PHYSICIAN-FOCUSED PAYMENT MODEL TECHNICAL ADVISORY COMMITTEE (PTAC)

PUBLIC MEETING

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

Friday, September 8, 2017
9:00 a.m.

PTAC COMMITTEE MEMBERS PRESENT:

JEFFREY BAILET, MD, Chair
ROBERT BERENSON, MD
PAUL N. CASALE, MD, MPH
TIM FERRIS, MD, MPH
RHONDA M. MEDOWS, MD
HAROLD D. MILLER
ELIZABETH MITCHELL, Vice Chair
LEN M. NICHOLS, PhD
KAVITA PATEL, MD, MSHS
BRUCE STEINWALD, MBA

STAFF PRESENT:
ANN PAGE, Designated Federal Officer, Office of Assistant Secretary for Planning and Evaluation (ASPE)
KATHERINE SAPRA, PhD, MPH, ASPE
MARY ELLEN STAHLMAN, ASPE

AGENDA PAGE

P R O C E E D I N G S

[9:08 a.m.]

* DR. O'BRIEN: Good morning, everyone, and welcome back. I'm still John O'Brien, Deputy Assistant Secretary for Health Policy here at ASPE, and welcome back to Day 2 of the PTAC meeting. I know you all had a very productive day yesterday discussing the Hospital at Home proposal submitted by the Icahn School of Medicine at Mount Sinai and the Advanced Care Model Service Delivery and Advanced Alternative Payment Model submitted by the Coalition to Transform Advanced Care.

I'd say there were a number of interesting firsts yesterday. I continue to be excited by the quality and depth and unexpected nature of the discussions that we had yesterday, and I am sure today will be just as productive and exciting.

I know there is a third proposal to discuss today, the Oncology Bundled Payment Program Using CNA (Cota Nodal Addresses)-Guided Care, submitted by Hackensack Meridian Health and Cota, Inc. We're looking forward to the results of your deliberation and voting on this proposal as well.

The Secretary will shortly be posting his response to PTAC's comments and recommendations on the CMS

(Centers for Medicare and Medicaid Services) website, and they will also be posted on the ASPE website. I don't know if it will be by the conclusion of my remarks, or at some time during this meeting. I can't discourage you from refreshing your browsers and missing the conversation that's happening here, but I do believe that they will be posted very shortly. And as the statute directs, not only are the responses posted, but I also just wanted to share a bit of insight and be sure that the following messages are clear.

The Secretary has a great deal of appreciation for the submitters, those who have carved time out of their hectic practice schedules to develop these payment models. It's a testament to their dedication to the profession that they've crafted these proposals to improve outcomes for patients across the country.

The Secretary expresses his thanks to the PTAC members for the incredible amount of work that you put in evaluating these proposals and advising the Secretary on the challenges and opportunities that these models may represent if tested and put into practice. He knows that you have day jobs as well and that this work requires a lot of time and effort. Your expertise and willingness to use that knowledge and serve as members of PTAC is a testimony to your commitment to improving U.S. health care. Again,

thank you for being here.

Related to the first three proposed physician-focused payment models, some messages from the letters may be worth calling out this morning. The Secretary was clear about several things. I think one is he doesn't want to hide the ball. The letters are intended to be very clear in what he either finds exciting or concerning in the proposal. For example, there's a reference to a concern about proposals that rely on a particular piece of proprietary technology in order for the model to be tested or successful.

He's also concerned about proposed models that may only be implemented by the submitter. The Secretary is most interested in proposals that many physicians and patients could benefit from. Over 900,000 clinicians, including over half a million physicians, deliver services worth over $70 billion to 50 million Medicare beneficiaries a year. So the Secretary is looking for ideas that many physicians could participate in and help those beneficiaries, not just individual submitters.

Proposed models that include particular proprietary items or that are tailored to work only for one practice or hospital or only for the submitter will not be as effective in achieving the outcomes we desire. And

while HHS is interested in broad models that address quality and payment, it does not plan to pursue models that mainly involve testing a particular form of proprietary technology or that are focused on implementation only by the submitter. So I think those are some key themes from the letters that will shortly be posted. I know the Secretary is looking forward to receiving PTAC's comments and recommendations on the proposals discussed this morning. He's received a download of what happened yesterday, and I know that you all have a very busy day ahead of you, and flights or trains, what have you, to catch this afternoon. So, I'll thank you again and wish you the best for a great meeting. Thank you.

* CHAIR BAILET: Thank you, John.

So my name is Jeff Bailet. I am the Chair of PTAC. To my left is Elizabeth Mitchell, and we will ultimately go around the room and introduce ourselves.

I just wanted to walk through the process today very quickly. As John said, we are going to be evaluating the Preliminary Review Team's work and looking at the proposal on the Oncology Bundled Payment Program Using CNA-Guided Care, which was submitted by Hackensack Meridian Health and Cota, Inc.

The first part of our meeting is going to involve

where individual members will make disclosures with potential conflicts of interest. We will then turn it over to the lead for the Proposal Review Team, and they will review their analysis. They've been working very closely with the submitter to thoroughly evaluate the proposal. The Committee will then have the opportunity to ask clarifying questions of the Proposal Review Team, and then we will invite the submitters up for their presentation. The Committee will then have the opportunity to dialogue with the submitters directly. And then, finally, before deliberations, the public will be invited to participate in the discussion, and then the next part of the process, as John said, is really the deliberative process.

The last point I'll make, I think, which is important to know, is that the discussions you'll see today are the first time that the Committee has discussed this proposal. With the exception of the physician -- the Proposal Review Team, there has been no discussion among the members of the Committee relative to this proposal at all. All of our deliberations are required to be done in public, so today, as we hear from the Review Team and then start to discuss and ask questions amongst ourselves and the submitters, this is all going to play through, if you will, live.

So I just wanted to make that point, and I think at this point I'd like to start with you, Tim, on this side of the room. If you could just start introducing yourselves, we'll go around.

DR. FERRIS: Tim Ferris, Mass General Hospital in Boston.

CHAIR BAILET: And the conflicts of interest. Maybe we can do that at the same time.

DR. FERRIS: And no conflict.

MR. MILLER: I'm Harold Miller, president and CEO (Chief Executive Officer) of the Center for Health Care Quality and Payment Reform. You surprised me on the conflicts here.

So I do have some things to disclose. I don't believe they are conflicts, but -- so from 2013 through early 2015, I did provide some fee-based consulting assistance to the American Society of Clinical Oncology, ASCO, in developing a payment model for oncology care called Patient-Centered Oncology Payment. I have not received any consulting fees from ASCO in over two years. I have no future involvement in the PCOP (Patient-Centered Oncology Payment) Model. ASCO did reimburse me last year for travel, for attending and participating in two meetings, in which issues related to value-based oncology

care were reimbursed. There were no fees involved with that.

In April 2017, I received a small honorarium and travel reimbursement for giving a presentation at the Florida Oncology Society Annual Meeting, in which I described opportunities to improve quality and reduce spending for cancer care, the need for new payment models to support better cancer care, and several different approaches to payment, including the CMMI (Center for Medicare & Medicaid Innovation) Oncology Care Model and the Patient-Centered Oncology Payment Model.

I do not have any financial relationship with any organizations or individuals that produce or deliver oncology care or services or products, and I do not know anyone from Hackensack Meridian Health Care or Cota. So I do not believe I have any conflicts, but lots of stuff to disclose.

DR. CASALE: Paul Casale, New York Presbyterian. Nothing to disclose.

MR. STEINWALD: Bruce Steinwald, health economist with a small consulting practice in Northwest Washington, and lots of government service before that, including a stint in this building in the first Reagan term. No -- nothing to disclose.

MS. PAGE: Ann Page, staff to PTAC, and also the Designated Federal Officer for this FACA, Federal Advisory Committee Act, Committee.

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

VICE CHAIR MITCHELL: Elizabeth Mitchell, president and CEO for the Network for Regional Health Care Improvement, and nothing to disclose.

DR. NICHOLS: Len Nichols. I'm a health economist at George Mason University, and I have nothing to disclose.

DR. PATEL: Hi. Kavita Patel. I'm a physician and I'm at Johns Hopkins and the Brookings Institution. And I don't believe it's a conflict, but I had a disclosure, and I realize I couldn't put proper grammar together, so I wrote, "I have not conflict," but I have no conflict, but I have heard Cota present, and I've also heard Dr. Pecora and others who have talked about similar concepts but not exactly this payment model.

DR. BERENSON: I'm Bob Berenson. I'm an institute fellow at the Urban Institute. I have no -- nothing to disclose.

DR. MEDOWS: I'm Dr. Rhonda Medows, executive vice president, Population Health, Providence St. Joseph

Health. No disclosures.

CHAIR BAILET: And as I said, I'm Jeff Bailet, the executive vice president of Health Care Quality and Affordability with Blue Shield of California, and I have no disclosures.

So at this point, I'd like to turn it over to Tim, Dr. Ferris.

* DR. FERRIS: Thank you, Mr. Chairman and members of the PTAC Committee. I'm here to represent the Preliminary Review Team that was -- Bob Berenson and Bruce Steinwald were my collaborators on this, and we were assisted, ably assisted and thank Ann Page for staffing our Preliminary Review Team.

I think my first obligation is to remind the public what our process was. So the PRT was assigned, including by the Chair and Vice Chair of PTAC, to serve on each complete proposal, and I was selected to serve as lead reviewer.

The PRT identifies additional information needed from the submitter and determines to what extent additional resources are needed. We review the proposal. Additional information is provided, including public comment. We review all that material and create a preliminary report. The report was posted on the PTAC website like two weeks

prior to this session, and then subsequently our deliberation by the full Committee.

Importantly, the PRT report is not binding on PTAC. It is a preliminary review and is intended to be the source of discussion for the PTAC deliberations and that the PTAC may reach different conclusions from that contained in the PRT report.

So I'm now going to go through the model overview, and let me start off by saying, relevant to John O'Brien's comments that we just heard, that this proposal was explicitly written as a pilot for Hackensack Meridian Health and Cota, and we'll come back to that point, I'm sure, during our discussions.

This is a proposal, it's a bundled payment for care with patients with newly diagnosed breast, colon, rectal, and lung cancer. The proposal has some significant clinical and payment complexity related to the hierarchy of conditions, bundles, something called "Cota Nodal Addresses" -- CNAs -- which is an aggregator, a classification system of demographic, biologic, and treatment factors. This is -- the CNAs are part of a proprietary software package or they are manifest in a proprietary software package.

In this system, each patient is assigned a CNA

based on demographic, biologic, and treatment factors. Only patients with an identifiable CNA in this system are enrolled into the payment model. Each CNA has multiple treatment lanes. "Lanes" is the word used in the proposal. These were -- we assess these as being very similar, if not identical to what has traditionally been referred to as "care paths" or "pathways" in which over the course of time, the treatment protocols, diagnostic -- not just treatment, but all of the care protocols are highly defined in these lanes according to the original designation of the CNA and the specific lane chosen based on such things as treatment preferences. So in the last line, the physicians and patients choose the treatment lane from among the options within a CNA.

I will say that this description -- I look forward to the submitter's response to this description. This is a very high-level description of what in the proposal was a very complex model. And so if this misrepresents that, I look forward to the clarification.

The bundles cover one year starting on the day of pathologic diagnosis of cancer. I'll come back to the point about the initiation point, the day of pathologic diagnosis. Prospective bundled payments, including costs of oncology care and unrelated services. There was some,

as we'll talk about, some ambiguity around whether or not this was a total-cost-of-care model or an oncology-only model, and we had some discussions about that with the submitters. Not sure we came to full resolution of that.

The HMH (Hackensack Meridian Health) proposal to work with CMS using historical claims on HMH patients to estimate the Medicare 12-month cost for each CNA -- this is a very important point. This is the method by which the pricing of the bundles was to be established. We're going to talk about that again some more when we get further down --

And then as we understand it, at the highest level, the costs of each CNA will be aggregated up to the bundle level using a weighted average approach. These would be used to compute a prospective 12-month price for each of the 27 bundles within each of the four diagnostic categories -- in the four cancer types. And the recipient of the payment -- in this case, HMH -- would be paid an amount that would be the sum of the bundled price and the number of patients in each bundle.

The case mix adjustment occurs as a natural consequence of that arrangement because of the second piece of [unintelligible] -- it's the bundled price times the number of patients in each bundle. If you have a different

number of patients in a particular bundle, that would by -- in and of itself adjust for the case mix in the bundle.

So to continue, HMH would receive the prospective payments and use them to compensate providers and pay for care coordination and other uncovered services -- Very importantly, prospective payment model.

They'll be at risk for costs of delivering care if costs exceed the prospective bundled payment. This has different implications if this is an oncology-only model or a total cost-of-care model.

At the end of one year, the bundled payment will no longer apply to an enrolled patient. They now fall out of the bundle -- the bundle ends.

The proposal requested a stop-loss arrangement. I won't go into the details. Once a patient is enrolled in a bundle, all claims billed to CMS from any HMH-related provider will be forwarded to HMH. HMH will then pay those claims and pay physicians based on the standard fee-for-service Medicare rate.

This proposed process was somewhat novel to us, and we could imagine -- as a PRT, we imagined some interesting potential complexities involved with completing that.

Part of the compensation of physicians would be

incentive-based. This was something that would be sort of below the external payment line, so how they would handle the money internal to the organization.

So an important slide -- and this slide was not in -- for the people in the audience, this slide was not in the group of slides that was posted last week or so, whenever this stuff was --

MS. PAGE: But it will be reposted, so these will be made available.

DR. FERRIS: These slides will be available, so --

MS. STAHLMAN: And they were sent out to participants, so the new slides should be in people's inboxes.

DR. FERRIS: -- in people's inboxes. Thank you. And this pertains to the statements we heard this morning -- So given unresolved questions, at the time that the PRT did its review regarding the acceptability of a recommendation for a single-site proposal, the PRT proceeded with the review assuming a single-site proposal would be acceptable. Our evaluation against criteria was for a single-site pilot, because that's how this proposal was written, and not for a deployable national model.

And the third point is, given unresolved

questions regarding the acceptability of a payment model that relied on proprietary software, the PRT proceeded with their review assuming proprietary software would be acceptable. Okay?

So, coming to the summary of our PRT review, you can see here -- I won't read through this -- all of our conclusions were unanimous. We believed against the criteria applied to this single-site pilot proposal -- we believe this met criteria, with all except for patient choice, and with 2, we thought it met criteria with priority.

So now I'm going to go through criteria by criteria. So, on scope, I think the protocol is that I'm supposed to read the criterion, just to make sure everyone is on the same page about this.

The proposal aims -- so, in considering Criterion 1, does the proposal aim to broaden or expand CMS' APM (Alternative Payment Model) portfolio by either, one, addressing an issue in payment policy in a new way, or two, including APM Entities whose opportunities to participate in APMs have been limited?

So, we looked at this in a couple different ways. The first was cancer cost of the highest growth rate for any clinical area for several years and predicted -- that

is predicted to continue. So, this is a very important area to have alternative payment models for.

And although CMS' Oncology Care Model already addresses this clinical area, we found several aspects of this model to be novel and potential improvements over OCM (Oncology Care Model), and so that statement is the principal reason why we thought this met the criteria.

If the model requires the use of proprietary software, this could limit its uptake, so this gets -- again, there's a scope -- the proprietary issue affects the scope question.

As written, the model is not generalizable. We did not think this was a model that was ready for going public on a national basis. There were too many questions, as we'll get into in the payment model, that were unresolved, although we found some very attractive aspects of the proposal, as we'll get into.

Overall, assuming concerns could be overcome, the proposed model would be a valuable addition to CMS' portfolio.

Criterion number 2, quality and cost, so here on the strength side, the treatment pathways, the lanes contained in this system, and the specificity with which the Cota Nodal Address is defined by very highly organized

and highly specified patient demographics, diagnostic testing, we thought this was quite innovative, and because of the precision of the diagnosis and treatment and the lanes created for the subsequent care of the patient that this was very likely to have a high degree of -- to reduce variation in the treatment of cancer patients, and so this is a very attractive piece of this.

We also thought people, as members of PTAC know, in bundled arrangements, there is a concern about entry into the bundle in order to take advantage of the bundled payment. We found that the specificity of criteria for entry into this really dramatically mitigated any potential gaming of a bundled payment around this, because you either fall into the criteria or you don't, and it's completely auditable and highly specified. So we found that to be a particular strength.

And we also found the patient unlikely to end up in the wrong bundle, given the specificity of the assignment. So we considered these strengths and reduced the potential for gaming of a payment model.

On our concerns, we were concerned about how patient preferences impacted lane assignment -- I'll get back to that -- verification of the pathology and stage, possibly through a clinical audit process. There wasn't

much detail in this proposal about this. Dr. Berenson had brought up during the PRT that there's actually considerable literature about misdiagnosis in cancer, and so we did have some concerns about what the audit process should be in this proposal, in such a model.

Then this one was particularly challenging. Assessing the proposal's impact on cost was quite challenging for us. It depends largely on the prices, and the method for determining the prices if this was a single-site method, which bakes in the practice of care at that single site. And so that was problematic for us.

Nonetheless, as we wrote here, the prospective nature of the payment method should result in more predictable costs for CMS and should reduce variation in cost. So anytime you have a prospective payment model, you should expect those things to happen.

Cancer care -- Oh, and then our last concern was cancer care changes really rapidly. It's unusual for a month to go by in which one of the major journals in the United States doesn't actually have a paper that suggests a significant change in what the protocol is for a particular type of cancer. That's how rapidly it's changing, and we did have concerns about the speed with which the software was being updated and updated appropriately.

So getting on to the payment methodology -- and here, I beg your indulgence. This -- I'm going to bog down a little bit here. This is quite complicated -- but we'll get through it.

So, first, on the benefits, four aspects of this model, as we've already stated, we found particularly strong. The cancer stage was included in the grouping. This was the thing -- because there's been quite a bit of literature that suggests that the failure to include stage in bundles, the difference between a Stage I cancer and a Stage IV cancer is like the difference between a heart attack and an autoimmune disease. I mean, they're really not even close to the same thing, and so to include them in the same bundle sort of begs a lot of questions about case mix adjustment and presentation and variation in the bundle. So, this proposal really fundamentally addressed that known problem with cancer bundles.

The one-year time frame was also -- we found that an attractive feature. The inherent case mix adjustment that comes along with the way this is done and the prospective payment, all of these, as I've said, we found positive.

The concerns. You know, I probably won't list all of these. These are available for everyone to read,

but we had a lot of concerns, just things that could not be answered without doing some sort of pilot or test of this model, so the low frequency of some of the CNAs, how would that affect the accuracy of the prospective prices? Will historic data accurately represent unit cost in the prospective model? How will the model handle leakage of both patients and doctors? How will the savings be calculated, and will they be valid estimates?

If it's an oncology cost-only model, how will oncology costs be isolated? It's a tricky thing to do in claims. I'm not sure that I've seen a successful demonstration of that.

Pricing the non-cancer services, as it falls from the prior point, is problematic.

The mechanism for initiating the bundles was not well specified in the proposal. While it was well specified in the concept, the concept was well specified, but actually the practical issue of what is the communication between the participant and CMS that actually triggers that was not clear, and we could think of several different ways of doing it. But these ways have not, to our knowledge, been tested.

