PHYSICIAN-FOCUSED PAYMENT MODEL TECHNICAL ADVISORY COMMITTEE MEETING
(Public Session)

December 16, 2016

Holiday Inn Capitol
550 C Street, S.W.
Capitol Rooms 1 and 2
Washington, D.C. 20024

TABLE OF CONTENTS

ATTENDEES

DR. JEFFREY BAILET - Aurora Healthcare

DR. ROBERT BERENSON - Urban Institute

DR. RHONDA MEDOWS – EVP, Providence Health Services

MS. ELIZABETH MITCHELL - NRHI

DR. LEN NICHOLS - George Mason University

MR. BRUCE STEINWALD – Steinwald Consulting

DR. GRACE TERRELL - Cornerstone Healthcare

MR. HAROLD MILLER – CHQPR

DR. TIM FERRIS - Mass General Physicians Organization;

CMS PRESENTERS

MS. KATHERINE COX

MS. ELLEN LUKENS

DR. RON KLINE

MR. L. DANIEL MULDOON

PUBLIC COMMENTERS

MS. SHEILA MADHANI - McDermott Plus

DR. ROBERT LOOKSTEIN - Society of Interventional Radiology

WELCOME AND OVERVIEW

DR. BAILET: Good morning and welcome to the Physician-Focused Payment Model Technical Advisory Committee public meeting. A little background on the committee. We've been in business for a year. All of us have been on the committee and highly interested in the process of getting ready. As of December 1st, we have and are accepting proposals.

That is what we have been doing as a committee, developing the process for evaluation. Our statutory goal on this committee is to make recommendations on alternative payment models to the Secretary, whether they should be tested and implemented. And that is our charge and we have set our processes in place, which we will walk through later this morning to actuate that.

Stakeholders, it's a transparent process. We have, and are, receiving proposals. We have officially received two proposals. We have now 10 letters of intent to submit proposals. These proposals come to the executive via Technical Advisory Committee and ultimately go through

our process whereby we render a recommendation to get all of that deliberation just in the public.

We are using the Secretary's criteria for evaluating the models. They're listed here. In our process you will see that we've put places of emphasis on specific criteria that we feel are highly important. And again, transparently we telegraph back to the stakeholders in advance so that as they craft their proposal, they have some directional sense of the committee's thinking about that.

There's a definition here of an alternative physician-focused payment model. I'm not sure it's beneficial to go through this, but if you stakeholders and folks on the phone have questions, we can address that because I'm trying to move us along here.

These are the characteristics that, from the committee's standpoint relative to physician-focus payment models, we feel will be favorably considered. And included in that is reduced spending without reducing the quality of care. Improving the quality of care without increasing spending. Or improving quality and reducing spending. Models that have those elements will be favorably

considered.

Unlikely for us to recommend proposals if the only change is essential to the -- that the eligible providers have the ability to -- essentially it's the fee modification in a vacuum. Those are probably unlikely for us to feel that those would warrant a recommendation.

And then just on a background, as I said, where we are, we've been accepting letters of intent starting in October. We have our systems and processes in place now to accept proposals as of December 1st. As I said, we have two that have been submitted and they are posted. We fully expect and anticipate that several more will be coming in based on the letters of intent.

We're very transparent as you guys know, and all of our comments are public. Our meeting minutes are published and we continue to invite you to visit our website. And as we go through our process we welcome -- as this meeting is the sole purpose -- we welcome the ability for stakeholders to provide feedback and input which helps sharpen the performance of our committee.

I'm going to stop there and open it up. Elizabeth?

MS. MITCHELL: I would add one thing. Even though we have started receiving proposals there is no deadline. It is a rolling submission so at any point they can come in. Letters of intent just have to come in 30 days prior. There's no deadline on receiving them.

DR. BAILET: Perhaps we'll balance out the presentation with Bruce who's going to talk about the actual process that we've put in place.

OVERVIEW OF PTAC RFP AND EVAL PROCESS/PUBLIC COMMENTS

MR. STEINWALD: I am briefly going to review the process that we have set down for reviewing and evaluating proposals. But first I would like to say that the person who's really been leading this effort is Dr. Kavita Patel. She is not present and I think she's probably not on the line especially since the line isn't working here. I'm pretty sure she's not.

She delivered a baby girl ten days ago and she, I guess, is on maternity leave. I have a picture on my cell phone if anybody, during the break, would like to see it. But she's adorable.

Many of you have seen the process because it's been posted on our website. And then some of you have submitted comments and questions that we have answers to, although we're going to try to get your additional comments and questions from the audience before we review those. We have a process, we're comfortable with it. We haven't tested it yet because we're just at the verge now of reviewing proposals.

We're hoping that our process will work very well but we need to gain some experience and that's what we want to do within the next few weeks. Here is a schematic of our process that enables us to come to a conclusion within a 16-week period. Starting with the letter of intent then we have 16 weeks to review a proposal and come out with a recommendation.

A recommendation could be that we don't recommend that the model be implemented by the Secretary. If we do recommend positively, there are several buckets that the proposal could fall into, including those that we deem are high priority for implementation and those that we deem are suitable for implementation but only on a small scale.

The initial reviews will be conducted by a

preliminary review team. Right now these review teams comprise of three members, one of whom has to be a physician. Anyone with a conflict of interest, having participated in some fashion in the development of the proposal, will not be a reviewer and potentially also will not be able to vote at the full committee level on whether the model should be adopted.

One member of the preliminary review team will be the lead reviewer who will present the proposal to the full committee when the full committee deliberates. And one of the questions that was raised -- and I can answer right now -- every proposal will be reviewed by the full committee, regardless of what the preliminary review team thinks of it. All will be reviewed.

We have staff support. We have very capable staff support; ASPE, the office of the Assistant Secretary for Planning and Evaluation at HHS. We also have a budget and contractors, so we can obtain expertise if we feel we need it to help evaluate the proposals.

That expertise can be of various kinds. It could be analytical expertise or it could be clinical expertise. And it’s up to the committee to determine whether we need

to utilize those experts in the course of evaluating proposals.

Some have asked will the submitter of the proposal be able to attend the public meeting where it's discussed and the answer is absolutely yes.

I am not going to go through this whole thing. I'll let you inspect it at your leisure just for a moment. But it does, in greater detail, outline our process. It is a very public process, especially when we get to the point of the full committee evaluating the proposal. And then of course what we recommend will be made public and there will be opportunity for public comment.

Here's another schematic of the process. The point of this one is this is a rolling process. Anyone can submit a proposal at any time and it will start the process of reviewing it and eventually coming out with a recommendation. As Jeff mentioned, we have two proposals to review. We expect to get several more very soon.

Here are the questions that were raised. But we thought that rather than me answering these questions right now, we give the audience an opportunity to raise questions and make comments, both in response to what Jeff just

presented and in response to the outline of the evaluation process that I just presented.

I would like to turn it back to you Jeff for public comments.

DR. BAILET: Okay. Let's go ahead and open it up for questions based on the proposals and information that's been shared so far. Any comments? We have three people on the phone but I'd like to get to the folks here before I get to these folks. Is there anyone who would like to make a comment? Otherwise, I'll start with the folks on the phone.

Okay. We have Randy Pilgrim from Schumacher Clinical Partners. He's a participant and has a question. Randy?

MS. ARGUETA: We can't get him on the phone.

DR. BAILET: Pardon me?

MS. ARGUETA: We can't get him on the phone not having the audio.

DR. BAILET: It's a beautiful thing. Bruce?

MR. STEINWALD: Okay. All right we have two slides here of some questions that were raised that we believe answerable. I already mentioned the full committee

will review every proposal that's complete. There is an initial review by the staff to make sure that the submitter has satisfied all the requirements of the RFP.

Once the preliminary review team reviews a proposal, it will go to the full committee no matter what. Can a proposal with a zero score in one of the high-priority criteria still receive a recommendation for implementation? Very unlikely. I think that's probably a simple no.

