, rather than you having to, you know, sort of actually do the work within your own model, to look at some real, live experience? I'm asking whether that -- if we looked at that, should we look at it as a corollary to what would happen, or how physicians look at it or respond to it?

DR. OPELKA: I don't have personal experience with their model to tell you, so I can't answer it. I know the grouper logic they use. I don't know the business associate agreements that are used at the point of implementation, and how that incorporates. So I can't tell you if you're comparing grouper to grouper or you're comparing apples to oranges.

CHAIR BAILET: Bob.

DR. BERENSON: Yeah, now I'm really confused. I mean, Francois was telling a story that CMMI is so -- at least the Obama CMMI was so sort of locked into ACOs and didn't want to support any competition to that, and you're
telling me that CMMI is ready to go, and we're now the ones who are the roadblocks. I'm confused about what your situation is with CMMI. Why do you even need us if they're ready to go, is my question.

DR. OPELKA: I can't speak for CMMI. I can tell you that the Innovation Center has been involved and engaged in this model since its inception. We've had many meetings. Our own Q&A is very similar to the PRT walk, but in a different sense they can give us technical support. They can tell us how they want the model shaped. They can help think about the implementation phases of this, and we have been doing that with the Innovation Center for almost a half a year.

DR. BERENSON: So you don't have that same perception that Francois had, about their sort of bias?

MR. DE BRANTES: My answer was specifically to Len's question, about why hadn't they done it to date, and I think the -- to date is different today than it was a year and a half ago. But, you know, that was the answer I got from every representative from CMMI, when we asked the question, "When are we finally going to get physician-focused episode-of-care payment?" The answer, systematically, was, "You're not because we don't believe
That doesn't make any sense to me. I mean, there --

Okay. So Grace and then Len.

One of the things that I want to make sure that the PTAC understands is that there's already been a significant burden on the proposers. I mean, we went through three rounds of questions and an interview that was on the phone. We did have -- to someone's question earlier -- a conversation with CMS. We just didn't have it recorded. It was part of -- there's been a lot of work on this.

And one of the other things that was pointed out, to someone's question, is if you go back into your packet, we did actually ask them, in one of those batches of questions, "We are having difficulty understanding exactly how you envision the model would work for you in an individual case. We believe the most effective way to address this would be for you to provide two detailed examples of how all aspects of the model might be implemented from one procedure and for one condition." And then we proceeded to have A through K, I believe, of very explicit information, which they provided.
So if we're going to ask them for a demo, which we need to read this and determine what it doesn't do for us. And I do believe a lot of the conversation today is about there's something that's still -- it doesn't do for us. But they did an enormous amount of work, trying to answer our question. So I would just suggest that we think through that.

CHAIR BAILET: Len.

DR. NICHOLS: So in the spirit of the PRT chair, I would like to amend my previous remarks and say we should make a decision today, and if we can't live with it, then we can't live with it. But my gut says what we're talking about here is what are the choices we have? We could say no, forget it, good luck with CMMI and we wish you well. We could say we think this should be explored on a limited basis. We can say this should be implemented. We could say it's high priority and we should erase all other payment systems.

But I would guess we're going to end up on a cusp between no and limited scale. That's where we are, and I'm comfortable making that judgment. But maybe if other people would rather wait, I'm not opposed to that. I just think -- I think everything we need to know is in the
appendices and the answer and some other reports I just
found on the Web, so I'm not worried about not knowing.
CHAIR BAILET: I'd like to -- I think this is
important enough that we should -- Harold?
MR. MILLER: You can go ahead.
CHAIR BAILET: No, no. Please. Go ahead. I
didn't see your card up.
MR. MILLER: No. I just put it up. I was just
going to -- I agree with Len. I don't think we should
postpone. I think we should decide today. I am still
trying to think through to decide what, but I do think we
should be thinking about what we could recommend with
comments, and the comments, to me, have to say that the
structure is very promising but has some gaps in it, and
has some weaknesses. And just as we were doing with the
other models, I think the judgment has to be, in my mind,
are those gaps sufficiently fatal problems that we really
can't move forward, and have them filled in afterwards, or
not.

And I am leaning at the moment to say I think we
could specify, in comments, what would be solutions to the
problems that I have with it, such that we could say,
recommend limited testing, whatever, if the following
things are done. The PROs have to be specified, that, to me, it can't be just pay for reporting initially. And CMMI can decide what they want to do with that. CMS, the Secretary can decide. But that would be what I would recommend that we say, and we can debate whether not that is a satisfactory recommendation.

But I don't feel, as I said earlier, if they said, "Hey, we've heard what you said and give us two months and we'll bring you all that stuff," I don't think they're going to say that but we can ask them. But in the absence of that, I don't think we're going to get any -- we're not going to get any information that, to me, is determinative, that I don't have today.