And the model proposes to exclude outliers. As a small matter, we considered winsorization a better approach

to the outliers.

So Criterion 3, again, we said this met the criterion. So I should say we said this met the payment methodology criterion. We said it met the criterion because we were evaluating it against this as a pilot, as a single-site proposal, where we thought it's possible in a pilot, you could work all this stuff out.

I think it's fair to say -- and I think I will look to my PRT collaborators -- that these are not questions you would want to work out as you scaled something at a national level.

Criterion 4, value over volume, we thought, again, the prospective nature and base -- I'm not going to repeat the comments -- they're similar to the previous -- about why this would produce value over volume. In terms of our concerns, we did have some risks of patients [unintelligible] while you said there were some strengths about gaming -- I mentioned earlier, there was one potential weakness that we -- that was unresolved in our minds, which was, if a doctor saw a patient and that patient, say, was particularly sick and they actually fell into the -- they did match a CNA, how does one know whether or not the physician just simply didn't sign them up for the program? What is the audit process by which one -- so

there is a potential method by which you could select patients out of this in a way that advantaged the participant, and we just didn't -- we could imagine ways to solve that problem, but we didn't -- they weren't in the proposal.

And then the mechanism -- we thought it was very plausible that costs would be reduced in a prospective payment. You get a prospective payment; you got to manage under that. We thought it was very plausible that costs would be reduced, but they did not actually specify the mechanism by which they thought costs would be reduced in the proposal. On balance, though, we found these risks balanced.

Flexibility, again, we thought it met criteria, but, again, there's a nuance here. If the Cota software was required for the model, then the proposed model, one would think this actually doesn't provide much flexibility to the practicing physician. On the other hand, we thought that the high number of CNAs and the specificity, that was actually a strength of the proposal. That, in fact, one of the things that's a problem that we're trying to address in U.S. health care is the extraordinary variability, and if the specificity of this is as presented, in fact, the reduction in variability, despite the constraint on

flexibility, would be a positive.

But one caveat, one important caveat to that is there's always situations that arise in clinical practice that doesn't fit the model, and if a patient-doctor dyad decided that it was actually in the best interest of the patient to disagree with the recommendation of the software, what's the path for that? Is that included in the bundle? Is that not included in the bundle? And so those were our concerns related to the specifics of the mechanism, assuming the use of the software.

And then we -- we then had this other issue with the software, this particular software, and I'll just read this. If any system of cancer care paths can be used in this payment model -- so if one were to imagine a payment model in which multiple other care paths, other systems of -- and there are other software systems out there that provide care paths for cancer patients -- actually, there are quite a few -- if a payment model was devised, which is not this payment model as proposed, but one could imagine a payment model that was devised that would include multiple different software, so that anyone could do this in a clinically specific way, but that would not be this proposal. It would be a different proposal. So just sort of conceptually, we wanted to put that on the table.

Criterion 6, ability to be evaluated, the PRT presumes the evaluation would compare historical to actual costs. This is, by its presentation, a single-site pilot. So we weren't thinking about an evaluation the way we often think about sort of national multi-site evaluations. We were thinking about how you evaluate a beta test of a new product, and so the plans to measure patient experience and the quality metrics -- and the particular strength of this is their ability to measure variance from protocol. That is a highly attractive feature of this proposal.

We did have some concerns about the challenges created in the overlap between this proposed model and the MSSP (Medicare Shared Savings Program) program, which, by the way, Hackensack is participating in, and so how do you handle, as we've discussed in this forum several times, the overlap between multiple models that are running simultaneously? And then, again, the single-site and proprietary software issue comes into play here.

Integration and care coordination. Here, we just wanted to point out that due to the excellent work of staff and the data that we were given access to, we did find that cardiovascular conditions were over-represented in this group of cancer patients in at least three of the four, and that this has implications for both the care coordination,

that this is not -- these are not patients with single discipline problems, and therefore, you are, by definition, coordinating care across a multidisciplinary group.

While there wasn't a lot of detail around that, there was certainly the potential with prospective payment and the incentive to deliver highly coordinated care. So I'll just leave it at that. Well, I guess to the extent that the care integration is an inherent characteristic of a clinically integrated network and all providers involved were using the same EHR (electronic health record), both components described in the pilot that they describe -- the PRT did not have significant concerns around that issue. But you could imagine if this was not a single organization providing comprehensive care, there would be significant -- the potential for significant care coordination issues.

On patient choice, this was the one that we did not feel it met criteria. We did in our -- as the transcripts will show of our conversations with the submitters, they did address this verbally and gave us some encouraging statements about how patient choice is incorporated into this, but we just want to really underline the point that in cancer care, patient choice is a very important piece of the care -- I guess, as with all care, but because of the high morbidity associated with

some treatment choices and the different [unintelligible] perfectly acceptable choices that are presented to patients, we just wanted to be sure that once you're assigned a bundle, a payment bundle, and you're in the process, if the patient changes their mind about what treatment lane they're in, how does that affect the payment? Because it affects the lane they're in. We heard that from the proposer. They switch lanes. But we didn't get a -- we didn't have a clear understanding of how that affected the payment.

On patient safety, here we thought the use of -- this is a great use of health information technology to, as I said before, really highly define and describe the delivery of cancer care.

We did want to see, as I mentioned before, more verification of the pathologic diagnosis, at least some method of assurance on that score. And then health information technology, again, this is an excellent use of that.

So I'm going to go back and summarize the key issues. This is a single-site proposal. If a single-site proposal is acceptable -- and we'll get into this discussion, I'm sure -- PTAC should consider whether and how the HMH-Cota pilot study would yield information that

would determine if expansion of the model is appropriate.

Again, the proprietary nature of the Cota software brings up the issues that we'll get into, I'm sure, more in discussion.

And then the total cost of care -- is it a total cost-of-care model or an oncology cost-of-care model? And, actually, there's both the conceptual issues there and then the practical issues there, and we look forward to the responses from the submitters and the discussion with PTAC.

Thank you.

CHAIR BAILET: Thank you, Tim.

I guess I would ask your colleagues --

DR. FERRIS: Yes. I'm sorry. I would ask my colleagues to weigh in.

MR. STEINWALD: All right. As you know --

CHAIR BAILET: Move the mic a little closer there, Bruce. Thank you.

MR. STEINWALD: -- the requirement is that each Preliminary Review Team have at least one physician member. This one has two, which I think is a good thing, because knowledge of the clinical care models and how this model contrasts with others in medicine generally is an important part of the model. I'm not the physician member of the team.

The economics of it are also very interesting, and I just would like to point out one thing. The model and the payment system are based on comparing current patients with historic patients at the same site, and if, for example, Hackensack is a high-performing health system, which there's some evidence that that's true, they've taken on the responsibility of comparing current patients with historic patients and basing the payment system and the profitability of it, if you want to call it that, on their ability to improve upon care of their historic patients.

From a more global standpoint, we'd probably like to know how the payment system would contrast not just with historic patients at that site, but with patients -- cancer patients, more globally. And there is at least the possibility that that comparison could yield even greater savings than the ones that would be obtained just at Hackensack.

So, this is kind of a round-about way of commending Hackensack for being willing to base payment on current patients versus historic patients, when that comparison might not yield as much difference as it would if it was more globally compared to cancer patients throughout the health care system.

DR. BERENSON: I will say two things. One, I

don't think, Tim, you mentioned that they are an MSSP recipient right now. So, again, that's local to this organization. They have experience in managing comprehensive care. It was quite striking that for three out of the four cancers, the rates of cardiovascular disease were remarkably higher than in the average Medicare population, and so that is a real issue. And so I would just emphasize we would have to deal with the overlap in payment and not double-count savings, and so that's a technical issue that CMMI has had to deal with in other places. We would have to deal with that here as well.

The second point, just to sort of summarize why we are attracted to this, there's been a lot of talk in recent years going back, actually many years, of precision medicine. This is an area where there is precision medicine, and so we are attracted to the notion of precision payment for precision medicine. And what this does do, and is consistent with how Medicare pays for other things like hospital care, is it passes through inputs -- inputs and input prices.

So I just want to read a couple of sentences from a response to the questions we asked them, which I think makes this clear: “A bundled program does not discourage appropriate use of high-cost therapies if they improve

clinical outcomes. In most settings, higher-priced therapies would be components of a separate bundle that would have a separate price. For example, one bundle of breast cancer would be anthracycline-based chemotherapy, and a different bundle would be anthracycline chemotherapy plus Herceptin antibody therapy. The bundles are distinct and do not compete with each other and can be priced separately."

So, we do not have a payment model, a prospective payment model that would encourage the owners of the bundle to sort of not provide state-of-the-art care. We actually pass through that. We can discuss whether that's a good thing or a bad thing. We thought it was a good thing that this is a very precise payment model.

One of the issues then becomes how generalizable and easy is it for CMS to administer something like this on a national basis, so that's why we were attracted to the notion of a pilot.

And we did, by the way, explore the potential that if it was successful in Hackensack, it wouldn't be a "one-of." It could actually be adopted more broadly, based on the lessons learned. We pursued that, but as Tim emphasized, we were considering this as like a pilot demonstration.

CHAIR BAILET: Thank you, Bob.

I just want to compliment the work of the Proposal Review Team; Tim, your leadership and working with the submitter and your thoughtful analysis as a review team.

* I guess I would look at my colleagues on the Committee, if you have clarifying questions that you would like to ask of the PRT? Kavita, Len, and then Elizabeth?

DR. PATEL: All right. Tim, to the whole PRT, thank you, and I think some of these questions can go to the submitter, but I just wanted to ask, so that I could make sure -- you mentioned the complexity of the payment methodology. I just want to make sure I understood some of the things that you've talked about because, in their response to some of your questions, how the bundled price would be calculated would be based on that three-year lookback. I just want to make sure I am clear, because the novelty, which I agree, is with this unique staging and kind of the ability to match these bundles with like precisely what's going on clinically. But the initial pricing would be done on a three-year lookback of traditional claims data, I assume, based on Medicare data, which has none of these elements. So did you all discuss that?

DR. FERRIS: Yes. Yeah. Let me just clarify one point, and then that would be a good question for the submitters.

They have -- because they have been using this system for the past three years --

DR. PATEL: At their site? --

DR. FERRIS: -- they actually can match -- if they had the claims, they could match the --

DR. PATEL: You would do a cohort matching.

DR. FERRIS: Exactly.

DR. PATEL: And kind of what I would do with SEER (Surveillance, Epidemiology, and End Results) --

DR. FERRIS: And assign, create the bundle --

DR. PATEL: -- and match with the claims. Right. Okay.

DR. FERRIS: -- based on the individual, the cost at the individual patient level, who were assigned to each of the CNAs.

DR. PATEL: But for another -- I guess, well, you looked at this as the only site --

DR. FERRIS: Right, right.

DR. PATEL: Okay. That's fine.

DR. FERRIS: So, exactly, the whole issue of --

DR. PATEL: Yeah. I don't want to -- okay.

DR. FERRIS: -- generalizing that.

DR. PATEL: And then just to clarify, it's one of the high -- I'm not going to try to paraphrase, I think, what Paul said yesterday were some of the weaknesses for one of the criterion where you actually did say that it met the high-priority criterion -- I believe it was 2 --

DR. FERRIS: Yeah.

DR. PATEL: -- one of the three high priorities. You outlined on the slide and spoke pretty substantially through significant weaknesses. So can any of you just help me balance that?

DR. FERRIS: Yeah.

DR. PATEL: It's similar to what we struggled with yesterday.

DR. FERRIS: Yeah. So I'll ask my colleagues to weigh in here because we did struggle with this, but, again, I want to emphasize what I said before and what Bob said. That we really applied the criteria to the proposal as a pilot, and having run dozens of pilots myself, there's no problem you can't overcome in a pilot, right? Because you're being creative and you're -- you make it work -- exactly. And so while we have a long list of like very significant questions that would need to be answered if this were to become a generalized model, no question about

it -- the strengths that we saw for the reasons we specify, we basically said -- we basically gave the benefit of the doubt on whether or not these problems could be overcome in a pilot to the applicant and said, like, you probably could figure out a way to do this if you worked hard enough at it, despite the long list.

DR. PATEL: And then just one final clarifying comment, in terms of the criterion that did not meet the patient choice, kind of, how -- in talking about what you just said were oncology patients, this is one of the areas where flexibility, choice, and a lot of kind of patient-sensitive preferences matter. Did you have a sense that -- it sounded like in the application, then, the questions, there is this -- kind of similar to MSSP, an opt-out. The OCM, interestingly enough, does not have an opt-out mechanism. So, did you engage in a conversation with CMMI directly about the current OCM program and just some of these issues of like not being able to opt out, for example, because you can't in that program? So one could argue that even CMS' own program doesn't have that kind of patient choice.

DR. FERRIS: I think I will maybe defer to Bob on this. I don't recall -- we did discuss the patient choice issue, as the transcript shows, with the applicants, and we

did talk to CMMI about OCM.

I don't recall that we talked about the patient choice issue with CMMI. It's a good question.

DR. BERENSON: Well, I'll just make two comments. One is, as a co-author of a paper criticizing OCM for not having a formal shared decision-making, I was sort of knowledgeable about --

DR. PATEL: I'm going to read that tonight, Bob.

DR. BERENSON: Friday night you're going to read –

[Laughter.]

DR. BERENSON: Basically, the concern that some of us had -- that I had -- let's put it that way -- was that the model seems so reductionist that for any patient, you could put in their genomics and their pathology and their stage and come up with the exact right treatment lane. The question is, “Where’s the patient?” Where is the shared decision-making about that?

Again, in conversations, they seem quite attuned to the need for active patient engagement and making those decisions, but there was just a reductionist quality to the technology, and I'd still be interested in pursuing that a little more in a real tangible way, where does the patient choice come in? But we didn't pursue with CMMI the flaws

in their model.

CHAIR BAILET: Thank you, Bob.

Len?

DR. NICHOLS: Nice job, Timmy.

So I'm going to focus on --

CHAIR BAILET: For the audience, there's a lot of mutual respect that you can see here.

DR. NICHOLS: Yeah.

[Laughter.]

DR. NICHOLS: So I'm going to focus on two criteria, payment and, I guess, flexibility or something -- evaluation.

The way I would give advice to future PRTs, including those that I might lead, is we should be more verbose when explaining the benefits and more concise when explaining the weaknesses. That will make it look more balanced on TV.

[Laughter.]

DR. NICHOLS: But the truth is, the way I would interpret what you're telling us here is that you like the structure so much, you're willing to overlook what I would call the development cost of making this thing operational, even in the one case, right?

So I guess what I start with is, “Why can't we

settle this total-cost-of-care versus oncology-cost-only?" It seemed like from what I read in the transcript, they're open to having it be total, so we're done here.

I don't know how you could do oncology-cost-only, given all those comorbidities and everything else. So why is there still a question about that?

DR. FERRIS: Well, and, again, I'll ask my colleagues to weigh in here. I think, in part, because the method for understanding total costs, if it -- again, it could be done for exactly the reasons that Bruce said.

Understanding the non-oncology costs and the payment issues associated with those costs that are occurring actually outside of the Hackensack system and all that, so leaving aside the practical claims payment issues associated there, how do those people get paid? Does it get deducted? You understand that there's --

DR. NICHOLS: Yeah.

DR. FERRIS: There's some complexity there on the practical side of just implementing a model that has multiple recipients of payments, but one who got a prospective payment that's supposed to cover all of it.

But aside from that, the conceptual issues that we were facing specifically relates to the uneven distribution of the comorbidities and how one correctly

projects total cost-of-care with that uneven distribution of comorbidities. Do you see what I'm saying?

DR. NICHOLS: I am, and I guess I'm just -- you know, I'm a simple country health economist, and so you risk adjust the bundle. How hard is this? I mean, you know, we need the data to do the math.

DR. FERRIS: Right. So I guess you can imagine that the -- this gets into some technical speak here, but variances inside the bundle could be really, really significant, and we haven't seen -- because no one's done it yet, right? So we haven't seen what the intra- and inter-bundle variances would be.

DR. NICHOLS: So you would say then, not to interrupt, but --

DR. FERRIS: Yeah.

DR. NICHOLS: -- in your mind, it's not clear whether it would be better to go with oncology-only versus some kind of variance-adjusted total?

DR. FERRIS: Well, so, yes.

DR. NICHOLS: Okay. That's good enough.

DR. FERRIS: In my mind, it's not clear. There's some technical issues. There's the technical issues associated with the practical aspects of payment. There's some technical issues around the risk adjustment and the

uneven distribution of comorbidities, and then there is the -- we haven't talked about this yet, but there's also preference, total cost of care. For sure, the easier, it would eliminate the practical questions.

But on the total cost-of-care, if you have two - or 300 -- if you have a cancer center -- and now I'm talking about a generalizable model here. If you have a cancer center that's got two- 300 patients in a model like this over the course of a year and you're taking on total cost-of-care, how many car accidents does it take before the bundle blows up on a total cost-of-care model? And that is -- and so is this putting risk, apportioning risk to the participant that's unreasonable? And, again, I don't have any -- I don't know.

DR. NICHOLS: Okay.

DR. BERENSON: Let me take a shot at that.

DR. NICHOLS: Okay.

DR. BERENSON: Last time we were here, we seem to have accepted from the American College of Surgeons and Brandeis that the new episode grouper could do just that, that it could, in fact, isolate the costs of cancer, because they were proposing, ultimately, it could be done for procedures and conditions, and that the grouper had now been advanced to -- I don't know that, but I think it's

worth knowing.

I can imagine this organization has done MSSP. They seem to be in a pretty good position to deal with total cost of care. There may well be other places that aren't, and Tim is raising issues around insurance risk and things that have nothing to do with cancer management.

So I think there are some questions. I think we as a committee probably need to know a little more about that episode grouper and what its capabilities are. I'm skeptical, myself, but --

DR. NICHOLS: Well, but the inference I'm drawing is we should do the math both ways in this case. Okay, okay.

DR. BERENSON: Yeah.

DR. NICHOLS: Which gets me to -- tell me a little more -- and maybe I missed it -- how much has been done already? Like it seems to me once you assign a CNA to a patient population, somebody somewhere also knows the claims that go with each of those people. So there's got to be a mapping already between the CNA and dollars, and that's been done, I presume, at Hackensack.

In principle, couldn't that be done for any patient population across the country? Because what I heard is the variables that actually are not in claims are

in either the EHR or some kind of specific screener or survey or whatever that's done.

So, theoretically, you could construct, if you will, control groups outside the Hackensack world and make this thing much bigger, but I take it --

DR. FERRIS: Yeah. I mean, that -- you just -- I think, Len, you just put your finger on why we were -- because we could imagine that you could do this.

DR. NICHOLS: Yeah.

DR. FERRIS: We didn't see in the proposal the method to do that, but we could imagine it could be done.

DR. NICHOLS: Well, I was going to say, so my understanding of the proposal is, basically, they're asking to work with CMS to essentially do this.

DR. FERRIS: Yeah.

DR. NICHOLS: Right. And if you did that, it seems to me -- that is to say, if the keys to the kingdom were granted, shall we say, then one could construct non-Hackensack-specific baselines. So you could take this larger, much quicker than one might imagine, in the sense of one could do a national mapping from the CNAs to this to do cost. No?