However, there can be some variations among all ten criteria in the extent to which the committee feels how well the criteria have been met. It's not the case that every criterion has to have a very high score. But the three that we've identified as high priority has to at least meet the criterion.

I mentioned earlier about the contractors and what their roles will be. Contractors exist to help us evaluate proposals. Someone said who will pay for their evaluation? And the answer is we will. We would not expect submitters to -- if the committee decides that some additional work is needed, we wouldn't expect the submitter to finance that or perform it, we would it do it on our own.

What is the process and instances when the preliminary review team is not reaching consensus? Their collective thoughts about the proposal will be taken to the full committee regardless of whether they are in consensus of what they feel about it or there are disagreements. That will all be brought to the full committee and the deliberation of the full committee will be made in the public session.

I already mentioned about the contractors. PTAC will absorb the cost. We have a nice budget. We have $5 million a year, is that right?

DR. BAILET: Right.

MR. STEINWALD: So we can afford to do some of our own analysis. Will PTAC have the discretionary authority to approve a plan for CMS review even if it doesn't meet all the ten criteria? Keep in mind that our statutory obligation is to make a recommendation to the secretary and it's up to the secretary to decide whether to accept that recommendation or not. There are no possibilities for substitute criteria because the criteria are subject to the law and regulations.

Will the submitter of the proposed model be

provided with specific information when the public meeting will be held? Yes. Of course. And if there is some problem of scheduling, we would try to be accommodative to the proposal submitter to make sure that the appropriate people could be present when their proposal is discussed and evaluated.

Will there be an opportunity to appeal? There is no appeal process. However, we are certainly leaving open the possibility that the submitter might want to revise their proposal and resubmit it. There is no constraint against that. However, there is no process for appealing PTAC's decision. Let's say we decided to not recommend, there wouldn't be a process for appeal, but there would be a process for reviewing and evaluating a new proposal that hopefully responded to some of the areas that we thought were deficient.

Once a proposed model has been approved, can it be implemented by any party? Would anyone with questions be told to contact the submitter? Once again, our process is to provide a recommendation to the Secretary of Health and Human Services. That recommendation will contain language that presents the rationale for PTAC's decision. But once

it leaves PTAC and goes to the secretary, we have no further role in determining whether it will be implemented and what organizations will be able to participate in implementation of the model.

Those are samples of the questions that we have gotten. We are trying to be very responsive to these questions. Some are easy to answer. Some have lead us to further discussion of our process. But for the time being, the process is as it was posted on our website. And that's the process that we will utilize to evaluate these early proposals that we are going to begin evaluating very soon.

DR. BAILET: Thank you Bruce. We're having trouble with the audio here. The transcript of this proceeding will be posted for those having difficulty hearing. Also I'd like to just open it up to members of the committee, so if there are comments that folks want to make at this point, the members of the committee. No? Harold?

MR. MILLER: Well, I would just say to the folks here we actually are interested if you have questions about -- if any of this is confusing, questions are welcomed. There is no such thing as a dumb question. If you have a

question we would welcome hearing them. I think we would welcome that, wouldn't we?

DR. BAILET: Yes. Of course we would. With open arms.

MR. MILLER: I know it's hard in a big room full of people to stand up and ask a question, but it would actually be helpful to us if things are not clear for you.

DR. LOOKSTEIN: My name is Robert Lookstein. I'm an interventional radiologist in New York City. My question is the committee offered their willingness to be as transparent as possible. Does that transparency translate to the actual proposals themselves? Specifically, are you at liberty to comment on the subject matter regarding the proposals that you have received and what the status is of the proposals that you've received? Were the proposals related to hypertension, diabetes or colon cancer or et cetera?

MR. MILLER: Sure.

DR. LOOKSTEIN: Does that level of transparency -- does the public have the ability to see which proposals have been submitted? And in relatively real time, you know based on the logistics of the committee, to understand what

the status is of each of the proposals that the committee is reviewing?

DR. BAILET: So there's a couple parts to your question. The first part about the proposals, when we get them they are posted on our website. Specifically, you can go in and see them. You'll see what the committee sees.

The second point, relative to real time evaluation, we have a review team that evaluates the proposals and sort of make sure that they're complete, working with staff. And then they tee up for the entire committee, sort of directionally, their feelings about the proposal relative to our evaluation, so that when we get to the point of deliberation, there's been some spade work that's been done.

They may ask the stakeholders or the submitters for questions back and forth to sharpen the proposal before it ultimately comes to the committee. And the review team will make a recommendation, after that iterative process takes place, so that they provide the full committee with their recommendation.

But that process that I just described, that will not be transparent. But to the point where the committee

is deliberating on a specific proposal, that will be very transparent. Thank you for your question.

DR. NICHOLS: You might just add, I think we would let the public know when those proposals will be discussed in the next public meeting. So there would be opportunity to come and observe the discussion and to contribute to it.

DR. LOOKSTEIN: Thank you.

DR. BAILET: Yes?

MS. SHEILA MADHANI: Sheila Madhani, McDermott Plus. Do you see this as an evolving process? So you have this process that's been through a few iterations. You're going to be looking at a couple of proposals. There's sort of ten, you know, queues. You have letters of intent. So do you anticipate that as you go through this, after you do a couple, you're going to learn something and you'll be adjusting this and nothing is written in stone? If that is the plan, can you talk about how you will be evolving the process?

DR. TERRELL: So the answer to that is yes. We believe -- and I believe I stated this at a previous public meeting that we're starting with a statute. We spent a year creating a process and now we actually have some real

proposals in front of us.

As we go through the process of evaluating these and making recommendations to the secretary, we're sure that we will learn things. And we hope to learn things from all of you about your experience with the process, whether we are meeting the criteria that we set forth with respect to what we stated were the criteria for submission as well as high priority as well as transparency. And then from that we were hoping to learn from you so that we can continue to have a continuous improvement type approach to this as we go along.

MS. SHEILA MADHANI: Just a follow up. The process document that you have online right now, is that the criteria that you'll be using for the current models that you have?

DR. TERRELL: Yes.

MS. SHEILA MADHANI: Okay.

MS. MITCHELL: The Secretary's criteria.

DR. TERRELL: The criteria were the Secretary's criteria by the way.

MS. SHEILA MADHANI: I'm sorry, not the criteria but that process.

DR. TERRELL: The process, yes. That's what we're using right now.

DR. BAILET: Any other questions? So hearing none, we're going to go ahead and start. We believe we're prepared for the CMS portion of our meeting this morning so we're going to go ahead and -- Bob would you invite our speakers to come up.

OVERVIEW OF THE ONCOLOGY CARE MODEL - CMS

DR. BERENSON: Thank you very much. If the CMS folks can come on up. We very much appreciate their willingness to come. We thought it would be very useful for the committee, in a public session, to have information about the Oncology Care Model.

We noted that in the letters of intent that we received, two of them -- I think it was two -- explicitly mentioned that the Oncology Care Model was what they were modeling their own proposal, or their letter of intent, after. It is a sort of prototypical bundled episode or episode approach that raises some generic issues that we anticipate will come up with many of the proposals that we

will see around episode-based payment.

Now you've got a nice long presentation. And what I think I want to do with your agreement is to try to put a limit of about 30 minutes, no more than 30 minutes, on the presentations. I mean you do have to get into some detail on this and yet we want an opportunity to explore some of these generic issues.

I'll give examples of the kinds of generic issues if perhaps in your presentation you could sort of address these. These are the kinds of things that we think will arise with almost any episode-based payment model.

One is the decision to trigger the episode with a treatment. With a procedure or a treatment you have to address the issue of appropriateness in some way perhaps. If you pick a condition rather than a treatment, then you would have to probably address the issue of accuracy of the diagnosis. So the decision that you made regarding triggering, as you'll explain, based on the claim for chemotherapy.

A second issue is the performance-based payment, which you'll explain, is a total cost of care analysis. The Innovation Center, in some of their models, have

adopted total cost of care. But in others like CPC Plus they moved away from total cost of care. We'd like to hear sort of some of the thinking around how that would work. Why you selected that?