CHAIR BAILET: Okay. Thank you, Harold. So my opinion, as an n of 1, I have the submitters in front of the Committee. I'm not hearing Harold, despite hearing from the Committee members, that there is some level of discomfort about the amount of knowledge that's been put on the field, for us to consider. I'm not hearing that they are going to rally, but I guess I'd give Frank one more crack at that question, specifically. But I'm not hearing that they are going to rally and that they have -- they are in a position to have more information that they feel they
could present to us, to help compel or sharpen our
deliberations, substantively, beyond where we are today.
I'm not hearing it and maybe I'll pause and turn to Frank,
or Dr. Tompkins. If there's a magic bullet, we'd like to
hear it.

DR. OPELKA: I don't think there's a magic
bullet. From the point when this was submitted to today,
we've moved a lot further down in specifications of the
PRO. That's work that's ongoing, and it's due to be out in
the fall. It's not going to be here in June. It's going
through reliability and validity testing, and all sorts of
things that are required in PRO-based activities.

The episode-based measure framework has gone
through the CCSQ. We're still waiting for their final
approval, as are many other specialties, but that measure
framework has also been fully specified and turned in and
was included in the submission, so that information is
there.

The ability to give a detailed example is
something that we could provide. I don't know that it
would materially change where you are, but it can be
provided. And then the same with demonstrating the grouper
and how it works and being able to answer detailed dive
questions on the grouper. That can also be done.

My concern is getting this to the point where it can move forward for 2018. Any pushback from today, and we're into June, I don't know how the Innovation Center could move forward and get this thing done, if we're pushing back any further from today.

CHAIR BAILET: Okay. So to complete my thinking, I would like to ask for a directional sense from the group, from the Committee. I ask this question before every proposal was deliberated on. Are we ready to vote? And so I would like just a nod. Do we feel comfortable that we are ready, based on the facts that have been presented, to deliberate and vote, understanding that it is imperfect, understanding that there are gaps, and understanding that despite our best efforts, even in June, there will still be gaps, based on what I'm hearing, relative to what we feel we need.

So I see Harold, Bruce --

MR. STEINWALD: Can we hear one more time from Bob? I would like for him to answer first.

DR. BERENSON: I don't get it. If you're down the road, what do you need us for? I mean, if CMMI now wants to proceed to 2018, I don't understand why you're
even here. So, that's a question.

DR. OPELKA: Well, again, I can't speak for CMMI. If they're waiting for the PTAC in order for them to proceed down the road, then that's why we're here. We've not been given an indication one way or the other. CMMI asked us to bring it to the PTAC, and if that holds up the CMMI, that's their call. But they asked us to go through the process and we're here under their direction.

DR. BERENSON: Okay. I didn't understand that. Did the PRT understand that CMMI has directed them to come to the --

CHAIR BAILET: No, but that's fair. That's important to know. So we're going to go ahead and begin our deliberative vote. You guys can step away from the table as the Committee will go ahead and start the process, going through the criterion. And again, for those who are new to the process, we are going to go through each criterion. It's a simple majority vote. We have an electronic system, and let's just go ahead and start that process now. There are nine of us who are actually in the queue to vote, and it will show 10, and that's because of the electronic support.

So Criterion 1, Scope of Proposed PFPM. This is
a high-priority item. The proposal aims to broaden or expand CMS's APM portfolio by either (1) addressing an issue in payment policy in a new way, or (2) including APM entities whose opportunities to participate in APMs have been limited. We're going to go ahead and vote now. Ann?

MS. PAGE: For Criterion 1, zero Committee members have voted 1 or 2, which means Does Not Meet; two Committee members voted 3, Meets; two Committee members voted 4, Meets; four Committee members voted 5, Meets and Deserves Priority Consideration; and one Committee member voted 6, Meets and Deserves Priority Consideration. We have five votes. Since there are nine Committee members voting, five votes constitutes a majority, so the Committee has voted that this proposal Meets and Deserves Priority Consideration for this first criterion.

CHAIR BAILET: Any comments from the Committee, based on the output here.

[No response.]

CHAIR BAILET: If not, we're going to go ahead and move to Criterion 2, which is Quality and Cost, again, another high-priority criterion. The proposal is anticipated to (1) improve health care quality at no
additional cost,(2) maintain health care quality while decreasing cost, or (3) both improve health care quality and decrease cost.

Any further comments before we vote?

[No response.]

CHAIR BAILET: Then we are going to go ahead and vote.

CHAIR BAILET: Ann?

MS. PAGE: Zero Committee members voted 1, Does Not Meet; four members voted 2, Does Not Meet; five committee members voted 3, Meets; and zero Committee members voted 4 or 5 or 6. Five members, the majority, voted that this proposal Does Meet Criterion 2.

CHAIR BAILET: Thank you, Ann.

Any committee comments, based on the output?

[No response.]

CHAIR BAILET: We're going to move to Criterion 3, Payment Methodology, the last of the high-priority criterion. Pay APM entities with a payment methodology designed to achieve the goals of the PFPM criteria, address in detail through this methodology how Medicare and other payers, if applicable, pay APM amenities, how the payment methodology different from current payment methodologies,
and why the PFPM cannot be tested under current payment methodologies.

Comments before we vote?

[No response.]

CHAIR BAILET: Go ahead and vote.

Someone has to push it one more time. There we go. Thank you.