MR. STEINWALD: Well, it would be good to hear from the proposer on this specific issue.

DR. NICHOLS: Well, I suspect they're going to answer that question.

MR. STEINWALD: But what makes it work at Hackensack, is their ability to assign CNAs to their historic patients, and to do that, they have to have in their database on those patients, a lot more than just Medicare claims. They have to have all of the elements that enable them to assign a CNA in order to establish --

DR. NICHOLS: So that includes the HR data.

MR. STEINWALD: Yeah.

DR. NICHOLS: And what else?

MR. STEINWALD: Well, what's in the HR data goes far beyond what's in claims, but, you know --

DR. NICHOLS: That's obtainable in life, right, and other places?

MR. STEINWALD: Yeah. What did he say? Theoretically. So I think that's what we economists like to call an empirical question.

[Laughter.]

DR. NICHOLS: Okay, okay, okay.

So, Tim, you talked about one of the complexities in imagining -- this future world would be. What if there were multiple competitors of CNA and they all had these different pathways? And good Lord have mercy, we can't

have an infinite number of bundles. Has the clinical superiority of CNA as a generator of clinical pathways been clearly demonstrated? I mean, surely in a market test, some of these are better than others. We wouldn't have to put up with 300 of them. I guess I'm asking the question. It's proprietary. That's a black box to me. How good is it?

DR. FERRIS: Yeah. So we had quite a bit of discussion on the PRT about this question, and I guess what I might do, Len, is defer that to the deliberation phase --

DR. NICHOLS: Okay.

DR. FERRIS: -- because I don't -- I don't have any more than what we've already said, because --

DR. NICHOLS: So there's not been some meta-analysis to compare X versus Y. Okay.

DR. FERRIS: No. I -- and this is just personal. I made some phone calls to people when we were doing this PRT about just the software that's out there, and there's a lot of software out there that is described somewhat differently, but it's -- and whether there's -- how many lane paths there are in the different pieces of software, but there are multiple versions of software out there that assign cancer patients based on demographics and, you know, genetic criteria associated with the cancer-specific

molecular diagnostics to specific pathways, and then the software follows the pathway.

So, this isn't the only piece of software out there that does that, so one could imagine that since mostly they're all based off of the same set of professional guidelines that they all use, but what I'm doing is I'm assuming an enormous amount and saying that, in theory, one could get to a point where you could either have multiple competing software but a meta-structure that allowed a payment model to use multiple different sets of -- or that through some process, like the one that got us our single national EHR process --

[Laughter.]

DR. NICHOLS: Oh, that one. Yes, okay.

DR. FERRIS: You know which one I'm referring to.

DR. NICHOLS: The one that worked.

DR. FERRIS: Right?

DR. NICHOLS: Yeah, okay.

DR. FERRIS: But I'm hand-waving here -- right? -- because none of this exists. We could imagine that it would be possible and actually beneficial, but we are as a country, we're certainly not there yet. And this proposal is not proposing to get us there, but it is potentially a step in the process.

CHAIR BAILET: Elizabeth.

VICE CHAIR MITCHELL: Thank you, and thank you to the PRT. Your excitement is palpable, and I think I actually have a less elegant version of Len's question.

But to that point, reading their responses, there's a real tension between how generic this is versus how special it is. Even saying that anyone could do this using any tools or by hand and that it is -- the entire concept is, "generic in theory," but then that Cota's classification system is unique and special, so particularly in regards to scalability and what we heard this morning about not wanting to sort of limit ourselves to a proprietary tool, do you have a sense -- maybe you just answered this -- that this could be done without Cota, or is that sort of inherent to this being effective?

DR. FERRIS: So I think -- and, again, I would ask my colleagues if they -- just particularly if they disagree. I think our response to this was it could be done, and that it would be good for patient care in the United States, oncology care, if it was done, but this proposal is not proposing to do that, right? I think it's a step in that direction.

CHAIR BAILET: All right. My question, as I read through the proposal at face value, it talks about the

bundle. It includes unrelated services. The backbone of the platform for this proposal is that there is a three-year lookback for the costs associated with these four tumor types.

They talk about outliers. They talk about stop-loss that impacts two times the bundle, and then those folks are considered outliers. So, I don't know if you had a discussion that might not have been captured in the transcript about that.

And my specific question is, when there was three-year lookback, was that same methodology applied where people -- based on the performance, were they stripped out when they set the price, if you will? And that may be a question for the submitters, but it wasn't clear to me when I looked at the model.

And then when these folks become outliers, who bears -- where does that expense go, and how is that sort of determined and addressed?

So those were questions that, again, I don't expect necessarily that you would have the answer as a PRT, but perhaps you had that discussion with them.

DR. FERRIS: I don't have the answers to those questions, but I would -- given the frequency with which my colleagues have answers to questions that I don't have

answers to, I'm going to defer to them.

DR. BERENSON: And I'm going to defer to the economists.

[Laughter.]

MR. STEINWALD: You know you're every bit as much an economist as you are a doctor. You know that.

Well, two things. One is I can't remember specifically, but you have to use the same methodology in the lookback as you do in the prospective pricing. You can't include the outliers in calculating historical costs and then strip them out of the payment, so it has to be symmetrical.

Second, they propose removing outliers, and we said in our PRT that we thought a more sensible approach was winsorization, which means you don't remove the outliers. You drop their cost down to a threshold, and once again, you would have to do it in the same for the historic as the prospective.

DR. FERRIS: And in our conversation when we brought that up with them, they were very open to that change.

CHAIR BAILET: Thank you.

Harold?

MR. MILLER: I have a number of questions for the

submitter, which I'll ask them.

But the question I had for the PRT was I searched in vain through all the material to understand exactly how the quality measures would factor into the payment model. There was an extraordinarily long list of quality measures, which is great. Usually, it leads to people saying, "No, no, no. You can't possibly have that many quality measures," but I couldn't figure out anywhere exactly what impact that would have on payment. There was references to careful monitoring of quality, et cetera, et cetera, et cetera.

And, I mean, you can give the patient the exact right evidence-based treatment and do a horrible job of managing their symptoms and have them ending up in the ER, in the hospital constantly, and there are some measures in there. But it wasn't clear to me what impact that had.

There was a reference in the August 30th response, which, of course, we all had a huge amount of time to read, but on page 15 -- and, again, the applicant may also have -- but I wanted to -- if you guys thought about this. At the very end of the page, it said, "Of greatest importance, the bundled program first requires achieving an expected clinical outcome based on evidence. Only after achieving that outcome would shared savings be

available, determined by the impact and the total cost of care."

Now, I did not see -- and, again, I searched back. I did not see any reference to this being a shared-savings model. It was a bundled, flat, fixed, prospective price model. I did not see any adjustment to the payment amount based on quality.

There were some very, very small references to the notion that somehow the individual physicians might get something, but there wasn't anything overall.

So I'm curious as to whether you saw something I didn't and whether -- because you didn't comment on kind of the quality aspects, other than the stinting on actual treatment.

DR. FERRIS: So, Harold, as usual, your acumen has identified a lesion in the PRT's process.

MR. MILLER: Lesion?

[Laughter.]

DR. FERRIS: So we'll have to ask the submitters, but I do not recall that there is a relationship between the CMS payment for the bundle, that is modified by any quality.

But to the -- a couple of points, though. One, they did actually describe how they intend to pay internal

to their organization, and that they would pay physicians, for example, the Medicare fee-for-service rate modified by those physicians' performance on their individual -- because, you know, when you have patients that are entered into a software system and on every single patient, you can measure variance to the protocol, you have -- you can at the individual physician level provide incentives, right? And so that's rather remarkably, to use Bob's words, precision payment, internal; but I will say I do not recall that there is a modification to the external payment.

I will say on your shared savings, I think my own understanding of that -- is that -- that is a loose use of language. I think as the model is, as you described, a fixed payment; and if your costs are under that fixed payment, you reap the savings. They described it as a shared savings. I'm not sure that -- that's not the same understanding of the term "shared savings" that we would normally use in a federal payment model, and that the risk --

MR. MILLER: Because in that case, it's not necessarily shared. Right?

DR. FERRIS: That's correct, except to the extent that the priced bundle itself presents savings to CMS, as we described, right?

MR. MILLER: Mm-hmm. Okay.

And then just one follow-on question, in terms of the physician compensation portion, did you focus on that at all, and did you have any opinion about whether you thought that was -- it sounds like that was not -- from my reading of it, that was not integral to the model in the sense that one wouldn't be required to compensate physicians in a particular way, and if you were in the model, that was kind of up to the -- again, we understand this is one site, but that would be kind of up to the site. And it would be -- potentially, it could change that at any point, but did you have an opinion about that or not?

DR. FERRIS: Yes. So, Harold, again, your acuity is right on target.

So, in general, we thought how you pay physicians underneath the -- is that’s up to -- that's up to them, but we did have a discussion about one thing that raised a concern with us, which is in our report, but I did not highlight in the slides. And that is, if you are incenting individual physicians to not be at variance with the protocol, what happens when the best thing for the patient is to be at variance with the protocol?

And we did actually have a discussion on the PRT about the -- we thought that that could be mitigated with

the -- either -- we actually, I think, described in our report two mitigation strategies for that. One was that you could minimize the penalty, just not make it an onerous penalty, so there wouldn't' be undue incentive on the physician; or that the physicians -- and this is the way we do it in my organization -- the physicians actually have an explicit method for explaining a variance and getting out of the penalty just through a peer-reviewed explanation. You can imagine several different models for doing that.

MR. STEINWALD: Can I add to what you said?

DR. FERRIS: Please.

MR. STEINWALD: The part of it --

DR. FERRIS: Because I'm currently, in that answer, practicing economics without a license.

MR. STEINWALD: When do I get to practice in medicine? That's what I want to know.

[Laughter.]

MR. STEINWALD: Another part of our discussion was if -- and I agree that underneath the payment system, the compensation of individual practitioners is an internal issue. However, if you're going to continue to compensate physicians on a fee-for-service basis, which carries all the incentives that we have talked about for years, it seemed to me that you need to have a strong integrated

delivery system to govern what physicians do and don't do, and part of that, of course, is adherence to the model as it was designed.

MR. MILLER: Just one closing comment. I guess my observation, though, is that one of the theoretical advantages of doing this in a physician group would be the averaging and across a number of patients, so you would have more flexibility to be able to treat some patients differently.

If you then sort of throw that all away and go down to the individual physician level and say you're sort of accountable for the spending on your particular patients, you have lost that. And then one of the general arguments for having a large physician group is you would pay the physicians not on a fee-for-service basis. So, at any rate -- so I think that's one issue in terms of how this all gets translated.

CHAIR BAILET: Okay. Paul.

DR. CASALE: So I have one specific question, but just to add on to the financial, provider financial risk, just a comment, because in the proposal, they say that the physicians don't take downside risk. But if they don't meet performance and quality standards, they will be asked to exit the team, which was, I guess, concerning,

potentially problematic.

I don't know. Did you have any discussion amongst the PRT around that whole --

DR. FERRIS: We did. We did have a little discussion about that, and I think -- and this is one of the things that happens when you're reviewing a proposal like this. So that's covered in one sentence in a very long proposal, to unpack that to a significant degree, which we did a little bit on the phone.

There's a lot -- as you're pointing out, there's potentially some problems underneath that, but in general, we -- and, again, I don't want to speak for my colleagues -- I'll just say -- so I'll say "I" -- viewed these as this is the kind of stuff management of an organization has to deal with every day, and we're just going to assume that they're going to do right by the process.

They have a strong incentive to keep people in and functioning to deliver care to their patients, and so we didn't think they would -- there would be much incentive to sort of willy-nilly kick people out. That would be sort of a somewhat self-destructive management technique.

But we did -- we did take note of that, that line of the proposal.

DR. CASALE: Great. Actually, my one specific --

and I may have missed it. I apologize. You know, in cancer care, a lot of patients are on research protocols, and I couldn't see -- are patients who are on sort of the NIH (National Institutes of Health) protocols -- are they excluded from this, or how does that work? Is there any mention? Did I miss that?

DR. FERRIS: That's a great question. I hope you ask it of our submitters.

I think, actually, we made just an assumption. Since research protocols are by definition highly protocol-ized, I assume that the lanes are themselves, where appropriate, protocol lanes. I guess I just -- I never asked the question, so it's great that you asked the question, but just made the assumption --

DR. CASALE: Okay. Well, I was just thinking that there may be, whatever, additional testing, additional -- that's part -- yeah, additional cost related to a, whatever, research protocol that --

DR. FERRIS: Yeah. Well, I mean, just as a matter of course, research protocol services that are not billed, generally academic medical centers have accounting systems that separate the bill paying, and so since it -- I would say it was true before the bundle was introduced and true after, and so it's a constant that flows through, so

it shouldn't affect the pricing. But, again, that's not a conversation I had with the submitters.

DR. CASALE: Again, that goes to the site-specific nature of this as opposed -- because in a general -- well, I understand that for in general, but --

DR. FERRIS: Yeah.

DR. CASALE: Well, I was just trying to think more broadly, if places hadn't been involved and now they're involved in recent -- you know, that again –

DR. FERRIS: Yep.

DR. CASALE: -- to the historical --

DR. FERRIS: It's a good set of questions that is raised by the point you're raising.

CHAIR BAILET: Kavita.

DR. PATEL: Just a follow-up question. Did you all talk at the PRT level about kind of this total cost issue that you wrestled with? I'm assuming post-acute hospice, all of that. I mean, we're talking true total cost.

And then if a patient switches, which is entirely possible, kind of overlap enrollment periods and they go from fee-for-service into MA (Medicare Advantage), I'm assuming kind of private Medicare plans are ineligible. But is that -- I couldn't see that also. It's just that --

did that come up at all?

DR. FERRIS: It did not come up. I guess I can put that on the category that Bruce -- which is CMS has ways of handling those situations, but that would happen. In real life, in this process, you would get a patient who is halfway through a protocol, halfway through their year, and they would sign up for Medicare Advantage. I assume the way it works now with all the shared savings programs is they're out of one and they're in the other. Yeah.

CHAIR BAILET: Any other questions for the PRT from the Committee members? Comments?

[No response.]

* CHAIR BAILET: So, at this time, I would like to go ahead and invite the submitters to the table. We have chairs here in the front, please. And once everyone is seated, if you could introduce yourselves, because there are people on the phone -- that would also be helpful.

[Pause.]

CHAIR BAILET: Welcome.

DR. PECORA: Thank you. I'm Andrew Pecora. I am the president of the Physician Enterprise and the chief innovation officer of Hackensack Meridian Health and also founder and executive chairman of Cota.

MS. CASTANEDA: Hello. I'm Elena Castaneda, and

I am on the payer-provider team at Cota.

DR. MENACKER: Hi. Morey Menacker. I'm a physician, vice president of the Physician Division, working with Andrew at Hackensack Meridian, and president and CEO of Hackensack's ACO (accountable care organization) since its inception.

DR. NORDEN: I'm Andrew Norden. I'm chief medical officer at Cota, have been in this role for 72 hours now.

[Laughter.]

DR. NORDEN: Pleasure to be here.

MS. KUDLACIK: I am Laura Kudlacik. I am a nurse, and I am the VP (Vice President) of Oncology at Hackensack.

CHAIR BAILET: Welcome.

DR. GOLDBERG: I am Dr. Stuart Goldberg from the Leukemia Division at Hackensack Meridian and also the chief science officer at Cota.

CHAIR BAILET: Welcome.

So we have a 10-minute spot for you guys to provide your presentation and perspective.

DR. PECORA: Thank you.

So, first and foremost, we want to thank you for your time and -- sure. Thank you. First and foremost, we

want to thank you for your time and this opportunity.

In regard to the questions we received in writing and now in follow-up to the commentary that we heard, including the starting-off commentary, I'd like to make a couple of comments for clarification.

So Hackensack Meridian Health's breast, colorectal, and lung cancer bundles are designed to improve clinical outcomes for every individual patient, which does require precision medicine, and reduce total cost of care for the population we will serve using a novel digital classification called the CNA to identify, to prevent adverse variance in care -- which means too much or too little care specific to that patient -- and that leads to a less than optimal clinical outcome and unnecessary course.

I want to say emphatically, we believe our model can be generalized and does not require the use of Cota or even CNAs. Embedded in the CNA -- and this is a fundamental important understanding that seemed to have gotten a little mixed -- the bundles, the bundles themselves, the care pathways are evidentiary-based pathways that come from the National Comprehensive Cancer Center Network, from ASCO, and other accrediting agencies. They have nothing to do with Cota, the software, or Epic, which is the EHR we will be using. Those are evidentiary-

based care paths that societies and peer-reviewed publications lead to.

The CNA is a digital classification system that assigns a number, a numeric code, to a person, an individual that encompasses everything that the peer-reviewed literature states is relevant about them, the condition they have, the treatment that's intended for them, and this includes all of the attributes of population health, like socioeconomic status, ability to get to a clinic. It's all embedded in this code, so you precisely look at the individual. It is up to the physician and the patient to decide, this individual, what care they will get for this specific disease, and it is the clarity of that lens, that CNA, that allows us to view variance in a way that before you could never do.

But if someone decided not to use the CNA, all of the elements that go into the CNA are not randomly selected. They come from the published literature, are evidentiary based, and could be reproduced by another health care system. And that, I think, is a very important point.

Pace and choice also came up. This is central to our model. Our bundles allow for a patient and their physician to choose any NCCN (National Comprehensive Cancer

Network), ASCO, or other accredited guideline path of care. In our bundles, we actually have bundles that are patients choosing no care, "I decide I don't want to do anything," and that's a separate and distinct bundle.

The only thing we will not allow in our system is patients or doctors to be offering choices that are inappropriate medical care, and in oncology specifically, this is becoming more and more important.

We now know that there are genomic profiles of individual patients that with that profile being reported, you can determine precisely what the right care is, but equally what wrong care is -- hurtful, harmful care would be. And we've built our algorithms to make certain that that information is available to patients and their physicians.

We are not telling doctors, "You precisely need to do this." We are not telling patients that either.

While the program is oncology-specific, our approach is not. HMH using precision analytic risk stratification -- in our case, we've chosen to use the CNA and Cota, but others could choose other methodologies -- are completing development of identical programs of bundles that we plan to launch with commercial payers in behavioral health, cardiovascular disease, and orthopedics. So this

is not specific to cancer. Cancer is the first example of the idea that if you want to match precisely the right care to precisely the right patient and minimize adverse variance, too much or too little care that results in unnecessary expenditures, this is applicable to all of medicine where you have a chronic condition, a serious chronic condition.

I think it's also important that we will assume responsibility for minimizing leakage using care coordination techniques mastered through the HMH experience in our MSSP program, and you have made reference to that. We are highly experienced and have been very good at doing this, and we look forward to doing it.

And, lastly, we have no issue with comorbidities being counted in our total cost of care, if that's how this is a better way of approaching it. We, using the CNA architecture, know and have the data -- and we plan to be -- we publish everything we do. We will be publishing this. We've already presented it in abstract form. This will be published in peer-review literature. It will be totally transparent to everybody that when you have this specific CNA, if you have no comorbidities, you have this number; if you have cardiovascular disease with breast cancer, it's a different number. And you can actually look at, for that

cohort of patients, what costs are.