The rationale for the length of the episode will come up. In this case six months. For some of the other BPCI models, shorter periods of time. How do you think about the length of the episode? And ultimately in any payment model that is incentivizing efficiency, how do you think about protecting against stinting on care?

Those are the kinds of issues that will come up generally. And so to the extent that you can address those in your presentation that would be great. But we want to leave 30 minutes -- we actually have a little extra time. Can we go until noon?

DR. BAILET: Right now we're scheduled to go until noon.

DR. BERENSON: All right if we can, that's great. But I'm still going to limit the presentations to 30 minutes. I think the first thing to do would be to have you folks introduce yourselves. And then for the first 30 minutes it's in your hands to do the presentation. Thank

you very much.

MS. LUKENS: Great. Thank you very much. I don't know if the audio is working now. I'm Ellen Lukens. I'm the Division Director of Ambulatory Payment Models at CMMI. To my left is Ron Kline. He's the medical officer on the model and also a medical oncologist. Dan Muldoon is our economist who is responsible for a lot of the modeling and probably will be answering a lot of your questions. And then Katy Cox here is the team lead and she is responsible for the day to day work on the model.

I also just want to introduce two folks in the audience. Chris Ritter is responsible -- she's our Group Director. She's responsible for all episodic payment models. And Laura Mortimer does our payer work as well as a lot of the QPP determinations.

We will definitely keep your comments in mind. We will also post this presentation to our public website. If you want to use it as a reference document that is absolutely fine as well. And we will definitely try to keep it down to the 30 minutes.

DR. BAILET: Can the audience in the room hear?

AUDIENCE: No.

MS. LUKENS: Is this working? We will try to speak loudly. I'll turn it over to Katy Cox who's going to start with an overview of the model.

MS. COX: So thanks Ellen and thanks to everyone here for the opportunity to present today. I'm going to start with a quick overview of the model. We started designing OCM back in 2013 and announced publically for the first time in February 2015.

In June of that year we did release applications. Physician group practices and also payers had the ability to apply for participation in the model. And then ultimately, on July 1st of this year, we did go live with almost 200 participating practices and also 16 payers participating in the model.

So OCM is a five-year episode-based payment model that really focuses on six-month episodes of care that are triggered by chemotherapy. The model really emphasizes practice transformation. And the three sort of overarching goals are to improve health outcome for patients with cancer, to improve quality of care and also to reduce spending.

As I mentioned OCM is a multi-payer model so we do

have several other payers that are participating with CMS. And essentially we have asked them to align their own individual payment models with that of CMS.

One of the key parts of practice transformation in the model are our three practice redesign activities that we require practices participating in the model to provide to beneficiaries. So the first is enhanced services and so that includes a few different items. The first is to provide 24/7 hour access to a clinician that also has access to your medical records.

The second is to provide core function of patient navigation. Also to provide a care plan that address the 13 elements of the IOM care plan. And also to treat OCM beneficiaries with therapies that are consistent with nationally recognized guidelines.

In addition to enhanced services we also require practices to use certified EHR technology. And along with that we also ask practices to utilize data for continuous quality improvement. And part of that is we'll be providing the participants in our model with a quarterly feedback report which is intended to give them more real-time information about their performance in the model.

This slide just identifies the 13 elements of the IOM care plan which as I mentioned is part of the enhanced services, which is that first practice redesign activity. And I just wanted to emphasize here that the goal is really to engage the patient in the care planning. And we've also included an element of that financial discussion around cost of care.

As part of the model design we did identify the beneficiary population that would be eligible to participate. So Medicare beneficiaries have to meet all of these eligibility criteria for the full six months in order for the episode to be included in OCM.

The first part is that they have to be covered by Medicare Part A and Part B. Medicare also has to be the primary payer. And the beneficiary has to have received one of the included chemotherapy treatments for cancer as well as have received at least one E&M visit with a diagnosis of cancer during that six-month episode.

As I mentioned, we have nearly 200 practices that are currently participating in the model. In our model the practices are identified as a single TIN. These are physician group practices. We have a wide range of

participants in the model covering both rural and more suburban areas. We also have some smaller practices, including solo practitioners participating in the model as well as some larger entities that we are working with, including hospital based practices and also some larger multi-specialty practices.

I did want to mention that because of our payment methodology, we have excluded some entities that are paid differently. One example of this is the PPS-exempt cancer hospitals; they've been excluded from OCM.

As I mentioned, OCM is a multi-payer model. The goal of the multi-payer model is really to allow us to provide aligned incentive for the practices participating in our model including also aligned quality measure reporting. So that they're really able to take the principles of the model and apply it to total practice transformation.

We will be working really closely with the payers that are participating in our model. And we plan to meet with them on a regular basis and share sort of lessons learned around how the model is being implemented and also how we can better support the practices that are

participating in OCM.

With that I'll turn it over to Ellen.

DR. BERENSON: You're doing very well on time.

MS. LUKENS: I'm just going to talk briefly about episode definition. And in this section we can address some of the questions that Dr. Berenson "raves" about. Why certain decisions were made and what some of the design considerations were.

OCM does include nearly all cancer types. When Dan walks through the payment methodology he will talk a little bit about there are certain cancers that are excluded for the performance-based payment methodology. And I'll talk a little bit about why.

We did trigger or initiate the episode when the beneficiary starts chemotherapy. That was for a few reasons that Dr. Kline and Dan can elaborate on. But part of it was that it was very observable in claims. As you know, we were really limited to the claims data when we were formulating this model.

We have launched a data registry which will give us much more information about clinical markers and staging. But at this point in time we really are relying

on the claims data. It was observable in claims and the feeling was it was not gameable. Those were two key criteria we were thinking about in the trigger.

We have actually devised a list of the chemotherapy drugs that trigger OCM episodes, and we do include endocrine therapies, but we exclude topical formulations of drugs. We are also including, as we talked about, a total cost of care model. I think the feeling there -- Ron can elaborate -- is that medical oncologists, we really wanted them to be coordinating the patient's care and have a very holistic view of the patient's care over the episode.

We did also include certain Part D expenditures. We included the low-income subsidy and also the 80 percent of cost that are over the catastrophic threshold, so essentially the cost that Medicare fee-for-service bears.

We identified a six-month episode duration. Part of the reason for that was that the data showed that there was a peak in spending between months two and four that stabilized between four and six months. That was part of the justification for the six-month episode. Beneficiaries may initiate multiple episodes during the five-year model.

In terms of the drug list; so the trigger is a chemotherapy drug as well as cancer diagnosis. We did include the vast majority of chemotherapy agents. We did not include radiation sensitizing agents, supportive care medications or growth factors. And we did find that some chemotherapy drugs are frequently used for nonmalignant conditions. So we were concerned about triggering episodes inappropriately.

There were some cases where they were used frequently in combination with other drugs where we just include the other drug. An example would be prednisone. But we did not include a few drugs that are infrequently used in cancer, but frequently used for nonmalignant conditions. And an example would be hydroxyurea. Someone's about to ask a question.

DR. BERENSON: Let's hold questions if we can. Just accumulate your questions if you will.

MS. LUKENS: We are using what we're calling a plurality approach. Just to clarify, the episodes here are retrospectively attributed. The practices don't know -- they know they're caring for the patient, they're not 100 percent sure that it will be their episode. They're

attributed to the practice that provided the most E&M visits with cancer diagnosis during the episode time period.

As we said earlier, OCM practices are defined by the TIN used to bill for professional services. And the specific practitioners are defined by the NPI. So the TIN NPI combo is what we used for identifying OCM practitioners and that's -- if you think about the MACs paying the claims, the MEOS payments, they actually identify the OCM practitioners based on that match. It has to be the TIN/NPI match.

With that I'll turn it over to Dr. Kline who's going to talk about quality measures.

DR. KLINE: Good morning everyone. My name is Ron Kline. I'm a pediatric hematologist oncologist and work at CMMI on the Oncology Care Model.