MS. PAGE: Two Committee members have voted 1, Does Not Meet; zero Committee members voted 2, Does Not Meet; four Committee members voted 3, Meets; two Committee members voted 4, Meets; one Committee member voted 5, Meets and Deserves Priority Consideration; zero members voted 6. The majority has voted that this Meets Criterion 3, Payment Methodology.

CHAIR BAILET: Thank you, Ann.

Criterion 4, Value over Volume. The proposal is anticipated to provide incentives to practitioners to deliver high-quality health care.

Any comments before we vote?

[No response.]

CHAIR BAILET: Seeing none, let's go ahead and vote.

MS. PAGE: One Committee member voted 1, Does Not
Meet; five Committee members voted 2, Does Not Meet; three Committee members voted 3, Meets; and zero Committee members voted 4 or 5 or 6. The majority of the Committee has voted that this Does Not Meet Criterion 4, Volume over Volume.

CHAIR BAILET: Thank you, Ann. Any committee comments before we move on?

[No response.]

CHAIR BAILET: Next criterion then, Flexibility, number 5. Provide the flexibility needed for practitioners to deliver high-quality health care.

Let's go ahead and vote, please.

CHAIR BAILET: Ann.

MS. PAGE: Zero Committee members voted 1, Does Not Meet; one Committee member voted 2, Does Not Meet; four Committee members voted 3, Meets; and another four Committee members voted 4, Meets; zero Committee members voted 5 or 6, Meets and Deserves Priority Consideration. The majority of the Committee has voted that it Does Meet Criterion 5, Flexibility.

CHAIR BAILET: Thank you, Ann. Seeing no committee comments, we're going to go ahead to number 6 Criterion, Ability to Be Evaluated. Have
valuable goals for quality of care cost and any other goals of the PFPM.

Go ahead and vote, please.

MS. PAGE: Zero Committee members have voted 1, Does Not Meet; two Committee members voted 2, Does Not Meet; six Committee members voted 3, Meets; one Committee member voted 4, Meets; and zero Committee members voted 5 or 6, Meets and Deserves Priority Consideration. The majority of the Committee has voted that this proposal Meets Criterion 6, Ability to Be Evaluated.

CHAIR BAILET: Comments from the Committee?

[No response.]

CHAIR BAILET: Seeing none we are going to go to Criterion 7, Integration and Care Coordination. Encourage greater integration and care coordination among practitioners and across setting where multiple practitioners or settings are relevant to delivering care to the population treated under the PFPM.

Please vote.

MS. PAGE: Zero Committee members voted 1, Does Not Meet; one Committee member voted 2, Does Not Meet; five Committee members voted 3, Meets; one Committee member voted 4, Meets; and one Committee member voted 5, Meets and
Deserves Priority Consideration; one Committee member voted 6, Meets and Deserves Priority Consideration. The majority of the Committee has voted that this proposal Meets Criterion 7.

CHAIR BAILET: Thank you, Ann. Criterion 8, 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.

MS. PAGE: Zero Committee members voted 1, Does Not Meet; two Committee members voted 2, Does Not Meet; five Committee members voted Meets; two Committee members voted 4, Meets; and zero Committee members voted 5 or 6, Meets and Deserves Priority Consideration. The majority of the Committee has voted that this proposal Meets Criterion 8, Patient Choice.

CHAIR BAILET: Thank you, Ann. And we're going to go ahead and finish with Criterion 9, and then we have Criterion 10. So 9 is Patient Safety, how well does the proposal aim to maintain or improve standards of patient safety.

Please vote.
CHAIR BAILET: There we go. Ann?

MS. PAGE: I'll summarize. One Committee member voted 2, Does Not Meet; eight Committee members voted 3, Meets; and the rest of the numbers are zero, so the majority of the Committee has voted that the proposal Meets Criterion 9, Patient Safety.

CHAIR BAILET: Thank you, Ann.

And last, Criterion 10, Health Information Technology. Encourage use of health information technology to inform care.

Please vote.

MS. PAGE: Zero Committee members voted 1 or 2, Does Not Meet; six Committee members voted 3, Meets; two Committee members voted 4, Meets; zero Committee members voted 5, Meets and Deserves Priority Consideration; and one Committee member voted 6, Meets and Deserves Priority Consideration. The majority of the Committee has voted that this proposal Meets Criterion 10, Health Information Technology.

CHAIR BAILET: Thank you, Ann. So there will be a small delay while they construct a summary slide, and during that period I would just like to summarize where we are, in our process.
The next phase is actually voting on the recommendation of the proposal to the Secretary, and prior to that we have the opportunity to comment, as a committee, and I see Harold has a comment.

MR. MILLER: I'm wondering whether we don't need, in this particular case, to be clear about what a comment will be, in order to determine what it is we are voting. So, in other words, if somebody is voting to recommend or recommend limited testing or whatever, what is the comment that goes along with that? Because people might have a different opinion about what they're voting for if they don't know what the comments are going to go along with it.

So I guess I'm just wondering -- we've kind of added the comments later, but, in a sense, it's like, you know, in an ordinary thing I might say, "I move that we recommend X with the following conditions." We haven't done that before but in a sense that's what's going to be coming out, will be a recommendation with a bunch of comments. So I just wonder -- we haven't really talked through that, but at least in my mind, my feeling about this is sort of connected closely to what the comments are, you know, that -- how this is -- how that would be done makes a difference to me.
CHAIR BAILET: Bruce.