We already have the data. We already know. We have done the matching. Someone said that. We've done that, because we're launching this program commercially with Horizon Blue Cross in New Jersey, January 1st. So we have all the data. We know what it's going to be. We are willing to do this with CMS as well.

Finally, everything we do -- and this was a requirement of DOBI in the State of New Jersey, the Department of Banking and Insurance. We had to prove to them, before they would let us do this in the commercial setting, that we were not in any way precluding patients from getting the care they needed and getting any inappropriate care, because they were giving us a prospective payment. Obviously, the risk of prospective payment is you're going to do less than you should do because then you have a greater operating margin, and what we showed them is -- is that everything we do is evidentiary-based. So we don't take a doctor's note to say a patient has breast cancer. We have the pathology report.

And here, I think -- is my last comment -- is a central element. As we move from where we are today in the field of medicine -- I'm a practicing oncologist -- to precision medicine, which, by the way, is not just going to

be in cancer, we will know more and more precisely what someone should do but, equally important, what someone should not do, with definitively, no argument. And as we move down that path, we are going to have to have the evidence, i.e., the actual pathology report, i.e., the actual molecular test in the record to show in an auditable fashion that you match the right patient to the right care, and that is our intent.

So thank you. We're now open to answer any questions.

CHAIR BAILET: Rhonda.

DR. MEDOWS: That was amazing. Thank you. You answered about the first six of my questions.

The seventh question is, “Can you share with me a little bit more about the quality aspect?” I love what you said about patient choice. I love what you said about precision medicine, about the idea that this is not limited to Cota, although you've got, obviously, the experience there. Talk a little bit about the quality piece. How does it tie in? When you go beyond measuring, monitoring, having quality improvement programs, how do you tie it in?

DR. PECORA: Yeah. No, absolutely, and thank you for asking that question. That's a great question.

I had the privilege of working with a team of

people in Washington that led to the OCM model, and we spent a lot of time talking about what are the measures of outcomes that actually matter.

When the intent of -- this is cancer now. When the intent of therapy is curative, the goal is to give the right medicine and the right dose in the right time, and that's called "delivered dose intensity." So that's the number one quality indicator. You must show that you are giving the right medicine and the right dose in the right time.

When the intent of therapy is palliative -- and, unfortunately, there's way still too many Americans that face cancer you can't cure -- it's no longer giving as much drug as you can as fast as you can. It's more how do you preserve quality of life.

So we have embedded -- and we are working with patient advocacy groups -- in the State of New Jersey, we have gone before numerous committees to discuss this; our partner, Horizon Blue Cross, has a whole enterprise working on this -- where we are matching what patients tell us are important to them as quality indicators. And we have patient-reported outcome tools. In the package, you can see what we did with "*Living with Cancer*," which we've published now, where we can actually determine when is the

best time to introduce the concept of palliative care using a numeric format to doing that.

So it's a very long list of things we're measuring. We are going to measure them. We are going to share them, and I think another critical point is we're going to share them with our patients. Everything is going to be transparent in what we do.

CHAIR BAILET: Paul and then Harold.

DR. CASALE: Thank you. Thank you very much.

I'm still struggling a little bit with, you know, your statement that this can be done not just with Cota but with other -- you know, anybody can sort of pick some of the other algorithms. I mean, you speak very confidently around Cota's precision and reducing variation, but do you have similar -- I'm still struggling because I don't hear the confidence that other software would potentially have the same degree of precision that Cota has. So for this to be generalizable, I'm still back to this will likely need to require Cota for other places to do. And I'm just --

DR. PECORA: Yeah. No, thank you. And I'm going to ask some of my colleagues to weigh in as well.

Cota is a breakthrough novel technology. It is what it is. It's being used by commercial payers now in several states. It is thought best in class. But I don't

know anything in America that's only one thing.

You know, the majority of Americans use one EHR system, you know, majority of doctors, but not all doctors. I think the market will determine that.

What's important -- and particularly given what's stated by the introduction -- is the evidentiary basis that goes into assigning the elements that all reasonable physicians would agree and are actually required by the agencies that Cota is working with to be transparent, that a particular test is necessary in this particular condition, is out there for everyone.

So someone could reproduce this. They would have to do it. They would have to choose, make the choice, “make” versus “buy,” and then there will be other competitors in the marketplace.

I will say that it is impossible for us and for me to think about how you can do this without the precision of the lens of a CNA-like structure, because how are you going to transfer that information?

What Cota did was it took that information, the biologic narrative, and it digitized it, and strings of numbers can be relayed back and forth instantaneously. Paragraphs of words, and based on how you say it, can't. So that was, I guess, the big breakthrough.

But, fundamentally, the attributes that go into what's important in breast cancer and colon cancer are known and used by everyone around the world.

Any other comments from my colleagues?

DR. MENACKER: I'd like to weigh in just for a brief second. I'm the non-oncologist at the table.

And the concept is to reduce variability in order to improve outcomes and eliminate waste. Let's assume that we were here talking about the treatment of congestive heart failure. We know about the variability. We know that even going from ICD-9 to ICD-10 (International Classification of Diseases), the number of codes for congestive heart failure has multiplied, but yet the evaluation of the treatment hasn't changed. And there are so many different types.

If we created a stratification system for congestive heart failure and a treatment protocol for each of the various types of congestive heart failure, our variability would go down, our outcomes would go up, our costs would go down.

So by using Cota, it merely gives us the database to say we know that this treatment protocol that's been decided by NCCN is the optimal one, where there may be four or five other programs that are similar, but it's all about

putting the right patient in the right protocol, utilizing whatever may be -- as Dr. Pecora mentioned, the market will determine what's the best way of doing it and the most efficient way of doing it.

DR. NORDEN: I would like to just add one point to strengthen a comment that Andrew made and maybe to clarify something that could be unclear, and that is that Cota is not determining the treatment. Cota does not have a set of the right treatment. Cota is a sophisticated digital grouping approach.

So, as Andrew -- and I should say that for -- that the grouping is based on the things that every oncologist in the United States would agree are critical grouping factors, things that are proven in peer-reviewed literature to have treatment relevance to impact outcomes.

So, I think it's not hard for me to imagine someone else developing their own grouping methodology that, in all likelihood, would look quite similar to the one Cota has and to use their own set of treatment pathways, and as Tim mentioned, there are a lot of vendors that offer pathway programs that are already in place.

DR. CASALE: Yeah. I still struggle, again, with the comments we heard this morning on the responses to the initial models around the Secretary's comments about

proprietary nature of software and trying to then translate your experience and to others, again, thinking from the patient protective point of view in terms of choice. And it's not about Cota, but I'm still struggling with, for this model if it's tested and evaluated in a pilot at Hackensack, to make it more generalizable -- again, maybe I'm thinking too simply, but it would be -- I would be more reassured if, well, Cota is going to -- if it worked in Hackensack, it's going to likely be used other places.

And although others could mimic it, it's not going to obviously be exact. Dr. Pecora said Cota is best in class. So that makes me a little uncomfortable in terms of sort of saying others could sort of replicate this.

DR. PECORA: And the other point is -- and I don't know if this may or may not be relevant -- the proposal, the care proposal, is a Hackensack Meridian Health proposal. We're going to be using a bunch of different software. The reason we put Cota as a partner is because it's integral to the description of what we're doing.

But, you know, I won't mix words. There's no way around -- if we're going to move from generalized states to precision states, so you're precisely matching the right care to the right patient, and you want to have an

evidentiary basis to do it and to know and to learn as things change, it's going to require precision analytics.

DR. GOLDBERG: I think that one of the things that we can learn from this pilot is, “Does putting patients into a smaller prognostic grouping really affect outcomes and costs?” I mean, if we can learn that -- we believe it does -- and everybody, I think, around this room believes that that's important -- but it really hasn't ever been shown. And if we can show that if we can group the patients into a smaller defined -- using, in our place, Cota because we have figured out a grouping we like, but if another institution says, "Well, we want to group just by stage and genetics," -- but if we can show that by grouping patients that the outcomes change and you reduce the variance, that's an important lesson for Medicare to learn. And then we can generalize that using other grouping systems in other diseases also that may not even use our Cota system.

DR. PECORA: I want to make -- I want to point the Committee's attention to two of the articles that were in your packet. We showed two, I think, very important things that got a lot of national attention.

One was in non-small cell lung cancer. In non-small cell lung cancer, there is a number of -- a

percentage of patients, about a third, that have a genetic mutation in their tumor that allows the use of an oral drug that is much less toxic, highly effective. Median survival is 44 months. If you don't have that mutation or you don't check for it and you get standard chemotherapy, median survival is 11 months. No one would argue 11 months is a lot less than 44 months, and quality of life is infinitely better when you're on those oral agents than when you're getting very aggressive chemotherapy.

When we did the analysis in the State of New Jersey in the biggest group of oncologists, the testing rate was only 60 percent. So that means 40 percent of Medicare beneficiaries weren't even getting the test.

So Medicare is paying for chemotherapy because it's non-small cell lung cancer, but it's not paying for the right thing at all. You would never know that if you didn't take this approach.

Second example is we showed using a genomic classification system in breast cancer, that that test cost $4,000, and there was a lot of resistance to get the test. But if the test showed a certain score, a woman did not need chemotherapy and -- if it was a low score. If it was a high score, then they did.

Well, it turned out that when we increased

testing rates to almost 100 percent in a very big group of patients -- and this is published; it's in your packet -- we showed that we reduced total cost of care by $11,000 per case, because a third of women were no longer getting chemotherapy that didn't need it. This is what the application of precision medicine is.

And so when we decide, we are arguing, well, should you do an MRI (magnetic resonance imaging) or not an MRI, that's important, but we're talking about life and death. We're talking about subjecting a person to six months of medicine they don't need that is highly toxic. That's where real reform should be, I think, and that's what we believe this proposal can do. And I do believe it's generalizable and is not limited, and I respect the fact that it does not want to be limited to a proprietary software, but I believe that this can be done more globally after a pilot.

I do think a pilot is a good idea to learn the issues and work out the things that were mentioned, but this could be a very short-term pilot, because we're also doing this with several commercial payers. So this isn’t going to be just with CMS.

CHAIR BAILET: Harold -- oh, go ahead, Len.

DR. NICHOLS: No.

CHAIR BAILET: No? Oh.

MR. MILLER: Thanks.

So, first of all, let me commend you for all of this work that you're doing. I am often frustrated by the fact that people who want to change payment are obsessed with the idea that it must be simple, and despite the fact that there are 7,000 CPT (Current Procedural Terminology) codes, an ungodly number of ICD-10 codes, and 700 DRGs (diagnosis-related groups,) and 700 OPPS (outpatient prospective payment system) codes, people will think that if you have even 10 different payment categories, somehow it's too complex. But the reality is that health care is complex, and that people differ.

So it seems to me that you're trying to find a way to strike the right balance between one big capitation payment -- and good luck with that -- versus fee-for-service, where God knows what will happen.

So all of my questions are really designed to get into some of the details, but I think that what you're trying to do seems to me to be exactly where we need to go in general.

So let me -- I have a number of questions. Let me start with the one kind of picking up on the CNA stuff. So, if I understand it correctly, CNA is sort of the --

your version of the Dewey Decimal System for cancer patients, and there are no proprietary tests or anything like that to determine that. It's all standard stuff. It's simply a way of saying, “Here's an organized way of saying all these things that matter about the patient to be able to put them in there,” and then to be able to then say, “A patient like this goes into this particular lane.”

Now, I was confused in some of the language here about "publicly available." Obviously, all the characteristics would be publicly available. Are they a woman or a man, you know, et cetera? But I'm not clear on whether your actual categorization system is publicly available.

This was an issue for years with episode groupers, was, you know, United had an episode grouper and other people had an episode grouper, [unintelligible] never was before proven, and then people got frustrated with the black box nature of the groupers and said, "You got to at least make the methodology transparent." You can compete on the effectiveness of the software and how well it works and how easy it is to use, but you can't say, "Just trust us. You know, this is the right way to group things together."

So I'm not clear on whether the method for sort

of how a patient gets into a lane is transparent, or is that a proprietary black box?

DR. PECORA: No. How a patient gets into a lane of care is completely the choice of the doctor and the patient.

MR. MILLER: No, I'm asking if it's publicly available.

DR. PECORA: Oh, yes.

MR. MILLER: Is there a place I can go --

DR. PECORA: Yes.

MR. MILLER: -- to say -- and I can find on a website -- because I looked at the website. I couldn't find anything like that, that would say, so a patient like this should be in this particular lane.

DR. PECORA: The way you're asking the question will not get you the answer you're looking for.

Let me answer it. What Cota will do will give Hackensack Meridian Health the three-year retrospective lookback of its data to say, "Here's the CNAs that you've taken care of the last three years. Here's where the choices the doctors made. Here's where the lanes they were assigned. Here's the clinical outcomes and the total cost of care." That's what Cota gives to Hackensack Meridian Health.

Hackensack Meridian Health then shares that with its doctors, and we plan on sharing it with the patients. And when we go to prospective, we will have the benefit of knowing that a particular CNA had all of these different choices that were made and already have the data -- and there's a ton of variance at the level of the CNA, a ton -- and here are the lanes of care that gave the best clinical outcome at the lowest cost, and that's the information that Hackensack Meridian Health is providing the doctor.

MR. MILLER: That's not quite the question I was asking, because the question I was asking was that you were saying, for example, we know what the wrong care is. We will not let somebody give the following treatment because it's the wrong care for that patient.

So what I'm asking is, “Is it publicly available to know the method by which you are saying a patient with a particular set of characteristics cannot get this particular set of care, that they shouldn't get Herceptin?”

DR. PECORA: Yes, yes.

MR. MILLER: And is that available somewhere --

DR. PECORA: Yes.

MR. MILLER: -- that one can go and see the following patients can't get it for the following reasons?

DR. PECORA: Yes, absolutely. It has to be

publicly available. That's a --

MR. MILLER: Okay.

DR. PECORA: -- requirement of DOBI in New Jersey for us to do that. Yes.

MR. MILLER: Okay. And so we can find that, find -- you will show us where to get that somewhere?

DR. PECORA: Yes.

MR. MILLER: Okay. So a second question is I was a little confused about the risk adjustment methodology to understand this, because you're basically -- you're looking at the CNAs. You're analyzing them. You're then adding them up to come up, though, with 27 bundles, but it sounded like then you go back during the year to essentially re-create what the bundle price is based on the actual number of people in each CNA. You don't say, "In the past, 27 percent of the people were in this CNA and 63 percent were in this other CNA, and we'll use the cost for each of those CNAs. We'll do a weighted average. Now we have the bundle price for one of the 27 bundles. That's the price going forward." It sounded like you're saying, "We're going to go back to the individual CNA prices and re-weight that to get" -- so that's where I was confused.

DR. PECORA: Yeah. No, let me be clear. The bundle -- the pricing is based at the bundle level, and

that's also transparent.

So, as an example, breast cancer has seven bundles -- not 70 or 80. It's seven.

MR. MILLER: Mm-hmm.

DR. PECORA: All breast cancer fits into seven different bundles. There's adjuvant and metastatic bundles. They're based on one year -- and this was based on what CMS had discussed. In the adjuvant setting, it's one year's worth of care. CMS was, at least before, talking about six months' worth of care when it's metastatic. We're happy to do that --

MR. MILLER: We'll get to that in a second.

DR. PECORA: Yeah. We're happy to make it a year.

You price it at the level of the bundle.

MR. MILLER: Okay.

DR. PECORA: So what we would show from patients that were in that bundle, with all the description of what's in the bundle, including not just the oncologic care -- the colonoscopies, the mammographies, the plastic surgery. It's all defined in a list, list file, that people who come into this bundle, these are the things that they may receive.

At the individual patient level, you aggregate

that all together, and you take the average cost, I would imagine, and say here's what the cost is going to be for that bundle.

MR. MILLER: Well, that's the question I'm just trying to get precisely at.

So you're looking at historical information to set the price of the bundle.

DR. PECORA: Correct.

MR. MILLER: So the last year, 27 percent of the people were in CNA-A and 63 percent were in CNA-B, and you calculated an average price. This year, all of a sudden, 80 percent of the patients are in CNA-A. So you have a very different mix at the patient -- CNA patient level --

DR. PECORA: Right.

MR. MILLER: -- but they're all in the same bundle. Does the bundle price change?

DR. PECORA: So this is where you're getting into the issue. If it's just on the oncology level, no. If it's the comorbidity level, maybe. So if you had no patients with heart failure in one year and then 100 percent of your patients were in heart failure in a second year, those two populations are going to have a different CNA number, because heart failure is a comorbidity that matters. They would cost more.

So we have a suggestion of how to manage that, but we're open to a discussion about it.

MR. MILLER: Okay. So it sounds like you're saying there's a subset of CNA differences that might actually be used to re-weight the bundle and others that might not.

DR. PECORA: Correct, correct.

MR. MILLER: Okay. So I'm just going to keep moving so we don't run out of time.

So a third question, on the quality side, I think many people would argue that palliative care starts when treatment starts. It is not a binary choice between -- there's treated patients, and then there's palliative care patients.

So I guess the question is I'm not sure I understand how palliative care, the supportive drugs, et cetera, factor into this and what the quality measures are associated with this, because you were describing it as though, if you're getting treatment, "The only thing we care about is that you're getting the right treatment. And we don't care about anything else. We don't care what your level of pain is, what your level of emesis is, et cetera. That's all we care about, and it's only if you're in palliative care."

I'm sure you don't really mean that, but the question becomes -- to me is, if I'm getting treatment, I'm getting curative treatment, how is all of the other aspects of quality in terms of symptom management, et cetera, being factored into the model, and what's the penalty if you don't do that well? Are you saying that you won't actually take payment for the patient if, in fact, the quality metrics or standards aren't met, or what?

DR. PECORA: Well, if I said anything -- I'm a practicing oncologist. If I said anything to lead the Committee to believe we don't care about quality in any way, shape, or form in the curative setting, I apologize because that's not my intent -- or was not my intent. Of course, quality matters.

What I was describing was how we actually specified clinical outcomes that matter from an oncologic perspective and how they're different when it's curative intent versus non-curative intent. That was my intent for that.

MR. MILLER: So just focus on curative intent for the moment.

DR. PECORA: Yeah.

MR. MILLER: I want to understand kind of how -- what you look at quality-wise, and how does it affect the

payment, if at all, if the quality is poor?

DR. PECORA: Right. So we look at preservation of performance status throughout the treatment course. We look at the incidence severity of toxicities. We look at ER (emergency room) visits. We look at days in the hospital. We look at days out-of-work, and we have a patient-reported outcome tool that we use as a standard patient-reported outcome tool for quality. We also have Press Ganey for patient satisfaction. So that's the -- you know, and there's subsets in there.

MR. MILLER: Mm-hmm.

DR. PECORA: In regard to how it affects payment, we on the commercial side of this, will have a base payment that is based on the fee-for-service, and when we said shared savings, it was correct. That it's internal. It's not between -- and maybe that's a wrong terminology, and I apologize for that. It is -- the price payment from CMS to Hackensack Meridian Health is fixed. Internally --

MR. MILLER: Regardless of quality, you're saying? Even if you manage to deliver the right treatment within the bundle, if all of those other things you describe were poor, you would still get the same payment from CMS? That's the proposal?