We had various quality measures as part of the model to ensure that patients continue to receive quality care. And they cut across the four NQS strategy domains which are communication and care coordination, person and caregiver-centered experience and outcomes, clinical quality of care, and patient safety. And to the extent

possible we wanted to use either claims-based measures or measures that aligned with other CMS programs in order to reduce provider burden on the quality measures.

We have basically three groups of measures; we have claims-based measures, we have practice-reported measures. We have patient-reported experience.

The first group are the claims-based measures. And you can see those are the risk-adjusted proportion of patients with all-cause hospital admissions within the six-month episode. Risk-adjusted emergency department visits and patients who are admitted to hospice for three days or more.

Those -- if you appreciate -- are cross-cutting across all cancer types and really spoke to the issue. In some of the literature review, there was a feeling that patients sometimes are unnecessarily in the emergency department, they don't need to be, unnecessarily admitted when they don't need to be; and perhaps some of the end-of-life care could be better coordinated. And that's an unfortunate part of cancer care, but we wanted to make that as positive as we could also.

We also have patient-reported experience measure.

And it's essentially a modification of the CAHPS oncology questionnaire, which has been validated. There are some modifications to that, but that's what we used. And what happens with this survey is there's an aggregated composite level score that used as part of the quality measures.

We also have practice-reported measures. And, as I said before, they are generally aligned to eCQMs when available and feasible. And when they're not, we try to align them either with PQRS or NQF measures. And the idea here was that hopefully some of the EHRs, that are already in existence, would have these measures as part of the EHR or they align with other CMS programs. And again, trying to capture quality data, meaningful cancer-care data, while at the same time minimizing provider burden.

These are some of the practice-reported measures that you see. And I don't know how well you can see those, but I would point out that the first three of those OCM-4a, 4b and 5 are really cross-cutting measures in terms of speaking to the whole oncology care experience.

One is, pain intensity is quantified. That's an NQF measure. The others, there's a plan of care for pain, another NQF measure. And that there was screening for

depression and having a follow-up plan as part of the cancer care.

The other measures that are practice reported are more specific to cancer types and really just sort of -- in my world -- sort of defines some minimum thresholds for what cancer patients should be receiving for different cancer types, for different types of treatment.

This is just a continuation of some of the quality measures. If you go back, I should mention OCM-7 through 11 are aggregate measures. And by that I mean that the practice will have to report data for all the patients in the practice, not just Medicare fee-for-service beneficiaries.

Those are measures such as patients receiving adjuvant hormonal therapy for breast cancer. How rapidly a person with colon cancer, who is less than 80 years old, receives chemotherapy and other measures such as that. Those are aggregate measures that practices will be reporting.

The other part of the quality measurement is our data registry. And this has been a fairly large effort on the part of CMMI and CMS to put this out. And we're going

to collect biological and molecular characteristics of neoplasms that were relevant to cost and outcome. And the reason that we're doing this -- I think one of the criticisms of OCM has been that we have very, very broad cancer measures, so we have breast cancer, we have colon cancer, we have lung cancer. And those align with the way CMS collects data.

But to a clinician there's obviously a fairly significant cost differential between a woman with low-risk breast cancer on tamoxifen and a woman with triple negative breast cancer, you know -- not triple negative but a woman who has metastatic breast cancer who's getting her septic. But we can't do that right now using our claims data because we don't collect that information.

Part of what we're doing in OCM is to collect the relevant molecular markers, relevant anatomical staging markers, so that hopefully in a few years we can come out with new bundles that are clinically narrower and perhaps more clinically relevant.

Other aspects of what we're collecting are dates of progression and relapse, dates of death as part of the quality measures. And I think Dr. Berenson talked about a

concern about stinting on care and that is certainly a concern. I think, in a cancer-care model, the ultimate way to make sure that people are getting good care is, is their overall survival, is their progression-free survival equivalent to what you see in a fee-for-service world or commercial world? So we're going to try to collect that as well.

All of those measures together will align into an aggregate quality score, AQS. I think Dan will speak to this later. The performance-based payment will be a combination of the reduction in expenditures compared to a target price for a given cancer benchmark. And that we'd multiply by how you do on your aggregate quality score.

If you're reducing expenditures a lot but you're doing very, very poorly on your quality measures, you're not going to get a very high performance-based payment. Really it's a combination of trying to provide high-value efficient care, cutting out waste for cancer patients and at the same time providing good quality care. With that I'll turn it over to Dan Muldoon.

MR. MULDOON: Hi. I'm Dan Muldoon and I'm an economist that works in our group that deal with the

episode-based payment models and I've worked a lot so far on the development and implementation of OCM. We'll talk a little bit about the different aspects of the payment structure that we include in OCM.

First of all we have that fee-for-service payment do continue as usual to participating practices. But we have a two-prong payment approach that we incorporate for participating practices. The first being a monthly payment of $160 that I think, as Ellen mentioned, practices can bill as they furnish enhanced oncology services to beneficiaries that they believe are likely to be OCM episodes that are attributable to the practice.

The second is a semiannual potential for a performance-based payment if expenditures are reduced below target prices and if the practice has an acceptable AQS.

The MEOS payment is a $160 payment we make on a monthly basis. It's for the practices to furnish enhanced services to beneficiaries including that 24/7 clinician access, other patient navigation care services, as well as the other enhanced services Katy mentioned earlier.

Practices can bill this monthly payment for each of the six months that a beneficiary has an episode except

in the instance of beneficiary electing hospice or if the beneficiary dies. The payments do count against the total cost of care when we calculate our performance-based payment. And when we were designing the model I think we tried to target the amount of what we thought was appropriate for this payment by looking at sort of estimates of staff time associated with furnishing these different enhanced services as well as the salaries of the different types of staff that would be furnishing or working most directly on those services.

The other aspect of the payment for OCM is our performance-based payment. And so we have grouped OCM into a six-month performance periods and we assign episodes to those performance periods based on the date those episodes end. We allow practices then, for their performance-based payments, to have two different risk-arrangement options. The first being a one-sided risk and there CMS incorporates a 4 percent discount to the target amount that we compare total cost of care against. And in that one-sided risk arrangement then we take sort of a higher discount for the target amount. If a practice's expenditures exceed that target amount, they're not required to pay back Medicare

for the difference.

However, if a practice is in the one-sided risk arrangement, we do have a requirement that they either qualify for a performance-based payment or elect the two-sided risk option by the middle of 2019. Otherwise, they must leave the model.

We also, beginning in 2017 will have the option for a two-sided risk arrangement. So there Medicare takes a lower discount of only 2.75 percent on the target amount. But if a practice's expenditures do exceed that target amount, they're required to pay back Medicare by the amount by which the expenditures overrun.

And as I think Ron mentioned earlier, we have at most, I think 21 cancer types -- so the common cancer types you think of prostate, lung, colorectal, leukemia, breast cancer, et cetera -- are eligible for the performance-based payment.

When we were determining what cancers we were going to include as eligible for this performance-based payment, we sort of looked both nationally and at the OCM practices at the volume of different episodes to which we would assign different cancer types; and looked at both the

spending and variation in spending and the volume of episodes for different cancer types to try to identify where we thought that we would be able to set sort of stable target prices in our risk-adjustment model.

And we ended up in a place where with these 21 different cancer types that we assigned to episodes -- I think we expect to cover around 95 percent of the OCM episodes that would be occurring nationally. Those other 5 percent of cancer types, there we would still allow practices to bill the monthly payment of $160. We would expect that as part of comprehensive practice transformation, those practices would be furnishing those enhanced services. But those monthly payments for the care-management fees would not count toward the total cost of care for determining the performance-based payment.

When we calculate the performance-based payment we have kind of seven overarching steps that we go through. The first is we just identify baseline episodes which we use episodes that started in 2012 to 2014 all throughout the country, not just those that are attributed to OCM practices. But we used those episodes to sort of serve as the basis for our historical risk-adjustment model. We

calculate from that the baseline expenditures as well as our risk-adjustment model.