MR. STEINWALD: I agree with Harold, and to take it one step further, if we were to recommend something other than full implementation, the choice, the steps down for that, is limited-scale testing. But I'm not sure what limited-scale testing means, with this proposed model. And, I mean, I have a clearer idea in the other two proposals that we already evaluated, but -- so my main purpose is to agree with Harold, but I think if we're going to talk about what we might recommend, we're going to need to address this concept.

CHAIR BAILET: Well, let me just sort of distill what I've heard sitting here for the last day and a half, relative to this notion on limited-scale testing, and I would ask that my colleagues jump in as well.

What I believe is that there is clearly the category of it's a fabulous, innovative idea, but doesn't have enough of a backbone fleshed out to warrant recommending to the Secretary that there is additional work to pursue, even if it's not full implementation. We've had that with our earlier proposal today -- again, novel, innovative concept, but we didn't feel there was enough fleshed out where we felt we could get behind a
recommendation to pursue.

So in that gray zone, if we feel that there is enough demonstrated here, that our recommendation would be to provide CMMI with guidance that we support some form of testing and evaluation, that it's worthy enough to pursue, at that level, I think, frankly, that should give enough guidance to CMS and CMMI our position, relative to feeling that it merits -- it's valuable enough to the clinical stakeholders and the patients that we should request that they consider strongly pursuing some, and we leave it up to them, to some degree -- we'll provide comments about potential areas. Bob raised a few already. But we'll provide some directional comments.

But, at the end of the day, we know that it's a recommendation and then the Secretary has the ability to distill that and respond to our recommendation.

So in my own mind's eye, it's either not strong enough to recommend implementation of any kind, worthy of exploration, or strong enough to recommend implementing -- and I'm not hearing a consensus around that at this point, but we will know soon -- or that we feel it is meritorious enough that we should take a position on further testing, of some format, and we, frankly, haven't fleshed out what
that would look like, but we do know that we have made that recommendation yesterday, with one of the proposals.

So, Harold, and then any other committee members.

MS. STAHLMAN: Kavita.


DR. PATEL: It did sound like the PRT, in some of your comments, actually included something about a potential for a revision. Now we heard from Dr. Opelka that there is a time sensitivity. I'm going to put that aside for a second and just say that it feels like there's this kind of other fourth category of, if these thing were present, and I'm looking at how the group voted, you know, on all the high priority -- anyway, just having said that, I agree with Jeff's assertion that you're either going to do this or you're not. But it did seem like the PRT was alluding to potential revisions that could be helpful, like Harold said, with PROs, et cetera.

My own question about how this -- aside from the examples that were included -- kind of what would this look like in the eyes of kind of a smaller practice, or a set of providers that were not tied to a facility. Those are the kinds of things that it sounded like there would be a
revision, and I just want to make sure I read that, because you read that in your PRT report.

So, for me, it might be, Jeff, that we're saying, you know, do not recommend, but that the comment is because these are the issues that would help to potentially be revised -- or I think that was the word you used, was "revised."

DR. TERRELL: Let me respond to that, Jeff --

CHAIR BAILET: Go ahead, please, Grace.

DR. TERRELL: -- just as a matter of -- so I think that there's a logic problem or logic path that we've set up for ourselves by this high-priority thing. Okay? So if you don't make high priority on any of the three, then, therefore, you can't recommend. So that probably leads you to the path of thinking, even if you think everything else is promising, or a lot is promising, revision. Okay?

If you look at that, that's very different than what we all just voted, where you see that had this been the vote, if you will, of the PRT, we would have recommended, by those criteria, to move forward, right, and so we would have had a different set of recommendations. So I'm not sure that what you're asking actually
is -- it may be relevant but it's not exactly the logic path of the way that we would be thinking about it, and it is relevant to the concept of even limited scale. I mean, my -- just following the logic, I would say this says we move forward with it, with massive comments, okay, even though everything else that we've been talking about all afternoon has been about limited scale.

So I'm just following the logic of the vote just then, and there's going to be people out there who disagree because we saw some 1s and 2s on practically every category. But if you take the way we've set this thing up, we had three PRTs that all say, "Uh-uh, not going forward" because with information that we extracted, at least there was one of the category 1 through 3 that said no.

We get to this. You know, the PTAC comes up with another category, and then it's not going to be about revisions, if we go by that. Had it looked like the PRT had looked, then I think revisions would have been the right thought process.

So my thought process is based upon this, if this is what we truly believe, at least two-thirds of us, then it would be moved forward with massive, massive, massive comments, that we still have to articulate better than
we've done today.

CHAIR BAILET: Thank you, Grace. Len, Harold.

DR. NICHOLS: Let the record show this is not the beginning of the massive comments, but I would -- a couple of things just come to mind, that I have to say. One is foolish consistency is the hobgoblin of little minds.

Look, this is how this thing worked out. That doesn't mean that's how I feel.

[Laughter.]