DR. PECORA: We don't have to necessarily do

that. I don't want to be presumptuous. This is a proposal.

MR. MILLER: I understand, but I'm asking, in the proposal, you're not -- you don't have a methodology right now --

DR. PECORA: Right.

MR. MILLER: -- for that?

DR. PECORA: No. We have --

MR. MILLER: But you're saying you would be open --

DR. PECORA: Yes.

MR. MILLER: -- to having a methodology like that?

DR. PECORA: Yes. Of course, of course. Yes.

MR. MILLER: Okay. Let me keep going.

I'm concerned about the 12 months. I was -- I am very concerned about the six months in the OCM. I am less concerned about 12 months than six months, but I am concerned about any fixed period of time associated with that.

You also have an interesting difference in your 12 months from the six months in the OCM. Six months in OCM starts with the first chemotherapy. Yours starts with a pathology showing up somewhere.

So the problem is that if you pick a fixed period of time and say here's the bundle for the 12 months and then it's fee-for-service after that, there is an unfortunate incentive that could develop that says anything we can stretch out past the 12 months suddenly triggers fee-for-service. So I think it's a big problem in the oncology care model.

So if you have a -- you're on a chemotherapy regimen that would last five months, but if you end up stretching it out to seven months, it triggers a second bundle under OCM, and it triggers a second calculation on shared savings.

You don't have quite that structure, but you're basically saying, "Anything I can push past the 12-month point suddenly becomes fee-for-service and isn't in the bundle," and moreover, I guess I'm troubled by the notion that if one delays starting treatment -- let's say that there's 12 months of treatment needed, but you didn't start the treatment for a month after the pathology registered. You potentially saved some money because the last -- the 12th month would fall into the fee-for-service category because it fell outside the 12-month limit.

So I'm wondering why you don't just say the bundle is for the treatment, period, and you have an

outlier mechanism built into it. You have a mechanism that says if the patient has progressed, they're going to be re-bundled at that point, anyway, because they're no longer in the same CNA. But if they're in the same CNA and they take 15 months to treat, why not just say we're taking the bundle for the life of their treatment rather than this arbitrary 12-month cutoff?

DR. PECORA: Right. And I'll answer that question, and there was a lot of discussion that went into the OCM model. And this is oncology-specific.

So in the adjuvant setting, the vast, vast -- maybe 95 percent of care is done in the first year in the adjuvant setting, so --

MR. MILLER: Mm-hmm.

DR. PECORA: And that's where all the expense is, and it's dramatic.

In the subsequent years, it's routine follow-up. It's an office visit and maybe a scan. So the disparity in cost is like this. That's why you put it in the adjuvant setting in the first year.

In the metastatic setting -- and this is changing with the new immuno-oncology drugs and will become a factor in the modeling -- is by six months, with standard chemotherapy, most people have progressed and are now on a

whole new regimen of chemotherapy, very different. And as they go from progression to progression, they're getting sicker and sicker. So that's why six months was chosen in the metastatic setting.

I want to assure the Committee that in our standards, the time between pathologic diagnosis and initiation of therapy is a Tier 1 quality event, and it's actually in the OCM standards that you must start chemotherapy within a certain time frame. We have surgical specifications of the surgical requirements, number of lymph nodes, surgical margins. It's all in there.

MR. MILLER: But if the patient should choose, for whatever reason, that they couldn't start right away, what happens?

DR. PECORA: Yeah. I mean, if --

MR. MILLER: And I'll just close on this particular item, but, I mean, if 90 percent, 95 percent of the costs are in 12 months, then why not just say it's the full treatment? If they're going to transition to something in metastatic, they're going to transition to a different CNA, right, because they're not going to be -- unless I'm misunderstanding something, they're not going to be the same patient anymore, and the likelihood is that -- so it seems to me that you could resolve the concern about

potential cost shifting across arbitrary date boundaries simply by saying this is, in fact, based on the patient's characteristics, and we will do what is necessary for that patient's characteristics --

DR. PECORA: No disagreement. We were following the guidance that we had gotten from OCM, and not that they gave us guidance --

MR. MILLER: Okay.

DR. PECORA: -- but what was standard.

MR. MILLER: Final question. Is --

CHAIR BAILET: Harold?

DR. BERENSON: I just want to jump in very briefly. We actually were concerned about the length of the period and ran the -- and the data tables we ran pretty much demonstrated that at about eight months, the spending levels are off at a lower level, still higher than baseline, but close to baseline, certainly much more so than the first couple of months. So we were reasonably comfortable with the 12 months for these particular ---

MR. MILLER: Yeah. I think the issue is it's not that -- I mean, the retrospective look at anything tells you one thing, but the question is when you -- all of a sudden you make the payment depends on that, when it didn't before, potentially it changes behavior.

So the final question is you're basing the bundle prices on a historical look at what people in that CNA got before, but as Tim said, cancer care is changing constantly. And the interesting thing about this is, in some sense, you're slotting people into particular treatment lanes that are specified in terms of what they're going to get. Here's the drugs and the surgery, et cetera, that you're going to get.

So I'm curious as to why you don't just think about prospectively pricing it. So if you're going to be in Lane X, Lane X involves [unintelligible] surgery, a little bit of radiation or whatever -- you can price that at the Medicare payment rates for that. You can factor in an estimate of what you think the complication rate is. That we think we'll be able to do it with a 2 percent ED (emergency department) visit rate, and an ED visit rate costs X, and basically create a prospective bundle that everyone will know exactly is right rather than -- because I didn't see in here how you're updating.

You had a pass-through for new drugs, but you looked at historical stuff. But you didn't say, "Well, this thing costs more now," or, you know, evidence is changed, and it might require, you know, the following number of fractions of radiation rather than what it was

before, et cetera, which is one of the problems in the OCM is this complicated "We're going to somehow project forward to the future, something from the past," and OCM can't do what I just described because it's not precise enough.

You're precise. So you could actually say “What should this thing cost that we're planning to give to the patient?”

DR. PECORA: So the balance there is between patient, physician choice and doing the right thing, and that was a big part of the discussion and one of the key questions.

And I think in the beginning, we're more comfortable having it retrospective to look at physicians, what they did, and as long as it wasn't the wrong lane, medically wrong, maintaining that choice for physician and patients.

But I agree with you. Over time, as it becomes more and more clear and the evidence becomes statistically valid, that, "Yes, precisely for you, this is the right choice," I think that is a possibility. I'm not sure you could start there.

MR. MILLER: Okay. So could you briefly describe to me how you would update the bundle price for your prospective period from the retrospective analysis? Would

it simply be exactly what it was? Would it be updated for inflation? Would you do some adjustment based on changes in the Medicare payment rates for Physician Fee Schedule services, JCAHO (Joint Commission on Accreditation of Healthcare Organizations) prices, et cetera? I mean, because the methodology says we're going to have a lookback for the prior three years, but it didn't say what adjustment would be made from that calculation to the current future year.

DR. PECORA: We are open to a conversation about how precisely to do that. Because of the complexity and because of the novelty of this new model, we believe this should be a dialogue between us and CMS if CMS chooses to do this.

CHAIR BAILET: Thank you.

I'm going to just jump in here and ask Kavita – Dr. Patel has to leave, so I want to make sure she has the opportunity.

DR. PATEL: No, no. I don't have to leave.

CHAIR BAILET: Like I said --

[Laughter.]

CHAIR BAILET: You don't have to leave, but you want to make a comment.

DR. PATEL: So I had had a series of questions.

By the way, this is -- I know Dr. Pecora. We were in the same -- the same committees talking about the precursor to the OCM. I think it's amazing that we actually have like clinically grounded proposals, and this is emblematic of exactly kind of what you said, from kind of the frustrations of your practice and practicing in a fee-for-service system.

If you heard yesterday, we talked about how this is all open. We had not deliberated before. It occurs to me, in listening not just to the responses from Dr. Pecora, but what sounds like a very different take than I had in reading the proposal that this is generalizable, one. That this is not proprietary technology in the sense that there's publicly available domains and aspects and variables for which a similar -- not a CNA precisely, because I think that's trademarked, but whatever, something could be reconstructed.

It feels to me like, Mr. Chair, that this is in the category similar to our proposal yesterday, where there is enough changes -- or I'm hearing enough differences from what was presented in all the written materials.

So I had had other questions, but I'd rather just see if there's -- you can tell -- you can ignore me, but I wondered if the rest of the --

CHAIR BAILET: Kavita, never.

DR. PATEL: I wondered if the rest of the Committee or the PRT felt that way, because that's certainly how I'm feeling. And that would make me feel like we -- we can go through our process as we have it, but I'm just curious --

CHAIR BAILET: Right.

DR. PATEL: -- if there is a reaction to that.

CHAIR BAILET: So, at a high level, this is the check-in with the Committee, where -- what we're seeing from our vantage points.

DR. PATEL: And what's making me nervous as an individual PTAC Committee member is that I'm hearing enough about things that really were not reflected in what we have in front of us and feel like it would be up to the submitter's benefit to have that potential process, whatever that is.

So I'm just -- I did have other questions, but in the interest of --

CHAIR BAILET: Sure. Absolutely.

DR. PATEL: -- dealing with that, I'd rather just put that out there.

CHAIR BAILET: So, Len, you have a --

DR. NICHOLS: Well, now I feel compelled to

comment on that. To me, that's a discussion, once the submitters have backed up from the table, because that's a discussion about how we proceed.

DR. PATEL: That's fine. That's fine.

DR. NICHOLS: So I don't think this is the right time to get into that.

DR. PATEL: That's fine. That's fine.

DR. NICHOLS: Because I just had a specific question for the submitters --

CHAIR BAILET: Go right ahead.

DR. NICHOLS: -- and that is I'd like to hear a little more elaboration about the arrangements you have with other private payers. You mentioned Horizon Blue Cross. Tell me about where they are and what stage they're in and what exactly they're going to do.

DR. PECORA: So we have shared claims data and matched it up to colon, lung, breast, and rectal cancers, identical to what's being proposed here. We are in the analysis phase of data transfer, and we're starting simulation. So we're actually going to, theoretically, put people into bundles and make sure all the data transfers occur properly, and our goal is to launch in a prospective payment model.

It won't be precisely prospective in the very

beginning because of an issue with their ability to pay prospectively. It's an inherent issue they have to work through, and it's going to take them six months. But, ultimately, they're going to go to full prospective payment with us.

And we're going to start with breast cancer and do that for the first quarter and then do colorectal and lung in the second quarter and start, you know, start the program.

DR. NICHOLS: [Unintelligible] Horizon.

DR. PECORA: Right.

DR. NICHOLS: You mentioned some others. Are there --

DR. PECORA: Horizon Blue Cross.

Those are in earlier discussions, and I'm not at liberty to disclose them.

CHAIR BAILET: Rhonda.

DR. MEDOWS: I wonder if you can talk a little bit more about how the individual physicians are incented for quality, just in general how that plays in.

DR. PECORA: What we envision is similar to what we've already done with the MSSP-type programs, and that is that we will show the data of actually what they did --

DR. MEDOWS: Right.

DR. PECORA: -- and show them if they optimized it, what it could be in regard to development of a shared -- our internal shared savings program.

DR. MEDOWS: Right. So do they get an incentive if they perform or exceed?

DR. PECORA: Correct.

DR. MEDOWS: Okay. That's what I -- just a simple question. That's all.

DR. MENACKER: Just to give you a little bit of specifics, currently with our MSSP program, which we've been lucky enough to have shared savings each and every year, we look at the attribution list and the quality metrics, create a digital number for each individual physician, and distribute the physician portion based upon that multiple.

In looking at this, it's a little more complex because we're dealing with oncologists, cardiologists, surgeons, et cetera, and we will create a percentage of responsibility for that patient, match up the quality metrics, and then globally look at all of our physicians and distribute should there be excess above the fee-for-service dollars and a physician portion to each doctor.

CHAIR BAILET: Go ahead. Yeah.

DR. FERRIS: I just want to jump in to reflect

Dr. Berenson's comments earlier about the application of the Brandeis methodology in this situation, because what he just described is precisely the way the Brandeis grouper was described.

And the reason why I want to get those two together is there's still some controversy about doing that. So while that is a great description and incredibly laudable goal, I'm not sure we can point to evidence that that's ever been done, which is one of those things that would be reassuring to know from my perspective. So I just wanted to tie those two together.

DR. PECORA: I think -- and we put this in the proposal -- we have 3,500 physicians in our CIN (clinically integrated network), and it's growing. And we have -- we wouldn't be here if we hadn't presented it to our physician leadership, and they're very excited about doing this because of the precision of the data and that it's evidentiary-based. And they feel like we're paying attention to what really matters.

CHAIR BAILET: Harold?

MR. MILLER: I did have one more question, which actually is related to this point we were just discussing.

So I guess sort of a three-part question is, “To what extent have any of the savings you've generated in

your ACO come from oncology? What is it that you think you need this particular model for that you can't get simply by being in an ACO? And do you think that if this is done in other sites, they should or should not be part of the overall shared savings program?" Whoever wants to answer.

DR. PECORA: Morey?

DR. MENACKER: Our ACO for year 2016, which is where I just got the data, actually this week, we've got about 40,000 patients enrolled in the MSSP. Of that, approximately 15 percent have an oncology diagnosis.

It's very difficult to cull out the data to determine how much of that is active treatment, how much of that is a diagnosis that the patient has carried. So I can't specifically say how much savings was directly related to oncology.

MR. MILLER: So just as a quick follow-up on that, so it sounds like you don't have any specific strategy in the ACO to try to reduce spending for the oncology patients?

DR. MENACKER: Our strategy in the ACO has been general to primary care patients, and our success has been driven by our ability to provide direct hand-offs, utilizing care coordination. And a very similar program has been started by Laura Kudlacik in our Oncology

Division, almost using the oncologists as primary care providers for the active cancer patients and having care coordinators directly handing off the patients.

Our success has been driven by eliminating what we all know are avoidable emergency room visits, avoidable hospitalizations, and leakage, and I think that this is very important, being that Medicare patients have the opportunity to basically shop for their medical care. And what we've been able to provide by giving that hands-on care is minimizing the leakage for patients going outside of our organization, where we have much less control over the appropriateness of care.

And we're planning on utilizing the same strategy with the bundled payments, because we already do that with our oncology patients today.

MR. MILLER: Okay. So part two of my question, though, was so many people say, "Well, the ACO can just do all these things." So why do you think you need this payment model in addition to the overall shared savings model in the ACO?

DR. PECORA: I just think that oncology, many times it's a different group of doctors. The therapy is very periodic in a short course of the patient's life, and it's so specific and so different than the rest of medicine

and growingly that I don't know that it's practical to include it. I just don't think it is.

DR. FERRIS: I will again jump in maybe --

CHAIR BAILET: All right, Tim.

DR. FERRIS: -- as the PRT Chair, just to say that the vast majority -- just based on incident cancer in a population of 40,000, you're talking about a relatively small number, whereas, as an oncology referral center, this would apply to the vast majority of cancer patients going through.

So there are two Venn diagrams, as I see it, here, and the value of the system is that the very large Venn diagram of cancer patients going through Hackensack only intersects in a small way with -- is that --

MR. MILLER: I was just making sure --

DR. FERRIS: I'm trying to help out here. Sorry.

MR. MILLER: I wanted to make sure we have on the record -- because many people just say ACOs can just do everything, and so I wanted to try to be clear about what it is you think that the ACO cannot do that you need a payment model like this for.

So part of it is there's lots of patients that you treat through oncology that don't get attributed to the ACO or get effectively managed that way, and is there

anything about this payment structure that would help you in terms of actually managing the ACO for the patients who are attributed?

DR. MENACKER: Two ways, very clearly. The first is this is a total risk model, which our ACO has been relatively -- to jump into because physicians are -- you know, they tend to be risk-averse, especially on a financial basis when it's their money.

And the second piece is the concept of the precision medicine will totally change the focus of ACO savings policy. ACO savings policy is really eliminating waste. It's not about eliminating variability. This ability of utilizing resources that currently exist to eliminate variability is the second piece of creating more savings and decreasing total cost of care.

CHAIR BAILET: Elizabeth.

VICE CHAIR MITCHELL: Thank you. Thank you for this. It has been incredibly compelling to me to understand some of the promise of applying precision medicine.

But I'm wanting to associate myself with Kavita's comments regarding how we are evaluating this proposal today. So maybe for you as the submitters or for the PRT, the way I read this proposal is a single site with a

specific intervention.

What we're talking about, which is so promising, is a much broader application across multiple conditions, multiple sites, multiple systems, and multiple software.

So I guess I'm trying -- maybe, Mr. Chair, if you have thoughts on do we -- are we evaluating this proposal as a single-site pilot, or are we evaluating the much broader application? Because if it's the latter, I think we might need to revisit how this is proposed to us.

CHAIR BAILET: Tim.

DR. FERRIS: I associate myself with Len's comments. I think that's a matter for our discussion in our deliberation, because that's not a question that is being addressed to the proposers. And I think we should defer that question until we -- until we are in that phase of the --

CHAIR BAILET: Yeah. Well, we're almost at that phase because I'm about to explode.

[Laughter.]

CHAIR BAILET: Bruce?

MR. STEINWALD: I agree with that, but I --

DR. CASALE: What, that Jeff is going to explode?

MR. STEINWALD: You know, yesterday you said surgeons don't need biological breaks. I didn't understand

that then; I don't understand it now.

DR. NICHOLS: The first surgical procedure is to enlarge the bladder.

MR. STEINWALD: All right. So an issue came up after Tim's presentation and the discussion among PTAC members, which really does bear on this issue of generalizability, which is your model relies on a three-year lookback to your own patients in order to set prospective price, so it's kind of integral to the system that exists at Hackensack.

Two-part question. If this were to be implemented in another location, does that other location need to have a three-year or some kind of lookback in order to set prospective prices, or is there some other way it could be done? And how doable do you think that is outside of the Hackensack environment?

DR. PECORA: So from the medical perspective, no. I mean, when we see what the patterns of care were, because the patterns -- the standards of care are set nationally. They're not different in different locations, but cost of care may be, because if you're in a rural area and you have to travel a hundred miles to get your care versus if you're in the Upper East Side of Manhattan and you can walk to get your care, it's very different in cost and how care is

applied. So I think there might be a component if people are going to be comfortable that their local factor is incorporated.

And then we don't have enough data on this yet, but we're getting there. That the population itself may affect total cost of care. You know, if you have a certain mix of population that may or may not be -- have greater sensitivities to drugs -- that may differ than a more uniform population of patients that may not. So there are some nuances -- as you get into precision medicine, there are some nuances.

To do the three-year lookback, as long as you have a willing payer, the data is in the EHR. It is difficult if it's paper charts. You can't say it's not. I mean, natural language processing is coming up to speed, but it's not quite there yet. But if you have any EHR to get that data and to go to the primary sources, it's not that difficult with the technologies that are available.

So I think it is doable, and I suspect that most centers, most regions at least, would want to look back at what it is for them, given all the things I said, the specificities.

CHAIR BAILET: Seeing no other questions from the Committee members, I'd like to ask to take a 10-minute

break, and then what we'd like to do is then come back. And that's at the point for public comment. We have a few folks who have raised their hand for that, and then we will start the deliberative process.