Then when we move to the performance period we identify episodes that are ending in any given six-month period. For those episodes we attribute them to practices, calculate actual episode expenditures, compare those against the target amount for practice, potentially make an adjustment based on the performance multiplier and then that set of calculations would result in the performance-based payment.

We'll go through a little more detail on each of these steps in the next couple slides. The first is for our baseline period. And so there we're using, again, episodes that started in 2012 to 2014. Those are six-month episodes so they go into 2015 when we're identifying them. We looked first for those potential trigger events that Ellen went over and so that, again, is receipt of a chemotherapy claim with a corresponding cancer diagnosis. One little wrinkle there is that for the Part D claim for oral chemotherapy, there you don't actually have like a diagnosis code on the claim, so we look for an E&M, evaluation and management, visit within the preceding 59

days of the fill date to try to associate the drug with cancer.

We determine that episode eligibility sort of along the criteria, beneficiary must be enrolled in Medicare Parts A and B, must not have their eligibility tied to end-stage renal disease, et cetera. And then we assign cancer types and then attribute those episodes to practices based on the plurality method that Ellen described.

When we calculate episode expenditures, we are a total cost of care models so that means we include all Medicare Part A expenditures and all Medicare Part B expenditures. When we calculate those amounts, we incorporate what's called a CMS payment standardization methodology which removes geographic pricing differentials that are paid for different services in different parts of the country, as well as the effects of various Medicare payment-adjustment programs, so things like hospital readmissions or hospital value-based purchasing.

We use that payment standardization methodology sort of throughout all of our calculations, at least for Parts A and B. For Medicare Part D, we include the low-

income cost subsidy and 80 percent of the gross drug cost above the catastrophic threshold amount. And those really are the types of payments for Part D drugs that Medicare is really reinsuring. I think most of the other payments in Part D program are made on a capitated basis. Dollar reduction spending on drugs doesn't translate into a dollar of saving for Medicare.

And one thing also that we don't do in OCM, but some other models do, is that we exclude beneficiary cost sharing from the payment amounts we calculate for OCM.

DR. NICHOLS: You do?

MR. MULDOON: We do not include beneficiary cost share. Once we have all of the baseline episodes sort of defined and attributed to practices, then we work to calculate baseline prices with our risk-adjustment model.

And so there we have a predictive risk-adjustment model where we essentially run a big regression of every OCM type episode in the country, from that baseline period. And we risk adjust for things like beneficiary age and sex, the assigned cancer type, whether a beneficiary has received certain surgeries or they received radiation therapy, whether they're dually eligible for Medicare and

Medicaid, if they have Part D coverage, different types of comorbidities they might have as well as time since last chemotherapy.

And so that risk-adjustment model adjusts for lots of beneficiary characteristics that we sort of looked at and spent a lot of time perseverating and going back and forth on how that model was specified. But ultimately trying to associate those characteristics that are most predictive, or at least in the baseline period, were most predictive of the different types of expenditures that occurred during an episode.

Once we have that risk-adjustment model specified, sort of moving into, I guess, the performance period, but there we would calculate a practice's target price for the episodes assigned to it; as well as then the risk-adjusted target amount, which is just basically we would trend forward those baseline prices for episodes based on changes in spending in a cancer arena; and tailor that to the practice's spending or their case mix in the performance period as well as some other adjusts that I'll talk about on future slides.

In the performance period, again we identify

episodes almost identically to how we identify them in the baseline period. Except this would be based on episodes ending in a six-month period of time. We go through those same steps, both to identify episodes and to attribute them to practices. Again, for those episodes we calculate the spending. Again, along the same lines as we would in the baseline period, except the only change here is that we also incorporate those monthly payments for the enhanced services.

At this point we sort of have that target amount set. We have actual expenditures for all those episodes that we can move to make that comparison, except that we first calculate the performance multiplier which Ron went over. And so there I think we looked across -- I think it's 12 quality measures -- and basically assigned points based on a practice's performance there. And then add up those points and divide by the maximum available.

If a practice has a score in one of these ranges, it gets a corresponding performance multiplier with the maximum being 100 percent. And if a practice falls below 30 percent, they are ineligible to receive a performance-based payment.

And then basically we just do a comparison of actual expenditures against the target amount and multiply that by the performance multiplier to come up with a performance-based payment. If the practice is in the two-sided risk arrangement, we neither increase nor decrease the amount they might owe back Medicare if spending exceeds that target amount.

And as this step, also not reflected in the slide, we also sort of all along the way we have not been accounting for things like sequestration. We've been assuming that all the payments had occurred as if sequestration had not been in place. We also incorporated a 2 percent reduction because of Medicare payments.

We also here, at this step, would incorporate a geographic adjustment that's based on the geographic practice cost index for a physician fee schedule professional services as well as hospital wage index for hospital services in an area. We don't have a geographic adjustment for any of the drug spending.

But this is sort of at the step at which we combine all of the actual spending compared against the target amount and then potentially reduce it for the

performance multiplier.

And then again just to sort of reiterate, we do have these requirements to receive a practice-base payment. The first being spending has to be below the target amount. The practice has to submit all of its required data to OCM. They must implement all of the practice redesign activities. And then they have they have to achieve an AQS above 30 percent.

One of the other adjustments that we incorporate here is for new therapies that come out during the performance periods of OCM. And so here we also incorporate a potential adjustment to a practice's target amount that could increase the benchmark price. And so this basically compares a practice's spending against spending at other practices in the country on new therapies.

Specifically, drugs that have received FDA approval after the end of 2014. And we look at the specific indication for those drugs. If a practice is spending more than other practices, it would be eligible to have its target prices increased a little bit to account for the fact that it's using novel therapies.

And so with that I think I'll turn it over to Ellen again to talk a little bit about monitoring and evaluation.

MS. LUKEN: Thank you Dan. We actually made Dan eliminate some slides and I'm just realizing that we didn't go through the practice-experience adjuster.

MR. MULDOON: Oh, we didn't. Yeah.

MS. LUKEN: So do you want to just talk quickly about that?

DR. BERENSON: You've got five minutes.

MR. MILLER: Let's take a vote on that.

DR. BERENSON: That's five minutes total. We're closing up. This has been great but we need to --

MR. MULDOON: Okay, I'll be quick. Also baked into the baseline prices, that I think we eliminated a slide on and we apologize for, is for practices we know what the actual cost that Medicare spent on the historical episodes in that 2012 to 2014 period, what Medicare paid. And then we also know what the risk-adjustment model there predicts for those practices. It doesn't come out to be exactly even all the time.

And so there what we can do is we have this thing

we call a practice-specific adjustment, or practice-experience adjustment factor, where we compare the actual expenditures for a practice's episodes in that historical period against what the risk-adjustment model predicts from that historical period. And so we can take that ratio there. And basically if the practice has actual spending above what the model would predict or conversely if it has actual spending below what the model would predict, we essentially increase or decrease the practice's baseline prices based on applying a 50 percent weight to that ratio of actual to predicted expenditures in that baseline period. And we use a 50 percent weight there.

Sort of again tested whether we should use a 100 percent weight. Maybe have that weight go from, you know, a higher amount like 100 percent down to 25 percent throughout the course of the model. We ultimately settled on using 50 percent throughout all the model years just to give a practice some credit for their historical experience. But also to account for reversion to the mean and the fact that a practice who historically had higher spending than what would have been predicted or conversely lower spending than what would have been predicted, would

be likely to sort of trend more toward the average over the course of the model.

Now to Ellen to wrap up.

MS. LUKEN: So we just wanted to highlight quickly two things that will take a minute each. One is that we are monitoring, during the course of the OCM model, to measure potential stinting on care. I just also wanted to note that we also are in the monitoring process trying to evaluate the MEOS. I think it's imperfect science trying to do that, but we are doing time and motion studies to try to understand the amount of time to provide these services.

We are also conducting an evaluation. We have an evaluation team and they're using a match comparison group to try to understand the counter factual, what spending would have been in the absence of OCM.