DR. NICHOLS: But I would say, at the end of the day, here's the deal. This one is above my pay grade, and by that I mean, I could see how we could, if certain circumstances were made available, we could deliver technical assistance to the other two. We can't help these people.

[Laughter.]

DR. NICHOLS: What we can do is tell CMS, or tell the Secretary what we think he ought to do with this, and that's where I would concur with the massive comments. But I don't -- to me, limited-scale implementation, they can't do this on a big scale. They could keep it alive, and that's sort of where, I think, we are here.

CHAIR BAILET: Thank you, Len. Harold.
MR. MILLER: I'm in a slightly different place but not necessarily an inconsistent place. I'm not sure that I would argue for massive, massive comments.

But as I think about the options, it seems to me that saying do not recommend, with comments, is not really consistent with what we came up with up there and doesn't, I don't think, give it kind of the sense that it deserves. I don't think that this, in my mind, limited testing of this, is consistent with the limited testing concept that we've talked about for other areas. In other areas, the idea of limited testing meant do this with a small number of practices because a bunch of data and measures and benchmarks have to be worked out and cannot possibly be worked out in any other way than actually putting it in the field. And I don't think that's the case here.

What I see here is a model that has two characteristics. One is it is not yet complete. All of the pieces aren't -- but are in process. There's PROs in process, et cetera, and it can't move forward without those. So I would say it should only move forward where those exists, but that doesn't mean that one waits for them to be developed across the entire board to do it. So it
may be that it only gets done in a limited way, simply because it's completed in a limited way.

The other comment that I would make is I do not believe that it should move forward with a reporting-only quality measure for something like this.

So my recommendation, I believe, sort of what is fuzzily forming in my mind right now, is a recommend Level 3 recommendation but with a comment that says it should only be implemented -- it can be implemented broadly, not on our current limited version, in a few places broadly, but only when the PROs are developed and only if there is actual accountability for those PROs, not sort of a vague transition reporting-only notion with tiers of quality.

So that's at least where I'm coming down, and that's why I say if I thought that that's what 3 meant, then I would be voting for 3. If I don't think that 3 means that, then I don't want to vote for 3.

So it's those caveats that to me make me able to say a 3, and I don't -- and I'm just projecting that maybe others feel the same. They may not agree with my particular caveats, but the concern is I don't want to first vote 3 and then discover that we're not going to agree on the caveats that led me to vote for 3. That's the
problem, if you follow me.

CHAIR BAILET: Thank you, Harold.

So let's go with Bob and then Elizabeth.

DR. BERENSON: My frustration is that a number of the items that Harold is now referring to, we never really discussed. I actually am pleased that they're expanding the quality measures beyond MIPS, that they have done PROs, and it looks like it's in the right direction. But Harold may be right that if it's simply reporting, that's not good enough.

We haven't talked through that stuff. I mean, there's a few other items also that the PRT had a problem with, which we haven't talked about either, so that's the frustration. But if that's where we are, I'll vote.

CHAIR BAILET: Elizabeth.

VICE CHAIR MITCHELL: Thank you.

I think we've been in this room too long because I'm agreeing with Harold again.

[Laughter.]

VICE CHAIR MITCHELL: One of the reasons I'm comfortable potentially moving forward is I don't see the same risks that I've seen in testing some of the others. I think it is hard to understand the risks of giving
physicians more information about who is getting what care, at what cost. I see that as a good thing.

Where I am uncomfortable is with my lack of understanding of accountability, so I'm exactly where you are in terms of not being able to say yes without -- at the pay-for-reporting level. So I would want to see some sort of connection to payment linked to metrics.

PROs, if they're in development, that's great, and if the timing doesn't work, I just think we need to make sure that those connections are articulated.

So if there are ways to emphasize and clarify in the comments that we expect some sort of mechanisms of accountability that aren't entirely clear but have been alluded to in the comments, then I'm really close to comfortable to recommending.

CHAIR BAILET: Grace?

[No response.]

CHAIR BAILET: Okay. So --

DR. TERRELL: I move the question.

CHAIR BAILET: So I'm a pragmatist, and I have struggled through the discussion because of a comment that was made earlier relative to behavioral change and working with physicians and trying to get them galvanized around
changing their care delivery models.

Having this kind of information does illuminate and raise a lot of awareness, and once you have awareness, then you can actually work with the clinical delivery arm to try and modify the behavior.

The challenge I have with this model is that there's a lot of migration in the construct of how it's analyzed. So you have data that is attributable to physicians who are not participating in the model but may actually be part of the care team delivering substantive care. That's just one example of a gap that I have relative to how this could play through, and I think to some degree, that's a different but perhaps similar question that Bob was asking.

So I have significant concerns about how this would play through trying to change physicians' behavior in an environment that is not an ACO but is in more of a free-form entity. There's a lot of moving parts, a lot of flexibility, which I like, but still with that uncertainty, I don't feel comfortable voting for implementation in the true sense, even with comments, because I think there's a difference between voting for implementation with comments versus voting for small-scale testing with comments. I
think it allows more degrees of freedom.