But I want to compliment, first of all, your patience with us, as we have not only the process that got us here with the PRT exchanges, but also today and the attention and engagement all of you have with the questions that we're asking, which really are helping sharpen our thinking and focus on evaluating the proposal.

So thank you for your work, and thank you for working with us here today specifically.

So we're going to take a 10-minute break, and we will be back at -- Mary Ellen?

MS. STAHLMAN: 11:40.

CHAIR BAILET: 11:40. Thank you.

[Recess.]

CHAIR BAILET: Okay. We're going to go ahead and reconvene, please. Thank you.

This is the opportunity for public comment. We have two individuals that are registered. They're both here on site. I'm going to go ahead and start with Anne Hubbard from the American Society for Radiation Oncology (ASTRO).

* MS. HUBBARD: Good afternoon. Is this on? Great.

Again, I'm Anne Hubbard, director of health policy with the American Society for Radiation Oncology. We represent the nearly 5,000 radiation oncologists across the country who serve on the front lines in the fight against cancer.

Thank you for providing this opportunity to comment on the Cota-Hackensack Meridian Health model.

Before I speak about the model, I just wanted to make a couple of quick observations. I really appreciate that PTAC hosts these public meetings to review the proposed APMs. For those of us who are working on APMs, it's been helpful to see how others have gone about developing their models.

Two common themes seem to be revisited over and over again that I thought were worth pointing out. First, each model is patient-centric, and that's an indication of the clinical involvement in their development. After all, the providers who are involved have been committed to ensuring their patients get the right care at the right time in the right place.

To Dr. Mitchell's point yesterday, we have all experienced, either through personal experience or through

the eyes of a loved one, care that is poorly managed leading to poor outcomes. This is most frequently due to a health system that has misaligned values, which we hope to fix with these models.

Secondly, because these models are generated by clinicians, they lack the data analysis necessary to demonstrate savings and model success. I applaud Dr. Bailet for outlining these issues in his letter to Secretary Price, and I'm hopeful that they will result in additional resources for those of us who are really committed to transforming how health care is delivered.

Now to the Cota-Hackensack Meridian Health model. ASTRO is appreciative that the model uses the Cota CNA-guided care system to assign patients to specific care pathways based on clinical indications. We agree that the use of clinical treatment pathways can reduce variation in care and maximize efficiencies, while improving quality and outcomes.

However, it's not clear whether the models consider the role of radiation oncologists. This is important because most cancer patients are treated by radiation oncologists in addition to medical oncologists. The treatment plans described in the model do not include references to radiation oncology guidelines, but rather

guidelines from ASCO and NCCI (National Correct Coding Initiative), which are certainly appropriate as well.

We would ask that there be some transparency regarding the guidelines used in the pathways to ensure they give appropriate consideration of all cancer modalities.

Additionally, the model proposes to be inclusive of all costs, including surgery, medical oncology, radiation oncology, and clinical diagnostics, but it's not clear how those various groups would be aligned to coordinate care and how the model would reimburse them for their portion of the care delivered. If finalized, it might be best that the model initially focus on medical oncology services, rather than the full scope of cancer care. In the future, it could be linked to APMs for radiation oncology, surgery, and clinical diagnostics [unintelligible] to create a multidisciplinary approach to care.

Thank you. Any questions?

CHAIR BAILET: No. Thank you, Anne. Thank you.

MS. HUBBARD: Thank you.

CHAIR BAILET: Appreciate that.

Mallory O'Connor from the Biotechnology Innovation Organization. Hi, Mallory.

MS. O'CONNOR: Thank you very much.

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to make public comment before today's meeting of the Physician-Focused Payment Model Technical Advisory Committee for review of the Oncology-Bundled Payment Program Using CNA-Guided Care proposed model.

BIO is the world's largest trade association, representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations.

As detailed in our April 27th comment letter to PTAC, while we appreciate the intention of this model to focus on multiple facets of cancer care, we believe there are several hallmarks of alternative payment models that are critical to meeting the shared goals of ensuring patient access to appropriate treatment and sustaining future health care innovation, including allowing patients and providers to choose from the range of available treatment options and supporting the tailoring of care to individual patient needs, adopting to the evolving field of medicine in a timely manner and ensuring patients' access to new-to-market therapies, using quality measures that are

appropriate and meaningful to the patient population and APM [unintelligible], recognizing that current and future health care systems spending on prescription drugs can offset other costs over the short and long term, incorporating feedback from a diverse array of external stakeholders throughout the development and implementation of a model in particular patients, and increasing transparency in the model process by making methodologies and analyses used publicly available.

In order to ensure high-quality cancer care is provided to patients, we respectfully urge the PTAC to seek the following updates and clarifications to the model before its acceptance: release of additional information around model structure and incorporation of stakeholder feedback for model refinement, particularly in the areas of Cota Nodal Addresses into which patients will be grouped, and the update process for quality measures to ensure they keep pace with the latest recognized treatment guidelines; provide further specificity around the use of patient-reported outcomes, measures and integration of patient preferences into the model's design; updates to the total cost of care metric to ensure it appropriately reflects advancements in care and is not solely reliant on retrospective data; creation of a pathway for cost

estimates for new-to-market therapies or new indications for existing therapies that considers an exclusion from the total cost of care for the first two to three years on market; development of a means for providers to switch lanes of treatment to allow for greater flexibility and providing the best treatment based on progression of clinical care, while still giving providers the opportunity to benefit from shared savings; further clarity around whether or not participating providers can be part of concurrent value-based models and how to avoid confounding results; an assurance that stakeholder feedback and particularly active participation from patients is incorporated in updates and changes to the model.

We again thank PTAC for the opportunity to provide these comments and ask the Committee to make these important considerations. We look forward to future opportunities for engagement.

Thank you.

CHAIR BAILET: Thank you, Mallory.

Is anyone else on the phone registered to speak? I don't see anybody on the list. No? Anyone on the phone for public comment? No?

[No response.]

CHAIR BAILET: Okay. So I want to go back to how

we started the meeting, which was a conflict of interest, and I think it's important just to level-set that as we reviewed our individual positions on conflict with this particular proposal that there was no conflicts that were concluded, and that we feel like everybody on the Committee can fully participate in both the deliberation and voting if that's where we decide to go.

So I'm now going to ask the Committee if we are ready to deliberate at this point or any other comments before we begin that.

Tim?

DR. FERRIS: I move to start deliberation.

MR. MILLER: Second.

CHAIR BAILET: All in favor?

[Chorus of ayes.]

CHAIR BAILET: Any opposed?

[No response.]

* CHAIR BAILET: All right. So we're going to go ahead, then, and start the deliberative process. Anybody want to kick it off?

I'm looking at you, Elizabeth.

VICE CHAIR MITCHELL: Sure, I'll start.

I would go back to the point I raised earlier in that there seems to be a lot that is compelling about the

issues that we just discussed and their broad application, but it is less clear to me that this particular proposal gets us to those bigger issues, because this still seems narrowly focused on a single site, and we don't even have feedback yet on whether or not limited-scale testing is going to be an option. And this is particularly limited scale.

So I am very intrigued and compelled by the promise of this but believe that we are not ready to consider it as a proposal for recommendation.

CHAIR BAILET: Harold?

MR. MILLER: I didn't get a chance to put my card up.

I guess as I think about it, there -- an applicant who comes in is, in some ways, inherently only able to say, "I have my hand up," in many cases, and we have talked in the past about whether we should expect applicants to bring in other potential applicants or not and decided that if they can, that's fine, but it's not necessary.

In listening to the discussion and asking the questions of the applicant, it didn't strike me that -- and others may disagree, but it didn't strike me that there was anything about what they were proposing that was inherently

limited to being done there. In other words, if, in fact, one would decide to try to do this, to test this model, if there were others who were similarly willing and capable, which I think there certainly could be around the country, that it could be done in multiple sites. So it didn't seem to me as to be something that was, by definition, only able to be done in this one site forever, in which -- because, in that case, I think it would be inappropriate, but -- so that then says we have discussed in the past that for many kinds of models that come to us, particularly those that are more complex and move farther away from the current system, that there is likely going to need to be a period of time in which the parameters of the model will need to be developed.

And it is difficult to develop the parameters of the model accurately without actually doing the model, which is why we had talked about the notion of limited-scale testing, was that you could have people go off and do analyses, you know, for the next 20 years and never be able to bring numbers and things that were comfortable for everybody to say, "Yep. You got it all worked out. Let's go and simply do it."

So, my personal feeling is this is one of those models that has lots of stuff that has been worked out. I

think that there are some pieces of it that -- more pieces of it that could be worked out before it gets tested anywhere than have been worked out, similar to some of the things that we talked about with the proposals yesterday, but there are other significant pieces of this that I think could not really be worked out until you actually did it somewhere.

So, I guess when I look at it, I don't see it as being something that is really a single-site model. I see it as something that is a potentially expandable proposal, national [unintelligible] expandable ultimately, that would need to be tested on a limited scale and would need to be ideally tested at multiple sites.

I think that, further, I would say when we talk about limited-scale testing, it's limited scale. Now, if you had one oncology practice with two docs and 20 patients coming in and saying, "We want to test this," we would say it wouldn't work. What we have is an applicant that has some scale. So I think the question would be, if only they were willing to sign up for the test, would that be a problem?

My personal sense of that is no, but that's different than saying that the model would be implemented only for them. CMS might say we want to do limited-scale

testing on this. We're going to make this open to anybody who wants to be able to do this, and if other sites sign up, fine. And if others don't, that's fine, too. But the nice thing is -- to me is that you have at least one site of scale that wants to be able to do something that, if it is workable, could be expanded more broadly.

So I personally feel comfortable. My view of this would be to treat this as a not-fully-specified payment model that could be used broadly but needs a lot of specification and vote on it that way.

CHAIR BAILET: Len?

DR. NICHOLS: I concur with Harold. I think there's at least as much promise here as was in the ACS (American College of Surgeons) model, and we tried to push that forward. There's actually maybe less uncertainty here. There's some technical details that have to be worked out, and they're going to have to be worked out, whether you do it just in Hackensack or whether you open it up to more. It seems to me while I take the point that stuff has changed since the original proposal came in, to me less has changed than we have learned about the flexibility on the ground in Hackensack, and the development that's got to be done independent of what's changed is still there. There's a lot of infrastructure

here.

Personally, I'm inclined to think it's worth investing in, and so that's why I would rather have us go ahead and make a determination about whether to recommend today rather than wait.

CHAIR BAILET: Thank you.

I think Bruce and then Paul and then Tim and then Kavita.

MR. STEINWALD: I generally agree with Harold and Len. I mean, putting aside what's in the Secretary's letters and what John talked about this morning, if we were just applying logic, although that's always risky, it would be logical to test the concept at the site that has the most experience with it.

We have already pointed out -- and they have acknowledged -- there are a lot of details that need to be worked out.

But I guess we would want to be explicit and satisfy ourselves that it was feasible that the model, if it were to be implemented on a limited scale and certainly one site -- even though it's scaled, it's one site -- explicit about the hope and the expectation that it could be expanded.

And then, therefore, the scope of work at the

site, the limited-scale testing site, should be explicit about not only what details need to be worked out to make this work well at Hackensack, what additional details need to be worked out to make sure it could be expanded to other sites, and that could potentially include more than just cancer. And so I think that kind of frame of thinking ought to be part of our deliberation.

CHAIR BAILET: Thank you, Bruce.

Paul?

DR. CASALE: So one area I'm struggling with and I would appreciate -- is, again, still back on this Cota, and looking at this model at Hackensack, which is using Cota, I think -- and maybe it's not correct -- I think a little bit back to Sonar, when we were talking to Sonar, right? And we said, you know – "these are guidelines from the American Gastroenterology Association" was Sonar's response. Anybody can do it, you know, sort of, and can replicate it. And so I don't want to bring in the Secretary's comments, but, you know, that is part of this, so what is proprietary and what is potentially not proprietary?

And there was a discussion. I mean, I know the PRT had several pages back and forth where, you know, that question was asked: If others participated in the model,

you know, do they need to use CNA? And Dr. Pecora initially said, "They can't because, I mean, this is our model." So that's why I'm -- so, and then it went on to, well, they probably could, blah-blah-blah, and then, ultimately, Tim said, "Just to be clear, we're not exactly sure what the answer is here."

So, I guess I'm still stuck on this, and I would appreciate others giving me some sort of guidance on this of, yes, others can sort of replicate it, but do we have enough information now to sort of just take that on faith, or do we need to sort of really understand this, if we're going to view this as a generalizable model, as opposed to this as a Hackensack model?

You know, I get it, if this is just a Hackensack model, then they're using Cota – then that's it, but I'm having a little trouble with the generalizability, given this issue around Cota.

CHAIR BAILET: I'm going to -- you know, if someone who has their card up can speak specifically to Paul's question, otherwise, Harold, you can.

MR. MILLER: Well, I'm not sure answering it, but I have a -- if you want us to stay on that point.

CHAIR BAILET: Yeah. Right.

MR. MILLER: I guess, as I think about it, when I

-- it isn't totally completely clear to me at this point exactly what is proprietary and what is not, but I heard a statement that says that a lot of what is proprietary is simply simplifying the process of attaching a patient to a particular category.

If, in fact, we were to suggest that this needs limited-scale testing, having some kind of an approach to being able to do that patient categorization and slotting into treatment lanes efficiently already in place would facilitate the process of limited-scale testing, because you could say, "We don't have to try to develop something like that. There's already something like that."

What you wouldn't want to do, though, is be testing it in a way that was dependent on that particular system.

We talked about the fact that there might be other competitor systems. There probably isn't anything, maybe -- I don't know -- at the moment that does exactly this. If there were -- this thing was being tested, it would be a signal to potential other people that they might want to be thinking about creating alternative approaches to be able to do the same thing, such that whenever this was ultimately expanded, that people would then have the choice of which to do it, because I still -- fundamentally,

what I'm hearing is that this is not really -- it's not dependent on CNA's digital classification, per se. It is based on being able to take patient characteristics and then appropriately put them into treatment lanes -- I'll use their term -- for effective patient management.

So the only thing that sounds to me -- again, I don't know -- I'm not them, but this is what I heard. The only thing that is proprietary is a particular piece of software that facilitates the process of getting from known patient characteristics into a treatment lane that is defined by NCCN, ASCO, ASTRO, whomever it is that's defining that. And it could be done using a different tool, if a different tool was available.

So, anyway, I don't -- just like I don't see that this is -- even though it's been defined as a one-site model, I don't think it has to be a one-site model, and at least what I'm hearing tells me that while it's using a particular proprietary tool, it would not have to, if it was scaled, use that same proprietary tool, which to me means it would be okay on that regard in the long run.

CHAIR BAILET: Thank you, Harold.

Tim?

DR. FERRIS: So, on that point, I think I'm going to take a different view from Harold, I know at my peril,

because I actually agree with everything that Harold said about conceptually not -- you could do this, but there's a process here that I believe we have to adhere to. And we have a proposal in front of us. And that proposal actually specifies very specifically that they are going to use CNAs to create the prices, right?

And so, as proposed, I think it would be possible, if I were to do the thought experiment, to take any proposal -- any proposal, no matter how specific -- and to come up with generalizable criteria that would allow us to say this could be done anywhere.

But I feel, maybe incorrectly, constrained by what I believe our task is, which is to evaluate the proposal that's in front of us and not invent a potential future proposal. Maybe that feeling of constraint is inappropriate; maybe it's appropriate. We can have that discussion, but I'm not finished.

[Laughter.]

DR. FERRIS: The second thing is the fact that it did come from a single site and we had some commenters point out the fact that there are national associations that would like to be involved in the process of presenting a model along -- so endorsing the idea of -- and I love that -- maybe coined here first by Dr. Berenson -- you

know, precision payment to go along with precision medicine. Maybe if there was a sound bite to come out of this, that would be it.

DR. BERENSON: That's what I was working.

DR. FERRIS: And Bob. That's you.

Endorsing the notion of precision payment, we can clearly endorse that notion and commend the submitters for an extraordinary job of providing us with a specific example of how one would do that and still potentially say, “you know, not quite ready for prime time,” and we would hope there would be a path to getting to a viable proposal. I don't know that limiting -- limited-scale testing is actually the next step, from my perspective, for this.

To me, it feels like the next step is actually more of a bigger group of oncologists coming together and proposing something that looked on its face, as written, as more generalizable. That might be the next step. So I would say that there are potentially multiple paths to the next step.

So those are my -- that's the constraint that I'm feeling around what our job is, and as we've pointed out many times, we're making this up as we go along. So I look forward to the discussion from those points.

CHAIR BAILET: Len?

DR. NICHOLS: So now that Tim has described the constraints he feels compelled to operate under, I want to put out a potential definition of our job here. I think the definition of our job is to recommend to the Secretary, yes or no, whether this thing is worth developing with the resources of CMS to help, or whether it should wait for further development outside.

I feel constrained to say other oncologists should join the party until we make the basic determination: Is it ready for CMS now or not? And that, to me, is what we're about, and that's what I think we could do, hopefully helpfully, in defining the contours of the constraints that we believe would be optimally relaxed but with CMS in the room or not. And to me, that's really why we're here: Is it ready for CMS or not?

CHAIR BAILET: Elizabeth and then Harold.

VICE CHAIR MITCHELL: On that specific point, I think that's what I'm most interested in, and I would just like to ask the PRT: Did you evaluate it on the merits of the specific proposal, or were you thinking about broader generalizability? And where would you land on that?

DR. FERRIS: [Unintelligible] We struggled with the dynamic that we are dealing with right now in this discussion. We really struggled with that, and we -- I

will say from my part, I voted on the criteria, basically giving the benefit of the doubt on all of that long list of concerns of things that hadn't been worked out that, gosh, that could be really, you know, troublesome and problematic, depending on how things played out, but sort of with the assumption that we could imagine a conceptual world in which a model like this could be done without the Cota system, so in complete agreement with the discussion that we just had and the responses to the questions.

But then, you know, on the other hand -- and there is that joke about one-armed economists that I won't refer to because you guys wouldn't look so good, but on the other hand, we balance that against the fact that, as written, this did not meet the criteria of, like, it's ready to go. So it’s a real -- this is an inherent problem. This isn't the first time it's come up. This is one of those moments where I believe I feel some palpable excitement about the conceptual issues that are raised here and how these conceptual issues could advance payment to the betterment of the health of the population of the United States, just to say it, as one of our commenters did.

And so we are struck with the dilemma of what then, to Len's point -- you know, at the end of the day, we

have to sort of say go/no-go, and we are caught between a dyadic outcome and a complex set of issues associated with a really well-thought-through proposal and how to take this complex set of issues and run it through sort of a yes/no, without injuring all the potential, but also not inflating the -- what's actually written down on the paper here.

There is this saying that the longer your answer, the less sure you are about what you're saying, so maybe --

CHAIR BAILET: That would be a good time to transition to Bruce.

MR. STEINWALD: Yeah.

Tim, aren't there any one-armed internists in the world?

[Laughter.]

MR. STEINWALD: I'll start out by kind of turning it around and saying I don't think the PRT would have scored the proposal as it did if it believed that the only potential implementation of the model would be at Hackensack Health System with the Cota system and never any future beyond that.

So we did talk about a number of different ways that there could be expandable -- including licensing Cota, maybe making it publicly available, similar to ACS Brandeis, so we could see through a glass darkly that there

certainly would be expansion potential of the model. And I think that was kind of inherent in the way we evaluated it.