And the other thing we just wanted to highlight is that we do have a learning collaborative as part of OCM. It is sort of a private web portal for participants where they have all of the resource documents. We also run webinars to help educate participants about the model. And we're going to be shifting to more of a peer-to-peer learning model where they can share best practices in the

next year.

And with that I'll turn it back to Dr. Berenson.

DR. BERENSON: Great. You guys did great and these slides will be very helpful to us. What I'm going to do is ask the first question and then we'll just go around the table and go as long as we have time for with Qs and As.

I want to ask the first one. As the people on the committee know, one of my major things is around appropriateness of intervention. And I want to quote one sentence in the OCM sort of summary on the CMS website. "Practitioners and OCM are expected to rely on the most current medical evidence and shared decision-making with beneficiaries to inform their recommendation about whether a beneficiary should receive chemotherapy treatment."

And yet the model seems to be triggered by a receipt of a claim for chemotherapy. So where does the evidence-based decision making and shared decision making come into the decision around initiating chemotherapy, I guess, is my question?

DR. KLINE: I think that the 13-point care plan, IOM care plan, requires that a visit -- well, there are

sort of two components here. One of the practice redesign elements is that you follow national guidelines, so the NCCN guidelines in terms of treatment of patient. I think that's an ASCO guideline. Any nationally recognized guidelines -- well, not any, but many are incorporated into the treatment. That's one component of it.

The second component of it is if you look at the elements in the 13-point IOM care plan, there's a requirement for extensive discussion about the risks and benefits of chemotherapy. The intent of chemotherapy. The side effects of chemotherapy. I think that's part of stimulating a conversation between patients and physicians on chemotherapy and what the ultimate goal is and what we expect the outcome to be.

DR. BERENSON: But is there any sort of verification that that's happened?

DR. KLINE: Well, as Ellen pointed out, there will be site visits to make sure that these things are being done. And I can just tell you just from the discussion among the practices that incorporating the 13-point IOM care plan is really something they're focusing on and struggling with, but moving forward on.

DR. BERENSON: Okay, great. Let's just go down around. Len?

DR. NICHOLS: The $160 MEOS seem to be roughly expected cost of delivering these enhanced services. Is there a MEOS for every type of cancer or is this across all?

MR. MULDOON: So there we set the MEOS, it's $160 regardless of the cancer type that is assigned to the episode. It's supposed to just support, at a practice level -- I think we anticipate that, across the different types of episodes, the different cancer types a practice is treating, that the $160 per episode will be enough to sort of support furnishing those services to the beneficiaries in OCM.

DR. NICHOLS: So it's kind of an implicit assumption that the case mix across practices is roughly identical. Is that fact?

MR. MULDOON: I think it sort of is, does and maybe have that baked in. But again, I think we do see variation in the practices, but that didn't necessarily have -- we were looking to sort of set some uniformed design parameters.

DR. NICHOLS: I'm not criticizing, I'm just trying to figure out

MR. MULDOON: I think it is an assumption that's sort of baked into that, although we do see that different practices certainly do see a different range of case mixes in their patients. I think what first and foremost comes to mind is like a urology practice that would be treating predominantly bladder and prostate cancer relative to a medical oncology practice or a multispecialty practice.

DR. NICHOLS: So one might imagine some day in the future you'll have cancer specific MEOSs. Maybe you won't, but we might have. The other question would be, is the target aggregate or is the target per episode?

MR. MULDOON: We do come up with a prediction and a target price that we have for each episode. But then we do the reconciliation at the practice level. Essentially, we calculate that individual price per beneficiary's episode. And then when we move to do our reconciliation calculations, we aggregate those target prices up and some across the different episodes. And then some, all of the expenditures up across each of the episodes. So the practice wouldn't actually be receiving, you know, $1000

for one beneficiary's episode and paying back, you know, $500. We would aggregate all of the intakes.

DR. NICHOLS: Oh yeah, yeah. But my question is, is the target against which the practice is being judged, is it N times P or is it just P for every episode?

MR. MULDOON: No. Each episode with like a specific set of risk-adjustment characteristics. Like if you're a male with lung cancer who's age 75 and has 4 comorbidities and lives in this part of the country, you would get a price. And then some other beneficiary with a different type of cancer would have a different price associated with their episode. And then we would sum each of those prices for each different episode up to the practice level. But the prices can vary between beneficiaries.

DR. NICHOLS: Okay. But sum across all the patients for that --

MR. MULDOON: That are attributed to that practice.

DR. NICHOLS: During a performance period?

MR. MULDOON: Yes.

DR. NICHOLS: And you compare it to the baseline

something. Is the baseline something a total span, P times Q or just P?

MR. MULDOON: So we came up with both a predicted price for each episode and then sum all of those predicted prices for episodes to come up with a practice-level target. And then against that practice-level target compare all of the actual spending. Because we allow all the actual spending under the fee for service system of Part D to continue to occur.

DR. NICHOLS: Okay. I'll quit badgering you. I'm headed to where Bob started, okay. If you have an N, a number of episodes baked into the target span --

MR. MULDOON: Right. No. No. No.

DR. NICHOLS: Then if you do -- do you not? Do you, or do you not?

MR. MULDOON: We do not.

DR. NICHOLS: Okay.

MR. MULDOON: It's a little confusing in the slides also, the way it's presented.

DR. NICHOLS: I was trying to solve Bob's problem. He had a N baked in, and then if they inflated episodes later, you could catch them.

MR. MULDOON: No. We don't have an N baked in. Each episode attributed in a performance period would get its own price, regardless of if the volume is higher in the performance period than it used to be or lower.

DR. BERENSON: Rhonda, do you have any questions?

DR. MEDOWS: I have one question about beneficiary cost sharing. You said it is not included in total cost of care? Is that because it's hard to get the data or because the focus is more on the government spend? Is there a reason or rationale?

DR. TERRELL: Can you repeat her question. She's got such a soft voice, to let the audience hear.

MR. MULDOON: Sure. The question is sort of explaining a little bit the rationale behind the decision to exclude beneficiary cost sharing in the model and focus on Medicare payments.

I think we decided here that we really did want to focus on Medicare payments. It's not because we'd have trouble accessing the beneficiary coinsurance or deductibles that beneficiaries pays. So that's information that we do have in the administrative claims data, but here decided that we're going to focus on Medicare payments.

MS. LUKENS: I just want to add one thing to the discussion about how would you know the beneficiary -- sort of what the predicted spending would be? We actually do give the practices a predict tool where they can put in all of the different variables associated with a patient and then it tells them because it is fairly complex. It helps them understand what that would be.

DR. BERENSON: Harold?

MR. MILLER: Two questions. One is you sort of portray this as being a total cost to care model. But if I understand it correctly, if a physician substitutes an expensive biologic oral drug, for a less expensive injectable drug, that would actually generate savings under the model for them because you're not counting Part D expenses and you are counting Part B expenses. Is that correct?

MR. MULDOON: So for Part A and B we include all the expenses. For Part D we include low-income cost subsidies as well as 80 percent of the drug cost above that catastrophic threshold. If a beneficiary, I guess, was receiving a more expensive biological drug I think we would anticipate that that would push them above that

catastrophic threshold.

MR. MILLER: So if they were using a somewhat less expensive biologic drug or they were simply using a Part D drug instead of a Part B drug, that would count as savings for them.

MR. MULDOON: It's possible.

MR. MILLER: And do I understand correctly, I was not aware of this, that you're excluding supportive drugs. That means Neulasta, Neupogen, and expensive antiemetics are not included in the total?

DR. KLINE: No. Let me clarify. They're counted as a total cost of care. They're not triggering agents for a chemotherapy episode.

MR. MILLER: Okay. Second question is I think we're going to be experiencing, with a lot of people who come in with proposed payment models, that they need to have some kind of a risk-adjustment mechanism. And the problem is that the data really to do that clinically doesn't exist.