And, again, this is a recommendation, and the Secretary and CMS then can -- as someone earlier alluded to on Day One, we could recommend moving forward or not moving forward, and they could say too bad, so sad, we want to move forward.

So I do think there's still the degrees of freedom, but as the PTAC, I think we have to be comfortable with the information that we have been given today -- and up to today, I should say -- with our recommendation, and we should just be mindful and thoughtful about the implications and the ramifications between small-scale testing -- support but small-scale testing versus support implementation with some caveats.

So I just think I would like to close with that, and then, Ann, you could just summarize for folks on the phone where we are on the 10. It's pretty straightforward and --

MS. PAGE: Harold had a comment, Mr. Chairman.

CHAIR BAILET: Thank you.

Harold, one more. One more time.

MR. MILLER: I want to suggest one more caveat on at least Harold's list of Recommendation 3 caveats, which
is that it should move forward where some majority of the members of the clinical affinity group, determined by the episode grouper, are participating.

I am troubled still, and I should have said that, not just the quality measures, but the notion that kind of one or two people -- I think one of the key elements of this notion is that it is a clinical affinity group. That's one of the core concepts, but it's not required the clinical affinity group participates.

And it seems to me that I would recommend that if it's going to go -- when it goes out first, maybe that might change later on, but when it goes out first, it should have clinical affinity groups, sort of the majority of them there, which will improve its evaluability. I think it will improve its likelihood of success, and it will then encourage the clinical affinity groups to, in fact, form because if there's no way to have the thing without having a clinical affinity group.

So it's kind of like halfway in between the individual physician model and the whole ACO, where you've got to have everybody there.

We could figure out exactly what the threshold is, but I think one of the concerns we had as a PRT --
again, I won't speak for my colleagues -- was that there
was no minimum threshold really in terms of who had to
participate. So some higher minimum threshold would make
me a whole lot more comfortable with it.

Again, you may not -- that may not be enough
caveats for you, but that would be enough caveats for me.

CHAIR BAILET: Thank you, Harold. Well said.

Bob, your card is up. Is it just from fatigue or
you just couldn't put it down?

[Laughter.]

CHAIR BAILET: All right. Very good.

So we are at the precipice, if you will, of
voting, and I was asking Ann, please provide a quick
summary.

MS. PAGE: Sure.

The Committee voted on Criterion 1, the Scope of
the Proposed PFPM, to rate this as having high -- Meeting
the Criterion with Priority Consideration.

On Criteria 2 and 3, the Committee found that
this Meets the criteria.

On Criterion 4, Value over Volume, the Committee,
the majority, decided that it Does Not Meet this criterion.

And then for Criteria 5 through 10, the
Committee, the majority of the Committee, voted that this meets those criteria.

CHAIR BAILET: Thank you, Ann.

So are we ready to proceed with making our recommendation and just to review the process one more time? It is a voice vote only. We don't have the technology.

A 1 is do not recommend the payment model to the Secretary. A vote of 2 means recommend proposed payment model to the Secretary for limited-scale testing; and 3, recommend to the Secretary for implementation; and 4 is recommend to the Secretary for implementation with a high priority.

Unlike the last 10 votes we have taken, this is a two-thirds majority vote, and I think -- I'm trying to remember. We went -- I think we started with you last time, Paul, so, Harold, we'll start with you and go for it.

MR. MILLER: Why don't we start with you, Jeff?

No. Kidding.

[Laughter.]

MR. MILLER: I vote for 3, with caveats. My caveats are that I vote for implementation, not what we called limited testing, with the caveats that it only be
implemented where PROs have been developed, where there is actual performance accountability associated with either the PROs or other quality measures, but not simply reporting only.

And where a majority or some super majority or whatever, but a significantly high proportion of the members of the clinical affinity group that would be determined through the episode grouper, as who were participating these things, are actually participating in the alternative payment entity.

CHAIR BAILET: Thank you, Harold.

Len.

DR. NICHOLS: I would say 2, with all of that.

CHAIR BAILET: Grace.

DR. TERRELL: 3.

MR. STEINWALD: I guess 3, although I'm not sure we should call it -- "caveat" means to me that if you do something, don't be surprised if something bad happens. I think we need to call them "conditions" or something like that.

MR. MILLER: Okay. I'll call them "conditions."

I think they're going to become comments for us, but to me, they're comments in the form of a condition.
DR. TERRELL: Massive comments.

MR. MILLER: No, not massive comments.

CHAIR BAILET: I am in the camp of 2.

Elizabeth, I'm looking to you. You turned it on.

It's time for you to step up to the microphone, please.

VICE CHAIR MITCHELL: It is exactly what it was.

I guess I'm at the 3, with the comments.

CHAIR BAILET: Kavita.

DR. PATEL: I'm going to say 1, because the massive comments or whatever -- caveats, massive comments, to me are the very reason that I don't know how we can move forward.

And we already said -- I just want to be clear. We've already talked about how we can't really think about how to do limited scale. So I struggled, just like Jeff does, where that sounds like an attractive option, but I just don't know how you do that because we've already heard we don't really know where we would do that limited-scale testing.

DR. BERENSON: I'm going to give it a 2 because I want it to go forward, but I don't know what the model is.