We do have the dichotomy that Tim mentioned, on one hand and the other hand, but at the risk of making my answer as long as Tim's, I'm going to stop.

CHAIR BAILET: Robert.

DR. BERENSON: Yeah. So, you know, I'm looking a little bit at our precedence of what we've already recommended and also at the kind of responses that the Secretary has given.

I guess -- and let me read just one sentence from the response to Brandeis -- I'm sorry -- to ACS Brandeis -- is – “we must think creatively -- we must learn from health” -- no, that's not the sentence I wanted to read. This is the sentence I wanted to read: "To address design concerns before HHS makes a final determination about testing this proposed model." Now, one, they used the word "testing," and I don't know whether they're using it in a generic sense or whether they sort of envision something like we were proposing, like limited testing, but they didn't use the word before deciding to have a demonstration.

But the point is, as we heard from Mai Pham a long time ago, there's 26 steps that CMMI has to go through

before they even make a decision whether to proceed. I think we have a threshold issue, which is, “Is this a model that has enough potential, realistic potential, that the Secretary and ultimately CMMI should take this very seriously and try to work with it?” In that sense, I think the precision part of this is so much superior to the OCM model that it is in the ball park of, yeah, we should try to figure out how to do this.

I thought some of the design approaches didn't make sense to me as a former CMS payer. I don't think we go and figure out every provider's costs in a three-year lookback to decide -- we tend in Medicare to equate payments with costs, and so there were things -- there would be a number of things that I think would be done differently.

The question is, “Does this sort of pass the threshold of this is a serious proposal to perhaps have a real new kind of payment model as opposed to some of what we have been seeing, which are not really innovative and creative in this way?”

So -- and, specifically, in responding to the question of did we consider this to be generalizable or not, I agree with just what Bruce said. We would not have proposed high marks for this if we thought this could only

apply to one institution. We had enough confidence, even though the answers tended to be equivocal at times and even contradictory at times, that this could be scaled to much broader than Hackensack. So, that's where I would come out, is I think it probably is something we want to recommend.

CHAIR BAILET: Thank you, Bob.

Harold and then Paul.

MR. MILLER: It seems to me there's four questions that were sort of -- just to try to be clear, at least what I'm hearing. One is, “Is this permanently a one-site model?” Is this permanently dependent on a particular patented technology? Is this -- does this proposal need refinements that -- before we can make a judgment about that the applicant could make, and does this proposal need refinements that can only be made if it's actually tested on a limited scale?

Because on the third point, I agree with Tim, and essentially, we shouldn't be trying to imagine what a proposal should look like and voting on it based on that, if, in fact, the applicant could fix some of those things, because that might be an argument, as we talked about yesterday, for bringing us back a better proposal.

The one thing I did want to say something more

about, though, is this proprietary technology issue. I guess if one thinks about what we are trying to do here is to enable a process for grassroots development of payment models, as a fundamentally different approach than the traditional approach of Medicare-designed payment models that then other people had to follow.

That puts a lot of burden on entities out there, and we said from the very beginning that we did not want this to be designed -- the process designed -- in a way that deterred small practices, independent practices from being able to do something because of lack of resources, but if you look at past payment systems, Medicare created RBRVS (resource-based relative value scale) and funded -- I don't know, Bob, how much they spent, but probably a lot of money to be able to develop the RBRVS system. They paid 3M to develop the DRG system, et cetera.

And to some extent, all of those things retain some proprietary elements today in some fashion. I mean, CPT (current procedural terminology) is copyrighted by the American Medical Association. DRGs are essentially -- you're still buying something from 3M. I don't exactly know how all that works, but I think -- and as I think back on the old episode grouper process, there were commercial episode groupers out there that people were using and

saying this seems to be a good idea to do something like this, and then Medicare said, "Okay. There needs to be something like that, but it can't be proprietary, so we'll develop one."

And so I guess I'm sort of -- I look at this, I'm thinking that that is not kind of special to this thing that we're imagining that that could be the process. It, in fact, would be parallel to other things in the past, and if somebody brings in one thing and you say let's test it that way, and then if it's good enough, there might need to be some other process to develop a less proprietary version of that in the long run.

But I do think if we're going to be realistic about this idea of having people bring us anything more than very simplistic models, that where are they exactly going to get the resources to be able to do that, and if some proprietary entity essentially puts some capital into that, I don't think we can just in this initial stage blow that off and say, "No, no, no. I'm sorry. We don't want proprietary things initially because of that," because the answer is going to be where exactly are we going to be able to get the resources to develop something like that until it's actually in place?

So I do think we have to factor the notion of who

these things are coming from in that evaluation.

CHAIR BAILET: Paul.

DR. CASALE: So sorry. So I'm still struggling, but with the comments from the three PRT members -- and I'm -- again, is this a one-site model versus generalizable in terms of your thinking? You know, I'm thinking when Tim did his presentation, I think it was on quality and cost, and Kavita said, "Well, you know, you have like three things for pros and like 10 things for con." And I think, Tim, you said, "Well, you know, if it's one site, you have all these weaknesses, but you can work them out because it's one site."

So, again, I go back to what am I going to be sort of voting on, because in the presentation, it seemed it was the one site. I didn't hear so much around -- even on the strengths and weaknesses related to generalizability. So if others can help me out, it would be appreciated.

CHAIR BAILET: Any -- I mean, maybe I'll -- maybe I'll make a comment. The lens in which I'm looking at this is we have to -- we have to address what's been put in front of us, and we can extrapolate, and we can hook on other potential, you know, guesstimates, recommendations, expansive suggestions. But at the end of the day, what we

have in front of us is what we need to deliberate on and then determine next steps.

There's a lot of very novel, in a positive way, aspects of this proposal that transcend oncology, potentially, and we are at the interface between the laboratory of clinical stakeholders striving to move towards value, and that's what is in front of us today.

And I want to make sure that in the spirit of how we stood this Committee up a year and a half ago, we wanted in our commitment to the stakeholders, where we were going to be transparent, we were going to be inclusive. We were going to be trying to illuminate and encourage, as best we can, the clinical stakeholder community bringing proposals that are promising forward, and then we need to complete -- as Len said, we need to complete the charge that we were given, which is to make a recommendation.

Where we sit today, we have a proposal, and we have four options if we decide to consider this proposal in which to filter this. We can say we're not going to recommend it. We can recommend it for limited-scale testing, and that's in our own frame of reference. That question is still unanswered. And then we have the other two, which are to recommend it or recommend it with priority implementation. So that is our process today, and

I think as we did yesterday, it is their proposal. It is not our proposal, and so while we have been very critically evaluating it, at the end of the day, it is still their proposal. And it's constructed, and that's what we -- as they have written it, and we need to be true and remain true to that.

So I think we're going to have to make a decision about where we are in the curve of our process. There's the deliberation piece, and then there's the next step. And I think we're right at that interface. Perhaps Bruce has the clue to the Gordian Knot.

MR. STEINWALD: I'm going to just make a brief comment that we've made before, is that our report has to include a recommendation, but it also includes comments. And we can fully explain all of the concerns and issues that were raised in this conversation in our comments part of the report.

CHAIR BAILET: Thank you for reminding us of that, Bruce, and so then I would sort of maybe reframe where I was going and turn it over to Len. But given that -- given the option that we have as a committee, we have the ability to inject our thinking behind our position that we ultimately take. That affords the Secretary and CMS to take that in, and at the end of the day, we know it's their

determination. I mean, our recommendation is our recommendation, but ultimately, there's another step in this process.

But I guess I'd go to Len and say --

DR. NICHOLS: That's what I was going to remind us of, that I look at this, just to get back to Paul's plea, help me think through this here -- friend, Paul, here's what I would say. This is not the end. We have to -- we can be the end, or we can push it down the road, and it seems to me that -- to me, the threshold question is, Can there be enough potential to merit the attention and resources of what the Secretary and CMS can bring to bear? And that's where to me the very long list of concerns that were attached to, say, the payment methodology, which is what I always focus on, you would have to work those out if you're doing it at Hackensack. You would have to work those out if you're doing it in 12 places in a bona fide RCT (randomized control trial). You would have to work those out to make it a program.

In my opinion, the clinical dimension of the value-add is sufficiently strong, deferring entirely to my physician colleagues. Hey, you all think this is cool, then I can see how we could make the payment model work, but it's going to require investment by CMS. Our judgment

is, “Is that investment worth it or not?” And that's really -- that's all there is to it.

DR. FERRIS: I move to proceed to start the voting process.

DR. BERENSON: Second.

CHAIR BAILET: So we have a motion and a second. Any other further comments?

[No response.]

CHAIR BAILET: So we're going to call the question. Are we ready to then proceed with voting? Do we have an all-in-favor?

[Chorus of ayes.]

CHAIR BAILET: Any opposed?

[No response.]

CHAIR BAILET: So we're going to proceed, but I want to make sure what we're voting on. We're voting on the proposal as it's constructed, not our interpretation, but as it's constructed and as it's presented, that is the proposal in which we are going to go through our process, right? Okay.

MS. PAGE: All right.

CHAIR BAILET: All righty, then. So what we do the first phase -- and I'm going to lead this part of it -- we are going to vote with an electronic device and go

through all 10 criteria, and you can see the numbers here: 1 to 2, does not meet; 3 to 4, meets; 5 to 6, meets and deserves priority consideration.

I'm going to defer to Ann Page, who is the Designated Federal Officer supporting this Committee. She will then summarize each one of our outcomes relative to voting, partly because it needs to be on the record, but also there are people listening around the country, and they're not here. So we need to make sure the results are verbalized.

So, first criteria, is the proposal -- scope of the proposed PFPM. Does it aim to broaden or expand CMS's alternative payment model portfolio by either addressing an issue in payment policy in a new way or, 2, including alternative payment model entities, whose opportunities to participate in alternative payment models have been limited? This is a high-priority designation, based on the perspective of the Committee.

Are we ready to vote?

[Vote in process.]

MS. STAHLMAN: There you go. That's always the one more.

CHAIR BAILET: Right. So there are 10 people voting, and then the monitor is the 11th individual, so,

Ann?

* MS. PAGE: Zero members have voted 6, meets and deserves priority consideration. Three members have voted 5, meets and deserves priority consideration. Five members have voted 4, meets. Two members have voted 3, meets. The Committee's decision requires a majority of votes, and that would be six votes, and so the Committee has determined that this meets Criterion 1, scope of proposed.

CHAIR BAILET: Great. Thank you.

Criterion 2, quality and cost, which also is a high-priority designation. 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. So we're going to go ahead and vote.

[Vote in process.]

* MS. PAGE: Zero Committee members have voted 6, meets and deserves priority consideration. One Committee member voted 5, meets and deserves priority consideration. Five members voted 4, meets. Four members voted 3, meets; and zero members voted 1 or 2, does not meet. The majority finds that the proposal meets Criterion 2.

CHAIR BAILET: Thank you, Ann.

We're going to go to the third criterion, which

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

Let's go ahead and vote.

[Vote in process.]

CHAIR BAILET: If someone could hold -- there we go. Wow.

* MS. PAGE: Zero members voted 6, meets and deserves priority consideration. One member voted 5, meets and deserves priority consideration; zero members, 4. Eight members voted 3, meets, and one member voted 2. The majority find that this proposal meets Criterion 3, payment methodology.

CHAIR BAILET: Thank you, Ann.

We're going to go with Criterion number 4, which is value over volume: The proposal is anticipated to provide incentives to practitioners to deliver high-quality health care.

[Vote in process.]

* MS. PAGE: Zero members rated this as 6, meets and deserves priority consideration. One member voted 5, meets and deserves priority consideration. Three members voted 4, meets. Four members voted 3, meets. And two members voted 2, does not meet. Zero members voted 1. The majority find that this proposal meets Criterion 4, value over volume.

CHAIR BAILET: Thank you.

Criterion number 5, which is flexibility: provides the flexibility needed for practitioners to deliver high-quality health care.

[Vote in process.]

* MS. PAGE: Zero members voted 6, meets and deserves priority consideration. Two members voted 5, meets and deserves priority consideration. One member voted 4, meets. Four members voted 3, meets. Three members voted 2, does not meet. And zero members voted 1, does not meet. The majority finds that this proposal meets Criterion 5, flexibility.

CHAIR BAILET: All right. Criterion number 6, ability to be evaluated: have evaluable goals for quality of care, cost, and any other goals of the PFPM.

Let's go ahead and vote.

[Vote in process.]

* MS. PAGE: Zero members voted 5 or 6, meets and deserves priority consideration. Two members voted 4, meets. Six members voted 3, meets. Two members voted 2, does not meet, and zero members voted 1, does not meet. The majority finds that the proposal meets Criterion 6, ability to be evaluated.

CHAIR BAILET: All right. Thank you.

Number 7, integration and care coordination: encourages greater integration and care coordination among practitioners and across settings where multiple practitioners or settings are relevant to delivering care to the population treated under the PFPM.

[Vote in process.]

CHAIR BAILET: One more time. Here we go.

* MS. PAGE: Zero members voted 5 or 6, meets and deserves priority consideration. Four members voted 4, meets. Four members voted 3, meets. One member voted 2, does not meet, and one member voted 1, does not meet. The majority finds that this proposal meets Criterion 7, integration and care coordination.

CHAIR BAILET: All right. Criterion number 8, patient choice: encourage greater attention to the health of the population served, while also supporting the unique

needs and preferences of individual patients.

[Vote in process.]

* MS. PAGE: Zero members voted 5 or 6, meets and deserves priority consideration. One member voted 4, meets. Four members voted 3, meets. Four members voted 2, does not meet, and one member voted 1, does not meet. We don't have a majority, so I think there may need to be a --

CHAIR BAILET: So let me, just as a point of order -- one of the -- this really hasn't surfaced before, but one of the options we discussed and one of the reasons that we have this voting methodology was to look at our thinking in front of us and then ask a clarifying question. If I went back, there's a couple of criteria where we have a very divergent perspective, like the last one, I think. And I'm wondering whether we should call when we see that, whether we should call that out and have a bit of a discussion around that.

This is obviously one we're going to have to discuss, but I'm just -- I would suggest that we probably have to revisit that and understand. I mean, that was clearly a very divergent perspective on that.

So we are going to have to discuss and potentially revote. Does anybody want to talk about their rationale for coming down, one way or the other?

Harold?

MR. MILLER: Well, I was persuaded by the PRT's argument on this that there was really not a specific process for shared decision-making, patient input, et cetera, that there were clearly choices and some potential approaches that could be used in the model to do different things that might be done today, but that it didn't have the proper mechanism in it for being able to assure that.

And I guess my view was it wasn't just sort of tweaking payment methodology. It was sort of a more fundamental missing element in some ways, so that was why I was a 2.

CHAIR BAILET: Anyone else?

Bob?

DR. BERENSON: So I came down on the 2 side because of the concern that it's not explicit. The words are right when you talk about patient choice and involving the patient, especially when it's palliative care, but I'd like to see something explicit, real process that is followed. If the culture is such as described, then they should be able to describe that in an improved document or as they go forward.

CHAIR BAILET: Bruce. And then we'll go ahead and revote.

MR. STEINWALD: Yeah. I was a 3. In large part, you're making a distinction between comments from the proposer that explain versus comments that seem to make change. I was more moved by the explanation of what already exists. Then move me up from a 2 to a 3.

CHAIR BAILET: All right. So let's go ahead and reset on patient choice and take another crack at it.

[Vote in process.]

CHAIR BAILET: Well, it's called deliberation.

MS. PAGE: Zero Committee members voted 5 or 6, meets and deserves priority consideration. Zero members voted 4, meets. Two members voted 3, meets. Eight members voted 2, does not meet, and zero members voted 1, does not meet. The majority has found that this proposal does not meet Criterion 8, patient choice.

CHAIR BAILET: Okay. Can we go backwards? Can we go back to 7 and just take a look at that again? No?

PARTICIPANT: You're the Chair.

CHAIR BAILET: No?

MS. STAHLMAN: We have the majority.

CHAIR BAILET: Like I said, we had the majority. I don't know what I was thinking.

PARTICIPANT: You want to go forward to 9.

CHAIR BAILET: I did say forward.

We're going on to number 9. Yep. There you go.

MR. MILLER: [Speaking off microphone.]

CHAIR BAILET: Thank you, Harold. Patient safety, number 9. How well does the proposal aim to maintain or improve standards of patient safety?

[Vote in process.]

* MS. PAGE: Zero Committee members voted 6, meets and deserves priority consideration. One member voted 5, meets and deserves priority consideration. Three members voted 4, meets. Five members voted 3, meets. One member voted 2, does not meet, and zero members voted 1, does not meet. The majority of members vote that this proposal meets Criterion 9, patient safety.

CHAIR BAILET: And number 10, health information technology (HIT), encourages the use of HIT to inform care. Let's go ahead and vote.

[Vote in process.]

* MS. PAGE: Zero Committee members voted 6, meets and deserves priority consideration. Seven members voted 5, meets and deserves priority consideration. Two members voted 4, meets. One member voted 3, meets, and zero members voted 1 or 2, does not meet. The majority finds that this proposal meets and deserves priority consideration on Criterion 10.

CHAIR BAILET: All right. So, Ann, do you want to summarize of the 10 criteria, where we are here?

MS. PAGE: Yes. The Committee found that the proposal met eight of 10 criteria, and on one criteria did not meet the criterion on patient choice, but on the tenth criteria found that it met the criterion and deserves priority consideration on the criterion for health information technology.

CHAIR BAILET: All right. Thank you.

So now the next step in our process is determining a recommendation to the Secretary. We have four options. We're going to vote. First, we will vote electronically, but then we will go individually around one at a time and be very specific about, A, how we voted, but also the rationale and any comments that we would like to incorporate with our determination for the recommendation.

We have four options in front of us, and they are -- the first, which as I've said, do not recommend that the proposal be considered. The second option is limited-scale testing, that the proposal be evaluated and considered for that. Implementation is the third option, to proceed with the payment model, and then the fourth option is implementation to proceed as a high priority. So those are the four options, and the numbers, I believe, are 1 through

4.

We have 10 people voting, and this particular criteria -- remind me. Is it two-thirds?

MS. PAGE: It requires --

CHAIR BAILET: So it's two-thirds that carries the day.

MS. PAGE: And we will roll down the votes until we have the votes of seven. So if a few members give it a higher score but it doesn't reach a two-thirds majority of seven, we will go down to the next category until we have reached a two-thirds majority of seven votes.

CHAIR BAILET: All right. So we're ready to proceed. I'm seeing a lot of head nods here.

All right. Then --

[Vote in process.]

* MS. PAGE: We have 10 votes. One member has voted do not recommend proposed payment model to the Secretary. Nine members voted to recommend proposed payment model to the Secretary for limited-scale testing, and zero members voted 3 or 4, which would be recommend for implementation or recommend for implementation as a high priority. So the two-thirds majority of the members have voted, and the PTAC's decision would be to recommend the proposed payment model to the Secretary for limited-scale

testing.

* CHAIR BAILET: Thank you, Ann.

So, at this point, what we are going to do is go around and verbalize our position and then include comments that we want to be incorporated into the Secretary's recommendation, starting with you, Tim.