And what you're doing, is you've launched a model with a claims-based risk adjustment system which I will say undoubtedly sucks. And you recognize that it's bad because

you're trying to set up the registry to be able to collect appropriate clinical data to do that. But you sort of launched everybody into the model initially with a claims-based risk adjuster which we know is not going to be any good.

I'm curious, one of the things that we've been talking about is whether for some of the models that come in where they really don't have the ability with claims data to do risk adjustment, that they should start in a more limited basis. That a small number of practices might start in this to be able to start actually setting up the clinical registry, collecting the data so that a better risk adjuster could be set up.

And I wonder whether you see any impediments or any problems in trying to do that as a two-phase model. One is to do it on a more limited scale to be able to get the clinical data and a more appropriate risk adjuster before you would expand to a broader population.

DR. KLINE: I'll delve into economics and then rapidly give it over to Dan. I think I agree with you in terms of there's a lot of variation with an episode. But the economics part of it would say that these are based on

historical expenditures for that practice, for that cancer type. There's been a lot of variations, but ultimately they do reflect reality, at least what was reality in the past.

And then I have no strong feelings about the two-phase model other than sort of the obvious statement that if you start out with a limited number of practices, your data collection will be slower early on, so that may be a slower process.

MS. LUKENS: So just one thing I also had to say, I think we certainly would not be opposed to collecting clinical data first. I think that one experience we have had -- and Katy's actually done a lot of work on the registry -- is that it is a fairly significant undertaking for the practices. It would probably need to be coupled with some sort of incentive for the practices to participate.

MR. MILLER: I wasn't suggesting that you collect the data first. I was saying actually put the model in place on a more limited scale to be able to collect the data with less risk associated with it so that you can actually develop a model. Because I think what we're going

to be seeing is a lot of people who would say, I'm not prepared to put a model in place and take risk for it unless there is an effective risk adjuster in place.

But we can't put in an effective risk adjuster in place if we aren't collecting the data that we need to be able to put an effective risk adjuster in place; so to move to a two-phase model where you start by trying something on a no-down-side model, and then move to something where you say now that we have a better risk adjuster, we can move to something where people can take accountability.

MR. MULDOON: I think that's also sort of how we have constructed OCM and, you know, initially had planned to have an extended period of time where it wasn't even an option for practices to opt for two-sided risk. But now practices who believe that they, you know, would be able to take on that type of two-sided risk do have the option.

MR. MILLER: Except that you said that if they don't reduce spending in the first two years, then they're dropped. That is a down size. Anyway, I don't want to hold us up anymore.

MR. MULDOON: Well, they can go to two-sided risk at that point if they would like to also.

MR. MILLER: That wasn't my point. But anyway.

DR. BERENSON: Tim?

DR. FERRIS: My question is about sustainability and I've heard -- and maybe this was part of the presentation, I'm sorry if I missed it -- but is the baseline rolling forward? I've heard from OCM participants that they get updates in the baseline. And I just wonder about the sustainability of a process in which they are improving and the updates are following along with them in the adjustments. So eventually don't you run into a problem?

MR. MULDOON: Actually, they are keeping that historical period set from the episodes for 2012 to 2014. And then when we do the trending forward for each of the performance periods, while we tailor the trend factor based on a practice's case mix, the actual like dollar amounts that are used to calculate the numerator and the denominator for that trend factor are actually based on non-participating practices. We tried to not bake in, sort of moving the goal post at each step along the way for practices that are in OCM.

DR. FERRIS: Thank you.

DR. BERENSON: Jeff?

DR. BAILET: I'm good.

MS. MITCHELL: My question is about the measure and payment standardization across pairs and sort of how aligned the measures actually are in terms of how they're calculated.

UNIDENTIFIED FEMALE: Excuse me, I'm sorry. Can you speak up for us? Thank you.

MS. MITCHELL: My question was about measure and payment standardization across pairs and sort of how standardized they actually are.

MS. COX: So we have asked payers to align what is essentially a core set of quality measures. I don't know them off the top of my head, but there are three claims-based measures. And we did that through a collaborative process with that and actually spent a lot of time getting their feedback and really focusing on getting a core set so we can all focus on collecting the same measures and then reducing the reporting in for the practices.

We have been pretty flexible with their payment approaches, but I think the key is that we're asking payers to also provide like a care-management fee or per

beneficiary, per month payment for enhanced services, very similar to the services that we're paying for. We've also asked them to include performance-based payment approach.

I think they have a little bit more flexibility to implement differently, but we've asked them to align on those core principles.

DR. BERENSON: Grace?

DR. TERRELL: My question for you is related to what you're calling this which is Oncology Care Model. There's a distinction between a payment model and a care model. And what I believe this really is is a payment model for which you're hoping to get care in ways that we haven't paid for before that is better for patients.

Well, every payment model out there, whether it's fee for service or anything else, has moral hazard in it. That's just the nature of payment. It's intrinsic moral hazard in any payment model. My question for you -- one of the things I'm most concerned about, not only for this but for what PTAC is doing or any sort of other alternative payment models -- is what do you do about that other than just program integrity that you spoke about specifically as it relates to innovation and evidence-based medicine?

I've been practicing medicine for a long time and I remember when coronary artery bypass grafting was the standard of care. And it moved to stents and now we have medications that often will prevent coronary artery disease. That was innovation and had we gotten stuck in a particular thing, we might not have actually gotten progress for what we should have been doing which occurred in the system that we had.

What are you all doing in your payment model in trying to provide an alternative for an approved-care model to make sure that there's the possibility for evidence-based medicine and innovation?

DR. KLINE: So a couple different points. I think it's a payment model, but I think it's also a care model because there are practice redesign elements, care navigation, access to your provider 24 hours a day, use of EHRs. Following national guidelines that really are care changes as well as payment changes.

I think in terms of following innovation, obviously oncology -- I think the whole oncology world is changing tremendously as we identify genes that cause cancer, molecular mutations that cause cancer, and then

develop medications that target those mutations. You know, Gleevec being the prototype from 15 years ago, I guess at this point it's changing.

I think the fact that we ask practices to follow nationally recognized guidelines, or document in the patient record why they're not following those guidelines, I think will ensure that physicians continue to follow the standard of care. Did I answer your question?

MR. STEINWALD: My question is about your non-randomized search and sign. Could you say a little bit more? How do you deal with the essential selection bias? When do you expect to get some results from that evaluation? And how do you intend to use it?

MR. MULDOON: So there, I think, as Ellen noted to me and what I was thinking too is I wish we had one of our evaluation colleagues here on the panel. But I know that it's sort of an ongoing effort I think. We have lots of collaboration with our evaluation colleagues. We provide them with as much detail as possible about the practices that are part of the model for them to use in the matching algorisms that they incorporate as part of their evaluation. And we have a healthy dialogue back and forth

there.

I don't know if I have that much more to say. We can ask our evaluation colleagues to provide, you know, a written answer on exactly more details there. I don't want to speak, sort of, out of turn there.

MR. STEINWALD: Maybe as a follow up; is there and evaluation grantee or contractor?

MS. LUKENS: Yes. We will definitely follow up with that question.

DR. BERENSON: Jeff?

DR. BAILET: I had a question relative to adjuvant therapy beyond the chemotherapeutic. The oncology practice has a lot of say in other treatments; surgery, radiation, referral, evaluation. Where is that body of work? How is that incorporated in the model? Because you can see where some practices may be very conservative and not offer the patient those kinds of referrals for other treatment. Is that factored in? How does that play through the model?

DR. KLINE: Thank you. If a patient is receiving surgery with an episode -- I guess that would be neoadjuvant therapy -- that would be after an episode of trigger with chemotherapy. Then we see surgery, there's a

surgical adjustment. We didn't want to financially penalize a practice if neoadjuvant therapy was better. If it was better for them to get chemotherapy first, shrink down the tumor, trigger an episode and then have the cost for surgery within an episode.

There is an adjustment for surgery. There is an adjustment for radiation therapy. There is an adjustment for bone marrow transplant. Wherever we felt that there was a fork in the road that had a subjective component to it, we wanted to make sure that we weren't penalizing the practices.