[Laughter.]

DR. CASALE: Sorry. That was just a great
CHAIR BAILET: Paul.

DR. CASALE: Yeah. I vote 2, and in terms of the limited scale, to me, when Kavita asked how will this change the way care is provided and the answer was we're going to change the payment and that will lead to change in care, to me, that's a big leap of faith.

And so the limited testing to me is not doing 50 whatever, 54. Limited to me is a very small number of surgical procedures, where, again, we talked about appropriateness, and the answer was, well, we'll do goals of care and PROs. Those clearly would have to be in place for the surgical procedures that are going to be tested.

CHAIR BAILET: Kavita.

DR. PATEL: Can I ask a point of order? I know we're not doing Robert's Rules, but the way Paul articulated that limited scale would make me very comfortable with a 2. Is that -- am I --

CHAIR BAILET: Yes. Yes.

DR. PATEL: Am I doing something illegal?

CHAIR BAILET: No. No. I was actually -- that was where I was going to go, was to just sort of re-filter people's perspectives to give them the opportunity to
modify their vote.

DR. PATEL: Because I was really scratching for a way to do that, but I had heard Dr. Opelka say we don't really have a geography or kind of a place.

But the way -- I think if we reduced and kind of did a limited number --

CHAIR BAILET: I think there's a way. Yeah.

DR. PATEL: -- then that, to me, would feel much -- I'm looking. I'm struggling, like could that be a way.

So I would respectfully revise my recommendation to a 2 and just kind of echo that it would be for the reduced number to have a little bit of a sense of what the kind of boundaries are on the episodes.

CHAIR BAILET: So I turn to my DFO, Ann.

MS. PAGE: So, according to the Committee's rules, a two-thirds majority vote of the nine votes would be six, so we need six votes to determine the Committee's decision.

We have four votes for limited-scale testing and four votes for recommending. So, according to the --

MS. STAHLMAN: Five votes are limited --


MS. STAHLMAN: Because Kavita --
CHAIR BAILET: Yes. Kavita changed her vote.

MS. PAGE: Sorry.

So, according to the Committee's rules, when we don't -- we start at the top, high priority and then recommend and recommend for limited-scale testing, and so top-down, we acquire six votes at the point of recommend for limited-scale testing, so that is the Committee's recommendation.

CHAIR BAILET: Thank you.

Len and then Grace. Is this the -- we're going to go to the comment period to support staff at this point?

DR. NICHOLS: Correct.

CHAIR BAILET: Thank you.

DR. NICHOLS: So I just wanted to say the reason I was for 2 was because, to me, what we're talking about here is a signal. It's just a signal to the Secretary and CMMI, and I would just amend Paul's. I love the idea of limited number, but I wouldn't limit it to just surgical.

I think one of the beauties of this thing is you could actually do yearly management of a real chronic condition by primary care. So, to me, I'd want a mix, but I want -- at the end of the day, CMMI is going to decide which ones, but I think it should be both.
CHAIR BAILET: Thank you.

Grace. And then we'll get Harold and keep going around.

DR. TERRELL: I just want to make the remark that from a process point of view -- or maybe it's just a psychoanalysis point of view, the 3 -- 3 is that time where the PRT members sit -- actually voted not to recommend.

CHAIR BAILET: I wasn't going to go there, Grace, for obvious reasons, but --

DR. TERRELL: But it really ought to be thought through as we're learning from this process because we did a lot of work. We came to a conclusion based on under what I think were constraints.

We saw stuff. We had discussion, and we got to a different place. But nobody else did in the room right now.

And so, as we're thinking through how to improve this process, we really need to understand what that means. I think it's significant.

And with respect to the comments, I think that the types of things that were brought up in the PRT report, either as comments on a 3 or how you create caveats for what may be a larger category than limited scale, we may
need to have other language around that, that we would all
feel comfortable for.

It's probably been well articulated by the
process both here today and in writing, but we need to
think through our process in the future to get this a
little bit better.

CHAIR BAILET: Well, can I just make a comment to
your comment, Grace? I think it actually shows the
strength of the deliberation. Right?

DR. TERRELL: Mm-hmm.

CHAIR BAILET: Because the first proposal
yesterday was the PRT review team did a body of work and
came to a conclusion. The Committee had a differing
opinion. Today, the PRT had an opinion, the Committee had
a different opinion, and the PRT changed their -- so I
think this is an iterative process. Right. I think that
we're learning.

We clearly need, and continue to request,
stakeholder input and public input, which is also shaping
our thought process. So it's a very dynamic circumstance,
and I think we need to drill down and figure out why the
PRT -- potentially what triggered in this process, changed
unanimously your position. And that's for a later date,
but I do agree with you that it's material.

Harold.

MR. MILLER: While I agree with Len, I do not think that this should be -- we should recommend limiting it to surgeries for a couple reasons.

One is I think that it fails to address -- first of all, that's where there are already some models. I think what it fails to address is the issue of the concern about the control of episodes, and it would fail to address what -- I agree with -- Francois made the point that I had been -- he and I both have been talking about for years, is we need condition-based models.

So I think it's important to say that however it's tested, it ought to be tried to be tested in a way that actually deals with whole conditions.