DR. FERRIS: So start off with the outlier. So I said do not recommend, and I said it because in our discussion, it was very helpful for me to hear the external comments and the comments of my colleagues about comparisons to the ACS as something that was limited-scale testing.

And it occurred to me that the -- literally, single-site nature of this proposal, not because of the technical aspects, which we discussed about, but the fact that this is one group of oncologists in the entire United States and how other oncologists in the entire United States think about this is important to me at this phase of this submission of a model, which was covered by the ACS proposal, because that is actually a national organization of surgeons. And I'm aware of the fact that they had to do quite a bit of vetting before that group was able to come forward with this.

So not based on the technical issues, but by the

very nature of the fact that this was a proposal by a single group, where I was not -- I did not have confidence that others in the -- in this country, who are delivering this kind of care, would have confidence that this is -- I would love to see that confidence in a proposal before I was recommending to the Secretary, so that was the basis for my decision that I would like reflected in the notes.

CHAIR BAILET: Thank you, Tim.

Harold.

MR. MILLER: Well, no surprise, I voted recommend for limited-scale testing.

I won't repeat all of the things I said earlier, but I think that this by its nature, the more -- the more advanced -- let me not use that term. The more sophisticated a model that comes to us and the more it is different than the current structure, I think the more likely it is that we'll need what we have been describing as limited-scale testing. And that while I think this proposal has a lot of details that need to be added to it, I think that that can be, as Len said earlier, worked out, and I think that many of the most important details have to be worked out in practice.

I do have -- to Tim's point, have had the benefit of spending a lot of time talking to oncologists around the

country who I have found -- while I can't give you an opinion poll, statistical certainty -- are very frustrated with the current payment system that they have and have been very concerned about alternative proposals, which do not have this level of specificity. And that this level of specificity about the differences in cancer patients is -- in fact, has been a barrier to being involved in other kinds of payment models.

So I think that this, in fact, fills the gap. That doesn't mean that I can say for sure that people will race in to say that they want to do it in this particular format, but I think that this has a lot of the elements that I've seen oncologists asking for.

I do think that all of the issues that we have raised, though, is that it shouldn't be done in a way that would be limited to one site, and it shouldn't be done in a way that forces it to have a particular type of technology in the long run. So I think that that would be to me what I would suggest needs to be part of that limited scale. So I think limited scale could certainly go beyond one site, and I think there's prospect of doing that. But, other than that, I think that it's -- of its nature that it's going to need some work and some assistance.

And I hope that CMS will find a way to provide

that assistance rather than to simply say that the applicant needs to go back and try to figure all that out before it will be given further consideration.

CHAIR BAILET: Thank you, Harold.

And, Paul, before you comment, it's important -- and you did it, Harold -- to define in your mind's eye for the letter, what limited-scale testing means and how you configured that relative to your decision. So, Paul, if you have the opportunity?

DR. CASALE: Sure. Yeah. So I voted for recommend it with limited-scale testing. I have to say I'm a little more concrete. I really felt like this was going to be one site.

I can't make the leap of faith that Cota -- you know, that other software can be -- sort of replicate Cota. I mean, I think you have to use Cota. You'd have to use Hackensack's experience as the test. So, to me, it's a very narrow but limited scope. But I guess that would provide the opportunity that others have said around sort of seeing if this works, and to the submitter's point, this whole idea of sort of the grouping and the lanes and all that, does that actually lead to their outcome? So, to me, it's very specific around limited.

CHAIR BAILET: Bruce.

MR. STEINWALD: We don't all need to say what we voted since --

CHAIR BAILET: I think we're pretty much there, based on the math.

MR. STEINWALD: Pretty much there.

CHAIR BAILET: You're an economist --

MR. STEINWALD: Right.

CHAIR BAILET: -- but you can validate that for me.

MR. STEINWALD: So the things that I would emphasize is what -- the central appeal of the model is combining precision medicine with precision payment, and so many of the models that we've already received don't really do that. A lot of them focus on the clinical model and then propose a payment model that doesn't match the clinical model very well or is undeveloped. So the fact that they have got both in place, acknowledging that there are a lot of details that need to be worked out, I think needs some emphasis.

Second, and sort of following on what Harold said, it should be implemented in such a way that it naturally follows to scale. Assuming that the initial implementation is promising, the scalability to other sites, if only in cancer and maybe even beyond that, needs

to be a central factor in the design of the implementation and the expectation that it will generate data that will facilitate expansion.

CHAIR BAILET: I echo your comments, Bruce.

I also think that we have to start somewhere, and there's enough here that's been thought through that I think with the support of CMS to help sharpen what needs to be done before they would move this forward, I am hopeful -- cautiously optimistic hopeful that they will see the value in pushing this forward. But I would ask that it's not limited-scale testing and it dies on the vine; it's limited-scale testing with the intent to get it ready for a much, much broader implementation and deployment. And that is, I think, an important point that should be constructed and incorporated in the recommendation.

Thank you.

VICE CHAIR MITCHELL: I was very close to being with Tim but did not go there because I felt that this sort of morphed into a hybrid Hackensack PTAC model as opposed to exactly what we received and was compelled by the combination of that prospective bundled payment with precision medicine and the broader applicability.

But I would add clearly to the letter, I do not think this should move forward with proprietary -- if the

tools are proprietary, so it would have to be broader and scalable. And I think there needs to be additional consideration given to how this might integrate with other things that we have already proposed, like ACS, and to patient engagement and information around inclusion in the model.

CHAIR BAILET: Len.

DR. NICHOLS: So I was persuaded by Bob's description of the clinical value-add here, the potential real advance, and the link of the payment to that clinical advance. In my mind, limited is more than one. I think it's not worth it if we can only do it at one, and in my mind, if we recommend, CMS will very likely solicit others to join the party in that development process. And that's exactly what I would hope would happen. It would still be limited, but it would be more than one.

If no one else showed up, that would kind of be a signal to CMS, but I honestly believe the analytic part of developing the actual payment amounts and the risk adjusting and everything else, it's got to go along. The marginal cost of that for a bigger group is not that great compared to the Hackensack group itself, so you might as well do it for a bigger group at one time. And then you can really get a sense of how unique are they, how much

variation should there be across the country, and that's exactly what these kinds of experiments ought to be teaching us.

CHAIR BAILET: Thank you, Len.

Kavita.

DR. PATEL: I also voted number 2, to recommend limited-scale testing, and I'll just echo Elizabeth's comments around my vote was contingent, so to speak, or at least in my recommendation to the Secretary, I wanted to make it very clear that this did not have a proprietary aspect to it. And then I also want to add to the Secretary's comment that the oncology care model, the current model, while it has many flaws, actually has a very large clinical staging data registry process that's also kind of very similar to the discrete elements that I have hypothesized during the CNAs, but do not know clearly. And so I would also ask the Secretary to try to understand, just speaking to the point of the fact that what's so innovative about this model is around the precision payment ability, but that it would be nice to confer with CMS colleagues in his recommendation about how this might overlap with future aspects of the current Medicare model.

CHAIR BAILET: Bob?

DR. BERENSON: Yeah. My first observation is

that I think we have moved from reviewing proposals as they originally came in to envisioning how a proposal might work out with lots of work, and so I think we need in our own sort of discussions about that to try to figure out how to get the best proposal, rather than the original proposal that we review. I don't know exactly how to do it, but with ACS, we've moved it forward, accepting basically a black box of the episode grouper, with sort of accepting, yeah, they said it works this way. If it works this way, then maybe we've got a payment model. If it doesn't work the way they sort of suggested, it's not going to go anywhere, would be my guess.

Similarly, with Hospital at Home, we moved it forward, even more forward, with a number of recommendations for how their initial proposal needed to be changed. There were all those bullets of weaknesses, and we said, “Yeah, but the idea is a good one and it's overdue and we should go ahead with it,” knowing that the model was going to change in implementation.

So I think that's where we are, and I agree with those who said we need more than one site. I would emphasize we need at least one site that is very sophisticated and doesn't use Cota. Comprehensive Cancer Care Center, I know some of them are paid in a different

way, but the ones that are paid under current Medicare payment, I want to know what they think. I'm with Tim that we want to broaden this out and get some buy-in from others who would be affected. So limited-scale testing does not mean one site, and I think that is the key thing we want to make sure happens, is that it happens in strong places, this limited testing.

CHAIR BAILET: Rhonda.

DR. MEDOWS: So I chose number 2, moving forward with limited-scale testing, and I did so because I really wanted to see the model go forward because of the precision medicine, because we're taking a next step beyond evidence-based medicine, appropriately using technology analytics to support clinical decision-making.

I will tell you that I think it's really important that included in our remarks to the Secretary that we include the part about making sure that the patient-shared decision-making process is formalized, that we have a more formalized plan or at least have it laid out and spelled out for the quality incentive payments for the physicians themselves, just call it out formally.

I have to acknowledge -- and I have great respect and understanding for the public comments about including input from not only other oncologists, but other clinicians

involved in the patient care, and I have a great deal of respect for my twin, Dr. Ferris, when he speaks about the need to make sure that we are looking not only for additional comment, but before we make the leap to talking about expansion of the model to other medical conditions, that we have additional data and have additional work done on this.

Thanks.

CHAIR BAILET: Thank you, Rhonda. Thank you, Committee, and thank you, submitters.

We -- pardon me. Ann, you have a question?

MS. PAGE: Yeah. And as staff who is going to take a first stab at writing this, I just want to underscore what I hear as the characteristics of the limited-scale testing, so if I've missed any. I have a list of eight. So this is not everything you all said, but when we say we want limited-scale testing, here's what the PTAC envisions that limited-scale testing to look like.

One, it would not be limited to one site, and it would have at least one large site that does not use Cota.

Second, that the testing would not require the use of one type of proprietary patient classification software.

Three -- oh, three is a repeat of two, do not

move forward with proprietary components.

Fourth, how it should be integrated with other models that the PTAC has recommended, such as the ACS model, so how to coordinate that with other models going forward.

Fifth, a strong emphasis on the need for formalized processes for patient engagement and shared decision-making.

Sixth, to highlight that the PTAC was very impressed by -- and a basis for this recommendation was an appreciation of the precision payment and how it can overlap with other models, like the OCM model. Again, the emphasis on precision medicine as a strong part of this proposal.

And then, finally, recommending that for the limited-scale testing, to go forward with input from other oncology groups.

Did I capture --

CHAIR BAILET: Harold.

MR. MILLER: I do not agree with the notion that this must be tested with a non-Cota site. I think that that would be desirable if it could happen. I understand what other people had to say. I think it would be desirable if that could happen, but I think to require that

could potentially slow down the testing.

To me, it should be implemented in a way that does not require ultimately that it use something like Cota, but at least as I view Cota, it is a mechanism for translating patient characteristics into a grouper -- treatment groups, and that if -- and that much about this model is all about that, not about that particular software that facilitates that.

And so I don't see it, personally, as a problem in the short run to test all the other aspects of the model using that as long as it's -- there's some due diligence done before that. That, in fact, when it is ultimately done at other sites that there could be other tools used to be able to do that process. That's how I feel about it. I'm not sure how other people feel about that.

MR. STEINWALD: I feel the same way, and there's still certainly a possibility that the Cota system could be made widely available and not necessarily as proprietary as it currently is.

If CMS, working with Hackensack Cota, could find a way to make it more widely available either through some modest licensing arrangement or even permit -- persuading Hackensack Cota to make it available to all, that would work for me.

CHAIR BAILET: Tim and then Len and Bob.

DR. FERRIS: So while I agree with Harold and Bruce about their description, I come to a different conclusion, and I actually -- and it would be fine for me for our comments to reflect that the Committee was divided, because I don't think we're going to resolve this issue.

I have a different opinion. I actually -- to me, it would not satisfy the criteria for generalizability, which is an essential nature of this, if this were to be implemented only in a Cota system, and the reason I come to that conclusion is because while I completely agree with the description about the Cota system [unintelligible] is fundamentally a system of classification, the fact is the devil is in the details. And if the payment and pricing mechanism is tied to this, to that system, then I think that is actually a problem for a generalizable payment model for the United States.

And so I would like to see it tested in a setting where there was both a Cota software system in place, as I expect it would be, but in addition to assure generalizability around a lot of the questions that I don't think we fully understand, I would like to see it tested without it.

CHAIR BAILET: Len?

DR. NICHOLS: So I love the idea of reflecting that we disagree.

What I would suggest is that we put on our agenda somewhere later a discussion of the proprietary issue, because I think it's heterogeneous and complex, and I'll just say in this particular case, I share Tim's sense that it would be better if we didn't have Cota in the limited-scale testing version.

It seems to me there's two elements of proprietary. One is essentially can someone reproduce it, and therefore, it is a “make or buy,” as I believe Dr. Pecora said, and to me, then, we're arguing about price. So that's way less threatening to me than -- I had this vague memory of one of the prior proposals having a particular device that was going to assess a patient that only was existing in some corner of Bavaria. Well, that's a problem. Okay? So -- and that's different than this kind of thing.

So I just think we should put this on the table in general. We need to talk about proprietary limits, if you will. In this case, I don't -- I'm with Harold. I don't want to slow this down because we -- no one else can write the software tomorrow. I believe a reasonable licensing fee and/or sharing -- I am totally with you in

the long run. We can't go national with a Medicare payment policy that's not transparent.

DR. BERENSON: Yeah. I'm with Tim. I think there is already other software, and I want to know that it applies and that they can -- and, I mean, how do you know if something can be generalizable unless you try to generalize it? And at the very least, they want CMS to be talking to some of those places --

CHAIR BAILET: Yes.

DR. BERENSON: -- and getting the feedback as to why, you know, that's -- I mean, if we don't say that, my concern is that they'll -- you know, Hackensack will identify a couple of places that will have Cota, and they won't do that kind of surveillance that they have to do about what do other people think about this model, and can we operationalize it broader than in Hackensack?

So I would keep at that, and I'm all for having a division in the house.

CHAIR BAILET: Awesome.

Paul and then Elizabeth.

DR. CASALE: Yeah. I'll just associate my comments with Bob and Tim. I think we need to have more than Cota, and we can have the discussion about proprietary, I guess, later, but just on that point, it has

to be broader than Cota.

CHAIR BAILET: Thank you, Paul.

Elizabeth.

VICE CHAIR MITCHELL: As you name the divisions, I will be on Tim's side of the line but would also just throw in there that I think particularly around evaluability, there's got to be transparency and visibility into all aspects of the software that is being tested, so that we understand what may be causing variation as we compare it across sites.

CHAIR BAILET: All right. Len, your card is -- yeah, Kavita.

DR. PATEL: Just one thing you didn't capture, Ann. I don't know -- we didn't verbally say it, but it seemed pretty, almost close to unanimous about the one criterion that did not get met, even though that's not a high-priority one, so I would just hope in the comments that it was reflected that that was something --

MR. STEINWALD: I have one.

DR. PATEL: Oh, I'm sorry.

MR. STEINWALD: One other thing. We never really resolved for ourselves the issue of total cost of care versus oncology only, did we, or did I miss it? I did snooze a little bit, I think when --

DR. BERENSON: As related to the black box of the episode grouper, I mean, I don't know what I want until I know more about what the episode grouper can actually do.

DR. NICHOLS: I think we agreed to do the math both ways, and that's what we're going to recommend. Yeah. Right.

CHAIR BAILET: Okay. So that was great work. Appreciate everybody's engagement. This was -- It reflects what's happening on a large scale nationally and the challenges in front of us, and what I say to my colleagues that I have the pleasure of working with, if it was easy, everybody would be doing it. So this is difficult.

We are concluded for this particular proposal, so thank you very much. But before people leave, we have one order of business potentially, one small order of business, if Jeffrey Micklos is here. And I see him standing up. So you are from the Health Care Transformation Task Force. You wrote the PTAC. Your organization, with a lot of signatures here, wrote a letter to us, and you want the opportunity to address the Committee.

* MR. MICKLOS: I appreciate that very much, and I'll be brief. The task force is a 43-member consortium of patients, purchasers, payers, and providers, and we're committed to accelerating the pace to value-based care.

Our providers and our payers are committed to having 75 percent of their business in value-based care by 2020.

We firmly believe that this is achieved across the spectrum and across the industry through public-private partnerships, and so we're fully supportive of the PTAC. Our members are very excited about the potential of the organization.

We've been following your work closely, especially since the April meeting and now as your Committee -- more models, and I think the one thing that we're observing is that the potential is here. And, in particular, sitting through this morning's discussion, the process challenges that you all face, I think, are significant.

As somebody who is a recovering lawyer and has sat through FACAs (Federal Advisory Committee Act) over the years, I'll say that I find this one is unique because you're finding the work as people bring it to you, and then you're dealing with it in the sequence you get it, and you're trying to figure out all these issues as you go forward.

So, when we offered our statement in August, it was about the PTAC. It wasn't necessarily to the PTAC because there are things in that letter that we know you

all on your own can't do. If there's anything, I have empathy a bit for the work that you are doing because I think the support that comes from HHS in this group is critical.

I think a lot of the promise -- and I will say officially that our executive committee has decided as a matter of policy that we will not weigh in on models in front of the PTAC, but we are very -- and keenly aware of your work and keenly interested in following it.

I do have some empathy, too, for the Hackensack folks today because you really do recognize that there's some real potential there. So if there could be a little bit more technical assistance and a little bit more give, back and forth, with the government in asking some of these questions, I think your decision-making will be better informed.

We definitely took a position in our letter that we think if proprietary information is an essential element to a model, we don't think that's a good thing. I'm encouraged by the statements from the Secretary this morning, and we have not yet had a chance to review the statements that have been made, but we do recognize that. I thought Dr. Nichols had that directly right. I think it's a complex issue. It's not one that really you can

just say a bright line, without further consideration, but a very important part of that.

I think we also, though, from an organizational standpoint -- we've grappled in our work over the past year just with model overlap, and we've really started to talk more about synchronization. So I'll go back to the fact that you take your work as you find it, right? You get the models that come through the door, and you have to manage your portfolio.

But one thing we would encourage the group to do is really think about how your models plug in well with other models. It's really critically important. The one thing we hear consistently across our membership is we don't want to move from an area where we were siloed fee-for-service, that we move into siloed value-based payment.

So easier said than done, but we certainly would urge you to have that as part of your thought process as you evaluate models and make those recommendations to the Secretary.

And I'll just close with -- and I think probably some of this may be out today, but we certainly encourage the Secretary to be transparent with what the process is from here. It's critically important that the work of this esteemed panel, you know, is exercised in a way that we

know exactly what the step forward is.

We also appreciate that that's challenging here too, because do you move forward with recommendations as they come in, or do you, as the Secretary, allow some of those to gather together and see how they may work together? So it's a challenging exercise on all fronts. We're certainly here to encourage your work and will be here to support you in any way we can.

CHAIR BAILET: Thank you for that. Appreciate it.

MR. MICKLOS: Yep.

CHAIR BAILET: Anybody want to comment?

[No response.]

CHAIR BAILET: No? We're good? Thank you. Appreciate it.

So do we have a motion to adjourn?

DR. FERRIS: Motion to adjourn.

CHAIR BAILET: Second?

MR. MILLER: Second.

CHAIR BAILET: All in favor?

[Chorus of ayes.]

CHAIR BAILET: We are done. Thank you very much.

* [Whereupon, at 1:15 p.m., the Committee was adjourned.]