DR. BAILET: Part of my question is to your original question for appropriateness because that could influence decision making.

DR. BERENSON: When you say adjustment, is it like a carve out? You're not holding the practice accountable for the radiation therapy and spending? What's the form of the adjustment?

MR. MULDOON: We incorporated it into the risk-adjustment model. It would be an increase in episode target price. However, I think for surgery we went through -- for example we went through not trying to just include

any surgery, but with Ron and other medical oncologists we worked to identify surgery. As Ron mentioned, there was this sort of it would be clinically appropriate to perform -- you know, administer chemotherapy prior to doing the surgery and not just trying to incentivize -- you know, doing any surgery or just giving radiation during any episode. I don't know, Ron, if you have anything else to add.

DR. KLINE: Well, I mean it was just a hard thing. Basically, if there's a surgery that always is going to occur prior to chemotherapy; so brain tumor, brain tumor resection always occur prior to chemotherapy. There was no surgical adjustment in that situation.

Where there are examples of, you know, a lumpectomy, a mastectomy where you might do it either before chemotherapy or after, to shrink the tumor down, there was an adjustment. We tried to sort of balance that so as not to penalize the practices for doing the right thing, but also not allow them to game the system for doing the wrong thing.

DR. BERENSON: So I wanted to ask another question and then maybe we have time for just a couple more. I

wanted to go back to -- by habit I'm a splitter rather than a lumper. And you've got a lot of cancers included in the cancer model from acute leukemia, where I would expect that the spending would be largely attributable to the intervention, to the chemotherapy and all the complications that could happen to, as you mentioned, tamoxifen for breast or hormonal treatment for prostate, where I would think that the cancer costs are relatively small in relationship to total cost of care. I guess one is just a factual question. In the baseline spending across these cancers, would some have shown significant variations in spending like I would expect with prostate or breast; whereas others would show much less variation like leukemia or lymphoma?

And then where I'm really going on this is do we really -- I mean I used to manage prostate cancer as just a primary care internist, the hormonal treatment. Do we really think a total cost of care for those kinds of cancers is the appropriate metric as I think it probably is for some of the other cancers?

MR. MULDOON: I think there we did work to try to identify where there was potentially, like within breast

cancer sort of a very large difference between a woman who's receiving tamoxifen or other oral hormonal therapies rather than a woman who has metastatic disease. And so in the risk adjustment we actually do, where we were able to identify, have more granular within cancer distinctions.

Like for breast cancer, if a woman only receives the oral chemotherapy throughout an episode, that is sort of the cancer type risk-adjustment factor there. Sort of cancer by receiving only the oral chemotherapy and that would allow for the prediction of a much lower price for a woman who is on this long-acting hormonal therapy than a woman who receives more systemic chemotherapy, who potentially has metastatic disease going on.

DR. BERENSON: It's affecting the price. Okay. But the model is still the same. Go ahead, Ron, you wanted to respond.

DR. KLINE: I was going to quote my old professor who said the splitters always win. But I agree in terms of trying to move towards more clinically relevant episodes. And I think that's the point of the data registry. I think, you know, the total cost of care model, there are so many different cancer types and so many different

chemotherapy side effects. But I think trying to figure out at a national level what's chemotherapy related and what's not would be a very, very difficult task.

You know, the example I've always used when I've spoken to people is someone with cancer comes to the emergency department and they've broken their leg. Did they break their leg because they slipped on ice? Did they break their leg because they have a metastatic lesion in their leg that wasn't radiated appropriately? Did they break their leg because they had a neuropathy from the chemotherapy? Did they break their leg because they were dehydrated because they didn't get appropriate hydration after chemotherapy? And all we see at CMS is a broken leg. That's why we sort of went to a total cost-care model.

DR. BERENSON: So in other words, episode grouper for cancer is still a work in progress. You don't think you can clearly attribute what claims are associated with the chemotherapy and which ones probably aren't? Or you don't know?

DR. KLINE: I think there's a lot of difficulty. And I always tell people that making ICD 10 work with the diversity of cancer, work with the CMS claim system is

really a challenge. And that's what we're trying to do.

DR. BERENSON: We have five minutes so just five minutes' worth of quick Qs and As. And we'll stop it in five minutes.

DR. BAILET: That's all we have.

DR. BERENSON: Grace?

DR. TERRELL: One question then. This works very well for folks for which chemotherapy is the appropriate therapy. Do you have the ability now to incorporate other types of modalities as a treatment event in other specialties into an oncology care model? For example, radiation oncologist, surgeons or other types of therapy into a more comprehensive model that could be disease focused as opposed to modality focus in terms of the trigger and the approach.

MS. LUKENS: I think the Oncology Care Model as it is currently constructed is trigger by chemotherapy. That's not to say that we couldn't modify in some way to expand to include other modalities. But the research and the work that we've done to date in the risk adjustment model is all --

DR. TERRELL: But it can be done?

MS. LUKENS: I think it can be done, yeah.

DR. BERENSON: Any final questions from -- go ahead Elizabeth.

MS. MITCHELL: Can you comment at all on the ability or the chance of making these payments actually prospective.

MR. MULDOON: I think there's where the Medicare like claims processing system I think to date is -- I also have experience working on our bundled payments for care improvement initiatives where we have both a retrospective payer methodology as well as a flavor of that that has a prospective payment methodology. In that model the prospective payment methodology really just covers, you know, the payment for an inpatient stay which is already sort of made on a prospective basis as well as physician Part B claims provided during that inpatient stay.

And I'll say that we had a lot of both operational challenges at CMS in terms of getting all of those claims to pay correctly as well as at the hospitals. You know, it puts a lot of burden on hospitals or the entity that would be receiving that prospective payment to also have contracts in place to be able to pay the other entities

involved.

I think that with this episode payment model and other episode payment models, it's like a goal to get there. But it's not something that, I guess, we see as being really easy to do, you know, tomorrow or in the next six months.

DR. BERENSON: Last question and then we're going to stop. Can you clarify any plans to have the two-sided risk approach qualify as an advanced APM?

MS. LUKENS: Sure. We actually accelerated the option for practices to be able to elect two-sided risk as of January 1, 2017. We are allowing them the entire month basically of December. They don't have to let us know until the 28th. We can certainly let Mary Ellen and other folks know how many end up electing two-sided risks. But at this point, we don't know how many will accept this. The folks that do elect two-sided risk will qualify as an advanced APM.

DR. BERENSON: So meets the EHR requirement?

MS. LUKENS: That's correct.

DR. BERENSON: It qualifies, okay. Any last --

MR. MILLER: But they'll be using the current risk

adjustment structure if they're doing that, right?

MS. LUKENS: Yes.

DR. BERENSON: You did a great job. This has been very helpful to us and thank you for coming by.

DR. BAILET: A couple of things. We're going to conclude the session. We apologize for the technical difficulties that the hotel is experiencing relative to the power which is impacting their visual and audio systems. And to that end as we conclude the session we're going to have Mary Ellen announce how we're going to go forward given the acuity of the problem here. Mary Ellen?

MS. MARY ELLEN: Thank you CMS for a great presentation under not the best circumstances. As you've noticed there's a power problem in the back half of this room which apparently blew the audiovisual soundboard, Murphy's Law, so the people on the phone cannot hear.

In light of that, and the fact that two of the speakers for the afternoon session were going to be calling in because of the weather in the Midwest, we've decided to postpone that afternoon session. It's just the one session that we so wanted to have ourselves and we wanted the public to hear. And so many people were on the phone,

about 100 people were on the phone. We want to postpone that so that everybody can hear and everybody can benefit from those perspectives. We are so sad about it.

For those of you who were going to miss a holiday luncheon with your office this afternoon, you can now attend. I do want to apologize, I'm not making light of it. We're so disappointed with the service here at the hotel today, but these things happen as you well know. And again, I want to thank CMS for being so gracious about having to do a presentation under such difficult circumstances.

We'll post on our website when we can do that session and thanks very much.

[PUBLIC MEETING ADJOURNED]