The other thing I think I would like to see us make the point, clarity, is that the limited-scale testing here is a different concept than what we had been talking about on the other things, and it's limited in this case simply because of the scope of this particular proposal, which is so broad -- and I'll see if everybody agrees with me on this -- that what we're talking about limiting is -- that, in a sense, is too broad to be implemented, as
proposed, right away, which in a sense the applicant themselves have acknowledged that it's not ready to be able to have done that broadly.

And we're just saying we think it should be somewhat more limited than even they said it was going to be limited initially, but that's a different concept than the limited-scale testing we described for other things.

And so I think to be clear about that category, rather than creating a separate category, we ought to be clear that this is kind of a different concept, my proposal.

CHAIR BAILET: Thank you, Harold.

Bruce.

MR. STEINWALD: Yeah. I agree with that. This is certainly different. The nature of the limitation is different than what we had done before.

In response to Grace's comment that we were all 3's, I mean, my -- I thought the choice was between 1 and 3, and 2 was off the table. And it wasn't until Paul kind of introduced the concept of --

DR. TERRELL: The new 2.

MR. STEINWALD: Yeah, the new 2, that I thought, hey, you know, he's got something there.
But I agree that we -- the staff will be challenged, but -- to articulate what we mean by limited. And I certainly agree that it shouldn't be surgical procedures, but conditions that, I guess, CMS would select based on criteria that we are unable and probably not qualified, actually, to identify ourselves.

CHAIR BAILET: Paul.

DR. CASALE: I would just say yeah, and I agree. Certainly, it's in the area of conditions where we really have no experience, and so there's the opportunity.

I guess part of my thinking was on the stipulation around having the quality measures and the PROs in particular where maybe there would be more around surgical than clinical conditions, but certainly, if we lay out what we think are the important conditions on the quality measures and they're available and the condition specific, then yeah, absolutely, that makes sense.

CHAIR BAILET: Harold, closing remarks?

MR. MILLER: Just to build on that very -- thank you, Jeff. Just to build on that very quickly, I think, in fact, by us saying that it will encourage that the PROs do get developed more than just for surgery, which is why I think it's important to say that otherwise there could be
something that turns out all or ends up having surgical episodes.

CHAIR BAILET: Okay.

Is that a comment? Excuse me. Is that a --

Please, Ann, go ahead.

MS. PAGE: This is just a question. It's a direction you want to give staff on one of the issues mentioned in the PRT report, but I haven't heard it discussed, and that's any direction around the proprietary nature of the episode grouper. So we talked about that in another proposal submission, but what, if anything, do you want said in the report to the Secretary around that proprietary nature of the grouper?

DR. TERRELL: Perhaps based on the conversations we've had earlier, given the fact that we've advised this one to move forward, our comments can be about scrutinizing and understanding and making sure that it's meeting the needs of the public.

There was a lot of questions that we ask, and because we didn't completely get the answers in great detail, a lot of what might need to be in the comments would be -- this really needs to be investigated and understood.
What we heard from the proposer yesterday was it was about getting this done, and their proprietary wasn't all that proprietary. This may not be the case in this, and that could have implications.

We have had, however, somebody that has other proprietary tools to basically also testify today in favor of this, so that in and of itself also leads to the thought process of how would CMS do this. Ought this to be something that is CMS-owned, operated?

On the other hand, Dr. Opelka's comment was quite relevant that it needs to be curated on a regular basis, and if that needs to be through a proprietary process, then it needs to be fleshed out ahead of time.

CHAIR BAILET: Go ahead, Harold.

MR. MILLER: I'll just add to that. I think Frank made it clear that they don't have the resources to do sort of the continued development of this on their own, and so it seems to me that if, in fact, CMMI decides to implement it, then it is going to be something that they have to figure out how to do. And I know that they are not going to do something that is proprietary. It might be secret, but it's not going to be proprietary.

So I think that -- but I think that we should say
specifically that we are not imagining that this be something that would be a proprietary thing. It would have to be, obviously, open source.

VICE CHAIR MITCHELL: I'm just going to agree.

CHAIR BAILET: Go ahead, please.

VICE CHAIR MITCHELL: That's what we have said for the other models. This has to be something that is in the public domain, and therefore, it's the functionality that we are looking for.

I don't know that there are a lot of other things out there that would have this functionality, so it may end up being the only option. But I think we do need to be quite clear about that and consistent.

DR. TERRELL: It could certainly have a vendor role. Many things do for CMS.

CHAIR BAILET: All right. So I want to personally thank the members of the Committee for their stalwartness, if that's a word, and thank the public for hanging in there with us over the last day and a half.

Staff, do you have what you need to complete the process?

[No response.]

CHAIR BAILET: Then any other final comments
before we move? Do I have a motion to adjourn?

DR. TERRELL: So moved.

MR. STEINWALD: Let's thank the Chair and Vice Chair, too.

DR. TERRELL: Thank you and staff.

CHAIR BAILET: Thank you. Thanks staff. Thank you.

We're adjourned. Thank you.

[Whereupon, at 5:30 p.m., the meeting was adjourned.]